

Risk Evaluation and Mitigation Strategy (REMS) Document

LEMTRADA® (alemtuzumab) REMS

I. Administrative Information

Application Number: BLA 103948
Application Holder: Genzyme Corporation
Initial REMS Approval: 11/2014
Most Recent REMS Update: 10/2019

II. REMS Goal

The goal of the LEMTRADA REMS is to mitigate the risks of autoimmune conditions, infusion reactions, stroke, and malignancies associated with LEMTRADA by:

Helping to ensure informed decisions about the safe use of LEMTRADA by:

1. Informing patients about the serious risks of autoimmune conditions, infusion reactions, stroke, and malignancies with LEMTRADA and the need for baseline and periodic monitoring; and
2. Informing healthcare providers about the serious risks of autoimmune conditions, infusion reactions, stroke, and malignancies with LEMTRADA, the need to counsel patients, and the need for baseline and periodic monitoring.

Helping to ensure the safe use of LEMTRADA by:

3. Ensuring that only certified prescribers prescribe LEMTRADA;
4. Ensuring that LEMTRADA is dispensed only in certain healthcare settings, by certified pharmacies, and certified healthcare facilities administering the infusion, which have on-site access to equipment and personnel trained to manage infusion reactions; and
5. Ensuring that only enrolled and authorized patients receive LEMTRADA;
6. Ensuring that certified prescribers submit documentation of periodic monitoring of patients who receive LEMTRADA to identify autoimmune conditions and malignancies.

III. REMS Requirements

Genzyme must ensure that healthcare providers, patients, pharmacies, healthcare facilities, and wholesalers-distributors comply with the following requirements:

1. Healthcare Providers who prescribe LEMTRADA must:

To become certified to prescribe	<ol style="list-style-type: none">1. Review the drug's Prescribing Information.2. Review the following: Program Overview and Education Program for Prescribers.3. Successfully complete the Knowledge Assessment and submit it to the REMS Program.4. Enroll in the REMS by completing the Prescriber Enrollment Form and submitting it to the REMS Program.
Before treatment initiation (first dose)	<ol style="list-style-type: none">5. Counsel the patient on the risks associated with LEMTRADA, including autoimmune conditions, infusion reactions, stroke and malignancies, and the need for baseline and periodic monitoring, using What You Need to Know About LEMTRADA Treatment: A Patient Guide, and the Patient Safety Information Card. Provide a copy of the materials to the patient.6. Enroll the patient by completing and submitting the Patient Enrollment Form to the REMS Program. Provide a completed copy to the patient and retain a copy in the patient's record.7. Order the prescription using the Prescription Ordering Form and submit it to the REMS Program.
Before treatment initiation and during treatment, within 30 days prior to the first infusion date of each treatment course	<ol style="list-style-type: none">8. Assess the patient's health status by completing the laboratory testing and monitoring as described in the Prescribing Information. Document and submit to the REMS Program using the Patient Authorization and Baseline Lab Form.
During treatment, at periodic intervals	<ol style="list-style-type: none">9. Assess the patient's health status by completing the laboratory testing and monitoring as described in the Prescribing Information.10. Order the prescription using the Prescription Ordering Form and submit it to the REMS Program.
During treatment, every 6 months	<ol style="list-style-type: none">11. Assess the patient for adverse events and completion of laboratory testing and monitoring. Document and submit to the REMS Program using the Patient Status Form.
After the last infusion, every 6 months for 48 months	<ol style="list-style-type: none">12. Assess the patient for adverse events and completion of laboratory testing and monitoring. Document and submit to the REMS Program using the Patient Status Form.

At all times	<p>13. Report any adverse events suggestive of autoimmune conditions, infusion reactions, stroke, and malignancies to Genzyme.</p> <p>14. Report if an enrolled patient who has received LEMTRADA within the last 48 months is no longer under your care to Genzyme.</p>
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2. Patients who are prescribed LEMTRADA:

Before treatment initiation	<p>1. Receive counseling from the prescriber on the risks associated with LEMTRADA, including autoimmune conditions, infusion reactions, stroke and malignancies, and the need for laboratory testing and monitoring, using What You Need to Know About LEMTRADA Treatment: A Patient Guide and the Patient Safety Information Card.</p> <p>2. Enroll in the REMS Program by completing the Patient Enrollment Form with the prescriber. Enrollment information will be provided to the REMS Program.</p> <p>3. Get a skin exam.</p>
Before treatment initiation, within 30 days prior to the first infusion date of each treatment course	<p>4. Be monitored for autoimmune conditions and/or malignancies.</p>
During treatment; after each infusion for at least 2 hours	<p>5. Be monitored for infusion reactions.</p>
During treatment, at periodic intervals	<p>6. Be monitored for autoimmune conditions and/or malignancies.</p> <p>7. Inform the prescriber if you have had a stroke.</p>
During treatment, yearly	<p>8. Get a skin exam.</p>
After last infusion, at periodic intervals for 48 months	<p>9. Be monitored for autoimmune conditions and/or malignancies.</p> <p>10. Inform the prescriber if you have had a stroke.</p>
At all times	<p>11. Inform the prescriber if any reactions or symptoms are experienced after receiving LEMTRADA.</p> <p>12. Have the Patient Safety Information Card with you.</p>

3. Pharmacies that dispense LEMTRADA must:

To become certified to dispense	<ol style="list-style-type: none"> 1. Designate an authorized representative to carry out the certification process and oversee implementation and compliance with the REMS Program on behalf of the pharmacy. 2. Have the authorized representative review the Program Overview. 3. Have the authorized representative enroll in the REMS Program by completing the Pharmacy Enrollment Form and submitting it to the REMS Program. 4. Train all relevant staff involved in dispensing LEMTRADA using the Program Overview. 5. Establish processes and procedures to verify that the Prescription Ordering Form is received for each prescription.
Before dispensing	<ol style="list-style-type: none"> 6. Verify that the Prescription Ordering Form is received for each prescription through the processes and procedures established as a requirement of the REMS Program. 7. Obtain authorization to dispense each prescription by contacting the REMS Program to verify that the prescriber is certified, the healthcare facility administering the infusion is certified, and the patient is enrolled and authorized to receive LEMTRADA.
To maintain certification to dispense, every 2 years	<ol style="list-style-type: none"> 8. Have the authorized representative re-enroll in the REMS Program by completing the Pharmacy Enrollment Form.
At all times	<ol style="list-style-type: none"> 9. Maintain records of training. 10. Maintain records of all processes and procedures including compliance with those processes and procedures. 11. Comply with audits carried out by Genzyme to ensure that all processes and procedures are in place and are being followed.

4. Healthcare facilities that dispense and administer LEMTRADA must:

To become certified to dispense and administer	<ol style="list-style-type: none"> 1. Have the necessary on-site equipment and personnel available to appropriately manage serious infusion reactions (including anaphylaxis, cardiac and respiratory emergencies). 2. Designate an authorized representative to carry out the certification process and oversee implementation and compliance with the REMS Program on behalf of the healthcare facility. 3. Have the authorized representative review the REMS Program Overview and Education Program for Healthcare Facilities. 4. Have the authorized representative enroll in the REMS Program by completing the Healthcare Facility Enrollment Form and submitting it to the REMS Program. 5. Train all relevant staff involved in the dispensing and administration of LEMTRADA using the Program Overview and Education Program for Healthcare Facilities. 6. Establish processes and procedures to verify that (1) the Prescription Ordering Form is received for each prescription, (2) patients are counseled, (3) the patient is monitored for infusion reactions during and for at least 2 hours after each infusion, (4) the Infusion Checklist is completed and submitted for each patient, and (5) Lemtrada is not dispensed outside of the certified healthcare facility administering the infusion.
Before administering	<ol style="list-style-type: none"> 7. Verify that the Prescription Ordering Form is received for each prescription through the processes and procedures established as a requirement of the REMS Program. 8. Obtain authorization to dispense each prescription by contacting the REMS Program to verify that the prescriber is certified and the patient is enrolled and authorized to receive LEMTRADA. 9. Counsel the patient about the risk for infusion reactions using the What You Need to Know about LEMTRADA Treatment and Infusion Reactions: A Patient Guide. Provide a copy of the material to the patient.
During and after administering for at least 2 hours	<ol style="list-style-type: none"> 10. Assess the patient for infusion reactions.
After the last infusion, within 5 business days	<ol style="list-style-type: none"> 11. Complete the Infusion Checklist for each patient and submit it to the REMS Program.

To maintain certification to dispense and administer every 2 years	12. Have the authorized representative enroll in the REMS Program by completing the Healthcare Facility Enrollment Form and submitting it to the REMS Program.
At all times, within 50 business days of submission of the Patient Authorization and Baseline Lab Form	13. Return unused product to the distributor.
At all times	14. Not distribute, transfer, loan, or sell Lemtrada. 15. Maintain records of training. 16. Maintain records of all processes and procedures including compliance with those processes and procedures. 17. Comply with audits carried out by Genzyme to ensure that all training, processes and procedures are in place and are being followed.

5. Wholesalers-distributors that distribute LEMTRADA must:

To be able to distribute	1. Establish processes and procedures to ensure that the drug is distributed only to certified pharmacies and certified healthcare facilities. 2. Train all relevant staff involved in distributing LEMTRADA on the REMS Program requirements.
At all times	3. Distribute only to certified pharmacies and certified healthcare facilities. 4. Maintain and submit patient level distribution records of all shipments of LEMTRADA to the REMS Program. 5. Maintain records of all processes and procedures including compliance with those processes and procedures. 6. Comply with audits carried out by Genzyme to ensure that all processes and procedures are in place and are being followed.

Genzyme must provide training to healthcare providers who prescribe LEMTRADA.

The training includes the following educational materials: [Program Overview](#), [Education Program for Prescribers](#), and [Knowledge Assessment](#). The training must be available online and in hard copy format by calling the REMS call center.

Genzyme must provide training to pharmacies that dispense LEMTRADA. The training includes the following educational materials: [Program Overview](#). The training must be available online and in hardcopy format by calling the REMS call center.

Genzyme must provide training to healthcare facilities that dispense and administer LEMTRADA.

The training includes the following educational materials: [Program Overview](#) and [Education Program for Healthcare Facilities](#). The training must be available online and in hardcopy format by calling the REMS call center.

To inform healthcare providers about the REMS Program and the risks and safe use of LEMTRADA, Genzyme must disseminate REMS communication materials according to the table below:

Target Audience	Communication Materials and Dissemination Plans
Healthcare Providers and Healthcare Facilities enrolled in the LEMTRADA REMS Program.	REMS Letter: REMS Letter 2 for Healthcare Providers <ol style="list-style-type: none">1. Email within 60 calendar days of approval of the REMS modification (04/2019).<ol style="list-style-type: none">a. Send by mail within 30 calendar days of the date the first email was sent if a healthcare provider's email address is not available or the email is undeliverable.b. Send a second email within 30 calendar days of the date the first email was sent if the first email is marked as unopened.c. Send by mail within 30 calendar days of the date the second email was sent if the second email is marked as unopened.
Healthcare providers who have written at least one prescription within the previous 2 years for a prescription drug indicated for the treatment of multiple sclerosis	REMS Letter: REMS Letter 1 for Healthcare Providers <ol style="list-style-type: none">1. Email within 60 days of approval of the LEMTRADA REMS and again at 12 months, 24 months, and 36 months from the date of the REMS approval (11/2014).<ol style="list-style-type: none">a. Send by mail within 30 calendar days of the date the first email was sent if a healthcare provider's email address is not available or the email is undeliverable.b. Send a second email within 30 calendar days of the date the first email was sent if the first email is marked as unopened.c. Send by mail within 30 calendar days of the date the second email was sent if the second email is marked as unopened.

To support REMS Program operations, Genzyme must:

1. Establish and maintain a REMS Program website, www.LemtradaREMS.com. The REMS Program website must include the capability to complete prescriber, pharmacy, and healthcare facility certification online, the capability to review patient authorization and enrollment status and prescriber and healthcare facility certification status, the capability to search for a REMS certified prescriber or healthcare facility, and the option to print the Prescribing Information, Medication Guide, and REMS materials. All product websites for consumers and healthcare providers must include prominent REMS-specific links to the REMS Program website. The REMS Program website must not link back to the promotional product website(s).

2. Make the REMS Program website fully operational and all REMS materials available through www.LemtradaREMS.com and the REMS Program call center.
3. Establish and maintain a REMS Program call center for REMS participants at 1-855-676-6326.
4. Establish and maintain a validated, secure database of all REMS participants who are enrolled and/or certified in the REMS Program.
5. Ensure prescribers, pharmacies, and healthcare facilities are able to complete enrollment by fax and online.
6. Ensure prescribers are able to complete enrollment of patients by fax.
7. Ensure prescribers are able to provide a [Prescription Ordering Form](#) for each LEMTRADA prescription by fax.
8. Ensure pharmacies and healthcare facilities are able to access and review the database of certified prescribers and enrolled patients to obtain certification status and authorization status via the REMS Program call center and the REMS Program website.
9. Provide the [Prescriber Enrollment Form](#), [Patient Enrollment Form](#), [Program Overview](#), [Education Program for Prescribers](#), [Patient Status Form](#), [Prescription Ordering Form](#), [Patient Authorization and Baseline Lab Form](#), [What You Need to Know About LEMTRADA Treatment: A Patient Guide](#) and the Prescribing Information to healthcare providers who (1) attempt to prescribe LEMTRADA and are not yet certified, or (2) inquire about how to become certified.
10. Notify prescribers, pharmacies, and healthcare facilities after they become certified in the REMS Program.
11. Provide certified prescribers access to the database of certified pharmacies, certified healthcare facilities, and enrolled patients.
12. Provide certified pharmacies and certified healthcare facilities access to the database of certified prescribers and enrolled patients.

To ensure REMS participants' compliance with the REMS Program, Genzyme must:

13. Verify annually that the authorized representative is the current designated authorized representative for the certified pharmacy and certified healthcare facility. If different, the pharmacy or healthcare facility or both must be required to re-certify with a new authorized representative.
14. Notify healthcare facilities if a completed [Infusion Checklist](#) has not been received by the REMS Program within 40 days from the date of submission of the [Patient Authorization and Baseline Lab Form](#).
15. Send a [Patient Letter: Monitoring Reminder](#) to patients monthly who have received at least one LEMTRADA treatment, reminding them of the requirement for ongoing monitoring.
16. Send a [Healthcare Provider Letter: Patient Status](#) to the prescriber who must submit a completed [Patient Status Form](#) for the patient. Send the letter electronically or by mail 6 months after the patient's first infusion with LEMTRADA, and every 6 months thereafter, for 48 months after the completion of the patient's last infusion of LEMTRADA.
17. Maintain adequate records to demonstrate that REMS requirements have been met, including, but not limited to records of: distribution and dispensing; certification of prescribers, pharmacies, and healthcare facilities; enrolled patients; and audits of REMS participants. These records must be readily available for FDA inspections.
18. Establish a plan for addressing noncompliance with REMS Program requirements.
19. Monitor certified prescribers, certified pharmacies, certified healthcare facilities, and wholesalers-distributors on an ongoing basis to ensure the requirements of the REMS are being met. Take corrective action if non-compliance is identified, including de-certification.

20. Audit wholesalers-distributors no later than 180 days after they become authorized, and annually thereafter, to ensure that all REMS processes and procedures are in place, functioning, and support the REMS Program requirements.
21. Audit certified pharmacies no later than 180 days after they become certified and after they have dispensed at least one LEMTRADA prescription, and annually thereafter, to ensure that all REMS processes and procedures are in place, functioning, and support the REMS Program requirements.
22. Audit 10% of the certified healthcare facilities that have received at least one shipment of Lemtrada over a 24-month period defined as the current and previous reporting period, to ensure that all REMS processes and procedures are in place, functioning, and support the REMS Program requirements. A minimum of 50 healthcare facilities must be audited annually.
23. Take reasonable steps to improve implementation of and compliance with the requirements in the LEMTRADA REMS Program based on monitoring and evaluation of the LEMTRADA REMS Program.

IV. REMS Assessment Timetable

Genzyme must submit REMS Assessments at 6 months and 12 months, and annually thereafter from the date of the initial approval of the REMS (11/14/2014). To facilitate inclusion of as much information as possible while allowing reasonable time to prepare the submission, the reporting interval covered by each assessment should conclude no earlier than 60 calendar days before the submission date for that assessment. Genzyme must submit each assessment so that it will be received by the FDA on or before the due date.

V. REMS Materials

The following materials are part of the LEMTRADA REMS:

Enrollment Forms:

Prescriber:

1. [Prescriber Enrollment Form](#)

Patient:

2. [Patient Enrollment Form](#)

Pharmacy:

3. [Pharmacy Enrollment Form](#)

Healthcare Facility:

4. [Healthcare Facility Enrollment Form](#)

Training and Educational Materials

Prescriber:

5. [REMS Program Overview](#)
6. [Education Program for Prescribers](#)
7. [Knowledge Assessment](#)

Pharmacy:

8. [REMS Program Overview](#)

Healthcare Facility:

9. [REMS Program Overview](#)
10. [Education Program for Healthcare Facilities](#)

Patient:

11. [What You Need to Know About LEMTRADA Treatment: A Patient Guide](#)

12. [Patient Safety Information Card](#)
13. [What You Need to Know about LEMTRADA Treatment and Infusion Reactions: A Patient Guide](#)

Patient Care Forms

14. [Patient Authorization and Baseline Lab Form](#)
15. [Prescription Ordering Form](#)
16. [Patient Status Form](#)
17. [Infusion Checklist](#)

Communication Materials

18. [REMS Letter 1 for Healthcare Providers](#)
19. [REMS Letter 2 for Healthcare Providers](#)

Other Materials

20. REMS Program website www.LemtradaREMS.com
 21. [Healthcare Provider Letter: Patient Status](#)
 22. [Patient Letter: Monitoring Reminder](#)
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LEMTRADA REMS PRESCRIBER ENROLLMENT FORM

Please fax this completed form to the LEMTRADA REMS at 1-855-557-2478 or enroll online at www.LemtradaREMS.com

LEMTRADA® (alempezumab) is available only through the LEMTRADA REMS, a restricted distribution program. Only prescribers, pharmacies, healthcare facilities, and patients enrolled in the REMS are able to prescribe, dispense, administer, and receive LEMTRADA.

Instructions:

1. Review the LEMTRADA REMS Education Program for Prescribers, including the Prescribing Information
2. Successfully complete the LEMTRADA REMS Knowledge Assessment
3. Complete and submit this LEMTRADA REMS Prescriber Enrollment Form
4. Verify your patients will receive LEMTRADA at a LEMTRADA REMS certified healthcare facility.

Please complete all required fields on this form and fax it to 1-855-557-2478. You will receive enrollment confirmation via your preferred method of communication (email or fax) within 2 business days.

*Indicates a mandatory field.

LEMTRADA PRESCRIBER INFORMATION (PLEASE PRINT)

Name (Last, First)/Degree*

Name of Institution or Healthcare Facility*

Street Address*

City*

State*

ZIP Code*

Office Phone Number*

Fax Number*

Email Address*

Mobile Phone Number

National Provider Identification (NPI) Number*

If you are dispensing LEMTRADA from your clinic, a LEMTRADA REMS Healthcare Facility Enrollment Form must also be completed and submitted.

PRESCRIBER AGREEMENT

By completing this form, I attest that:

- I understand that LEMTRADA is indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include relapsing-remitting disease and active secondary progressive disease, in adults. Because of its safety profile, the use of LEMTRADA should generally be reserved for patients who have had an inadequate response to two or more drugs indicated for the treatment of MS. LEMTRADA is not recommended for use in patients with clinically isolated syndrome (CIS) because of its safety profile.
- I understand that LEMTRADA is only available through the LEMTRADA REMS and that I must comply with the program requirements in order to prescribe LEMTRADA.
- I have completed the *LEMTRADA REMS Education Program for Prescribers*, including a review of the LEMTRADA Prescribing Information, and successfully completed the LEMTRADA REMS Knowledge Assessment.
- I understand that by completing the training program and signing this LEMTRADA REMS Prescriber Enrollment Form, I will be enrolled in the LEMTRADA REMS and can prescribe LEMTRADA.
- I understand that I am responsible for reviewing *What You Need to Know About LEMTRADA Treatment: A Patient Guide* with each patient, and counseling each patient on an ongoing basis about the serious risks associated with the use of LEMTRADA and how to mitigate these risks through periodic monitoring.
- I understand that I must enroll all patients being treated with LEMTRADA into the LEMTRADA REMS prior to initiating the patient on treatment with LEMTRADA. I am responsible for completing a LEMTRADA REMS Patient Enrollment Form with the patient (or patient's legal representative), obtaining the patient's (or patient's legal representative's) signature on the form, and submitting the signed form to the LEMTRADA REMS. A completed copy should be provided to the patient and another copy should be stored in the patient's records.
- I will provide enrolled patients with a LEMTRADA Patient Safety Information Card and instruct patients to carry this card with them at all times in case of an emergency.
- I understand that I must submit a LEMTRADA REMS Prescription Ordering Form for each LEMTRADA prescription.
- I understand that I am responsible for completing baseline lab monitoring within 30 days prior to infusion of LEMTRADA.
- I understand that I must submit a LEMTRADA REMS Patient Authorization and Baseline Lab Form indicating completion of each patient's baseline labs within 30 days prior to the patient's infusion date.

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PRESCRIBER AGREEMENT (CONTINUED)

- I understand the risks of autoimmune conditions and malignancies associated with the use of LEMTRADA, and the need for periodic monitoring in order to identify and mitigate these risks:
 - Complete blood counts with differential obtained within 30 days prior to initiation of treatment and at monthly intervals thereafter until 48 months after the last infusion.
 - Serum creatinine levels obtained within 30 days prior to initiation of treatment and at monthly intervals thereafter until 48 months after the last infusion.
 - Urinalysis with urine cell counts obtained within 30 days prior to initiation of treatment and at monthly intervals thereafter until 48 months after the last infusion.
 - Measure the urine protein to creatinine ratio within 30 days prior to initiation of treatment
 - Thyroid function tests, such as thyroid stimulating hormone (TSH) level, obtained within 30 days prior to initiation of treatment and every 3 months thereafter until 48 months after the last infusion.
 - Serum transaminases (alanine aminotransferase [ALT] and aspartate aminotransferase [AST]) and total bilirubin levels prior to initiation of treatment and periodically thereafter.
 - Baseline and yearly skin examinations.
- I understand the risk of stroke during and following the administration of LEMTRADA
- I will report any adverse events of autoimmune conditions, infusion reactions, stroke or malignancies to Genzyme.
- I will complete the LEMTRADA REMS Patient Status Form 6 months after the patient's first infusion and every 6 months thereafter, until 48 months after the completion of the patient's last infusion.
- I understand that I will notify Genzyme if a patient is no longer under my care.
- I understand that if I fail to comply with the requirements of the LEMTRADA REMS, I may no longer be able to participate in the program.
- I understand that Genzyme and its agents may contact me via phone, mail, fax, or email to support administration of the LEMTRADA REMS.

WEBSITE CONSENT

I understand that the LEMTRADA REMS will publish my name, business address, and phone number ("Contact Information") on its website in a directory of physicians certified to prescribe and administer LEMTRADA and consent to the foregoing. I understand that I am waiving the right to inspect my Contact Information prior to its inclusion on the website, and I agree to hold harmless and release the LEMTRADA REMS and Genzyme Corporation and its affiliates from any and all actions, claims, or demands arising out of or in connection with the use of my Contact Information on the website. I understand that I can request the removal of my Contact Information from the LEMTRADA REMS website at any time by contacting the LEMTRADA REMS at 1-855-676-6326.

Yes No

SIGNATURE

Prescriber Signature*

Date*

Print Name*

Please fax this completed form to the LEMTRADA REMS at 1-855-557-2478 or enroll online at www.LemtradaREMS.com

If you have any questions regarding the LEMTRADA REMS, call 1-855-676-6326



LEMTRADA REMS PATIENT ENROLLMENT FORM

Please fax this completed form to the LEMTRADA REMS at 1-855-557-2478

This form must be completed before you can receive LEMTRADA® (alem tuzumab). LEMTRADA is available only through a restricted distribution program called the LEMTRADA REMS. Your prescriber will help you complete this form and will give you a copy.

*Indicates a mandatory field.

PATIENT INFORMATION (PLEASE PRINT)

Name (Last, First)*	Date of Birth (MM/DD/YYYY)*		
Street Address*	City*	State*	ZIP Code*
Phone Number*	Gender* <input type="checkbox"/> Male <input type="checkbox"/> Female		
Secondary Contact (Last, First)	Phone Number		

PRESCRIBER INFORMATION (PLEASE PRINT)

Prescriber Name (Last, First)*	NPI Number*	Phone Number*
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PATIENT AGREEMENT

By signing this form, I acknowledge that:

- I have received, read, and understand *What You Need to Know About LEMTRADA Treatment: A Patient Guide* that my doctor has given to me.
- My doctor has reviewed with me the benefits and risks of treatment with LEMTRADA.
- I am aware that LEMTRADA is associated with serious risks, including autoimmune conditions, infusion reactions, stroke and malignancies, and that these complications can be identified through periodic monitoring and awareness of the initial signs and symptoms.
 - I understand the need to have blood and urine tests within 30 days prior to my first LEMTRADA treatment, then each month for 4 years following my last treatment with LEMTRADA.
 - I understand the need to have thyroid testing within 30 days prior to my first LEMTRADA treatment, then every 3 months for 4 years following my last treatment with LEMTRADA.
 - I understand the need to have yearly skin exams prior to my first LEMTRADA treatment, and continuing for 4 years following my last treatment with LEMTRADA.
 - I will tell my doctor if I have any reactions or symptoms after receiving LEMTRADA.
- I understand that I must tell all of my doctors that I have received LEMTRADA.
- I understand that in order to receive LEMTRADA, I am required to enroll in the LEMTRADA REMS and my information will be stored in a secure and confidential database of all patients who receive LEMTRADA in the United States. After enrolling, my doctor will provide me with a signed copy of the enrollment form.
- My doctor has counseled and provided me with a LEMTRADA Patient Safety Information Card, which I should carry with me at all times in case of an emergency.
- I understand that I must tell Genzyme if I change my doctor.
- I understand that I must tell Genzyme if my contact information changes.
- I give permission to Genzyme and its agents to use and share my personal health information for the purposes of enrolling me into the LEMTRADA REMS, coordinating the dispensing of receiving LEMTRADA, administering the LEMTRADA REMS, and releasing my personal health information to the Food and Drug Administration (FDA) as necessary.
- By completing the information below, I understand Genzyme and its agents will contact me via phone, mail, or email to support administration of the LEMTRADA REMS.

I prefer to be contacted:

- By mail By phone
 By email (please provide email address)

PATIENT SIGNATURE

_____ Patient/Legal Representative	_____ Relationship to
_____ Print Name*	_____ Date*

PRESCRIBER SIGNATURE

I acknowledge that I have explained the LEMTRADA REMS to this patient.

_____ Prescriber Signature*	_____ Date*
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Please fax this completed form to the LEMTRADA REMS at 1-855-557-2478

If you have any questions regarding the LEMTRADA REMS, call 1-855-676-6326



LEMTRADA REMS PHARMACY ENROLLMENT FORM

Please fax this completed form to the LEMTRADA REMS at 1-855-557-2478 or enroll online at www.LemtradaREMS.com

LEMTRADA® (alemtezumab) is only available through the LEMTRADA REMS, a restricted distribution program. Only prescribers, pharmacies, healthcare facilities, and patients enrolled in the program are able to prescribe, dispense, administer, and receive LEMTRADA. An authorized representative of the pharmacy must enroll the pharmacy in the LEMTRADA REMS .

- New Enrollment
- Re-enrollment (every 2 years)

*Indicates a mandatory field.

PHARMACY INFORMATION (PLEASE PRINT)

Name of Pharmacy*		NPI Number*	
Pharmacy Address*			
City*		State*	ZIP Code*
Name of Authorized Pharmacy Representative*		Title*	
Phone Number*	Fax Number*	Email Address	

PHARMACY AGREEMENT

I am the authorized representative designated by my pharmacy to coordinate the activities of the LEMTRADA REMS . By signing this form, I agree to comply with the following program requirements:

- I understand that my pharmacy must be certified with the LEMTRADA REMS to dispense LEMTRADA.
- I will oversee implementation and compliance with the LEMTRADA REMS requirements.
- I have reviewed the LEMTRADA REMS Program Overview.
- I will ensure that all relevant staff involved in the dispensing of LEMTRADA are educated and trained using the LEMTRADA REMS .
- I will put processes and procedures in place, and follow such processes and procedures, to ensure the following verifications are met prior to dispensing LEMTRADA:
 - The LEMTRADA REMS Prescription Ordering Form is received for each prescription.
 - The prescriber is certified, the infusion site is certified, and the patient is enrolled and authorized to receive LEMTRADA by contacting the LEMTRADA REMS prior to dispensing LEMTRADA.
- Ensuring LEMTRADA is only dispensed to a certified infusion center.
- This pharmacy will establish procedures and protocols that are subject to audit, to help ensure compliance with the requirements of the LEMTRADA REMS .
- I understand that my pharmacy must renew enrollment in the LEMTRADA REMS every 2 years from initial enrollment.
- To make available to Genzyme, documentation to verify understanding of, and adherence to, the requirements of the LEMTRADA REMS .

SIGNATURE

Authorized Pharmacy Representative Signature*		Date
Print Name*	Title	

Please fax this completed form to the LEMTRADA REMS at 1-855-557-2478 or enroll online at www.LemtradaREMS.com

If you have any questions regarding the LEMTRADA REMS , call 1-855-676-6326



LEMTRADA REMS HEALTHCARE FACILITY ENROLLMENT FORM

Please fax this completed form to the LEMTRADA REMS at 1-855-557-2478 or enroll online at www.LemtradaREMS.com

LEMTRADA® (alemtezumab) is only available through the LEMTRADA REMS, a restricted distribution program. Only prescribers, pharmacies, healthcare facilities, and patients enrolled in the REMS are able to prescribe, dispense, administer, and receive LEMTRADA. An authorized representative of the healthcare facility must enroll the facility in the LEMTRADA REMS.

- New Enrollment
 Re-enrollment (every 2 years)

*Indicates a mandatory field.

Please complete a separate Healthcare Facility Enrollment Form for each facility site, if applicable.

HEALTHCARE FACILITY INFORMATION (PLEASE PRINT)

Name of Institution or Healthcare Facility*		NPI Number*	
Infusion Facility Address*			
City*		State*	ZIP Code*
Ship-to Street Address (if different)*			
City*		State*	ZIP Code*
Phone Number*	Fax Number*	Email Address	
Name of Authorized Healthcare Facility Representative*		Title*	
Site Affiliation			
<input type="checkbox"/> Academic	<input type="checkbox"/> Government	<input type="checkbox"/> Ambulatory/Freestanding	<input type="checkbox"/> Hospital Based
		<input type="checkbox"/> Private Practice (in office)	

HEALTHCARE FACILITY AGREEMENT

I am the authorized representative designated by my healthcare facility to coordinate the activities of the LEMTRADA REMS. By signing this form, I agree to comply with the following REMS requirements:

- | | |
|---|---|
| <ul style="list-style-type: none"> I understand that my healthcare facility must be certified with the LEMTRADA REMS to receive or administer LEMTRADA. I have completed the review of the <i>LEMTRADA REMS Education Program for Healthcare Facilities</i> and the LEMTRADA REMS Program Overview. I understand that my healthcare facility must confirm that the patient is authorized to receive LEMTRADA by contacting the LEMTRADA REMS or verifying online at www.LemtradaREMS.com prior to initiation of each treatment course. I understand the risk of serious infusion reactions during and following the administration of LEMTRADA. I understand the risk of stroke during and following the administration of LEMTRADA. | <ul style="list-style-type: none"> I understand the need to monitor patients for infusion reactions during and for at least 2 hours after each LEMTRADA infusion. <ul style="list-style-type: none"> - To include the monitoring of patient vital signs before the infusion and periodically during the infusion. I understand that my healthcare facility must be equipped with the necessary on-site equipment and personnel to manage anaphylaxis or serious infusion reactions. I understand that my healthcare facility must renew enrollment in the LEMTRADA REMS every 2 years from initial enrollment. |
|---|---|

HEALTHCARE FACILITY AGREEMENT (CONTINUED)

- This healthcare facility will establish procedures and protocols that are subject to audit, to help ensure compliance with the safe-use conditions required in the LEMTRADA REMS , including the following:
 - Ensure that a LEMTRADA REMS Prescription Ordering Form is received for each prescription.
 - Ensure that the prescriber is certified and the patient is enrolled and authorized by either calling the LEMTRADA REMS or verifying this information via the LEMTRADA REMS website prior to dispensing and administering LEMTRADA.
 - Ensure that the infusion site is equipped to manage infusion reactions.
 - Ensure that LEMTRADA is not dispensed outside of the authorized representative’s certified healthcare facility.
 - Prior to the first day of each treatment course, counsel and provide a copy of *What You Need to Know About LEMTRADA Treatment and Infusion Reactions: A Patient Guide* to each patient to inform them about the risk of serious infusion reactions.
 - Observe each patient administered LEMTRADA at my healthcare facility during and for at least 2 hours after each LEMTRADA infusion, in order to provide appropriate medical treatment in the event of serious infusion reactions following LEMTRADA infusion.
- For each patient, complete and return the LEMTRADA REMS Infusion Checklist to the LEMTRADA REMS Program within 5 business days from the patient’s last infusion of LEMTRADA within a specific treatment course.
- Renew enrollment into the LEMTRADA REMS Program every 2 years from the initial enrollment.
- To make available to Genzyme documentation to verify understanding of, and adherence to, the requirements of the LEMTRADA REMS .
- To return to Genzyme any unused vials of LEMTRADA within 50 days from the submission date of the LEMTRADA REMS Patient Authorization and Baseline Lab Form.
- To ensure that a LEMTRADA REMS Patient Authorization and Baseline Lab Form is received for each prescription by either calling the LEMTRADA REMS or verifying this information via the LEMTRADA REMS website.
- To ensure that all non-prescribing HCPs who administer LEMTRADA in my healthcare setting are trained using the LEMTRADA REMS Program Overview and the *LEMTRADA REMS Education Program for Healthcare Facilities*, and a record regarding such training must be maintained.

SIGNATURE

Authorized Healthcare Facility Representative Signature*

Date*

Print Name*

Title

Please fax this completed form to the LEMTRADA REMS at 1-855-557-2478 or enroll online at www.LemtradaREMS.com

If you have any questions regarding the LEMTRADA REMS , call 1-855-676-6326

What Is the LEMTRADA REMS (Risk Evaluation and Mitigation Strategy)?

A REMS is a strategy to manage known or potential risks associated with a drug. It is required by the FDA to ensure that the benefits of the drug outweigh its risks. Due to serious risks of autoimmune conditions, infusion reactions, stroke and malignancies, LEMTRADA[®] (alemtuzumab) is only available through a restricted program called the LEMTRADA REMS.

LEMTRADA REMS Requirements

- Prescribers must be enrolled in the LEMTRADA REMS to be able to prescribe LEMTRADA.
- Pharmacies must be enrolled in the LEMTRADA REMS to be able to dispense LEMTRADA.
- Healthcare Facilities must be enrolled in the LEMTRADA REMS to be able to dispense and administer LEMTRADA.
- Patients must be enrolled and authorized in the LEMTRADA REMS in order to receive LEMTRADA.

PRESCRIBER ENROLLMENT INSTRUCTIONS

1. Complete the training program, which includes reviewing the following:
 - LEMTRADA Prescribing Information
 - LEMTRADA REMS Program Overview
 - *LEMTRADA REMS Education Program for Prescribers*
2. Successfully complete the 8-question LEMTRADA REMS Knowledge Assessment.
3. Enroll in the program by completing a LEMTRADA REMS Prescriber Enrollment Form.
4. Submit the completed and signed Forms to the LEMTRADA REMS.

PHARMACY ENROLLMENT INSTRUCTIONS

1. An authorized representative must enroll on behalf of the pharmacy by reviewing the LEMTRADA REMS Program Overview and completing the LEMTRADA REMS Pharmacy Enrollment Form, which acknowledges that the pharmacy agrees to follow the procedures outlined in the LEMTRADA REMS, including:
 - All relevant staff at the pharmacy who will be involved with the dispensing of LEMTRADA must be educated and trained.
 - The pharmacy will verify that a LEMTRADA REMS Prescription Ordering Form is received for each prescription.
 - The pharmacy will verify that prescribers and healthcare facilities are certified and patients are authorized to receive LEMTRADA prior to dispensing LEMTRADA.
 - Enrollment in the LEMTRADA REMS must be renewed every 2 years from initial enrollment.
2. Submit the completed and signed LEMTRADA REMS Pharmacy Enrollment Form to the LEMTRADA REMS.

HEALTHCARE FACILITY ENROLLMENT INSTRUCTIONS

1. An authorized representative must enroll on behalf of the healthcare facility by reviewing the *LEMTRADA REMS Education Program for Healthcare Facilities* and completing the LEMTRADA REMS Healthcare Facility Enrollment Form, which acknowledges that the healthcare facility agrees to follow the procedures outlined in the LEMTRADA REMS, including:
 - All staff at the facility who will be involved with the dispensing and administration of LEMTRADA must be trained, and a written record of all staff REMS trainings must be kept on file.
 - The healthcare facility will verify that prescribers are certified and patients are authorized to receive LEMTRADA prior to dispensing or administering LEMTRADA.
 - The healthcare facility will provide a copy of *What You Need to Know About LEMTRADA Treatment and Infusion Reactions: A Patient Guide* to the patient on the first day of each treatment course when LEMTRADA is dispensed.
 - The healthcare facility will complete a LEMTRADA REMS Infusion Checklist for each patient at the conclusion of each treatment course and submit it to the LEMTRADA REMS within 5 business days.
 - Enrollment in the LEMTRADA REMS must be renewed every 2 years from initial enrollment.
2. Submit the completed and signed LEMTRADA REMS Healthcare Facility Enrollment Form to the LEMTRADA REMS.

PATIENT ENROLLMENT INSTRUCTIONS

1. Complete the LEMTRADA REMS Patient Enrollment Form, which contains information to be completed by both the prescriber and the patient.
2. Provide a copy of *What You Need to Know About LEMTRADA Treatment: A Patient Guide* and a LEMTRADA Patient Safety Information Card to each patient who will receive LEMTRADA. You must use *What You Need to Know About LEMTRADA Treatment: A Patient Guide* to counsel your patients on the serious risks and REMS requirements with the use of LEMTRADA.
3. Submit the completed and signed LEMTRADA REMS Patient Enrollment Form to the LEMTRADA REMS.
4. Provide the patient with a copy of the LEMTRADA REMS Patient Enrollment Form and keep a copy in the patient's medical record.

Where to Find REMS Information and Resources

To enroll in the LEMTRADA REMS, call 1-855-676-6326. For information related to enrollment in the LEMTRADA REMS, call 1-855-676-6326 or visit www.LemtradaREMS.com

Indication and Usage

LEMTRADA is indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include relapsing-remitting disease and active secondary progressive disease, in adults. Because of its safety profile, the use of LEMTRADA should generally be reserved for patients who have had an inadequate response to two or more drugs indicated for the treatment of MS.

Limitations of Use:

LEMTRADA is not recommended for use in patients with clinically isolated syndrome (CIS) because of its safety profile.

The Prescribing Information includes a **BOXED WARNING** for LEMTRADA.

Please see accompanying Prescribing Information for complete safety information, including **BOXED WARNING**.

LEMTRADA REMS Education Program for Prescribers

This education program includes information about:

- The LEMTRADA REMS requirements
- Serious risks of autoimmune conditions, infusion reactions, stroke and malignancies
- Counseling and management of your patient


LEMTRADA[®]
alemtuzumab^{12mg}
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What Is the LEMTRADA REMS?

A REMS (Risk Evaluation and Mitigation Strategy) is a strategy to manage known or potential risks associated with a drug, and is required by the FDA to ensure that the benefits of the drug outweigh its risks. Due to serious risks of autoimmune conditions, infusion reactions, stroke and malignancy, LEMTRADA is only available through a restricted program called the LEMTRADA REMS.

This brochure has been developed as part of the LEMTRADA REMS to help educate prescribers about the risks associated with LEMTRADA and how to help mitigate these risks through periodic monitoring for, and prompt identification of, signs and symptoms of these events.

- Prescribers must be enrolled in the LEMTRADA REMS to be able to prescribe LEMTRADA.
- Pharmacies must be enrolled in the LEMTRADA REMS to be able to dispense LEMTRADA.
- Healthcare Facilities must be enrolled in the LEMTRADA REMS to be able to dispense and administer LEMTRADA.
- Patients must be enrolled and authorized in the LEMTRADA REMS in order to receive LEMTRADA.

Steps for Prescriber Certification and Enrollment in the LEMTRADA REMS

1. Complete the training program, which includes reviewing the following materials:

- LEMTRADA Prescribing Information
- LEMTRADA REMS Program Overview
- LEMTRADA REMS Education Program for Prescribers

2. Successfully complete the 8-question Knowledge Assessment

3. Enroll in the program by completing a LEMTRADA REMS Prescriber Enrollment Form

4. Submit the completed and signed Forms to the LEMTRADA REMS

The LEMTRADA REMS Program Overview, Knowledge Assessment, LEMTRADA Prescribing Information, and other REMS materials are available online at www.LemtradaREMS.com or by contacting the LEMTRADA REMS at 1-855-676-6326.

To enroll in the LEMTRADA REMS Program, call 1-855-676-6326 or go to www.LemtradaREMS.com

Genzyme will send confirmation of a prescriber's enrollment in the LEMTRADA REMS, including the prescriber's assigned LEMTRADA REMS identification number.

You will not be able to prescribe LEMTRADA without completing your certification in the LEMTRADA REMS.

You should understand that if you fail to comply with the LEMTRADA REMS requirements, you may no longer be able to participate in the LEMTRADA REMS.



Overview of Important Safety Information

INDICATION AND USAGE

LEMTRADA is indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include relapsing-remitting disease and active secondary progressive disease, in adults. Because of its safety profile, the use of LEMTRADA should generally be reserved for patients who have had an inadequate response to two or more drugs indicated for the treatment of MS.

Limitations of Use

LEMTRADA is not recommended for use in patients with clinically isolated syndrome (CIS) because of its safety profile.

The Prescribing Information includes a **BOXED WARNING** for LEMTRADA.

Please see the Prescribing Information for complete safety information, including **BOXED WARNING**.

SERIOUS RISKS ASSOCIATED WITH LEMTRADA

Autoimmune Conditions

LEMTRADA has been associated with risk of autoimmune conditions, including immune thrombocytopenia, other cytopenias (including neutropenia, hemolytic anemia, and pancytopenia), thyroid disorders and glomerular nephropathies, which may occur many years after treatment and may be serious or life-threatening. Early detection and treatment of these conditions may decrease the risk of poor outcomes.

Please review the sections that follow to gain a better understanding of the risks of autoimmune conditions.

Immune Thrombocytopenia (ITP)

Immune thrombocytopenia (ITP) occurred in 2% of LEMTRADA-treated patients in clinical studies (controlled and open-label extension) in MS. Immune thrombocytopenia is an autoimmune disorder usually associated with anti-platelet antibodies. Platelet depletion reduces the ability of the blood to clot. Symptoms of ITP could include (but are not limited to) easy bruising, petechiae, spontaneous mucocutaneous bleeding (epistaxis, hemoptysis), and heavier than normal or irregular menstrual bleeding. These clinical signs of ITP may be apparent before serious bleeding develops.

ITP can be a serious condition leading to morbidity and mortality, and may occur several years after dosing. It is important to monitor all patients for ITP as follows:

- Complete blood counts with differential should be obtained ≤ 30 days prior to initiation of treatment and at monthly intervals thereafter until 48 months after the patient's last infusion of LEMTRADA. After this period of time, testing should be performed based on clinical findings suggestive of ITP.
- Check the patient for clinical symptoms of ITP.
- Counsel the patient on the importance of complying with monthly monitoring of their blood and the need to continue for 48 months after their last infusion.
- Educate the patient on how to recognize ITP related symptoms, and emphasize the need to remain vigilant for them.
- If ITP is suspected, appropriate medical intervention should be promptly initiated, including immediate referral to a specialist. Severe or widespread bleeding is life-threatening and demands immediate care.

The potential risk associated with retreatment with LEMTRADA following the occurrence of ITP is unknown.

Potential Clinical Presentations of ITP

Note: These pictures are only a guide in order to show examples of bruises or petechiae. The patient may have a less severe type of bruise or petechiae than these pictures and still have ITP.



This is an example of a leg with petechiae.

Petechiae are small, scattered, “pinprick” spots under the skin that are red, pink or purple.

Petechiae can occur anywhere on the patient’s body, not just the legs.



This is an example of easy or excessive bruising.

This could occur anywhere on the patient’s body.



This is an example of purpura under the tongue.

Purpura could occur on any mucous membrane, including anywhere in the mouth (under the tongue, roof of the mouth, inner cheeks, tongue, gums).

Images © 2015 Genzyme Corporation.

Other Autoimmune Cytopenias (including neutropenia, hemolytic anemia, and pancytopenia)

Autoimmune cytopenias such as neutropenia, hemolytic anemia, and pancytopenia have been reported in clinical studies (controlled and open-label extension) in MS. One LEMTRADA-treated patient with autoimmune pancytopenia died from sepsis. Symptoms of autoimmune hemolytic anemia may include weakness, chest pain, jaundice, dark urine, and tachycardia. Use the monthly CBC results to monitor for cytopenias. If a cytopenia is confirmed, appropriate medical intervention should be promptly initiated.

Glomerular Nephropathies

Glomerular nephropathies, including anti-glomerular basement membrane (GBM) disease, have been reported after treatment with LEMTRADA in multiple sclerosis patients in clinical trials. Cases of anti-GBM disease have been diagnosed up to 40 months after the last dose of LEMTRADA.

In postmarketing cases, some LEMTRADA-treated patients with anti-GBM disease developed end-stage renal disease requiring dialysis or renal transplantation. Urgent evaluation and treatment is required, because early treatment can improve the preservation of renal function. Anti-GBM disease can be life-threatening if left untreated.

Clinical manifestations of nephropathy may include elevation in serum creatinine, edema, hematuria, change in urine color, decreased urine output, fatigue, dyspnea, and/or proteinuria. While not observed in clinical trials, alveolar hemorrhage manifested as hemoptysis is a common component of anti-GBM disease. Since patients may be asymptomatic, it is important that the monthly tests are conducted.

- Serum creatinine levels, urinalysis with cell counts, and urine protein to creatinine ratio should be obtained ≤ 30 days prior to the first infusion of LEMTRADA. Serum creatinine and urinalysis with cell counts should be obtained at monthly intervals thereafter until 48 months after the patient's last infusion. After this period of time, testing should be performed based on clinical findings suggestive of nephropathies.
- In menstruating females, consider the timing of urinalysis to avoid false positives. The observation of clinically significant changes from baseline in serum creatinine, unexplained hematuria, and/or proteinuria, should prompt further evaluation for nephropathies, including referral to a specialist.
- Early detection and treatment of nephropathies may decrease the risk of poor outcomes.
- Immediate referral to a specialist for further assessment for patients with suspected nephropathy is strongly recommended.

Thyroid Disorders

During clinical trials, autoimmune thyroid disorders including Graves' disease, hyperthyroidism, hypothyroidism, autoimmune thyroiditis, and goiter were reported. Thyroid endocrine disorders, including autoimmune thyroid disorders occurred in 36.8% of LEMTRADA-treated patients in clinical studies (controlled and open-label extension).

Newly diagnosed thyroid disorders occurred throughout the uncontrolled clinical study follow-up period, more than 7 years after the first LEMTRADA dose. Serious thyroid events occurred in 5.2% of patients. Of all LEMTRADA-treated patients, 3.8% underwent thyroidectomy.

It is important to monitor all patients for thyroid disorders as follows:

- Thyroid function tests such as thyroid stimulating hormone (TSH) levels should be obtained ≤ 30 days prior to the first infusion of LEMTRADA and then every 3 months thereafter continuing until 48 months following the last infusion. Continue to test thyroid function after 48 months if clinically indicated.
- Additionally watch out for signs and symptoms of thyroid disorders, which may include excessive sweating, unexplained weight loss, eye swelling, nervousness and fast heartbeat (hyperthyroidism), or unexplained weight gain, feeling cold, worsening tiredness and newly occurring constipation (hypothyroidism).



- Thyroid disease poses special risks in women who become pregnant. Untreated thyroid disease can cause harm to the unborn and newborn baby. Special caution should be taken for pregnant women with Graves' disease, as maternal thyroid stimulating hormone receptor antibodies can be transferred to a developing fetus and can cause transient neonatal Graves' disease. The HCP responsible for managing the patient's pregnancy must be made aware of the increased risk of thyroid disorders due to the patient's LEMTRADA treatment, and the need for these to be appropriately treated.

Autoimmune Hepatitis

Autoimmune hepatitis causing clinically significant liver injury, including acute liver failure requiring transplant, has been reported in patients treated with LEMTRADA in the postmarketing setting. If a patient develops clinical signs, including unexplained liver enzyme elevations or symptoms suggestive of hepatic dysfunction (e.g., unexplained nausea, vomiting, abdominal pain, fatigue, anorexia, or jaundice and/or dark urine), promptly measure serum transaminases and total bilirubin and interrupt or discontinue treatment with LEMTRADA, as appropriate.

Prior to starting treatment with LEMTRADA, obtain serum transaminases (ALT and AST) and total bilirubin levels. Obtain transaminase levels and total bilirubin levels periodically until 48 months after the last dose.

Strategies to Mitigate the Risk of Autoimmune Conditions

In order to minimize possible risks and side effects of LEMTRADA, prescribers and patients must commit to 48 months of follow-up after the last infusion of LEMTRADA. It is important that patients understand that they should continue with the monitoring, even if they are feeling well.

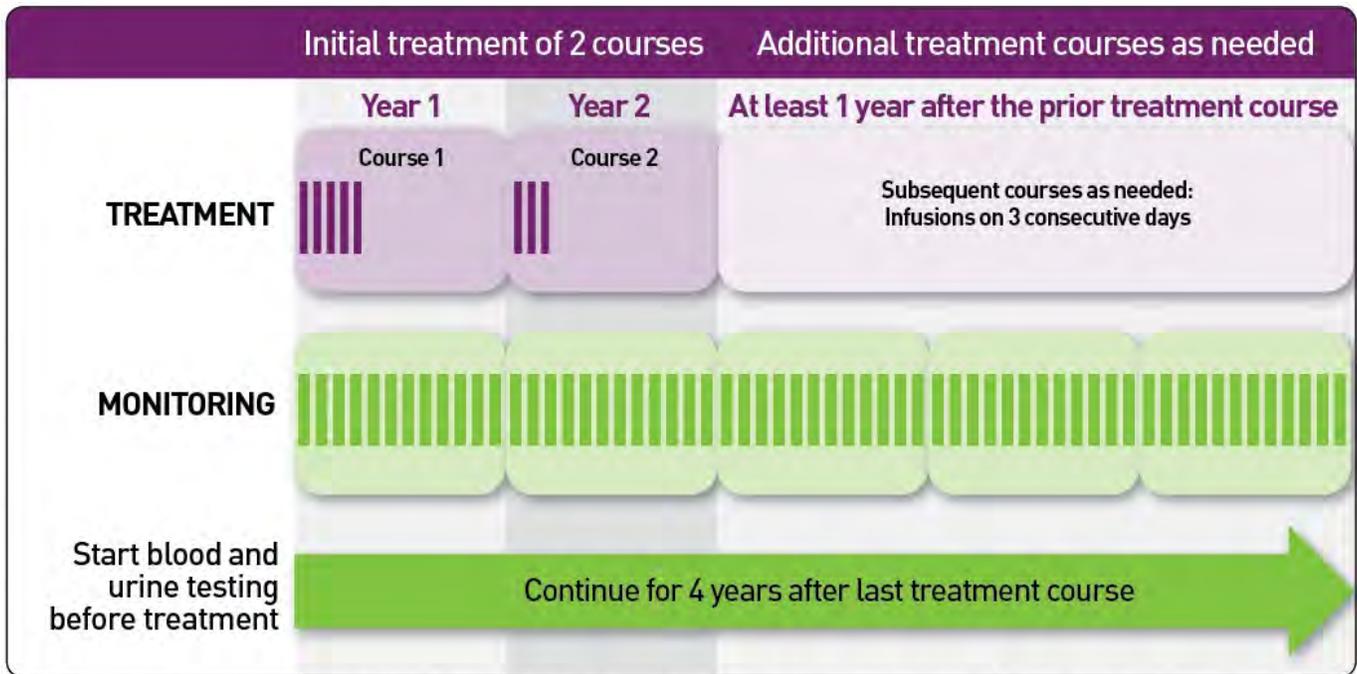
Creating a partnership between you and your patient, along with careful review of the patient education tool (*What You Need to Know About LEMTRADA Treatment: A Patient Guide*) with your patient, will help patients to:

- Comply with periodic tests
- Identify and report symptoms early
- Receive prompt and appropriate treatment if needed

To enhance your understanding of the duration of the effects of treatment and the length of required follow-up, please refer to the diagrams below titled *Overview of LEMTRADA Treatment* and *Overview of LEMTRADA Monitoring*.



Overview of LEMTRADA Treatment



Mandatory monthly laboratory testing is required until 4 years after the last infusion with LEMTRADA. If more than 2 courses are deemed necessary, administer subsequent course(s) at least 1 year after the prior treatment course. Mandatory monthly monitoring may extend beyond 5 years, until at least 4 years after the last infusion.

Overview of LEMTRADA Monitoring

Condition	Activity	Timing	
Immune Thrombocytopenia (ITP)	Complete blood count with differential	Prior to initiating LEMTRADA treatment	Monthly until 48 months after last infusion
Glomerular Nephropathies, including anti-GBM disease	Urine protein to creatinine ratio	Prior to initiating LEMTRADA treatment	
	Serum creatinine	Prior to initiating LEMTRADA treatment	Monthly until 48 months after last infusion
	Urinalysis with microscopy	Prior to initiating LEMTRADA treatment	Monthly until 48 months after last infusion
Thyroid Disorders	Thyroid function tests (such as TSH)	Prior to initiating LEMTRADA treatment	Every 3 months until 48 months after last infusion
Autoimmune Hepatitis	Serum transaminases (ALT and AST) and total bilirubin levels	Prior to initiating LEMTRADA treatment	Periodically until 48 months after last infusion
Melanoma	Skin examinations	Prior to initiating LEMTRADA treatment	Yearly

Infusion Reactions

Most patients treated with LEMTRADA in controlled clinical trials in MS experienced infusion reactions during or after LEMTRADA administration. Some of these reactions were serious and life-threatening. In some patients, infusion reactions were reported more than 24 hours after LEMTRADA infusion. Serious reactions occurred in 3% of patients, including cases of anaphylaxis in 2 patients (including anaphylactic shock), angioedema, bronchospasm, hypotension, chest pain, bradycardia, tachycardia (including atrial fibrillation), transient neurologic symptoms, hypertension, headache, pyrexia, and rash. Other infusion reactions included nausea, urticaria, pruritus, insomnia, chills, flushing, fatigue, dyspnea, pulmonary infiltrates, dysgeusia, dyspepsia, dizziness and pain. In clinical studies, 0.6% of patients with infusion reactions received epinephrine or atropine.

Cases of pulmonary alveolar hemorrhage and myocardial ischemia have been reported with onset within 48 hours of LEMTRADA infusion.

Premedicate with high-dose corticosteroids (1000 mg of methylprednisolone or equivalent) immediately prior to LEMTRADA infusion and for the first 3 days of each treatment course. Consider pretreatment with antihistamines and/or antipyretics prior to LEMTRADA administration. Infusion reactions may occur in patients despite pretreatment.

Consider additional monitoring in patients with medical conditions which predispose them to cardiovascular or pulmonary compromise. Physicians should alert patients that an infusion reaction could occur within 48 hours of infusion.

LEMTRADA can only be administered in certified healthcare settings that have on-site access to equipment and personnel trained to manage infusion reactions (including anaphylaxis and cardiac and respiratory emergencies).

Patients must be observed for infusion reactions during and for at least 2 hours after each LEMTRADA infusion. Consider longer periods of observation if clinically indicated. Vital signs should be monitored before the infusion and periodically during the infusion. If an infusion reaction occurs, appropriate symptomatic treatment should be provided as needed. The duration of the infusion may be extended if clinically indicated. If severe infusion reactions occur, immediate discontinuation of the infusion should be considered.

Stroke and Cervicocephalic Arterial Dissection

Stroke

In the postmarketing setting, serious and life-threatening stroke (including ischemic and hemorrhagic stroke) has been reported within 3 days of LEMTRADA administration, with most cases occurring within 1 day.

Cervicocephalic Arterial Dissection

In the postmarketing setting, cases of cervicocephalic (e.g., vertebral, carotid) arterial dissection involving multiple arteries have been reported within 3 days of LEMTRADA administration. Ischemic stroke was reported in one of these cases.

Educate patients on the symptoms of stroke and cervicocephalic (e.g., carotid, vertebral) arterial dissection. Instruct patients to seek immediate medical attention if symptoms of stroke or cervicocephalic arterial dissection occur.

Malignancies

LEMTRADA is an immunomodulatory therapy, and caution should be exercised in initiating LEMTRADA in patients with pre-existing or ongoing malignancies.

Thyroid Cancer

LEMTRADA may increase the risk of thyroid cancer. In controlled clinical studies, 0.3% of LEMTRADA-treated patients developed thyroid cancer, compared to none in the interferon beta-1a-treated group. However, screening for thyroid cancer was performed more frequently in the LEMTRADA-treated group, because of the higher incidence of autoimmune thyroid disorders in those patients. Two additional cases of thyroid cancer in LEMTRADA-treated patients occurred in uncontrolled studies.

Melanoma

LEMTRADA may increase the risk of melanoma. In clinical studies, including extension data, 0.3% LEMTRADA-treated patients developed melanoma or melanoma in situ. One of those patients had evidence of locally advanced disease.

Lymphoproliferative Disorders and Lymphoma

Cases of lymphoproliferative disorders and lymphoma have occurred in LEMTRADA-treated patients with MS, including a MALT lymphoma, Castleman's Disease, and a fatality following treatment of non-Epstein Barr Virus-associated Burkitt's lymphoma. There are postmarketing reports of Epstein Barr Virus-associated lymphoproliferative disorders in non-MS patients.

Monitoring for Malignancies

Patients and healthcare providers should monitor for symptoms of thyroid cancer, including a new lump or swelling in the neck, pain in the front of the neck, persistent hoarseness or other voice changes, trouble swallowing or breathing, or a constant cough not due to an upper respiratory tract infection.

Perform baseline and yearly skin examinations to monitor for melanoma in patients receiving LEMTRADA.

Patient Enrollment, Counseling, and Management

To enroll your patient in the LEMTRADA REMS, you must:

- Complete the LEMTRADA REMS Patient Enrollment Form for each patient and provide a completed copy to the patient. The completed form should be submitted to the LEMTRADA REMS and a copy stored in the patient's records.
- Enrollment forms can be obtained online (www.LemtradaREMS.com) or by phone (1-855-676-6326).
- Completed forms should be faxed to 1-855-557-2478.
- Genzyme will provide confirmation of patient enrollment.

As part of patient management and counseling, you must:

- Inform your patient about the risks associated with LEMTRADA, including the risks of autoimmune conditions, infusion reactions, stroke and malignancies, and the need for baseline and periodic monitoring. A patient-directed educational guide has been developed for you to use in counseling your patients on the risks associated with LEMTRADA (*What You Need to Know About LEMTRADA Treatment: A Patient Guide*). You should review this guide with your patient on an ongoing basis. You must provide each patient with a copy of this guide and a LEMTRADA Patient Safety Information Card
- Perform the baseline and periodic monitoring described above and in the Prescribing Information for LEMTRADA.
- Complete the LEMTRADA REMS Patient Status Form 6 months after the patient's first infusion with LEMTRADA, and every 6 months thereafter, until 48 months after the completion of the patient's last infusion of LEMTRADA, and submit the completed form to the LEMTRADA REMS.
- Notify Genzyme if an enrolled patient who has received LEMTRADA within the last 48 months is no longer under your care.

Ordering LEMTRADA

To order LEMTRADA, you must submit a LEMTRADA REMS Prescription Ordering Form for each LEMTRADA prescription to the LEMTRADA REMS. The ordering form can be obtained online (www.LemtradaREMS.com) or by phone (1-855-676-6326).

Completed forms should be faxed to 1-855-557-2478.

Administering LEMTRADA

As part of the LEMTRADA REMS, a healthcare facility must be enrolled in the LEMTRADA REMS to be able to dispense/administer LEMTRADA. It is important that you select a healthcare facility that is enrolled and active in the LEMTRADA REMS for your patient's infusion. A database of certified healthcare facilities is available by phone at 1-855-676-6326.

Prior to your patient's infusion, you must submit a LEMTRADA REMS Patient Authorization and Baseline Lab Form to the LEMTRADA REMS indicating completion of each patient's baseline labs within 30 days of the infusion date.

PRIOR TO EACH TREATMENT COURSE OF LEMTRADA

- Administer corticosteroids (1000 mg methylprednisolone or equivalent) immediately prior to LEMTRADA administration for the first 3 days of any treatment course
- Administer anti-viral prophylaxis for herpetic viral infection starting on the first day of each treatment course and continuing for a minimum of 2 months following treatment with LEMTRADA or until the CD4+ lymphocyte count is ≥ 200 cells per microliter, whichever occurs later
- Consider pretreating patients with antihistamines and/or antipyretics prior to LEMTRADA administration as needed

Adverse Event Reporting

Report suspected adverse events to Genzyme Medical Information at 1-800-745-4447 (option 2) or to FDA at 1-800-FDA-1088 or www.FDA.gov/medwatch.





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US.MS.LEM.14.10.003-v6 Last Updated 07/19



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alemtuzumab^{12mg} iv

VV-REG-0833078 0.1

LEMTRADA REMS Knowledge Assessment

To Become a Certified Prescriber in the LEMTRADA REMS, You Will Need to Answer ALL 8 Questions Correctly

- Complete the Knowledge Assessment, populate and sign the one-time LEMTRADA REMS Prescriber Enrollment Form. Fax your responses to the 8 Knowledge Assessment questions and the LEMTRADA REMS Prescriber Enrollment Form to 1-855-557-2478. You can also complete the Knowledge Assessment online at www.LemtradaREMS.com
- You will receive correspondence from the LEMTRADA REMS via the preferred communication method (email or fax) selected on your enrollment form within two business days. Correspondence may include:
 - How to retake the Knowledge Assessment, if necessary
 - A confirmation of your enrollment and certification in the LEMTRADA REMS (which requires no further action)



Questions 1-8

QUESTION 1 (check one)

Which of the following laboratory tests are required prior to initiating LEMTRADA treatment and within 30 days of the first infusion?

- A. Complete blood count (CBC) with differential
- B. Serum creatinine and urinalysis with urine cell counts
- C. Urine protein to creatinine ratio
- D. Thyroid function test
- E. All of the above

QUESTION 2 (check one)

My patient must have monthly blood and urine tests for:

- A. 12 months after their last infusion
- B. 24 months after their last infusion
- C. 36 months after their last infusion
- D. 48 months after their last infusion

QUESTION 3

I should assess my patient's compliance with required lab testing on an ongoing basis and document their compliance on the LEMTRADA REMS Patient Status Form every 6 months.

- True
- False

QUESTION 4 (check one)

Which of the following symptoms could be associated with immune thrombocytopenia (ITP)?

- A. Headache, rash, pyrexia, nausea
- B. Easy bruising, petechiae, purpura, spontaneous mucocutaneous bleeding
- C. Weight gain, fatigue, constipation
- D. Pyrexia, chills, swollen glands

QUESTION 5 (check one)

Which of the following could be associated with glomerular nephropathy?

- A. Elevation in serum creatinine, hematuria, or proteinuria
- B. Easy bruising, petechiae, purpura, spontaneous mucocutaneous bleeding (e.g., epistaxis, hemoptysis), and heavier than normal or irregular menstrual bleeding
- C. Weight gain, fatigue, constipation
- D. Weight loss, tachycardia, nervousness

QUESTION 6 (check one)

Prior to enrolling a patient in the LEMTRADA REMS, you should:

- A. Provide *What You Need to Know About LEMTRADA Treatment: A Patient Guide* to the patient
- B. Counsel the patient on the serious risks associated with LEMTRADA and how to mitigate these risks through periodic monitoring
- C. Provide a LEMTRADA Patient Safety Information Card to the patient
- D. All of the above

QUESTION 7

Cases of serious and life-threatening stroke (including ischemic and hemorrhagic stroke) have been reported within 3 days of LEMTRADA administration, with most cases occurring within 1 day.

- True
- False

QUESTION 8

The healthcare facility that will administer LEMTRADA infusions to my patient is required to be REMS certified and enrolled, and should have the necessary equipment and personnel to manage serious infusion reactions (including anaphylaxis, and cardiac and respiratory emergencies).

- True
- False

Please provide your prescriber name and NPI number so we can associate your progress with your stakeholder record. You can provide this information below.

Prescriber Name: _____

Prescriber NPI: _____



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US.MS.LEM.14.10.006-v4 Last Updated 03/19

LEMTRADA REMS Education Program for Healthcare Facilities

This Educational Piece Includes Information About:

- The LEMTRADA REMS requirements to implement in your healthcare facility
- Serious risks of autoimmune conditions, infusion reactions, stroke and malignancies
- Proper administration of LEMTRADA® (alemtuzumab)


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alemtuzumab^{12mg}
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What Is the LEMTRADA REMS (Risk Evaluation and Mitigation Strategy)?

A REMS is a strategy to manage known or potential risks associated with a drug and is required by the FDA to ensure that the benefits of the drug outweigh its risks. LEMTRADA is only available under a restricted program called the LEMTRADA REMS because of the risks of infusion reactions, autoimmune conditions, stroke and malignancies. The *LEMTRADA REMS Education Program for Healthcare Facilities* is designed to educate and train healthcare facilities' authorized representatives on the serious risks associated with LEMTRADA, the LEMTRADA REMS requirements, and how to properly administer LEMTRADA.

- **Prescribers** must be enrolled in the LEMTRADA REMS to be able to prescribe LEMTRADA.
- **Pharmacies** must be enrolled in the LEMTRADA REMS to be able to dispense LEMTRADA.
- **Healthcare Facilities** must be enrolled in the LEMTRADA REMS to be able to dispense and administer LEMTRADA.
- **Patients** must be certified and authorized in the LEMTRADA REMS in order to receive LEMTRADA.

STEPS FOR HEALTHCARE FACILITY CERTIFICATION

- | | |
|---|---|
| 1 | Designate an authorized representative. |
| 2 | Review the <i>LEMTRADA REMS Education Program for Healthcare Facilities</i> , including the Prescribing Information. |
| 3 | Complete and sign the LEMTRADA REMS Healthcare Facility Enrollment Form. This enrollment must be renewed every 2 years. |
| 4 | Implement the necessary staff training and processes to comply with the LEMTRADA REMS requirements. |

The *LEMTRADA REMS Education Program for Healthcare Facilities*, LEMTRADA REMS Healthcare Facility Enrollment Form, and other LEMTRADA REMS tools are available online at www.LemtradaREMS.com or by contacting the LEMTRADA REMS at 1-855-676-6326.

To enroll in the LEMTRADA REMS, call 1-855-676-6326 or enroll online at www.LemtradaREMS.com.

Who Can Be An Authorized Representative?

An authorized representative at the healthcare facility can be a:

- Pharmacist
- Director of infusion center
- Prescriber
- Nurse
- Or any responsible individual in the healthcare facility

Please check with your manager to ensure the appropriate person represents the healthcare facility and attests to the enrollment requirements as stated on the LEMTRADA REMS Healthcare Facility Enrollment Form.

- One representative needs to enroll per healthcare facility (the “authorized representative”). One authorized representative can manage more than one healthcare facility.
- Please note, there are no LEMTRADA REMS requirements for staff at a healthcare facility who will not be involved with dispensing or administering LEMTRADA.

Overview of Important Safety Information

INDICATION AND USAGE

LEMTRADA is indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include relapsing-remitting disease and active secondary progressive disease, in adults. Because of its safety profile, the use of LEMTRADA should generally be reserved for patients who have had an inadequate response to two or more drugs indicated for the treatment of MS.

Limitations of Use:

LEMTRADA is not recommended for use in patients with clinically isolated syndrome (CIS) because of its safety profile.

The Prescribing Information includes a **BOXED WARNING** for LEMTRADA.

Please see the Prescribing Information for complete safety information, including **BOXED WARNING**.

SERIOUS RISKS ASSOCIATED WITH LEMTRADA

Infusion Reactions

Most patients treated with LEMTRADA in controlled clinical trials in MS experienced infusion reactions during or after LEMTRADA administration. Some of these reactions were serious and life-threatening. In some patients, infusion reactions were reported more than 24 hours after LEMTRADA infusion. Serious reactions occurred in 3% of patients, including cases of anaphylaxis in 2 patients (including anaphylactic shock), angioedema, bronchospasm, hypotension, chest pain, bradycardia, tachycardia (including atrial fibrillation), transient neurologic symptoms, hypertension, headache, pyrexia, and rash. Other infusion reactions included nausea, urticaria, pruritus, insomnia, chills, flushing, fatigue, dyspnea, pulmonary infiltrates, dysgeusia, dyspepsia, dizziness, and pain. In clinical studies, 0.6% of patients with infusion reactions received epinephrine or atropine. Cases of pulmonary alveolar hemorrhage and myocardial ischemia have been reported with onset within 48 hours of LEMTRADA infusion.

Premedicate patients with high-dose corticosteroids (1000 mg of methylprednisolone or equivalent) immediately prior to LEMTRADA infusion for the first 3 days of each treatment course. Consider pretreatment with antihistamines and/or antipyretics prior to LEMTRADA administration. Infusion reactions may occur in patients despite pretreatment.

Consider additional monitoring in patients with medical conditions which predispose them to cardiovascular or pulmonary compromise. Prescribers should alert patients that an infusion reaction could occur within 48 hours of infusion.

LEMTRADA can only be administered in certified healthcare settings that have on-site access to equipment and personnel trained to manage infusion reactions (including anaphylaxis and cardiac and respiratory emergencies).

Patients must be observed for infusion reactions during and for at least 2 hours after each LEMTRADA infusion. Consider longer periods of observation if clinically indicated. Vital signs should be monitored before and periodically during the infusion. If an infusion reaction occurs, appropriate symptomatic treatment should be provided as needed. If the infusion is not well tolerated, the duration of the infusion may be extended. If severe infusion reactions occur, immediate discontinuation of the infusion should be considered.

Stroke and Cervicocephalic Arterial Dissection

Stroke

In the postmarketing setting, serious and life-threatening stroke (including ischemic and hemorrhagic stroke) has been reported within 3 days of LEMTRADA administration, with most cases occurring within 1 day.

Cervicocephalic Arterial Dissection

In the postmarketing setting, cases of cervicocephalic (e.g., vertebral, carotid) arterial dissection involving multiple arteries have been reported within 3 days of LEMTRADA administration. Ischemic stroke was reported in one of these cases.

Educate patients on the symptoms of stroke and cervicocephalic (e.g., carotid, vertebral) arterial dissection. Instruct patients to seek immediate medical attention if symptoms of stroke or cervicocephalic arterial dissection occur.

Autoimmune Conditions

LEMTRADA has been associated with risk of autoimmune conditions, including immune thrombocytopenia, other cytopenias (including neutropenia, hemolytic anemia, and pancytopenia), thyroid disorders, and glomerular nephropathies, which may occur many years after treatment and may be serious or life-threatening. Early detection and prompt treatment can help prevent serious and potentially fatal outcomes associated with these events.

Please review the sections that follow to gain a better understanding of the risks of autoimmune conditions.

Immune Thrombocytopenia (ITP)

Immune thrombocytopenia (ITP) is an autoimmune disorder usually associated with anti-platelet antibodies. Platelet depletion reduces the ability of the blood to clot.

ITP was reported in 2% of patients in clinical trials in MS. ITP can be a serious condition leading to morbidity and mortality, and may occur several years after dosing. Prescribers are required to monitor all patients for ITP by obtaining complete blood counts with differential ≤ 30 days prior to initiation of treatment and at monthly intervals thereafter until 48 months after the patient's last infusion of LEMTRADA. After this period of time, testing should be performed based on clinical findings suggestive of ITP. Patients should also be monitored for clinical symptoms of ITP. Symptoms of ITP could include (but are not limited to) easy bruising, petechiae, spontaneous mucocutaneous bleeding (epistaxis, hemoptysis), and heavier than normal or irregular menstrual bleeding. These clinical signs of ITP may be apparent before serious bleeding develops.

POTENTIAL CLINICAL PRESENTATIONS OF ITP

Note: These pictures are only a guide in order to show examples of bruises or petechiae.

The patient may have a less severe type of bruise or petechiae than these pictures and still have ITP.



This is an example of a leg with petechiae.

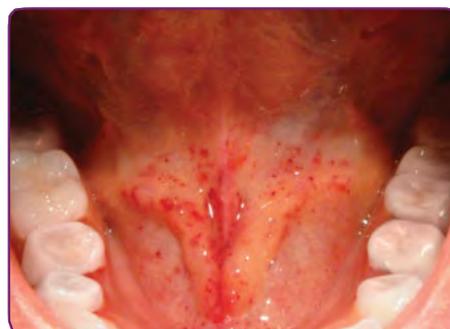
Petechiae are small, scattered, "pinprick" spots under the skin that are red, pink, or purple.

Petechiae can occur anywhere on the patient's body, not just the legs.



This is an example of easy or excessive bruising.

This could occur anywhere on the patient's body.



This is an example of purpura under the tongue.

Purpura could occur on any mucous membrane, including anywhere in the mouth (under the tongue, roof of the mouth, inner cheeks, tongue, gums).

Images © 2015 Genzyme Corporation.

Other Autoimmune Cytopenias (including neutropenia, hemolytic anemia, and pancytopenia)

Autoimmune cytopenias such as neutropenia, hemolytic anemia, and pancytopenia have been reported in clinical studies in MS. One LEMTRADA-treated patient with autoimmune pancytopenia died from sepsis. Symptoms of autoimmune hemolytic anemia may include weakness, chest pain, jaundice, dark urine, and tachycardia. Monthly CBC results will also be used to monitor for cytopenias. If a cytopenia is confirmed, appropriate medical intervention should be promptly initiated.

Glomerular Nephropathies

Glomerular nephropathies, including anti-glomerular basement membrane (anti-GBM) disease, have been reported after treatment with LEMTRADA in MS patients in clinical trials.

In postmarketing cases, some LEMTRADA-treated patients with anti-GBM disease developed end-stage renal disease requiring dialysis or renal transplantation. Urgent evaluation and treatment is required, because early treatment can improve the preservation of renal function. Anti-GBM disease can be life-threatening if left untreated. Cases of anti-GBM disease have been diagnosed up to 40 months after the last dose of LEMTRADA.

Clinical manifestations of nephropathy may include elevation in serum creatinine, hematuria, and/or proteinuria. While not observed in clinical trials, alveolar hemorrhage manifested as hemoptysis may occur with anti-GBM disease. Since patients may be asymptomatic, prescribers are required to monitor patients by obtaining serum creatinine levels, urinalysis with cell counts, and urine protein to creatinine ratio prior to initiation of treatment. Obtain serum creatinine levels and urinalysis with cell counts at monthly intervals thereafter until 48 months after the patient's last infusion. After this period of time, testing should be performed based on clinical findings suggestive of nephropathies.

Thyroid Disorders

Thyroid endocrine disorders, including autoimmune thyroid disorders occurred in 36.8% of LEMTRADA-treated patients in clinical studies (controlled and open-label extension). Newly diagnosed thyroid disorders occurred throughout the uncontrolled clinical study follow-up period, more than 7 years after the first LEMTRADA dose. Serious thyroid events occurred in 5.2% of patients. Prescribers are required to monitor all patients for thyroid disorders by obtaining thyroid function tests, such as thyroid-stimulating hormone (TSH) levels ≤ 30 days prior to the first infusion of LEMTRADA, and then every 3 months thereafter continuing until 48 months following the last infusion. Continue to test thyroid function after 48 months if clinically indicated. Prescribers should also monitor for signs and symptoms of thyroid disorders, which may include excessive sweating, unexplained weight loss, eye swelling, nervousness and fast heartbeat (hyperthyroidism), or unexplained weight gain, feeling cold, worsening tiredness, and newly occurring constipation (hypothyroidism).

Autoimmune Hepatitis

Autoimmune hepatitis causing clinically significant liver injury, including acute liver failure requiring transplant, has been reported in patients treated with LEMTRADA in the postmarketing setting. If a patient develops clinical signs, including unexplained liver enzyme elevations or symptoms suggestive of hepatic dysfunction (e.g., unexplained nausea, vomiting, abdominal pain, fatigue, anorexia, or jaundice and/or dark urine), prescribers should promptly measure serum transaminases and total bilirubin and interrupt or discontinue treatment with LEMTRADA, as appropriate.

Prior to starting treatment with LEMTRADA, prescribers are to obtain serum transaminases (ALT and AST) and total bilirubin levels. Prescribers should obtain transaminase levels and total bilirubin levels periodically until 48 months after the last dose.

Malignancies

LEMTRADA may increase the risk of thyroid cancer. Patients and prescribers should monitor for symptoms of thyroid cancer, including a new lump or swelling in the neck, pain in the front of the neck, persistent hoarseness or other voice changes, trouble swallowing or breathing, or a constant cough not due to an upper respiratory tract infection.

LEMTRADA may increase the risk of melanoma. Prescribers should perform baseline and yearly skin examinations to monitor for melanoma in patients receiving LEMTRADA. Cases of lymphoproliferative disorders and lymphoma have occurred in LEMTRADA-treated patients with MS.

Strategies to Implement in Your Healthcare Facility to Mitigate Risk of Infusion Reactions

- Ensure the infusion site is equipped with the necessary equipment and personnel to manage infusion reactions (including anaphylaxis and cardiac and respiratory emergencies).
- Premedicate patients with high-dose corticosteroids (1000 mg of methylprednisolone or equivalent) immediately prior to LEMTRADA infusion for the first 3 days of each LEMTRADA treatment course. Consider pretreatment with antihistamines and/or antipyretics prior to LEMTRADA administration. Infusion reactions may occur despite pretreatment.
- Observe patients for infusion reactions during and for at least 2 hours after each LEMTRADA infusion.
- Consider longer periods of observation if clinically indicated. Monitor vital signs before and periodically during the infusion.
- Provide appropriate symptomatic treatment as needed if an infusion reaction occurs.
- Consider extending the duration of the infusion if the infusion is not well tolerated.
- Consider immediate discontinuation of the infusion if severe infusion reactions occur.
- Do not administer LEMTRADA outside of the authorized representative's certified healthcare facility.

Proper Storage and Administration

STORAGE OF LEMTRADA

- LEMTRADA is packaged in 12 mg/1.2 mL (10 mg/mL) single-dose vials.
- LEMTRADA vials should be stored at 2° to 8°C (36° to 46°F). Do not freeze or shake. Protect from light.

PRIOR TO EACH TREATMENT COURSE OF LEMTRADA

- Confirm prescriber is certified and patient is enrolled and authorized to receive LEMTRADA.
- Counsel each patient about the risk for infusion reactions.
- Provide the patient with *What You Need to Know About LEMTRADA Treatment and Infusion Reactions: A Patient Guide* prior to dispensing LEMTRADA.
- Administer corticosteroids immediately prior to LEMTRADA administration for the first 3 days of each treatment course.
- Ensure oral prophylaxis for herpes infection is available or has been prescribed to start on the first day of each treatment course. Consider pretreating patients with antihistamines and/or antipyretics prior to LEMTRADA administration as needed.
- Monitor vital signs before and periodically during the infusion.



ADMINISTRATION OF LEMTRADA

1. Inspect vial for particulate matter/discoloration prior to use.
2. Withdraw 1.2 mL of LEMTRADA from the vial into a syringe using aseptic technique.
3. Inject into 100 mL sterile 0.9% Sodium Chloride, USP or 5% Dextrose in Water, USP. Gently invert the bag to mix the solution.
4. Cover IV solution bag to protect from light.
5. Administer 12 mg/day over approximately 4 hours.
6. Do not administer as IV push or bolus.
7. If infusion is not well tolerated, infusion duration may be extended.
8. Use the LEMTRADA diluted product within 8 hours after dilution. LEMTRADA diluted product may be stored at room temperature (15° to 25°C) or refrigerated conditions (2° to 8°C).
Protect from light. Do not administer as IV push or bolus.
9. Monitor patient vital signs before and periodically during the infusion, and provide appropriate symptomatic treatment for infusion reactions as needed.
10. Monitor patients for at least 2 hours after each LEMTRADA infusion or longer if clinically indicated.

FOLLOWING THE CONCLUSION OF EACH LEMTRADA TREATMENT COURSE

- Complete a LEMTRADA REMS Infusion Checklist for each patient at the conclusion of each treatment course and fax (1-855-557-2478) to the LEMTRADA REMS or submit online at www.LemtradaREMS.com within 5 business days of the last infusion.
- Return unused vials of LEMTRADA to Genzyme within 50 days of receipt of the LEMTRADA REMS Patient Authorization and Baseline Lab Form.

Adverse Event Reporting

Report suspected adverse events to Genzyme Medical Information at **1-800-745-4447** (option 2) or to FDA at 1-800-FDA-1088 or www.FDA.gov/medwatch.



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US.MS.LEM.14.10.002-v6 Last Updated 08/19



What You Need to Know About LEMTRADA[®] (alemtuzumab) Treatment: A Patient Guide

Patients: Your doctor or nurse will go over this patient guide with you. It is important to ask any questions you might have prior to each time LEMTRADA[®] (alemtuzumab) is given to you. Keep this guide for important safety information about the serious risks and reactions of LEMTRADA.

Healthcare Providers: Review this patient guide with your patient prior to each treatment course, and provide your patient a copy to take home.



LEMTRADA[®]
alemtuzumab^{12mg}_{iv}

What Is LEMTRADA?

LEMTRADA is a prescription medicine used to treat relapsing forms of multiple sclerosis (MS), to include relapsing-remitting disease and active secondary progressive disease, in adults. Since treatment with LEMTRADA can increase your risk of getting certain conditions and diseases, LEMTRADA is generally prescribed for people who have tried 2 or more MS medicines that have not worked well enough. LEMTRADA is not recommended for use in patients with clinically isolated syndrome (CIS) because of its safety profile.

It is not known if LEMTRADA is safe and effective for use in children under 17 years of age. LEMTRADA is only available at your doctor's office, clinic or hospital. It is not a medicine you will give yourself at home because of the serious risks of LEMTRADA.

What Is the Most Serious Risk Information About LEMTRADA Treatment?

LEMTRADA can cause serious side effects, including infusion reactions and autoimmune conditions, stroke, and may cause certain cancers.

- Most patients treated with LEMTRADA will experience side effects at the time of the infusion or within 24 hours after the infusion (infusion reactions). Common infusion reactions include nausea, hives, itching, difficulty sleeping, chills, flushing, fatigue, shortness of breath, congestion of the lungs, upset stomach, dizziness, and pain.
- Some people receiving LEMTRADA develop a condition where the immune cells in the body attack other cells or organs in the body (autoimmunity) which can be serious and may cause death.
 - Some people have had serious and sometimes deadly strokes and tears in the arteries that provide blood to their brain within 3 days of receiving LEMTRADA. Get help right away if you have any of the following symptoms that may be signs of a stroke or tears in your arteries:
 - drooping of parts of your face
 - weakness on one side
 - sudden severe headache
 - difficulty with speech
 - neck pain

It is important to continually monitor for signs of stroke even after you've received your LEMTRADA infusion. Be sure to tell your doctor if you have had a stroke.

- Receiving LEMTRADA may increase your chance of getting some kinds of cancers (malignancies), including thyroid cancer, skin cancer (melanoma), and blood cancers called lymphoproliferative disorders and lymphoma. Call your healthcare provider if you have the following symptoms that may be a sign of thyroid cancer:
 - new lump
 - swelling in your neck
 - pain in the front of your neck
 - hoarseness or other voice changes that do not go away
 - trouble swallowing or breathing
 - cough that is not caused by a cold

You should have your skin checked before you start receiving LEMTRADA and each year while you are receiving treatment to monitor for symptoms of skin cancer.

What Are the Signs and Symptoms of Infusion Reactions and Autoimmune Conditions After LEMTRADA Treatment, and What Should I Do?

INFUSION REACTIONS

Most patients treated with LEMTRADA will experience side effects at the time of the infusion, some of which may be serious or life-threatening. Serious infusion reactions may happen while you receive LEMTRADA, or up to 24 hours or longer after you receive LEMTRADA.

Tell your healthcare provider right away if you have any of the following symptoms of a serious infusion reaction during the infusion or after you have left the healthcare facility:

- swelling in your mouth or throat
- trouble breathing
- weakness
- fast, slow, or irregular heartbeat
- chest pain
- rash
- symptoms of stroke (drooping of parts of your face, weakness on one side, sudden severe headache, difficulty with speech, neck pain)

In order to try to reduce these effects, your doctor will give you medication (corticosteroids) prior to the first 3 infusions of a treatment course. You may also be given other treatments before or after the infusion to try to reduce your chances of these reactions or to treat them after they happen. In addition, you will be observed during the infusion and for at least 2 hours after the infusion has been completed, or longer if your healthcare provider decides you need to stay longer. In case of serious reactions, it is possible that the infusion may be stopped.



DELAYED SIDE EFFECTS

As mentioned previously, patients receiving LEMTRADA are at risk of certain autoimmune conditions. The autoimmune conditions include:

- immune thrombocytopenia (ITP, or low platelets)
- other blood disorders (including neutropenia, hemolytic anemia, and pancytopenia)
- certain types of kidney diseases
- thyroid disorders
- liver disorders

All of these conditions can be treated and when identified early, treatment may decrease the risk of complications. It is very important to recognize and immediately report any signs or symptoms of these conditions to your doctor.

In the following pages, you will learn more about each of these side effects, including the signs and symptoms that you may experience and what to do if they happen.

Immune Thrombocytopenia (ITP, or low platelets)

ITP is a condition which results in a decrease in the number of platelets in the blood. ITP has been observed in approximately 2% of patients treated with LEMTRADA in MS clinical trials. Platelets are necessary for normal blood clotting. ITP can cause severe bleeding. Delaying treatment of ITP raises the chance of more serious problems.

A blood test will help your doctor watch for changes in your platelet count in order to catch this side effect early. Therefore, your doctor will have your blood tested before starting LEMTRADA and on a monthly basis after your first infusion. The monthly testing must continue until 4 years after your last infusion, or longer if you have signs or symptoms of ITP.

Importantly, ITP may also be detected by certain signs or symptoms that you need to be aware of.

What are the signs and symptoms of ITP?

- Small, scattered spots on your skin that are red, pink, or purple
- Easy bruising
- Bleeding from a cut that is harder to stop
- Coughing up blood
- Heavier, longer, or more frequent menstrual periods than normal. Bleeding between your menstrual periods could also be a sign of ITP
- Bleeding from your gums or nose that is new or takes longer than usual to stop

Call your doctor immediately if you have any of these signs or symptoms. If you cannot reach your doctor, seek immediate medical attention.

These pictures show examples of spots and bruises caused by ITP.



This is an example of a leg with scattered spots under the skin that are red, pink, or purple. They might look like pinpricks.

It is important to note that the spots could occur anywhere on your body, not just on your leg.



This is an example of arms with easy or excessive bruising.

It is important to note bruises could occur anywhere on your body, not just on your arms.



This is an example of spots due to bleeding under the tongue.

It is important to note that this could occur anywhere in your mouth—under the tongue, on the roof of your mouth, on your inner cheeks, on your tongue, or on your gums.

Note: These pictures are only a guide in order to show examples of bruises or rashes.

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What if I develop ITP?

It is best to identify and treat ITP as early as possible. That is why it is so important that you continue to have your monthly blood test and check for symptoms, which could detect a problem before you have symptoms. It is also important that you, your family members, and/or caregivers are watching for any of the signs or symptoms described in this guide. Delaying treatment of ITP raises the chance of more serious problems.

Delaying treatment of ITP raises the chance of more serious problems. If you develop ITP, you and your doctor will decide which treatment is best for you.

If you notice any of the signs or symptoms as described above, call your healthcare provider right away to report the symptoms. If you cannot reach your healthcare provider, seek immediate medical attention.

Other blood disorders (including neutropenia, hemolytic anemia, and pancytopenia)

LEMTRADA may cause a decrease in some types of blood cells. Some people with these low blood counts have increased infections. Symptoms of low blood counts may include weakness, dark urine, chest pain, yellowing of the skin or whites of your eyes (jaundice), or fast heartbeat. Your healthcare provider will do blood tests to check for low blood counts.

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Kidney disorders (such as anti-glomerular basement membrane disease)

LEMTRADA may cause a condition known as anti-glomerular basement membrane disease, or anti-GBM disease. Kidney disorders, including anti-GBM disease, have been observed in 0.3% (3 per 1000) patients treated with LEMTRADA in MS clinical trials. Anti-GBM disease is an autoimmune side effect that can result in severe damage to the kidneys. Anti-GBM disease can also damage the lungs, although this was not seen in clinical trials with LEMTRADA. If untreated it can cause kidney failure requiring chronic dialysis or transplant, and may lead to death. It is best to begin treatment for kidney problems as early as possible.

A blood test and a urine test will help your doctor watch for signs of kidney disease to help catch this potential side effect early. Your doctor will have your blood and urine tested in the month before you start treatment with LEMTRADA, and on a monthly basis after your initial infusion. Your doctor will test your urine monthly, so if you are a woman, it is important to avoid urine testing during your menstrual period as this may give a false result. This testing will continue until 4 years after your last infusion, or longer if you have signs or symptoms of a kidney disorder.

Importantly, anti-GBM disease can also be detected by certain signs and symptoms that you need to be aware of.

What are the signs and symptoms of kidney problems or anti-GBM disease?

- Blood in the urine (red or tea-colored urine)
- Swelling in your legs or feet
- Decrease in urine
- Fatigue
- Coughing up blood

What if I develop kidney problems?

It is best to begin treatment as early as possible. It is important that you are familiar with the signs and symptoms of kidney problems and anti-GBM disease, and complete your regular laboratory tests (blood tests and urine tests). Kidney problems will almost always need treatment.

If you notice any of the signs or symptoms as described above, call your doctor right away to report the symptoms. If you cannot reach your doctor, seek immediate medical attention.

Thyroid disorders

The thyroid is a gland found in the lower part of the neck. This gland produces hormones that are important throughout your body. In some people, the immune system may mistakenly attack the cells of the thyroid gland (autoimmune thyroid condition) which affects its ability to make and control the level of hormones.

LEMTRADA may cause development of thyroid disorders including:

- overactive thyroid gland, or hyperthyroidism, when the thyroid produces too much hormone
- underactive thyroid gland, or hypothyroidism, when the thyroid does not produce enough hormone

An estimated 36.8% of patients experienced thyroid endocrine disorders, including autoimmune thyroid disorders following treatment with LEMTRADA, in MS clinical trials.

Your blood will be checked in the month before you start treatment with LEMTRADA, and every 3 months after your initial infusion, until 4 years after your last LEMTRADA infusion, or longer if you show signs or symptoms of a thyroid disorder. This blood test will help your doctor detect thyroid disorders early.

What are the signs and symptoms of a thyroid disorder?

Overactive thyroid, or hyperthyroidism	Underactive thyroid, or hypothyroidism
<ul style="list-style-type: none">• Excessive sweating• Unexplained weight loss• Eye swelling• Nervousness• Fast heartbeat	<ul style="list-style-type: none">• Unexplained weight gain• Feeling cold• Worsening tiredness• Newly occurring constipation

What if I develop a thyroid disorder?

Tell your doctor if you experience these symptoms. Depending on the type of thyroid disorder, your doctor will decide which treatment is best for you. In some cases, you may have to take medication for the rest of your life for your thyroid disorder. In some situations, your thyroid may need to be removed.

If you develop a thyroid disorder, it is very important that you are properly treated for it, especially if you become pregnant after using LEMTRADA. Having an untreated thyroid disorder could harm your unborn baby, or harm your baby after birth.



Liver disorders

Inflammation of the liver (autoimmune hepatitis) causing serious liver injury, including liver failure requiring a liver transplant, has been reported in patients treated with LEMTRADA. A blood test will help your doctor watch for signs of inflammation of the liver. Your doctor will have your blood tested in the month before you start treatment with LEMTRADA, and from time to time after your initial infusion. This testing will continue until 4 years after your last infusion.

What are the signs and symptoms of autoimmune hepatitis?

- Unexplained nausea
- Vomiting
- Stomach pain
- Tiredness
- Not wanting to eat (loss of appetite)
- Yellowing of skin or whites of the eyes (Jaundice)
- Dark urine
- Easily bleeding or bruising (more than normal)

What if I develop autoimmune hepatitis?

It is best to identify and treat autoimmune hepatitis as early as possible. That is why before starting treatment with LEMTRADA, your doctor will test your blood for signs of inflammation of the liver and will also check those tests from time to time until 4 years after your last infusion.

If you notice any of the signs or symptoms as described above, call your healthcare provider right away to report the symptoms. If you cannot reach your healthcare provider, seek immediate medical attention.

IMPORTANT!

Since all of these autoimmune conditions could occur long after you received a course of treatment with LEMTRADA, it is very important that you continue to have your monthly blood and urine tests (even if you are feeling well).

 You must continue to watch for signs and symptoms

 Do this until 4 years after your last LEMTRADA infusion

Carry your LEMTRADA Patient Safety Information Card with you at all times and show it to any healthcare professionals who are providing you with treatment (including for non-MS conditions) or in the event of a medical emergency.

These are **NOT** all the possible side effects of LEMTRADA. Refer to the LEMTRADA Medication Guide that you were given, or talk to your doctor or nurse for medical advice about other side effects.

How Can I Detect the Delayed Side Effects From LEMTRADA?

To check for the development of autoimmune conditions (previously described), you will have to be monitored monthly by having your blood and urine tested. Your doctor will order blood and urine tests in the month before you start LEMTRADA treatment, and these tests will continue each month until 4 years after your last LEMTRADA infusion. Monitoring may need to continue for longer if you have signs or symptoms of autoimmune conditions. Your doctor will check the results of these tests to see if you have developed any side effects. You should have your skin checked before you start receiving LEMTRADA and each year while you are receiving treatment to monitor symptoms of skin cancer.

It is very important that you continue to have these tests until 4 years after your last LEMTRADA infusion, even if you are feeling well (no symptoms or side effects). Side effects may occur many months to years after your LEMTRADA infusion and may be life-threatening, so it is very important that you continue to be checked and that you watch out for symptoms. This will help allow a problem to be detected and treatment to begin right away.

This means that you commit to the monthly blood and urine laboratory tests, continuing until 4 years after your last infusion with LEMTRADA. You and your doctor will work together as a team to make sure you get these tests done, and to plan them around your normal activities. If you are a woman, it is also important to avoid urine testing during your menstrual period, as this may give a false result.



The following table shows you which laboratory tests are done, when, and for how long.

Test	When?	For how long?
Blood tests	Before treatment starts and every month after treatment	until 4 years after your last LEMTRADA infusion
Urine tests	Before treatment starts and every month after treatment	until 4 years after your last LEMTRADA infusion

How Is LEMTRADA Given?

You will receive LEMTRADA through an intravenous line in your vein (infusion). LEMTRADA is initially given in two treatment courses. Generally, you will receive LEMTRADA for 5 days for the first treatment course and then for 3 days approximately 1 year later (second treatment course).

Additional treatment courses, if needed, may be given for 3 days in a row (consecutive) at least 1 year after the prior treatment course.

The infusion takes place in a healthcare facility or infusion center. It takes about 4 hours to receive a full dose each day, but can take longer if you have side effects (infusion reactions), in which case the infusion may need to be slowed down or stopped. In order to try to reduce some of these reactions, your doctor will give you medication (corticosteroids) prior to the first 3 infusions of a treatment course. You may also be given other treatments before, during, or after the infusion to lower your chances of getting these reactions or to treat them once they happen. In addition, you will be observed during the infusion and for at least 2 hours after the infusion has been completed, or longer if your healthcare provider decides you need to stay longer. In case of serious reactions, it is possible that the infusion may be stopped.

Where Can I Get More Information on LEMTRADA?

There is a LEMTRADA Medication Guide that your doctor or nurse will give you at the beginning of your treatment course. You can also find additional information at www.LemtradaREMS.com or call the LEMTRADA REMS at 1-855-676-6326.

How Can I Reach My Doctors?

To make it easier to contact your doctor(s) or your healthcare team, please fill in their telephone numbers and addresses in the chart below.

Doctor/Healthcare Team	Telephone Number	Address



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US.MS.LEM.14.10.003-v6 Last Updated 07/19



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For more information on LEMTRADA, including important risks, please refer to the Prescribing Information and/or www.LEMTRADAREMS.com.
 For information on LEMTRADA or the LEMTRADA REMS, call **1-855-676-6326**.

SANOFI GENZYME
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 Reference ID: 4512344
 US:MS:LEM.14.10.001-v4 Last Updated 03/19



	Healthcare Provider's Name (e.g., neurologist)	Healthcare Provider's Name (e.g., primary care provider)
Name:		
Phone Number:		
Fax Number: (for medical records or lab tests)		VV-REG-0833078.0.1

Important information to know about LEMTRADA

<<insert your name>>
 has been treated with LEMTRADA, a treatment for multiple sclerosis (MS), which lowers the number of circulating white blood cells for a period of time after treatment and also affects the immune system. Therefore, the patient is part of a laboratory monitoring program that continues until 4 years after his/her last treatment.



Patient Safety Information Card

Please show this card to all emergency workers and healthcare providers.

LEMTRADA treatment can increase the risk of:

Autoimmune conditions such as:

- a bleeding problem called immune thrombocytopenia (ITP)
- other blood disorders (including neutropenia, hemolytic anemia, and pancytopenia)
- disorders of the thyroid gland (hypo/hyperthyroidism)
- kidney disorders (nephropathies, including anti-glomerular basement membrane [anti-GBM] disease)
- liver disorders (autoimmune hepatitis)

Reference ID: 4512344

Infusion reactions (may occur more than 24 hours after the infusions), such as:

- hypersensitivity reactions (including anaphylaxis)
- fever
- hives
- irregular heartbeat
- nausea
- chest pain
- low blood pressure

Strokes and tears in the arteries that provide blood to the brain. Symptoms of stroke or tears in the arteries include:

- drooping of parts of your face
- weakness on one side
- sudden severe headache
- difficulty with speech
- neck pain

Malignancies such as:

- thyroid cancer
- melanoma
- lymphoproliferative disorders and lymphoma

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LEMTRADA[®]
alemtuzumab^{12mg}_{iv}

What You Need to Know About LEMTRADA Treatment and Infusion Reactions: A Patient Guide

LEMTRADA® (ALEMTUZUMAB) INFUSION REACTIONS: WHAT YOU NEED TO KNOW

- Infusion reactions are side effects linked to the infusion of LEMTRADA® (alemtuzumab). LEMTRADA can cause serious infusion reactions that may cause death. Serious infusion reactions may happen while you receive, or up to 24 hours or longer after you receive LEMTRADA.
- Most patients treated with LEMTRADA will experience side effects at the time of the infusion.
- The most common infusion reactions for patients who receive LEMTRADA were nausea, hives, itching, difficulty sleeping, chills, flushing, fatigue, shortness of breath, congestion of the lungs, upset stomach, dizziness, and pain.
- Some serious reactions are possible, such as life-threatening allergic reactions, swelling, wheezing, low blood pressure, chest pain, a fast, slow, or irregular heartbeat, transient neurologic symptoms, high blood pressure, headache, fever, and rash.
- A serious allergic reaction called anaphylaxis, which can cause death if not properly treated, was reported rarely.
- Some people have had serious and sometimes deadly strokes and tears in the arteries that provide blood to their brain within 3 days of receiving LEMTRADA.

LEMTRADA can only be given at a certified healthcare facility that has the necessary equipment and personnel to manage infusion reactions.

Steps You and Your Healthcare Provider Can Take to Help Manage Infusion Reactions

- The healthcare facility where you receive LEMTRADA has personnel who are trained and medical equipment needed to treat infusion reactions.
- Your healthcare provider will give you medication called a corticosteroid, and possibly other medications—such as anti-allergy medications (antihistamines) and anti-fever medications (antipyretics)—to help avoid infusion reactions or make them milder. Corticosteroids are usually given through a vein in your arm on the first 3 days of your infusions—just before your LEMTRADA infusion.


LEMTRADA[®]
alemtuzumab ^{12mg} iv

- You will be closely monitored during the infusion and for at least 2 hours following the completion of the infusion to watch for any infusion reactions. Your healthcare provider may continue to monitor you for longer if needed.
- Should an infusion reaction occur, your healthcare provider will likely provide treatment as needed.
 - Medication may be given for relief of your symptoms. For example, antihistamines may help relieve an itchy rash.
 - Infusions usually take about 4 hours; however, your healthcare provider may slow down the infusion or stop it temporarily.
 - If an infusion is stopped, your healthcare provider might try to administer LEMTRADA again, but more slowly and with additional medicine to try to stop an infusion reaction from happening again.
 - If your healthcare provider suspects you might be having a serious allergic reaction, the LEMTRADA infusion will be stopped, and you may receive medication or other measures to treat this reaction. In addition to medication, IV fluids may be given.

Make Sure to Speak Up

If you experience any discomfort or anything that feels out of the ordinary during your infusion, be sure to immediately tell the healthcare provider providing the infusion. If symptoms occur after you have left the healthcare facility, be sure to notify your doctor as soon as possible.

Tell your healthcare provider right away if you have any of the following symptoms of a serious infusion reaction during the infusion or after you have left the healthcare facility:

- swelling in your mouth or throat
- trouble breathing
- weakness
- fast, slow, or irregular heartbeat
- chest pain
- rash
- symptoms of stroke
 - drooping of parts of your face
 - weakness on one side
 - sudden severe headache
 - difficulty with speech
 - neck pain



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LEMTRADA REMS PATIENT AUTHORIZATION AND BASELINE LAB FORM

Please fax this completed form to the LEMTRADA REMS at 1-855-557-2478
or submit online at www.LemtradaREMS.com

This form must be completed within 30 days prior to the first infusion date of each LEMTRADA® (alemtuzumab) patient's treatment course.

*Indicates a mandatory field.

PRESCRIBER INFORMATION (PLEASE PRINT)

Name (Last, First)*		Office Phone Number*	
Address*			
City*		State*	ZIP Code*
Prescriber LEMTRADA REMS Program Identification Number*			

PATIENT INFORMATION (PLEASE PRINT)

Name (Last, First)*
Patient LEMTRADA REMS Identification Number*
Date of Birth (MM/DD/YYYY)*

AUTHORIZATION AND BASELINE LABS

Do you authorize LEMTRADA treatment for the above referenced patient?* Yes No

Do you attest that required baseline laboratory testing has been completed prior to LEMTRADA treatment and within 30 days of the patient's first infusion?* Yes No

PRESCRIPTION INFORMATION

Check one* Initial course (1 vial [12 mg/day]) X 5 consecutive days Total number of vials: _____

Subsequent course (1 vial [12 mg/day]) X 3 consecutive days Total number of vials: _____

SIGNATURE

Prescriber Signature* Date*

Please fax this completed form to the LEMTRADA REMS at 1-855-557-2478 or submit online at www.LemtradaREMS.com
If you have any questions regarding the LEMTRADA REMS, call 1-855-676-6326



LEMTRADA REMS Prescription Ordering Form

Please fax this completed form to 1-855-557-2478

*Indicates a mandatory field.

I: PATIENT INFORMATION (PLEASE PRINT)

Name (Last, First)*

Date of Birth (MM/DD/YYYY)*

Gender*

Male

Female

Street Address 1*

Street Address 2*

City*

State*

ZIP Code*

Phone Number*

THIS SECTION SHOULD BE FILLED OUT BY THE PRESCRIBER

II: INSURANCE INFORMATION[†]

Patient does not have insurance.

Primary Insurance Company

Phone Number

Name of Insured

Policy Number

Group/Policy Number

Secondary Insurance Company

Phone Number

Name of Insured

Policy Number

Group/Policy Number

III: PRESCRIBER INFORMATION

Prescriber Name (Last, First)*

NPI Number*

Name of Institution or Facility*

Tax ID*

Office Contact*

Street Address*

City*

State*

ZIP Code*

Email Address

Phone Number*

Fax Number*

IV: PRESCRIPTION INFORMATION

LEMTRADA® (alemtuzumab) 12 mg IV

Check one* Initial course (1 vial [12 mg/day]) X 5 consecutive days

Total number of vials ordered: ____

Primary diagnosis: ICD-9 CM340I

Subsequent course (1 vial [12 mg/day]) X 3 consecutive days

Total number of vials ordered: ____

CD-10 G35

[†]Note: Provision of the patient's insurance coverage(s) is not a requirement of the LEMTRADA REMS but may support additional services provided by Genzyme.

Infusion center where patient is referred*

Phone Number*

Street Address*

City*

State*

ZIP Code

[†]Note: LEMTRADA can only be infused at REMS Certified infusion sites. Genzyme Corporation will contact you if the infusion center you have indicated is not certified to infuse LEMTRADA.

VI. SIGNATURE

Note to Prescribers: This form does not authorize the certified pharmacy or infusion center to dispense LEMTRADA. The LEMTRADA REMS Patient Authorization and Baseline Lab Form must be submitted in order to authorize LEMTRADA to be dispensed.

By signing below, I authorize the LEMTRADA REMS and its agents and representatives to forward this prescription on my behalf to a certified pharmacy or infusion center to dispense LEMTRADA to the patient named above.

X

Licensed Prescriber Signature* (Signature required; no stamps accepted)

Print Name*

Date*

Please fax this completed form to the LEMTRADA REMS at 1-855-557-2478

If you have any questions regarding the LEMTRADA REMS, call 1-855-676-6326



LEMTRADA REMS INFUSION CHECKLIST

*Please fax this completed form to the LEMTRADA REMS at 1-855-557-2478
or submit online at www.LemtradaREMS.com*

As a condition of your healthcare facility's authorization to infuse LEMTRADA® (alempezumabiv), this Infusion Checklist **must** be completed for each patient by the last day of each patient's treatment course and submitted within **5 business days**. **This Infusion Checklist must also be completed and returned even if LEMTRADA is not infused.** Keep a copy of this checklist in the patient's medical record.

All fields on this form are mandatory.

PATIENT INFORMATION (PLEASE PRINT)

Patient Name (Last, First)

DOB (MM/DD/YYYY)

Patient LEMTRADA REMS Identification Number

PRESCRIBER INFORMATION (PLEASE PRINT)

Prescriber Name (Last, First)

Prescriber LEMTRADA REMS Identification Number

HEALTHCARE FACILITY INFORMATION (PLEASE PRINT)

Healthcare Facility Name

Healthcare Facility LEMTRADA REMS Identification Number

STEP 1: CONFIRM THAT THE PATIENT IS AUTHORIZED TO RECEIVE LEMTRADA

You must contact the LEMTRADA REMS by phone (1-855-676-6326) prior to initiation of each treatment course.

Is the patient authorized to receive LEMTRADA? Yes No

Yes Continue to next question.

No STOP – DO NOT INFUSE. Refer patient back to the LEMTRADA prescriber.

STEP 2: CONFIRM THAT THE PATIENT HAS BEEN COUNSELED AND HAS RECEIVED *What You Need to Know About LEMTRADA Treatment and Infusion Reactions: A Patient Guide*

The patient must be counseled about the risk for infusion reactions and provided with *What You Need to Know About LEMTRADA Treatment and Infusion Reactions: A Patient Guide* prior to the first infusion of each treatment course. Has the patient been counseled and received the guide?

Yes No

Yes Continue to next question.

No STOP – provide the patient guide. Proceed to the next question after the patient has received this guide and has been counseled.

STEP 3: CONFIRM APPROPRIATE MEDICAL MEASURES AVAILABLE FOR INFUSION

Appropriate medical support measures are available:

1. In case of serious infusion reactions.
2. To monitor patient's vital signs before, during, and post-infusion.

Are the appropriate medical measures listed above available? Yes No

Yes Continue to next question.

No STOP – DO NOT INFUSE until appropriate medical support measures are available. Please contact the LEMTRADA REMS for additional information.

PATIENT INFORMATION (PLEASE PRINT)

Patient Name (Last, First)

DOB (MM/DD/YYYY)

STEP 4: RECORD INFUSION INFORMATION

Was patient infused with LEMTRADA? Yes No

Yes Fill in Dates of Infusion below and then proceed to Step 5.

No Proceed to Step 5.

LEMTRADA Infusions

Dates of Infusion:

Date: _____

Date: _____

Date: _____

Date: _____

Date: _____

STEP 5: RETURN UNUSED VIALS OF LEMTRADA

Unused vials of LEMTRADA must be returned within 50 days of submission of the LEMTRADA REMS Patient Authorization and Baseline Lab Form. Contact the LEMTRADA REMS at 1-855-676-6326 for additional information.

**Report all adverse events to Genzyme Medical Information at 1-800-745-4447 (option 2) or
FDA at 1-800-FDA-1088 (1-800-332-1088) or www.FDA.gov/medwatch**

STEP 6: SIGNATURE

Signature of staff completing checklist

Date

Name of staff completing checklist (Please Print)

**STEP 7: FAX THE INFUSION CHECKLIST TO THE LEMTRADA REMS AT 1-855-557-2478 OR
SUBMIT ONLINE AT WWW.LEMTRADAREMS.COM WITHIN 5 BUSINESS DAYS.**

If you have any questions regarding the LEMTRADA REMS, call 1-855-676-6326.

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VV-REG-0833078 0.1

[Month] [Year]

IMPORTANT DRUG WARNING

SUBJECT: Serious risks of autoimmune conditions, infusion reactions, and malignancies with LEMTRADA® (alemtuzumab); FDA-Required REMS Program

IMPORTANT SAFETY NOTICE

Dear Healthcare Provider:

The purpose of this letter is to inform you of the approval of LEMTRADA (alemtuzumab); a CD52-directed cytolytic monoclonal antibody for intravenous infusion indicated for the treatment of patients with relapsing forms of multiple sclerosis (MS). Because of its safety profile, the use of LEMTRADA should generally be reserved for patients who have had an inadequate response to two or more drugs indicated for the treatment of MS.

The LEMTRADA REMS Program was developed by Genzyme in collaboration with the FDA to ensure that the benefits of LEMTRADA outweigh the serious risks. Under the LEMTRADA REMS Program, only prescribers, pharmacies, healthcare facilities, and patients enrolled in the Program are able to prescribe, dispense, administer, and receive LEMTRADA.

SERIOUS RISKS OF LEMTRADA

AUTOIMMUNE CONDITIONS

- LEMTRADA causes serious, sometimes fatal, autoimmune conditions such as immune thrombocytopenia and anti-glomerular basement membrane disease. Monitor complete blood counts with differential, serum creatinine levels, and urinalysis with urine cell counts at periodic intervals for 48 months after the last dose of LEMTRADA.

INFUSION REACTIONS

- LEMTRADA causes serious and life-threatening infusion reactions. LEMTRADA can only be administered in certified healthcare settings that have on-site access to equipment and personnel trained to manage infusion reactions (including anaphylaxis and cardiac and respiratory emergencies).

MALIGNANCIES

- LEMTRADA may cause an increased risk of malignancy including thyroid cancer, melanoma, and lymphoproliferative disorders. Perform baseline and yearly skin exams to monitor for signs of melanoma.

IMPORTANT SAFETY INFORMATION ON KNOWN RISKS

Treatment with LEMTRADA can result in the formation of autoantibodies and increase the risk of serious autoimmune mediated conditions, including ITP, other cytopenias, thyroid disorders and glomerular nephropathies, which may occur many years after treatment. In order to identify these risks, laboratory tests are required. Complete blood counts with differential, serum creatinine levels, and urinalysis with urine cell counts should be obtained prior to initiation of treatment and at monthly intervals until 48 months after the last infusion with LEMTRADA. Thyroid function tests should be obtained prior to initiation of treatment and every 3 months until 48 months after the last infusion with LEMTRADA. Monitoring may need to continue past 48 months based on clinical findings of autoimmune conditions.

Most patients treated with LEMTRADA in controlled clinical trials in MS experienced infusion reactions during or after LEMTRADA administration. Some infusion reactions may be serious and life threatening. Serious reactions occurred in 3% of patients and included anaphylaxis in 2 patients (including anaphylactic shock), angioedema, bronchospasm, hypotension, chest pain, bradycardia, tachycardia (including atrial fibrillation), transient neurologic symptoms, hypertension, headache, pyrexia and rash. Premedicate patients with high dose corticosteroids (1000 mg methylprednisolone or equivalent) immediately prior to the LEMTRADA infusion and for the first 3 days of any treatment course. Observe patients for infusion reactions during and for at least 2 hours after each LEMTRADA infusion. Longer periods of observation may be required if clinically indicated.

LEMTRADA may cause an increased risk of malignancy including thyroid cancer, melanoma, and lymphoproliferative disorders. Baseline and yearly skin examinations should be performed in LEMTRADA patients to monitor for signs of melanoma. Caution should be exercised in initiating LEMTRADA therapy in patients with pre-existing or ongoing malignancies.

The LEMTRADA REMS Program Requirements:

- **Prescribers** must be enrolled in the LEMTRADA REMS Program to be able to prescribe LEMTRADA.
- **Healthcare Facilities and Pharmacies** must be enrolled in the LEMTRADA REMS Program to be able to dispense and/or administer LEMTRADA.
- **Patients** must be enrolled and authorized in the LEMTRADA REMS Program in order to receive LEMTRADA.

Reporting Adverse Events

It is important that you promptly report all suspected adverse events with the use of LEMTRADA. Please contact Genzyme at 1-800-745-4447 (option 2) or the FDA at 1-800-FDA-1088 (1-800-332-1088) or www.fda.gov/medwatch.

This letter is not a comprehensive description of the risks associated with the use of LEMTRADA. Please see the enclosed Prescribing Information for a complete description of these risks.

If you have any questions about the LEMTRADA REMS Program, please call 1-855-676-6326 for more information or visit www.LemtradaREMS.com.

Sincerely,



[Name]
[Title]
Genzyme

Enclosures: LEMTRADA Prescribing Information

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LEMTRADA[®]
alemtuzumab^{12mg}
iv

[Treating Provider First Name] [Treating Provider Last Name], [Treating Provider Title]
[Practice Site Name]
[Treating Site HCP Practice Address 1]
[Treating Site HCP Practice City, Site ZIP]

LEMTRADA® (alemtuzumab)

FDA-Required Updated REMS Safety Information

Risk of:

- Autoimmune Conditions
- Infusion Reactions
- Stroke
- Malignancies

[Date]

Dear Healthcare Provider,

The Food and Drug Administration (FDA) has required this safety notice as part of the LEMTRADA REMS (Risk Evaluation and Mitigation Strategy) to highlight new risk information about stroke for LEMTRADA.

The goals of the LEMTRADA REMS have been modified to reflect the following new safety risk added to the BOXED WARNING of the Prescribing Information:

Serious and life-threatening stroke has been reported within 3 days of LEMTRADA administration. Instruct patients to seek immediate medical attention if symptoms of stroke occur.

LEMTRADA REMS Goals

- Informing patients about the serious risks of LEMTRADA, and the need for baseline and periodic monitoring
- Informing healthcare providers about the serious risks of autoimmune conditions, infusion reactions, stroke, and malignancies with LEMTRADA, the need to counsel patients, and the need for baseline and periodic monitoring

LEMTRADA REMS Requirements

- **Prescribers** must be enrolled in the LEMTRADA REMS
- **Healthcare Facilities and Pharmacies** must be enrolled in the LEMTRADA REMS
- **Patients** must be enrolled and authorized in the LEMTRADA REMS

Reporting Adverse Events

Report all suspected adverse events to Genzyme at 1-800-745-4447 (option 2) or the FDA at 1-800-FDA-1088 (1-800-332-1088) or www.fda.gov/medwatch.

This letter does not contain the complete safety profile for LEMTRADA. Please see the enclosed Prescribing Information.

If you have any questions about the LEMTRADA REMS, please call 1-855-676-6326 for more information or visit www.LemtradaREMS.com.

Sincerely,

LEMTRADA REMS

SANOI GENZYME 

LEMTRADA REMS DESKTOP

PUBLIC and Prescriber Desktop Pages Only

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LEMTRADA
alemtuzumab^{12mg} iv

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LEMTRADA REMS (Risk Evaluation and Mitigation Strategy)

What is the LEMTRADA REMS?
 A REMS is a strategy to manage known or potential serious risks associated with a drug product and is required by the FDA to ensure the benefits of a drug outweigh its risks. The purpose of the LEMTRADA REMS is to inform prescribers, pharmacies, healthcare facilities, and patients about the risks of:

AUTOIMMUNE CONDITIONS
 LEMTRADA causes serious, sometimes fatal, autoimmune conditions such as immune thrombocytopenia and anti-glomerular basement membrane disease. Monitor complete blood counts with differential, serum creatinine levels, and urinalysis with urine cell counts at periodic intervals for 48 months after the last dose of LEMTRADA.

INFUSION REACTIONS
 LEMTRADA causes serious and life threatening infusion reactions. LEMTRADA must be administered in a setting with appropriate equipment and personnel to manage anaphylaxis or serious infusion reactions.

STROKE
 Serious and life-threatening stroke (including ischemic and hemorrhagic stroke) has been reported within 3 days of LEMTRADA administration. Instruct patients to seek immediate medical attention if symptoms of stroke occur.

MALIGNANCIES
 LEMTRADA may cause an increased risk of malignancy including thyroid cancer, melanoma, and lymphoproliferative disorders. Perform baseline and yearly exams.

Enroll in the LEMTRADA REMS



Prescribers, healthcare facilities, pharmacies, and patients must be enrolled in the LEMTRADA REMS to be able to dispense, administer, or receive LEMTRADA, respectively. Enroll in the program and gain access to the online tools and resources available to help you manage your LEMTRADA patients.

[Information for Prescribers >](#)
[Information for Healthcare Facilities >](#)
[Information for Pharmacies >](#)
[Already registered? Log In >](#)

Enroll Now

Find a REMS Certified Prescriber or Healthcare Facility



Search for prescribers or healthcare facilities that are certified by the LEMTRADA REMS to prescribe, dispense, or administer LEMTRADA.

Enter ZIP Code

REMS Certified Prescriber
 REMS Certified Healthcare Facility

Find

LEMTRADA REMS Requirements

PRESCRIBERS

Prescribers must be enrolled in the LEMTRADA REMS to prescribe LEMTRADA for patients with multiple sclerosis.
[Learn about Prescriber Enrollment >](#)

HEALTHCARE FACILITIES

Healthcare facilities must be enrolled in the LEMTRADA REMS to dispense/administer LEMTRADA for patients with multiple sclerosis. *One representative needs to enroll per healthcare setting.*
[Learn about Healthcare Facility Enrollment >](#)

PHARMACIES

Pharmacies must be enrolled in the LEMTRADA REMS to be able to dispense LEMTRADA for patients with multiple sclerosis.
[Learn about Pharmacy Enrollment >](#)

If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6326, Mon – Fri, 8:30 am – 8:00 pm ET.

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Enroll Now

Find a REMS Certified Prescriber or Healthcare Facility



Search for prescribers or healthcare facilities that are certified by the LEMTRADA REMS to prescribe, dispense, or administer LEMTRADA.

Enter ZIP Code

Please enter ZIP Code.

REMS Certified Prescriber
 REMS Certified Healthcare Facility

Please make a selection.

Find

LEMTRADA REMS Requirements

PRESCRIBERS

Prescribers must be enrolled in the LEMTRADA REMS to prescribe LEMTRADA for patients with multiple sclerosis.
[Learn about Prescriber Enrollment >](#)

HEALTHCARE FACILITIES

Healthcare facilities must be enrolled in the LEMTRADA REMS to dispense/administer LEMTRADA for patients with multiple sclerosis. *One representative needs to enroll per healthcare setting.*
[Learn about Healthcare Facility Enrollment >](#)

PHARMACIES

Pharmacies must be enrolled in the LEMTRADA REMS to be able to dispense LEMTRADA for patients with multiple sclerosis.
[Learn about Pharmacy Enrollment >](#)

If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6326, Mon – Fri, 8:30 am – 8:00 pm ET.

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The screenshot shows a web browser window displaying the LEMTRADA REMS website. The browser's address bar shows a Google search. The website header includes the LEMTRADA logo (alemtezumab iv) and navigation links for Prescribing Information, Medication Guide, Register, and Log In. A main navigation bar contains links for Home, Prescriber Enrollment, Healthcare Facility Enrollment, Pharmacy Enrollment, Patient Guides, Forms & Resources, and REMS Certified Prescriber & Healthcare Facility Locator.

The main content area is titled "LEMTRADA REMS (Risk Evaluation and Mitigation Strategy)". It includes sections for "What is the LEMTRADA REMS?", "AUTOIMMUNE CONDITIONS", "INFUSION REACTIONS", "STROKE", and "MALIGNANCIES". A central "Enroll in LEMTRADA REMS" section features a laptop icon and text explaining enrollment requirements for prescribers, healthcare facilities, and pharmacies. To the right, a "Find" section includes a location pin icon, a search prompt, a ZIP code input field, and radio buttons for "REMS Certified Prescriber" (selected) and "REMS Certified Healthcare Facility".

On the right side, there are three panels under "LEMTRADA REMS Requirements": "PRESCRIBERS", "HEALTHCARE FACILITIES", and "PHARMACIES", each with detailed enrollment instructions and links to learn more.

A white interstitial dialog box is overlaid in the center, titled "You Are Leaving www.LemtradaREMS.com". It contains the text: "You are leaving www.LemtradaREMS.com to view another Sanofi Genzyme website." Below the text are two green buttons: "Go Back" and "Continue".

At the bottom of the page, there is a footer with links for Privacy Policy, Terms and Conditions, and Contact Us. It also includes a disclaimer: "This site is intended for United States residents only." and copyright information: "©2019 Genzyme Corporation. All rights reserved." The Sanofi Genzyme logo is in the bottom right corner.

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alemtuzumab^{12mg}
iv

Prescribing Information Medication Guide

Register | Log In

Home Prescriber Enrollment Healthcare Facility Enrollment Pharmacy Enrollment Patient Guides Forms & Resources REMS Certified Prescriber & Healthcare Facility Locator

Log In

Email Address

Password

Remember Me

[Forgot Password](#)
[Go to Registration Page](#)

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or need help enrolling, call 1-855-676-6326, Mon - Fri, 8:30 am - 8:00 pm ET.**

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The screenshot shows a web browser window displaying the LEMTRADA REMS Desktop website. The browser's address bar shows a Google search engine. The website header includes the LEMTRADA logo (alemtezumab 12mg iv) and navigation links for Prescribing Information, Medication Guide, Register, and Log In. A dark purple navigation bar contains links for Home, Prescriber Enrollment, Healthcare Facility Enrollment, Pharmacy Enrollment, Patient Guides, Forms & Resources, and REMS Certified Prescriber & Healthcare Facility Locator. The main content area features a 'Log In' section with input fields for Email Address and Password. A red error message states 'Your email or password is incorrect.' Below the fields are a 'Remember Me' checkbox and a green 'Log In' button. Links for 'Forgot Password' and 'Go to Registration Page' are also present. A message below the login section reads: 'If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6326, Mon - Fri, 8:30 am - 8:00 pm ET.' A pink dashed line labeled 'FOLD' is positioned across the middle of the page. The footer contains links for Privacy Policy, Terms and Conditions, and Contact Us, along with a disclaimer: 'This site is intended for United States residents only. ©2019 Genzyme Corporation. All rights reserved. Lemtrada, MS One to One, Sanofi and Genzyme registered in U.S. Patent and Trademark Office US.MS.LEM.14.10.013-v7 Last Updated 09/19'. The SANOFI GENZYME logo is located in the bottom right corner.

The screenshot shows a web browser window displaying the LEMTRADA REMS Desktop Public Home page. The browser's address bar shows a Google search engine. The page header includes the LEMTRADA logo (alem tuzumab 12mg iv) and navigation links for Prescribing Information, Medication Guide, Register, and Log In. A horizontal menu contains links for Home, Prescriber Enrollment, Healthcare Facility Enrollment, Pharmacy Enrollment, Patient Guides, Forms & Resources, and REMS Certified Prescriber & Healthcare Facility Locator. The main content area features a 'Set Password' section with instructions: 'Passwords must be at least 8 characters in length and contain a minimum of 3 out of the following: A number, an upper-case letter, a lower-case letter, a special character (e.g. !, ", #, \$, etc.)'. Below this are two input fields labeled 'New Password' and 'Confirm Password', and a green 'Log In' button. A callout box with a pink dashed border and the word 'FOLD' on the left contains the text: 'If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6326, Mon - Fri, 8:30 am - 8:00 pm ET.' The footer is a dark purple bar with links for Privacy Policy, Terms and Conditions, and Contact Us. It also contains the text: 'This site is intended for United States residents only. ©2019 Genzyme Corporation. All rights reserved. Lemtrada, MS One to One, Sanofi and Genzyme registered in U.S. Patent and Trademark Office US.MS.LEM.14.10.013-v7 Last Updated 09/19' and the SANOFI GENZYME logo.

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alemtuzumab^{12mg} iv

[Prescribing Information](#) [Medication Guide](#)
[Register](#) | [Log In](#)

[Home](#) [Prescriber Enrollment](#) [Healthcare Facility Enrollment](#) [Pharmacy Enrollment](#) [Patient Guides](#) [Forms & Resources](#) [REMS Certified Prescriber & Healthcare Facility Locator](#)

Set Password

Passwords must be at least 8 characters in length and contain a minimum of 3 out of the following: A number, an upper-case letter, a lower-case letter, a special character (e.g. !, ", #, \$, etc.)

New Password

Please enter a new password.

Confirm Password

Please confirm your password.

[Log In](#)

If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6326, Mon – Fri, 8:30 am – 8:00 pm ET.

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The screenshot shows a web browser window displaying the LEMTRADA REMS desktop website. The browser's address bar shows a Google search engine. The website header includes the LEMTRADA logo (alemtezumab 12mg iv) and navigation links for Prescribing Information, Medication Guide, Register, and Log In. A horizontal menu contains links for Home, Prescriber Enrollment, Healthcare Facility Enrollment, Pharmacy Enrollment, Patient Guides, Forms & Resources, and REMS Certified Prescriber & Healthcare Facility Locator. The main content area is titled "Set Password" and contains instructions: "Passwords must be at least 8 characters in length and contain a minimum of 3 out of the following: A number, an upper-case letter, a lower-case letter, a special character (e.g. !, ", #, \$, etc.)". Below this are two input fields: "New Password" and "Confirm Password". The "New Password" field has a red error message: "Password does not meet strength requirements." The "Confirm Password" field has a red error message: "Passwords do not match." A green "Log In" button is positioned below the fields. A horizontal line separates this section from a message: "If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6326, Mon - Fri, 8:30 am - 8:00 pm ET." A dashed pink line labeled "FOLD" is positioned to the left of this message. The footer contains links for Privacy Policy, Terms and Conditions, and Contact Us. It also includes the text: "This site is intended for United States residents only. ©2019 Genzyme Corporation. All rights reserved. Lemtrada, MS One to One, Sanofi and Genzyme registered in U.S. Patent and Trademark Office US.MS.LEM.14.10.013-v7 Last Updated 09/19" and the SANOFI GENZYME logo.

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The screenshot shows a web browser window displaying the LEMTRADA REMS website. The browser's address bar shows a search for "Google". The website header includes the LEMTRADA logo (alemtezumab iv) and navigation links for "Prescribing Information" and "Medication Guide". A secondary navigation bar contains links for "Home", "Prescriber Enrollment", "Healthcare Facility Enrollment", "Pharmacy Enrollment", "Patient Guides", "Forms & Resources", and "REMS Certified Prescriber & Healthcare Facility Locator".

The main content area features a "Log In" section with input fields for "Email Address" and "Password", a "Remember Me" checkbox, and a "Log In" button. Below these fields are links for "Forgot Password" and "Go to Registration Page".

A modal dialog box titled "Reset Your Password" is centered on the screen. It contains the text: "Please enter your email address and you will receive a link to reset your password." Below this is an email input field with a red error message: "That email address was not found in our system." A green "Reset Password" button is located at the bottom of the modal.

Below the login section, there is a message: "If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6326, Mon - Fri, 8:30 am - 8:00 pm ET." A "FOLD" indicator is visible on the left side of this section.

The footer contains links for "Privacy Policy", "Terms and Conditions", and "Contact Us". It also includes the text: "This site is intended for United States residents only", "©2019 Genzyme Corporation. All rights reserved.", and "Lemtrada, MS One to One, Sanofi and Genzyme registered in U.S. Patent and Trademark Office US MS LEM 14.10.013-47 Last Updated 09/19". The Sanofi Genzyme logo is positioned in the bottom right corner.

The screenshot shows a web browser window displaying the LEMTRADA REMS Desktop website. The browser's address bar shows a Google search engine. The website header includes the LEMTRADA logo (alemtezumab iv) and navigation links for Prescribing Information and Medication Guide. A secondary navigation bar contains links for Home, Prescriber Enrollment, Healthcare Facility Enrollment, Pharmacy Enrollment, Patient Guides, Forms & Resources, and REMS Certified Prescriber & Healthcare Facility Locator. A Register | Log In link is also present. The main content area features a Log In form with fields for Email Address and Password, a Remember Me checkbox, and a Log In button. A notification modal titled "Instructions Sent" is displayed in the center, containing text about password reset instructions and a Return to Home button. Below the login form, there is a link for "Forgot Password" and a link to "Go to Registration Page". A "FOLD" label is visible on the left side of the page. The footer contains links for Privacy Policy, Terms and Conditions, and Contact Us, along with copyright information for Genzyme Corporation and the Sanofi Genzyme logo.

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Prescribing Information Medication Guide

Register | Log In

Home Prescriber Enrollment Healthcare Facility Enrollment Pharmacy Enrollment Patient Guides Forms & Resources REMS Certified Prescriber & Healthcare Facility Locator

Log In

Email Address

Password

Remember Me

[Forgot Password](#)
[Go to Registration Page](#)

Instructions Sent

You should receive an email with instructions to reset your password. Please check your email that you registered your account with. If you do not receive an email, please call **1-855-676-6326**, Mon – Fri, 8:30 am – 8:00 pm ET.

IF you have questions about or need help enrolling, call

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Prescribing Information Medication Guide

Register | Log In

Home Prescriber Enrollment Healthcare Facility Enrollment Pharmacy Enrollment Patient Guides Forms & Resources REMS Certified Prescriber & Healthcare Facility Locator

LEMTRADA REMS Prescriber Enrollment

- Prescribers must be enrolled in the LEMTRADA REMS to be able to prescribe LEMTRADA for patients with relapsing forms of multiple sclerosis (MS). Because of its safety profile, the use of LEMTRADA should generally be reserved for patients who have had an inadequate response to two or more drugs indicated for the treatment of MS
- Note that your healthcare facility must be separately enrolled in the LEMTRADA REMS to dispense/administer LEMTRADA

To enroll in the program, prescribers must complete the following steps:

1	Register with the LEMTRADA REMS Online Training Center
2	Review the LEMTRADA REMS Education Program for Prescribers, including the LEMTRADA REMS Program Overview and the LEMTRADA full Prescribing Information in the online module on this site
3	Successfully complete the 8-question Knowledge Assessment at the end of the module
4	After completing the assessment, complete and sign the LEMTRADA REMS Prescriber Enrollment Form

[Register for Online Enrollment](#)

PROGRAM MATERIALS

For Prescribers

- LEMTRADA REMS Program Overview
- LEMTRADA REMS Education Program for Prescribers
- LEMTRADA REMS Knowledge Assessment
- Healthcare Provider Letter: Patient Status
- LEMTRADA REMS Prescriber Enrollment Form
- LEMTRADA REMS Patient Authorization and Baseline Lab Form
- LEMTRADA REMS Patient Enrollment Form
- LEMTRADA REMS Prescription Ordering Form
- LEMTRADA REMS Patient Status Form
- What You Need to Know About LEMTRADA Treatment: A Patient Guide

Adobe® Reader® is required to view all of these PDFs. If you do not have it installed, download it free here.

If you have questions about the LEMTRADA REMS or need help enrolling, call **1-855-676-6326**, Mon - Fri, 8:30 am - 8:00 pm ET.

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Prescribing Information Medication Guide
Register | Log In

Home Prescriber Enrollment Healthcare Facility Enrollment Pharmacy Enrollment Patient Guides Forms & Resources REMS Certified Prescriber & Healthcare Facility Locator

LEMTRADA REMS Healthcare Facility Enrollment

- Healthcare facilities must be enrolled in the LEMTRADA REMS to be able to dispense/administer LEMTRADA for patients with relapsing forms of multiple sclerosis (MS). Because of its safety profile, the use of LEMTRADA should generally be reserved for patients who have had an inadequate response to two or more drugs indicated for the treatment of MS.

To enroll in the program, an authorized representative of the healthcare facility must complete the following steps:

1	Designate an authorized representative
2	Register the authorized representative with the LEMTRADA REMS Training Center
3	Authorized representative must review the LEMTRADA REMS Education Program for Healthcare Facilities and the LEMTRADA REMS Program Overview through the online module on this site
4	After completing the online module, complete and sign the LEMTRADA REMS Healthcare Facility Enrollment Form. This enrollment must be renewed every 2 years
5	Implement the necessary staff training and processes to comply with the LEMTRADA REMS requirements

[Register for Online Enrollment](#)

PROGRAM MATERIALS

For Healthcare Facilities

- LEMTRADA REMS Program Overview
- LEMTRADA REMS Education Program for Healthcare Facilities
- LEMTRADA REMS Healthcare Facility Enrollment Form
- LEMTRADA REMS Infusion Checklist
- What You Need to Know About LEMTRADA Treatment and Infusion Reactions: A Patient Guide

Adobe® Reader® is required to view all of these PDFs. If you do not have it installed, download it free here.

If you have questions about the LEMTRADA REMS or need help enrolling, call **1-855-676-6326**, Mon – Fri, 8:30 am – 8:00 pm ET.

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Prescribing Information | Medication Guide
[Register](#) | [Log In](#)

Home | Prescriber Enrollment | Healthcare Facility Enrollment | **Pharmacy Enrollment** | Patient Guides | Forms & Resources | REMS Certified Prescriber & Healthcare Facility Locator

LEMTRADA REMS Pharmacy Enrollment

- Pharmacies must be enrolled in the LEMTRADA REMS to be able to dispense LEMTRADA for patients with multiple sclerosis

To enroll in the program, an authorized representative of the pharmacy must complete the following steps:

1	Designate an authorized representative
2	Register the authorized representative with the LEMTRADA REMS Training Center
3	Authorized representative must review the LEMTRADA REMS Program Overview through the online module on this site
4	After reviewing the material , complete and sign the LEMTRADA REMS Pharmacy Enrollment Form. This enrollment must be renewed every 2 years
5	Implement the necessary staff and training processes to comply with the LEMTRADA REMS requirements

[Register for Online Enrollment](#)

PROGRAM MATERIALS

For Pharmacies

- LEMTRADA REMS Program Overview
- LEMTRADA REMS Pharmacy Enrollment Form

Adobe® Reader® is required to view all of these PDFs. If you do not have it installed, download it free here.

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Prescribing Information Medication Guide
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Home Prescriber Enrollment Healthcare Facility Enrollment Pharmacy Enrollment Patient Guides Forms & Resources REMS Certified Prescriber & Healthcare Facility Locator

LEMTRADA REMS Enrollment Forms and Resources

Below are downloadable forms needed to support the LEMTRADA REMS.

MATERIALS FOR PRESCRIBERS

- LEMTRADA REMS Program Overview
- LEMTRADA REMS Education Program for Prescribers
- LEMTRADA REMS Knowledge Assessment
- Healthcare Provider Letter: Patient Status
- LEMTRADA REMS Prescriber Enrollment Form
- LEMTRADA REMS Patient Authorization and Baseline Lab Form
- LEMTRADA REMS Patient Enrollment Form
- LEMTRADA REMS Prescription Ordering Form
- LEMTRADA REMS Patient Status Form
- What You Need to Know About LEMTRADA Treatment: A Patient Guide

MATERIALS FOR HEALTHCARE FACILITIES

- LEMTRADA REMS Program Overview
- LEMTRADA REMS Education Program for Healthcare Facilities
- LEMTRADA REMS Healthcare Facility Enrollment Form
- LEMTRADA REMS Infusion Checklist
- What You Need to Know About LEMTRADA Treatment and Infusion Reactions: A Patient Guide

MATERIALS FOR PHARMACIES

- LEMTRADA REMS Program Overview
- LEMTRADA REMS Pharmacy Enrollment Form

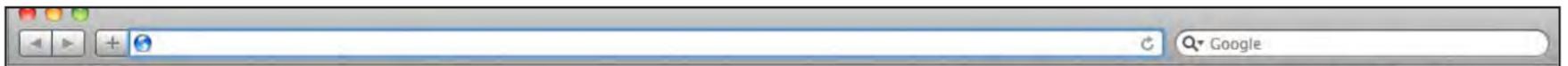
Adobe® Reader® is required to view all of these PDFs. If you do not have it installed, download it free here.

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SANOFI GENZYME



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[Register](#) | [Log In](#)

- Home
- Prescriber Enrollment
- Healthcare Facility Enrollment
- Pharmacy Enrollment
- Patient Guides
- Forms & Resources
- REMS Certified Prescriber & Healthcare Facility Locator

REMS Certified Prescriber & Healthcare Facility

Search for prescribers or healthcare facilities that are enrolled and certified in the LEMTRADA REMS and able to prescribe or dispense/administer LEMTRADA.

Please enter street address, city, state, or ZIP Code you would like to search for.

New Search:

REMS Certified Prescribers

- Certified Prescriber Name**
Address
Address
P. (888) - 888 - 8888
- Certified Prescriber Name**
Address
Address
P. (888) - 888 - 8888
- Certified Prescriber Name**
Address
Address
P. (888) - 888 - 8888
- Certified Prescriber Name**
Address
Address
P. (888) - 888 - 8888
- Certified Prescriber Name**
Address
Address
P. (888) - 888 - 8888
- Certified Prescriber Name**
Address
Address
P. (888) - 888 - 8888

REMS Certified Healthcare Facilities



FOLD

Genzyme is providing this search feature to help patients find prescribers and healthcare facilities that have been certified by the LEMTRADA REMS. Genzyme does not receive payment for providing this feature, and does not endorse, recommend, have jurisdiction over, or accept responsibility for the actions of any of the prescribers or healthcare facilities listed herein.

If you are a prescriber that would like to request the removal of your contact information from this website, please call the LEMTRADA REMS at 1-855-676-6326.

This site is provided as a resource for prescribers and is not intended as medical advice.
Information on the site is updated periodically (approximately every 12 hours).

If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6326, Mon - Fri, 8:30 am - 8:00 pm ET.

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[Register](#) | [Log In](#)

Home

Prescriber Enrollment

Healthcare Facility Enrollment

Pharmacy Enrollment

Patient Guides

Forms & Resources

REMS Certified Prescriber & Healthcare Facility Locator

REMS Certified Prescriber & Healthcare Facility

Search for prescribers or healthcare facilities that are enrolled and certified in the LEMTRADA REMS and able to prescribe or dispense/administer LEMTRADA.

Please enter street address, city, state, or ZIP Code you would like to search for.

New Search:

REMS Certified Prescribers

REMS Certified Healthcare Facilities

Certified Center Name

Address

Address

P. (888) - 888 - 8888

Certified Center Name

Address

Address

P. (888) - 888 - 8888

Certified Center Name

Address

Address

P. (888) - 888 - 8888

Certified Center Name

Address

Address

P. (888) - 888 - 8888

Certified Center Name

Address

Address

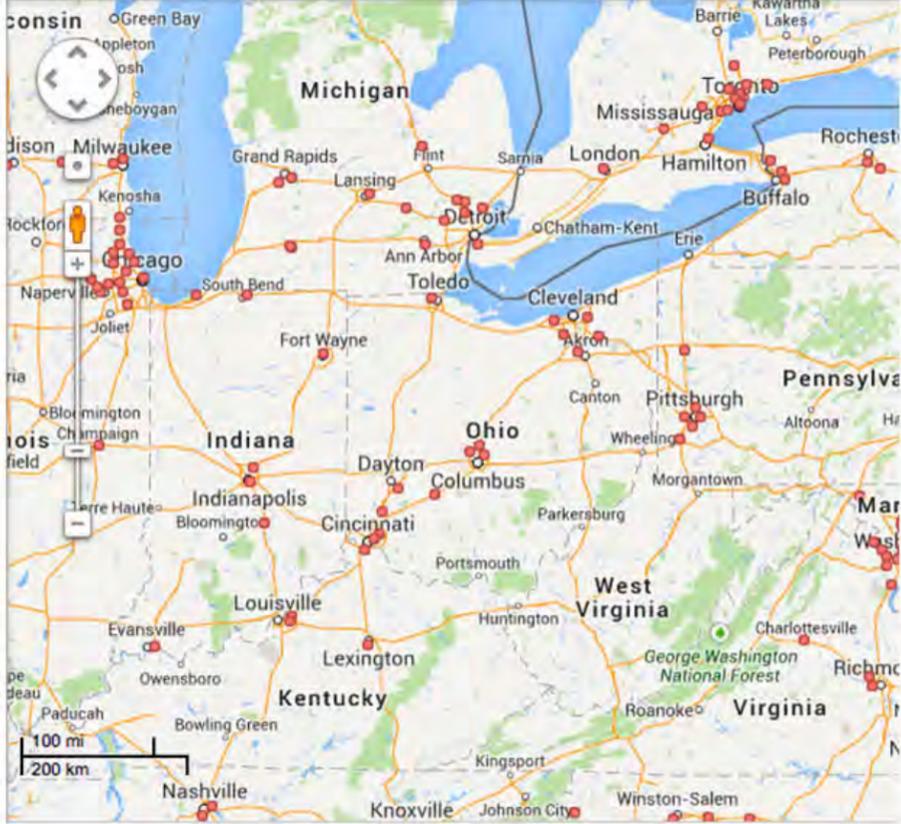
P. (888) - 888 - 8888

Certified Center Name

Address

Address

P. (888) - 888 - 8888



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If you are a prescriber that would like to request the removal of your contact information from this website, please call the LEMTRADA REMS at 1-855-676-6326.

**This site is provided as a resource for prescribers and is not intended as medical advice.
Information on the site is updated periodically (approximately every 12 hours).**

If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6326, Mon – Fri, 8:30 am – 8:00 pm ET.

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SANOFI GENZYME

VV-REG-0833078 0.1

Reference ID: 4512344

The screenshot shows a web browser window displaying the LEMTRADA REMS website. The browser's address bar shows a Google search. The website header includes the LEMTRADA logo (alemtuzumab iv) and navigation links for Prescribing Information, Medication Guide, Register, and Log In. A main navigation bar contains links for Home, Prescriber Enrollment, Healthcare Facility Enrollment, Pharmacy Enrollment, Patient Guides, Forms & Resources, and REMS Certified Prescriber & Healthcare Facility Locator.

The main content area is titled "REMS Certified Prescriber & Healthcare Facility" and includes a search prompt: "Search for prescribers or healthcare facilities that are enrolled and certified in the LEMTRADA REMS and able to prescribe or dispense/administer LEMTRADA. Please enter street address, city, state, or ZIP Code you would like to search for." Below this is a "New Search" section with a search input field and a magnifying glass icon.

A prominent white interstitial box with a purple border and a close button (X) is overlaid on the search area. The interstitial contains the following text:

You Are Submitting Information to Genzyme

Genzyme respects individual privacy and values the confidence of its customers, partners, patients, and employees.

This Privacy Policy and Notice of Information Practices sets forth Genzyme's practices regarding the collection, use and disclosure of information that you may provide through this site. Whenever you submit information through this site to Genzyme, you agree with the terms of Genzyme's Privacy Policy and Notice of Information Practices. Please review the privacy policy before submitting information through this website. By clicking "Continue" you are agreeing to the terms of Genzyme's privacy policy.

At the bottom of the interstitial are two green buttons: "Go Back" and "Continue".

The background of the page shows a map of the Eastern United States (Indiana, Ohio, Kentucky, West Virginia, Virginia, Pennsylvania, Maryland) with several red location pins. To the left of the map is a list of "REMS Certified Prescriber" entries, each with a red location pin icon and placeholder text: "Certified Center Name", "Address", "Address", and "P. (888) - 888 - 8888".

Below the map, there is a disclaimer: "Genzyme is providing this search feature to help patients find prescribers and healthcare facilities that have been certified by the LEMTRADA REMS. Genzyme does not receive payment for providing this feature, and does not endorse, recommend, have jurisdiction over, or accept responsibility for the actions of any of the prescribers or healthcare facilities listed herein." Below this is contact information: "If you are a prescriber that would like to request the removal of your contact information from this website, please call the LEMTRADA REMS at 1-855-676-6326." A note states: "This site is provided as a resource for prescribers and is not intended as medical advice. Information on the site is updated periodically (approximately every 12 hours)." At the bottom, there is a section for questions: "If you have questions about the LEMTRADA REMS or need help enrolling, call 1-359-676-6326, Mon - Fri, 8:30 am - 8:00 pm ET." The footer contains links for Privacy Policy, Terms and Conditions, and Contact Us, along with copyright information: "©2019 Genzyme Corporation. All rights reserved." and "Lemtrada, MS One to One, Sanofi and Genzyme registered in U.S. Patent and Trademark Office. US MS LEM-14.10.013-v7 Last Updated 09/19". The Sanofi Genzyme logo is in the bottom right corner.

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[Prescribing Information](#) [Medication Guide](#)

[Register](#) | [Log In](#)

- Home
- Prescriber Enrollment
- Healthcare Facility Enrollment
- Pharmacy Enrollment
- Patient Guides
- Forms & Resources
- REMS Certified Prescriber & Healthcare Facility Locator

Contact Us

For any questions about LEMTRADA, please contact LEMTRADA Support Services by phone or complete the form below.

Phone: **1-855-676-6326**

Call Center Hours: Mon – Fri, 8:30 am – 8:00 pm ET

All fields are required.

First Name

Last Name

What can we help you with?

How would you like to be contacted?

Email Phone

Email

Submit

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LEMTRADA
alemtuzumab^{12mg} iv

[Prescribing Information](#) [Medication Guide](#)
[Register](#) | [Log In](#)

Home Prescriber Enrollment Healthcare Facility Enrollment Pharmacy Enrollment Patient Guides Forms & Resources REMS Certified Prescriber & Healthcare Facility Locator

Contact Us

For any questions about LEMTRADA, please contact LEMTRADA Support Services by phone or complete the form below.

Phone: **1-855-676-6326**
Call Center Hours: Mon – Fri, 8:30 am – 8:00 pm ET

All fields are required.

First Name

Last Name

What can we help you with?

- Select
- ✓ Patient Support
- Product
- Technical
- Other

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Prescribing Information Medication Guide
Register | Log In

Home Prescriber Enrollment Healthcare Facility Enrollment Pharmacy Enrollment Patient Guides Forms & Resources REMS Certified Prescriber & Healthcare Facility Locator

Contact Us

For any questions about LEMTRADA, please contact LEMTRADA Support Services by phone or complete the form below.

Phone: **1-855-676-6326**
Call Center Hours: Mon – Fri, 8:30 am – 8:00 pm ET

All fields are required.

First Name

Please enter your first name.

Last Name

Please enter your last name.

What can we help you with?

Please make a selection.

How would you like to be contacted?
 Email Phone

Please enter a valid email address.

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The screenshot shows a web browser window displaying the LEMTRADA website. The browser's address bar shows a Google search engine. The website header features the LEMTRADA logo (alemftuzumab 12mg iv) and navigation links for 'Prescribing Information' and 'Medication Guide'. A secondary navigation bar includes links for 'Home', 'Prescriber Enrollment', 'Healthcare Facility Enrollment', 'Pharmacy Enrollment', 'Patient Guides', 'Forms & Resources', and 'REMS Certified Prescriber & Healthcare Facility Locator'. The main content area displays a 'Thank You' message, stating that the user's information is confidential and that they will be contacted by a Genzyme representative. A green 'Home' button is located below the message. The footer contains links for 'Privacy Policy', 'Terms and Conditions', and 'Contact Us', along with copyright information for 2019 Genzyme Corporation and the Sanofi Genzyme logo. A pink dashed line labeled 'FOLD' is positioned on the left side of the footer area.

PRESCRIBER TRAINING PAGES

The screenshot shows a web browser window displaying the LEMTRADA REMS registration page. The browser's address bar shows a Google search engine. The page header includes the LEMTRADA logo (alemTuzumab^{12mg} iv) and navigation links for Prescribing Information, Medication Guide, Register, and Log In. A horizontal menu contains buttons for Home, Prescriber Enrollment, Healthcare Facility Enrollment, Pharmacy Enrollment, Patient Guides, Forms & Resources, and REMS Certified Prescriber & Healthcare Facility Locator. The main content area is titled "Registration for LEMTRADA REMS Training" and provides instructions for new users. It includes three radio button options: "I am a Prescriber" (selected), "I represent a Healthcare Facility", and "I represent a Pharmacy". A button labeled "Already Registered? Log In" is positioned to the right of these options. Below the options, there is a note for already certified users and a phone number: "1-855-676-6326". At the bottom of the registration section are "Cancel" and "Next" buttons. A pink dashed line labeled "FOLD" is drawn across the page, indicating a fold line. The footer contains links for Privacy Policy, Terms and Conditions, and Contact Us, along with copyright information for Genzyme Corporation (©2019) and the Sanofi Genzyme logo.

The screenshot shows a web browser window displaying the LEMTRADA REMS Desktop registration page. The browser's address bar shows a Google search. The page header includes the LEMTRADA logo (alemftuzumab 12mg iv) and navigation links for Prescribing Information, Medication Guide, Register, and Log In. A main navigation bar contains links for Home, Prescriber Enrollment, Healthcare Facility Enrollment, Pharmacy Enrollment, Patient Guides, Forms & Resources, and REMS Certified Prescriber & Healthcare Facility Locator. A progress bar below the navigation bar shows four steps: Registration (highlighted), Training, Assessment, and Enrollment. The main content area is titled "Prescriber Registration for LEMTRADA REMS Training" and includes a sub-header "To complete your training for the LEMTRADA REMS, please set up an account." Below this is a form with various fields: Email Address*, Create a Password*, Confirm Password*, First Name*, Last Name*, Degree* (dropdown), National Provider Identification (NPI) Number*, Name of Institution or Healthcare Facility*, Street Address* (two lines), City*, State* (dropdown), ZIP Code*, Office Phone Number*, Office Fax Number*, and Mobile Phone Number. A note specifies password requirements: "Passwords must be at least 8 characters in length and contain a minimum of 3 out of the following: A number, an upper-case letter, a lower-case letter, a special character (e.g. !, ", #, \$, etc.)." At the bottom of the form is a checkbox: "By checking this box, you indicate you will comply with our terms and conditions." Below the form are "Cancel" and "Register" buttons. A footer section contains contact information: "If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6326, Mon - Fri, 8:30 am - 8:00 pm ET." The footer also includes links for Privacy Policy, Terms and Conditions, and Contact Us, along with copyright information for Genzyme Corporation (©2019) and the Sanofi Genzyme logo.

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Prescribing Information Medication Guide
[Register](#) | [Log In](#)

Home Prescriber Enrollment Healthcare Facility Enrollment Pharmacy Enrollment Patient Guides Forms & Resources REMS Certified Prescriber & Healthcare Facility Locator

Registration Training Assessment Enrollment

Prescriber Registration for LEMTRADA REMS Training

To complete your training for the LEMTRADA REMS, please set up an account.

***Required**

Email Address*

Create a Password* Passwords must be at least 8 characters in length and contain a minimum of 3 out of the following: A number, an upper-case letter, a lower-case letter, a special character (e.g. !, ", #, \$, etc.)

Confirm Password*

First Name*

Last Name*

Degree*

✓ Doctor of Osteopathy
Doctor of Pharmacy
Medical Doctor
Nurse Practitioner
Physician Assistant
Registered Nurse
Registered Pharmacist

City*

State* ZIP Code*

Office Phone Number*

Office Fax Number*

Mobile Phone Number

*By checking this box, you indicate you will comply with our [terms and conditions](#).

[Cancel](#)

If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6326, Mon – Fri, 8:30 am – 8:00 pm ET.

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The screenshot shows a web browser window displaying the LEMTRADA REMS Desktop registration page. The page features a navigation menu with options like Home, Prescriber Enrollment, and Healthcare Facility Enrollment. A progress bar indicates the current step is 'Registration'. The main heading is 'Prescriber Registration for LEMTRADA REMS Training', with a sub-heading 'To complete your training for the LEMTRADA REMS, please set up an account.' The form includes fields for Email Address, Password, Confirm Password, First Name, Last Name, Degree, NPI Number, Name of Institution, Street Address, City, State, ZIP Code, Office Phone Number, Office Fax Number, and Mobile Phone Number. A password strength error message is displayed: 'Passwords must be at least 8 characters in length and contain a minimum of 3 out of the following: A number, an upper-case letter, a lower-case letter, a special character (e.g. !, ", #, \$, etc.)'. The form also includes a checkbox for terms and conditions and 'Cancel' and 'Register' buttons.

FOLD

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alemftuzumab 12mg iv

Prescribing Information Medication Guide

Welcome, Adam Smith! [My Profile](#) | [Log Out](#)

Home Forms and FAQs REMS Certified Prescriber & Healthcare Facility Locator About REMS

Registration Training Assessment Enrollment

Thank You for Registering

Your account is your personal online center for LEMTRADA REMS training, resources, and support. Please complete training to become certified to prescribe or dispense/administer LEMTRADA.

I have passed an assessment test and am REMS enrolled.

[Continue](#)

FOLD

If you have questions about the LEMTRADA REMS or need help enrolling, call **1-855-676-6326**, Mon - Fri, 8:30 am - 8:00 pm ET.

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Prescribing Information Medication Guide

Welcome, Adam Smith! [My Profile](#) | [Log Out](#)

Home Forms and FAQs REMS Certified Prescriber & Healthcare Facility Locator About REMS

Registration Training Assessment Enrollment

LEMTRADA REMS Online Training Module

If inactive on the training module for 20 minutes, you will be automatically logged off the LEMTRADA website and lose your training progress.

- Please review the LEMTRADA REMS Training Materials, including the full Prescribing Information, the LEMTRADA REMS Program Overview, and the *LEMTRADA REMS Education Program for Prescribers*. You may review the material at your own pace and go back to any point of the presentation at your discretion
- At the end of the module, you will be required to answer 8 questions. You must answer ALL 8 questions correctly in order to complete your training. If you do not answer all 8 questions correctly after 3 attempts, you will need to go back and review the training materials before taking the assessment again
- If you do not successfully complete the assessment after 6 attempts, you will be ineligible for online enrollment in the LEMTRADA REMS and will not be certified to prescribe/dispense LEMTRADA

Online training will take approximately 20 minutes. Please allow enough time to view the entire module. You will be automatically logged out after 20 minutes of inactivity and your training progress may be lost.

[Continue](#)

If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6326, Mon – Fri, 8:30 am – 8:00 pm ET.

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LEMTRADA[®]
alemtozumab 12mg

Prescribing Information Medication Guide

Welcome, Adam Smith! [My Profile](#) | [Log Out](#)

Home Forms and FAQs REMS Certified Prescriber & Healthcare Facility Locator About REMS

Registration Training Assessment Enrollment

Inactivity Alert

There has been no activity for 15 minutes. You will be logged out if there is no activity before your session expires.

00:04:39

Continue

LEMTRADA

If inactive
LEMTRADA

- Please re
LEMTRADA
review th
- At the en
correctly
will need
- If you do
enrollme

Online training will take approximately 20 minutes. Please allow enough time to view the entire module. You will be automatically logged out after 20 minutes of inactivity and your training progress may be lost.

Continue

**If you have questions about the LEMTRADA REMS
or need help enrolling, call 1-855-676-6326, Mon - Fri, 8:30 am - 8:00 pm ET.**

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alem tuzumab^{12mg} iv

Prescribing Information Medication Guide
[Register](#) | [Log In](#)

Home Prescriber Enrollment Healthcare Facility Enrollment Pharmacy Enrollment Patient Guides Forms & Resources REMS Certified Prescriber & Healthcare Facility Locator

Your Session Has Timed Out

There has been no activity for 20 minutes, so you have been timed out.

[Restart](#)

If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6326, Mon - Fri, 8:30 am - 8:00 pm ET.

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LEMTRADA
alemtuzumab 12mg iv

Prescribing Information Medication Guide

Welcome, Adam Smith! [My Profile](#) | [Log Out](#)

Home

Forms and FAQs

REMS Certified Prescriber & Healthcare Facility Locator

About REMS

Registration
Training
Assessment
Enrollment

LEMTRADA REMS Training

Full Prescribing Information (1 of 27) Total Training Screens: 1 of 41

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use LEMTRADA safely and effectively. See full prescribing information for LEMTRADA.

LEMTRADA[®] (alemtuzumab) injection, for intravenous use
Initial U.S. Approval: 2001

WARNING: AUTOIMMUNITY, INFUSION REACTIONS, STROKE, AND MALIGNANCIES

See full prescribing information for complete boxed warning.

- LEMTRADA causes serious, sometimes fatal, autoimmune conditions such as immune thrombocytopenia and anti-glomerular basement membrane disease. Monitor complete blood counts with differential, serum creatinine levels, and urinalysis with urine counts at periodic intervals for 48 months after the last dose. (5.3)
- LEMTRADA causes serious and life-threatening infusion reactions. LEMTRADA must be administered in a setting with appropriate equipment and personnel to manage anaphylaxis or serious infusion reactions. Monitor patients for two hours after each infusion. Make patients aware that serious infusion reactions can also occur after the 2-hour monitoring period. (5.2)
- Serious and life-threatening stroke has been reported within 3 days of LEMTRADA administration. Instruct patients to seek immediate medical attention if symptoms of stroke occur. (5.3)
- LEMTRADA may cause an increased risk of malignancies, including thyroid cancer, melanoma, and lymphoproliferative disorders. Perform baseline and yearly skin exams. (5.4)
- LEMTRADA is available only through a restricted distribution program. (5.5)

RECENT MAJOR CHANGES

Boxed Warning	11/2018
Indications and Usage (1)	8/2018
Dosage and Administration (2.3)	11/2018
Dosage and Administration (2.6)	01/2019
Warnings and Precautions (5.1, 5.3, 5.7)	11/2018
Warnings and Precautions (5.2)	xx/2019
Warnings and Precautions, Autoimmune Hepatitis (5.10)	01/2019
Warnings and Precautions, Infections (5.11)	01/2019
Warnings and Precautions, PML (5.12)	07/2019

INDICATIONS AND USAGE

- LEMTRADA is a CD52-directed cytolytic monoclonal antibody indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include relapsing-remitting disease and active secondary progressive disease, in adults. Because of its safety profile, the use of LEMTRADA should generally be reserved for patients who have had an inadequate response to two or more drugs indicated for the treatment of MS [see Warnings and Precautions (5.7)]. (1)
- LEMTRADA is not recommended for use in patients with clinically isolated syndrome (CIS) because of its safety profile [see Warnings and Precautions (5.7)]. (3)

DOSAGE AND ADMINISTRATION

- Baseline laboratory tests are required prior to treatment. (2.1)
- Administer LEMTRADA by intravenous infusion over 4 hours for 2 or more treatment courses:

Initial treatment of 2 courses:

- First course: 12 mg/day on 5 consecutive days. (2.3)
- Second course: 12 mg/day on 3 consecutive days 12 months after first treatment course. (2.3)

Subsequent treatment courses of 12 mg per day on 3 consecutive days (36 mg total dose) may be administered, as needed, at least 12 months after the last dose of any prior treatment course. (2.3)

- Premedicate with corticosteroids prior to LEMTRADA infusion for the first 3 days of each treatment course. (2.2)
- Administer antiviral agents for herpetic prophyllaxis starting on the first day of LEMTRADA dosing and continuing for a minimum of two months after completion of LEMTRADA dosing or until CD4+ lymphocyte count is more than 200 cells per microliter, whichever occurs later. (2.2)
- Must be diluted prior to administration. (2.4)

DOSAGE FORMS AND STRENGTHS

Injection: 12 mg/1.2 mL (10 mg/mL) in a single-dose vial. (3)

CONTRAINDICATIONS

Infection with Human Immunodeficiency Virus (4)

WARNINGS AND PRECAUTIONS

- **Immune Thrombocytopenia:** Obtain complete blood counts (CBCs) with differential prior to initiation of treatment and at monthly intervals thereafter until 48 months after the last infusion. (5.6)
- **Glomerular Nephropathies:** Obtain serum creatinine levels, urinalysis with cell counts and urine protein to creatinine ratio prior to initiation of treatment. Monitor serum creatinine levels and urinalysis with cell counts at monthly intervals thereafter until 48 months after the last infusion. (5.7)
- **Thyroid Disorders:** Obtain thyroid function tests prior to initiation of treatment and every 3 months until 48 months after the last infusion. (5.8)
- **Other Autoimmune Cytopathies:** Monitor CBCs monthly until 48 months after the last infusion. (2.6, 5.9)
- **Autoimmune Hepatitis:** If signs of hepatic dysfunction occur, promptly measure serum transaminases and total bilirubin and interrupt or discontinue treatment. (5.10)
- **Infectious:** Consider delaying initiation of LEMTRADA in patients with active infections until the infection is fully controlled. Do not administer live viral vaccines following a course of LEMTRADA. (5.11)
- **Progressive Multifocal Leukoencephalopathy (PML):** Withhold LEMTRADA at the first sign or symptom suggestive of PML. (5.12)

ADVERSE REACTIONS

Most common adverse reactions (incidence ≥10% and > interferon beta-1a): rash, headache, pyrexia, nasopharyngitis, nausea, urinary tract infection, fatigue, insomnia, upper respiratory tract infection, herpes viral infection, urticaria, pruritus, thyroid gland disorders, fungal infection, arthralgia, pain in extremity, back pain, diarrhea, sinusitis, oropharyngeal pain, paresthesia, dizziness, abdominal pain, flushing, and vomiting. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Genzyme Corporation at 1-800-745-4447 (option 2) or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

USE IN SPECIFIC POPULATIONS

Pregnancy: May cause fetal harm. (8.1)

Women of childbearing potential should use effective contraception during and for 4 months after a course of treatment with LEMTRADA. (8.3)

See 17 for PATIENT COUNSELING INFORMATION and Medication Guide.

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If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6326, Mon – Fri, 8:30 am – 8:00 pm ET.

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Reference ID: 4512344

The screenshot shows a web browser window displaying the LEMTRADA REMS Desktop interface. The browser's address bar shows a Google search. The page header includes the LEMTRADA logo (alemftuzumab 12mg iv) and navigation links for Prescribing Information and Medication Guide. A user is logged in as Adam Smith, with links for My Profile and Log Out. A navigation bar contains Home, Forms and FAQs, REMS Certified Prescriber & Healthcare Facility Locator, and About REMS. Below this is a progress bar with steps: Registration, Training (current), Assessment, and Enrollment. The main heading is LEMTRADA REMS Training, with sub-headings for Full Prescribing Information (2 of 27) and Total Training Screens: 2 of 41. The central content area displays a table of contents for the Full Prescribing Information, listing sections 1 through 17. A 'FOLD' label is visible on the left side of the page. At the bottom of the content area are 'Previous' and 'Next' buttons, and a page indicator '(2 of 41)'. Below the content area is a call to action: 'If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6326, Mon - Fri, 8:30 am - 8:00 pm ET.' The footer contains links for Privacy Policy, Terms and Conditions, and Contact Us, along with copyright information for Genzyme Corporation (©2019) and the Sanofi Genzyme logo.

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FULL PRESCRIBING INFORMATION

WARNING: AUTOIMMUNITY, INFUSION REACTIONS, STROKE, AND MALIGNANCIES

- LEMTRADA causes serious, sometimes fatal, autoimmune conditions such as immune thrombocytopenia and anti-glomerular basement membrane disease. Monitor complete blood counts with differential, serum creatinine levels, and urinalysis with urine cell counts at periodic intervals for 48 months after the last dose of LEMTRADA [see Warnings and Precautions (5.1)].
- LEMTRADA causes serious and life-threatening infusion reactions. LEMTRADA must be administered in a setting with appropriate equipment and personnel to manage anaphylaxis or serious infusion reactions. Monitor patients for two hours after each infusion. Make patients aware that serious infusion reactions can also occur after the 2-hour monitoring period [see Warnings and Precautions (5.2)].
- Serious and life-threatening stroke (including ischemic and hemorrhagic stroke) has been reported within 3 days of LEMTRADA administration. Instruct patients to seek immediate medical attention if symptoms of stroke occur [see Warnings and Precautions (5.3)].
- LEMTRADA may cause an increased risk of malignancies, including thyroid cancer, melanoma, and lymphoproliferative disorders. Perform baseline and yearly skin exams [see Warnings and Precautions (5.4)].
- Because of the risk of autoimmunity, infusion reactions, and malignancies, LEMTRADA is available only through restricted distribution under a Risk Evaluation Mitigation Strategy (REMS) Program. Call 1-855-676-6326 to enroll in the LEMTRADA REMS program [see Warnings and Precautions (5.5)].

1 INDICATIONS AND USAGE

LEMTRADA is indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include relapsing-remitting disease and active secondary progressive disease, in adults. Because of its safety profile, the use of LEMTRADA should generally be reserved for patients who have had an inadequate response to two or more drugs indicated for the treatment of MS [see Warnings and Precautions (5)].

Limitations of Use

LEMTRADA is not recommended for use in patients with clinically isolated syndrome (CIS) because of its safety profile [see Warnings and Precautions (5)].

2 DOSAGE AND ADMINISTRATION

2.1 Testing and Procedures Prior to Treatment

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Baseline laboratory tests are required prior to treatment with LEMTRADA [see Dosage and Administration (2.6)]. In addition, prior to starting treatment with LEMTRADA [see Warnings and Precautions (5.11)]:

- complete any necessary immunizations at least 6 weeks prior to treatment.
- determine whether patients have a history of varicella or have been vaccinated for varicella zoster virus (VZV). If not, test the patient for antibodies to VZV and consider vaccination for those who are antibody-negative. Postpone treatment with LEMTRADA until 6 weeks after VZV vaccination.
- perform tuberculosis screening according to local guidelines.
- instruct patients to avoid potential sources of *Listeria monocytogenes*.

2.2 Recommended Premedication and Concomitant Medication

Corticosteroids
Premedicate patients with high dose corticosteroids (1,000 mg methylprednisolone or equivalent) immediately prior to LEMTRADA infusion and for the first 3 days of each treatment course [see Warnings and Precautions (5.2)].

Herpes Prophylaxis
Administer anti-viral prophylaxis for herpetic viral infections starting on the first day of each treatment course and continue for a minimum of two months following treatment with LEMTRADA or until the CD4+ lymphocyte count is at least 200 cells per microliter, whichever occurs later [see Warnings and Precautions (5.11)].

2.3 Recommended Dosage

- The recommended dosage of LEMTRADA is 12 mg/day administered by intravenous infusion for 2 treatment courses: First Treatment Course: 12 mg/day on 5 consecutive days (60 mg total dose).
- Second Treatment Course: 12 mg/day on 3 consecutive days (36 mg total dose) administered 12 months after the first treatment course.

Following the second treatment course, subsequent treatment courses of 12 mg per day on 3 consecutive days (36 mg total dose) may be administered, as needed, at least 12 months after the last dose of any prior treatment courses.

2.4 Preparation Instructions

Follow the steps below to prepare the diluted solution of LEMTRADA for intravenous infusion:

- Inspect LEMTRADA visually for particulate matter and discoloration prior to administration. Do not use if particulate matter is present or the solution is discolored. Do not freeze or shake vials prior to use.
- Withdraw 1.2 mL of LEMTRADA from the vial into a syringe using aseptic technique and inject into a 100 mL bag of sterile 0.9% Sodium Chloride, USP or 5% Dextrose in Water, USP.

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- Gently invert the bag to mix the solution. Ensure the sterility of the prepared solution, because it contains no antimicrobial preservatives. Each vial is for single use only.

Prior to administration, protect diluted LEMTRADA solution from light and store for as long as 8 hours either at room temperature 15°C to 25°C (59°F to 77°F) or keep refrigerated at conditions 2°C to 8°C (36°F to 46°F).

2.5 Infusion Instructions

Infuse LEMTRADA over 4 hours starting within 8 hours after dilution. Extend the duration of the infusion if clinically indicated.

Administer LEMTRADA in a setting in which equipment and personnel to appropriately manage anaphylaxis or serious infusion reactions are available [see Warnings and Precautions (5.2)].

Do not add or simultaneously infuse other drug substances through the same intravenous line. Do not administer as an intravenous push or bolus.

Monitor vital signs before the infusion and periodically during the infusion. Provide appropriate symptomatic treatment for infusion reactions as needed. Consider immediate discontinuation of the intravenous infusion if severe infusion reactions occur.

Observe patients for infusion reactions during and for at least 2 hours after each LEMTRADA infusion. Consider longer periods of observation if clinically indicated. Inform patients that they should report symptoms that occur during and after each infusion because they may indicate a need for prompt medical intervention [see Warnings and Precautions (5.2)].

2.6 Laboratory Testing and Monitoring to Assess Safety

Measure the urine protein to creatinine ratio prior to initiation of treatment. Conduct the following laboratory tests at baseline and at periodic intervals until 48 months after the last treatment course of LEMTRADA in order to monitor for early signs of potentially serious adverse effects:

- Complete blood count (CBC) with differential (prior to treatment initiation and at monthly intervals thereafter)
- Serum creatinine levels (prior to treatment initiation and at monthly intervals thereafter)
- Urinalysis with urine cell counts (prior to treatment initiation and at monthly intervals thereafter)
- A test of thyroid function, such as thyroid stimulating hormone (TSH) level (prior to treatment initiation and every 3 months thereafter)
- Serum transaminases (alanine aminotransferase [ALT] and aspartate aminotransferase [AST]) and total bilirubin levels (prior to treatment initiation and periodically thereafter)

Conduct baseline and yearly skin exams to monitor for melanoma [see Warnings and Precautions (5.4)].

3 DOSAGE FORMS AND STRENGTHS

Injection: 12 mg/1.2 mL (10 mg/mL) in a single-dose vial. LEMTRADA is a clear and colorless to slightly yellow solution that requires dilution prior to intravenous infusion.

4 CONTRAINDICATIONS

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LEMTRADA is contraindicated in patients who are infected with Human Immunodeficiency Virus (HIV) because LEMTRADA causes prolonged reductions of CD4+ lymphocyte counts.

5 WARNINGS AND PRECAUTIONS

5.1 Autoimmunity

Treatment with LEMTRADA can result in the formation of autoantibodies and increase the risk of serious autoimmune mediated conditions.

In clinical studies (controlled and open-label extension), LEMTRADA-treated patients experienced thyroid disorders (36.8%), immune thrombocytopenia (2%), and glomerular nephropathies (0.3%) [see *Warnings and Precautions* (5.7, 5.8, 5.9)]. Vitiligo and autoimmune hemolytic anemia occurred in 0.3% of patients. Autoimmune pancytopenia [see *Warnings and Precautions* (5.9)], undifferentiated connective tissue disorders, and type 1 diabetes each occurred in 0.2% of patients. Rheumatoid arthritis, retinal pigment epitheliopathy, and acquired hemophilia A (anti-Factor VIII antibodies) occurred in 0.1% of patients. During postmarketing use, cases of vasculitis, autoimmune hepatitis [see *Warnings and Precautions* (5.10)], and Guillain-Barré syndrome have been reported [see *Adverse Reactions* (6.5)].

Chronic inflammatory demyelinating polyradiculoneuropathy has been reported in the treatment of patients with B-cell chronic lymphocytic leukemia (B-CLL), as well as other autoimmune disorders, generally at higher and more frequent doses than recommended in MS. An oncology patient treated with alemtuzumab had fatal transfusion-associated graft-versus-host disease.

Autoantibodies may be transferred from the mother to the fetus during pregnancy. A case of transplacental transfer of anti-thyrotropin receptor antibodies resulting in neonatal Graves' disease occurred after alemtuzumab treatment in the mother [see *Use in Specific Populations* (8.1)].

LEMTRADA may increase the risk of other autoimmune conditions because of the broad range of autoantibody formation with LEMTRADA.

Measure the urine protein to creatinine ratio prior to initiation of treatment. Monitor complete blood counts with differential, serum creatinine levels, and urinalysis with urine cell counts before starting treatment and then at monthly intervals until 48 months after the last dose of LEMTRADA to allow for early detection and treatment of autoimmune adverse reactions [see *Dosage and Administration* (2.6)]. After 48 months, testing should be performed based on clinical findings suggestive of autoimmunity.

LEMTRADA is available only through a restricted program under a REMS [see *Warnings and Precautions* (5.5)].

5.2 Infusion Reactions

LEMTRADA causes cytokine release syndrome resulting in infusion reactions, some of which may be serious and life threatening. In clinical studies, 92% of LEMTRADA-treated patients experienced infusion reactions. In some patients, infusion reactions were reported more than 24 hours after LEMTRADA infusion. Serious reactions occurred in 3% of patients and included anaphylaxis in 2 patients (including anaphylactic shock), angioedema, bronchospasm, hypotension, chest pain, bradycardia, tachycardia (including atrial fibrillation), transient neurologic symptoms, hypertension, headache, pyrexia, and rash. Other infusion reactions included nausea, urticaria, pruritus, insomnia, chills, flushing, fatigue, dyspnea, pulmonary

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infiltrates, dysgeusia, dyspepsia, dizziness, and pain. In clinical studies, 0.6% of patients with infusion reactions received epinephrine or atropine.

During postmarketing use, cases of pulmonary alveolar hemorrhage and myocardial ischemia have been reported with onset within 48 hours of LEMTRADA infusion. Cases of severe (including fatal) neutropenia have been reported within 2 months of LEMTRADA infusion; some cases resolved with receiving granulocyte-colony stimulating factor treatment. Mild to moderate decreases in platelet counts, starting at the time of alemtuzumab infusion and often resolving without treatment, have been reported. Other serious and sometimes fatal infusion reactions (e.g., hypoxia, syncope, acute respiratory distress syndrome, respiratory arrest, myocardial infarction, acute cardiac insufficiency, cardiac arrest) have been reported in the treatment of patients with B-CLL, as well as other disorders, generally at higher and more frequent doses than recommended in MS.

In the postmarketing setting, serious and life-threatening stroke (including ischemic and hemorrhagic stroke) has been reported within 3 days of LEMTRADA administration, with most cases occurring within 1 day [see Warnings and Precautions (5.3)].

Premedicate patients with corticosteroids immediately prior to LEMTRADA infusion for the first 3 days of each treatment course. In clinical studies, patients received 1,000 mg of methylprednisolone for the first 3 days of each LEMTRADA treatment course. Consider pretreatment with antihistamines and/or antipyretics prior to LEMTRADA administration. Infusion reactions may occur despite pretreatment.

Consider additional monitoring in patients with medical conditions which predispose them to cardiovascular or pulmonary compromise. Physicians should alert patients that an infusion reaction could occur within 48 hours of infusion.

LEMTRADA can only be administered in certified healthcare settings that have on-site access to equipment and personnel trained to manage infusion reactions (including anaphylaxis and cardiac and respiratory emergencies).

LEMTRADA is available only through a restricted program under a REMS [see Warnings and Precautions (5.5)].

5.3 Stroke and Cervicocephalic Arterial Dissection

Stroke

In the postmarketing setting, serious and life-threatening stroke (including ischemic and hemorrhagic stroke) has been reported within 3 days of LEMTRADA administration, with most cases occurring within 1 day.

Cervicocephalic Arterial Dissection

In the postmarketing setting, cases of cervicocephalic (e.g., vertebral, carotid) arterial dissection involving multiple arteries have been reported within 3 days of LEMTRADA administration. Ischemic stroke was reported in one of these cases.

Educate patients on the symptoms of stroke and cervicocephalic (e.g., carotid, vertebral) arterial dissection. Instruct patients to seek immediate medical attention if symptoms of stroke or cervicocephalic arterial dissection occur.

5.4 Malignancies

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Thyroid Cancer

LEMTRADA may increase the risk of thyroid cancer. In controlled clinical studies, 3 of 919 (0.3%) LEMTRADA-treated patients developed thyroid cancer, compared to none in the interferon beta-1a-treated group. However, screening for thyroid cancer was performed more frequently in the LEMTRADA-treated group, because of the higher incidence of autoimmune thyroid disorders in those patients. Two additional cases of thyroid cancer in LEMTRADA-treated patients occurred in uncontrolled studies.

Patients and healthcare providers should monitor for symptoms of thyroid cancer including a new lump or swelling in the neck, pain in the front of the neck, persistent hoarseness or other voice changes, trouble swallowing or breathing, or a constant cough not due to an upper respiratory tract infection.

Melanoma

LEMTRADA may increase the risk of melanoma. In MS clinical studies (controlled and open-label extension), 5 of 1486 (0.3%) LEMTRADA-treated patients developed melanoma or melanoma *in situ*. One of those patients had evidence of locally advanced disease.

Perform baseline and yearly skin examinations to monitor for melanoma in patients receiving LEMTRADA.

Lymphoproliferative Disorders and Lymphoma

Cases of lymphoproliferative disorders and lymphoma have occurred in LEMTRADA-treated patients with MS, including a MALT lymphoma, Castleman's Disease, and a fatality following treatment of non-Epstein Barr Virus-associated Burkitt's lymphoma. There are postmarketing reports of Epstein Barr Virus-associated lymphoproliferative disorders in non-MS patients.

Because LEMTRADA is an immunomodulatory therapy, caution should also be exercised in initiating LEMTRADA in patients with preexisting or ongoing malignancies.

LEMTRADA is available only through a restricted program under a REMS [see *Warnings and Precautions* (5.5)].

5.5 LEMTRADA REMS Program

LEMTRADA is available only through a restricted program under a REMS called the LEMTRADA REMS Program because of the risks of autoimmunity, infusion reactions, and malignancies [see *Warnings and Precautions* (5.1, 5.2, 5.4)].

Notable requirements of the LEMTRADA REMS Program include the following:

- Prescribers must be certified with the program by enrolling and completing training.
- Patients must enroll in the program and comply with ongoing monitoring requirements [see *Dosage and Administration* (2.6)].
- Pharmacies must be certified with the program and must only dispense to certified healthcare facilities that are authorized to receive LEMTRADA.
- Healthcare facilities must enroll in the program and verify that patients are authorized before infusing LEMTRADA. Healthcare facilities must have on-site access to equipment and personnel trained to manage infusion reactions.

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Further information, including a list of qualified healthcare facilities, is available at 1-855-676-6326.

5.6 Immune Thrombocytopenia

Immune thrombocytopenia (ITP) occurred in 2% of LEMTRADA-treated patients in MS clinical studies (controlled and open-label extension).

In a controlled clinical study in patients with MS, one LEMTRADA-treated patient developed ITP that went unrecognized prior to the implementation of monthly blood monitoring requirements, and died from intracerebral hemorrhage. Nadir platelet counts $\leq 20,000$ cells per microliter as a result of ITP occurred in 2% of all LEMTRADA-treated patients in clinical studies in MS. Anti-platelet antibodies did not precede ITP onset. ITP has been diagnosed more than 3 years after the last LEMTRADA dose.

Symptoms of ITP include easy bruising, petechiae, spontaneous mucocutaneous bleeding (e.g., epistaxis, hemoptysis), and heavier than normal or irregular menstrual bleeding. Hemoptysis may also be indicative of anti-glomerular basement membrane (GBM) disease [see Warnings and Precautions (5.7)], and an appropriate differential diagnosis has to be undertaken. Remind the patient to remain vigilant for symptoms they may experience and to seek immediate medical help if they have any concerns.

Obtain complete blood counts (CBCs) with differential prior to initiation of treatment and at monthly intervals thereafter until 48 months after the last infusion [see Dosage and Administration (2.6)]. After this period of time, testing should be performed based on clinical findings suggestive of ITP. If ITP is suspected, a complete blood count should be obtained immediately. If ITP onset is confirmed, promptly initiate appropriate medical intervention.

5.7 Glomerular Nephropathies Including Anti-Glomerular Basement Membrane Disease

Glomerular nephropathies occurred in 0.3% of LEMTRADA-treated patients in MS clinical studies. There were 3 cases of membranous glomerulonephritis and 2 cases of anti-glomerular basement membrane (anti-GBM) disease.

In postmarketing cases, some LEMTRADA-treated patients with anti-GBM disease developed end-stage renal disease requiring dialysis or renal transplantation. Urgent evaluation and treatment is required, because early treatment can improve the preservation of renal function. Anti-GBM disease can be life-threatening if left untreated. Alveolar hemorrhage, manifested as hemoptysis, is a common component of anti-GBM disease and has been reported in postmarketing cases. Cases of anti-GBM disease have been diagnosed up to 40 months after the last dose of LEMTRADA.

Symptoms of nephropathy may include edema, hematuria, change in urine color, decreased urine output, fatigue, dyspnea, and hemoptysis. Patients and caregivers should be instructed to seek medical advice if they have concerns.

Obtain serum creatinine levels, urinalysis with cell counts, and urine protein to creatinine ratio prior to initiation of treatment. Obtain serum creatinine levels and urinalysis with cell counts at monthly intervals thereafter until 48 months after the last infusion. After this period of time, testing should be performed based on clinical findings suggestive of nephropathies.

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For urine dipstick results of 1+ protein or greater, measure the urine protein to creatinine ratio. For urine protein to creatinine ratio greater than 200 mg/g, increase in serum creatinine greater than 30%, or unexplained hematuria, perform further evaluation for nephropathies. Increased serum creatinine with hematuria or signs of pulmonary involvement of anti-GBM disease (e.g., hemoptysis, exertional dyspnea) warrant immediate evaluation. Early detection and treatment of nephropathies may decrease the risk of poor outcomes.

5.8 Thyroid Disorders

Thyroid endocrine disorders, including autoimmune thyroid disorders, occurred in 36.8% of LEMTRADA-treated patients in MS clinical studies (controlled and open-label extension). Newly diagnosed thyroid disorders occurred throughout the uncontrolled clinical study follow-up period, more than 7 years after the first LEMTRADA dose. Autoimmune thyroid disorders included Graves' disease, hyperthyroidism, hypothyroidism, autoimmune thyroiditis, and goiter. Graves' ophthalmopathy with decreased vision, eye pain, and exophthalmos occurred in 2% of LEMTRADA-treated patients. Seven patients required surgical orbital decompression. Serious thyroid events occurred in about 5.2% of LEMTRADA-treated patients in clinical studies and included cardiac and psychiatric events associated with thyroid disease. Of all LEMTRADA-treated patients, 3.8% underwent thyroidectomy.

Thyroid disease poses special risks in women who are pregnant [see Use in Specific Populations (8.1)].

Obtain thyroid function tests, such as TSH levels, prior to initiation of treatment and every 3 months thereafter until 48 months after the last infusion. Continue to test thyroid function after 48 months if clinically indicated.

In patients with ongoing thyroid disorder, LEMTRADA should be administered only if the potential benefit justifies the potential risks.

5.9 Other Autoimmune Cytopenias

Autoimmune cytopenias such as neutropenia (0.1%), hemolytic anemia (0.3%), and pancytopenia (0.2%) occurred in LEMTRADA-treated patients in MS clinical studies (controlled and open-label extension). In cases of autoimmune hemolytic anemia, patients tested positive for direct antiglobulin antibodies, and nadir hemoglobin levels ranged from 2.9-8.6 g/dL. Symptoms of autoimmune hemolytic anemia include weakness, chest pain, jaundice, dark urine, and tachycardia. One LEMTRADA-treated patient with autoimmune pancytopenia died from sepsis.

During postmarketing use, additional autoimmune cytopenias, including fatal autoimmune hemolytic anemia and aplastic anemia, have been reported in the treatment of patients with B-CLL, as well as other disorders, generally at higher and more frequent doses of alemtuzumab than recommended in MS.

Use CBC results to monitor for cytopenias. Prompt medical intervention is indicated if a cytopenia is confirmed.

5.10 Autoimmune Hepatitis

Autoimmune hepatitis causing clinically significant liver injury, including acute liver failure requiring transplant, has been reported in patients treated with LEMTRADA in the postmarketing setting. If a patient develops clinical signs, including unexplained liver enzyme

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elevations or symptoms suggestive of hepatic dysfunction (e.g., unexplained nausea, vomiting, abdominal pain, fatigue, anorexia, or jaundice and/or dark urine), promptly measure serum transaminases and total bilirubin and interrupt or discontinue treatment with LEMTRADA, as appropriate.

Prior to starting treatment with LEMTRADA, obtain serum transaminases (ALT and AST) and total bilirubin levels. Obtain transaminase levels and total bilirubin levels periodically until 48 months after the last dose.

5.11 Infections

Infections occurred in 71% of LEMTRADA-treated patients compared to 53% of patients treated with interferon beta-1a in controlled clinical studies in MS up to 2 years in duration. Infections that occurred more often in LEMTRADA-treated patients than interferon beta-1a patients included nasopharyngitis, urinary tract infection, upper respiratory tract infection, sinusitis, herpetic infections, influenza, and bronchitis. Serious infections occurred in 3% of patients treated with LEMTRADA as compared to 1% of patients treated with interferon beta-1a. Serious infections in the LEMTRADA group included: appendicitis, gastroenteritis, pneumonia, herpes zoster, and tooth infection.

Do not administer live viral vaccines following a course of LEMTRADA. Patients treated with LEMTRADA have altered immunity and may be at increased risk of infection following administration of live viral vaccines.

Consider delaying LEMTRADA administration in patients with active infection until the infection is fully controlled.

Concomitant use of LEMTRADA with antineoplastic or immunosuppressive therapies could increase the risk of immunosuppression.

Opportunistic Infections

In the postmarketing setting, serious, sometimes fatal, opportunistic infections have been reported in patients taking LEMTRADA, including aspergillosis, coccidioidomycosis, histoplasmosis, *Pneumocystis jirovecii* pneumonia, nocardiosis and cytomegalovirus infections.

Listeria Monocytogenes Infections

Listeria monocytogenes infections (e.g., meningitis, encephalitis, sepsis, and gastroenteritis), including fatal cases of *Listeria* meningoenkephalitis, have occurred in LEMTRADA-treated patients. *Listeria* infections have occurred as early as 3 days after treatment and up to 8 months after the last LEMTRADA dose. The duration of increased risk for *Listeria* infection after LEMTRADA treatment is unknown.

Advise patients to avoid or adequately heat foods that are potential sources of *Listeria monocytogenes* (e.g., deli meat, dairy products made with unpasteurized milk, soft cheeses, or undercooked meat, seafood, or poultry). Initiate these *Listeria* precautions prior to starting LEMTRADA treatment. The incubation period for *Listeria monocytogenes* ranges from 3 to 70 days. In most cases, signs and symptoms of invasive listeriosis start within 1 month of exposure to *Listeria monocytogenes*. Symptoms of *Listeria* infection include fever, chills, diarrhea, nausea, vomiting, headache, pains in joints and muscles, neck stiffness, difficulty walking, mental status changes, coma, and other neurologic changes. As is the case with many infections, treatment cannot always prevent mortality and morbidity related to *Listeria* infections. Therefore, advise

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patients to watch for symptoms of *Listeria* infection and seek prompt medical help if symptoms occur.

Herpes Viral Infections

In controlled clinical studies, 16% of LEMTRADA-treated patients developed a herpes viral infection compared to 3% of interferon beta-1a patients. These events included oral herpes (8.8%), herpes zoster (4.2%), herpes simplex (1.8%), and genital herpes (1.3%). Serious herpetic infections in LEMTRADA-treated patients included primary varicella (0.1%), herpes zoster (0.2%), and herpes meningitis (0.1%). Administer antiviral agents for herpetic prophylaxis at appropriate suppressive dosing regimens. Administer antiviral prophylaxis for herpetic viral infections starting on the first day of each treatment course and continue for a minimum of two months following treatment with LEMTRADA or until the CD4+ lymphocyte count is ≥ 200 cells per microliter, whichever occurs later [see *Dosage and Administration (2.2)*].

Human Papilloma Virus

Cervical human papilloma virus (HPV) infection, including cervical dysplasia, occurred in 2% of LEMTRADA-treated patients. Annual HPV screening is recommended for female patients.

Tuberculosis

Tuberculosis occurred in patients treated with LEMTRADA and interferon beta-1a in controlled clinical studies. Active and latent tuberculosis cases occurred in 0.3% of LEMTRADA-treated patients, most often in endemic regions. Perform tuberculosis screening according to local guidelines prior to initiation of LEMTRADA. For patients testing positive in tuberculosis screening, treat by standard medical practice prior to therapy with LEMTRADA.

Fungal Infections

Fungal infections, especially oral and vaginal candidiasis, occurred more commonly in LEMTRADA-treated patients (12%) than in patients treated with interferon beta-1a (3%) in controlled clinical studies in MS.

Infections in Non-MS Patients

During postmarketing use, serious and sometimes fatal viral, bacterial, protozoan, and fungal infections, including some due to reactivation of latent infections, have been reported in the treatment of patients with B-CLL, as well as other disorders, generally at higher and more frequent doses than recommended in MS.

Hepatitis

No data are available on the association of LEMTRADA with Hepatitis B virus (HBV) or Hepatitis C virus (HCV) reactivation because patients with evidence of active or chronic infections were excluded from the clinical studies. Consider screening patients at high risk of HBV and/or HCV infection before initiation of LEMTRADA and exercise caution in prescribing LEMTRADA to patients identified as carriers of HBV and/or HCV as these patients may be at risk of irreversible liver damage relative to a potential virus reactivation as a consequence of their pre-existing status.

5.12 Progressive Multifocal Leukoencephalopathy (PML)

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Progressive multifocal leukoencephalopathy (PML) has occurred in a patient with MS treated with LEMTRADA. PML is an opportunistic viral infection of the brain caused by the JC virus (JCV) that typically only occurs in patients who are immunocompromised, and that usually leads to death or severe disability. PML was diagnosed two months after the second course of LEMTRADA. The patient had previously received multiple MS therapies, but had not received other drugs for treatment of MS for more than one year. The patient had no other identified systemic medical conditions resulting in compromised immune system function and had not previously been treated with natalizumab, which has a known association with PML. The patient was not taking any immunosuppressive or immunomodulatory medications concomitantly. After the diagnosis of PML, the patient developed immune reconstitution inflammatory syndrome (IRIS). The patient's condition improved, but mild residual neurologic sequelae remained at last follow-up.

At the first sign or symptom suggestive of PML, withhold LEMTRADA and perform an appropriate diagnostic evaluation. Typical symptoms associated with PML are diverse, progress over days to weeks, and include progressive weakness on one side of the body or clumsiness of limbs, disturbance of vision, and changes in thinking, memory, and orientation leading to confusion and personality changes.

MRI findings may be apparent before clinical signs or symptoms. Cases of PML, diagnosed based on MRI findings and the detection of JCV DNA in the cerebrospinal fluid in the absence of clinical signs or symptoms specific to PML, have been reported in patients treated with other MS medications associated with PML. Many of these patients subsequently became symptomatic with PML. Therefore, monitoring with MRI for signs that may be consistent with PML may be useful, and any suspicious findings should lead to further investigation to allow for an early diagnosis of PML, if present. Following discontinuation of another MS medication associated with PML, lower PML-related mortality and morbidity have been reported in patients who were initially asymptomatic at diagnosis compared to patients who had characteristic clinical signs and symptoms at diagnosis. It is not known whether these differences are due to early detection and discontinuation of MS treatment or due to differences in disease in these patients.

5.13 Acute Acalculous Cholecystitis

LEMTRADA may increase the risk of acute acalculous cholecystitis. In controlled clinical studies, 0.2% of LEMTRADA-treated MS patients developed acute acalculous cholecystitis, compared to 0% of patients treated with interferon beta-1a. During postmarketing use, additional cases of acute acalculous cholecystitis have been reported in LEMTRADA-treated patients. Time to onset of symptoms ranged from less than 24 hours to 2 months after LEMTRADA infusion. Typical risk or predisposing factors such as concurrent critical illness were often not reported. Abnormal ultrasound or computed tomography was used to support the diagnosis of acute acalculous cholecystitis in some cases. Some patients were treated conservatively with antibiotics and recovered without surgical intervention, whereas others underwent cholecystectomy.

Symptoms of acute acalculous cholecystitis include abdominal pain, abdominal tenderness, fever, nausea, and vomiting. Leukocytosis and abnormal liver enzymes are also commonly observed. Acute acalculous cholecystitis is a condition that is associated with high morbidity and mortality rates if not diagnosed early and treated. If acute acalculous cholecystitis is suspected, evaluate and treat promptly.

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5.14 Pneumonitis
In clinical studies, 6 of 1217 (0.5%) LEMTRADA-treated patients had pneumonitis of varying severity. Cases of hypersensitivity pneumonitis and pneumonitis with fibrosis occurred in clinical studies. Patients should be advised to report symptoms of pneumonitis, which may include shortness of breath, cough, wheezing, chest pain or tightness, and hemoptysis.

5.15 Drug Products with Same Active Ingredient
LEMTRADA contains the same active ingredient (alemtuzumab) found in CAMPATH®. If LEMTRADA is considered for use in a patient who has previously received CAMPATH, exercise increased vigilance for additive and long-lasting effects on the immune system.

6 ADVERSE REACTIONS
The following serious adverse reactions are described below and elsewhere in the labeling:

- Autoimmunity [see Boxed Warning and Warnings and Precautions (5.1)]
- Infusion Reactions [see Boxed Warning and Warnings and Precautions (5.2)]
- Stroke and Cervicocephalic Arterial Dissection [see Warnings and Precautions (5.3)]
- Malignancies [see Warnings and Precautions (5.4)]
- Immune Thrombocytopenia [see Warnings and Precautions (5.6)]
- Glomerular Nephropathies Including Anti-Glomerular Basement Membrane Disease [see Warnings and Precautions (5.7)]
- Thyroid Disorders [see Warnings and Precautions (5.8)]
- Other Autoimmune Cytopenias [see Warnings and Precautions (5.9)]
- Autoimmune Hepatitis [see Warnings and Precautions (5.10)]
- Infections [see Warnings and Precautions (5.11)]
- Progressive Multifocal Leukoencephalopathy (PML) [see Warnings and Precautions (5.12)]
- Acute Acalculous Cholecystitis [see Warnings and Precautions (5.13)]
- Pneumonitis [see Warnings and Precautions (5.14)]

6.1 Clinical Trials Experience
Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

In controlled clinical trials (Study 1 and Study 2), a total of 811 patients with relapsing forms of MS received LEMTRADA. The population was 18 to 55 years of age, 65% were female, and 92% were Caucasian. A total of 811 patients received 1 course of therapy, and 789 patients received a second course of therapy at 12 months. The overall follow-up in the controlled trials was equivalent to 1622 patient years.

In MS clinical studies (controlled and open-label extension), overall, a total of 1217 patients received LEMTRADA. Approximately 60% of patients received a total of 2 treatment courses and approximately 24% of patients received a total of 3 treatment courses; others received a total of 4 or more treatment courses, although data beyond 3 treatment courses are limited. The

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overall follow-up was 6858 person-years. Patients had a median of 6 years of follow-up from the first LEMTRADA dose, with approximately 14% having at least 7 years of follow-up.

Most Common Adverse Reactions

In controlled clinical trials, the most common adverse reactions with LEMTRADA (in at least 10% of patients and more frequently than in interferon beta-1a) were rash, headache, pyrexia, nasopharyngitis, nausea, urinary tract infection, fatigue, insomnia, upper respiratory tract infection, herpes viral infection, urticaria, pruritus, thyroid gland disorders, fungal infection, arthralgia, pain in extremity, back pain, diarrhea, sinusitis, oropharyngeal pain, paresthesia, dizziness, abdominal pain, flushing, and vomiting.

Table 1 lists adverse reactions occurring in ≥5% of LEMTRADA-treated patients in Study 1 and 2 and at the same or at a higher rate than interferon beta-1a.

Table 1: Adverse Reactions in the Pooled 2-Year Active-Controlled Studies in Patients with Relapsing-Remitting Multiple Sclerosis

	LEMTRADA (N=811) %	interferon beta-1a 44 meg (N=389) %
Rash	53	6
Headache	52	23
Pyrexia	29	9
Nasopharyngitis	25	19
Nausea	21	9
Urinary tract infection	19	8
Fatigue	18	13
Insomnia	16	15
Upper respiratory tract infection	16	13
Herpes viral infection	16	3
Urticaria	16	2
Pruritus	14	2
Thyroid gland disorders	13	3
Fungal infection	13	4
Arthralgia	12	9
Pain in extremity	12	9
Back pain	12	8
Diarrhea	12	6
Sinusitis	11	8
Oropharyngeal pain	11	5
Paresthesia	10	8
Dizziness	10	5
Abdominal pain	10	5
Flushing	10	4
Vomiting	10	3
Cough	9	4
Chills	9	3
Dysgeusia	8	7
Influenza	8	6
Dermatitis	8	5
Dyspepsia	8	4
Blood in urine	8	3

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	LEMTRADA (N=811) %	interferon beta-1a 44 mcg (N=389) %
Dyspnea	8	1
Tachycardia	8	1
Anxiety	7	6
Muscular weakness	7	6
Bronchitis	7	4
Chest discomfort	7	2
Muscle spasms	6	5
Myalgia	6	5
Decrease in CD4 lymphocytes	6	2
Decrease in CD8 lymphocytes	6	2
Asthenia	5	4
Decrease in T-lymphocyte count	5	3
Erythema	5	2
Peripheral edema	5	2
Epistaxis	5	2
Neck Pain	5	2
Abnormal uterine bleeding	5	1

6.2 Lymphopenia

Nearly all (99.9%) patients treated with LEMTRADA in MS clinical trials experienced lymphopenia. The lowest lymphocyte counts occurred approximately by 1 month after each course of treatment. The mean lymphocyte count at 1 month after LEMTRADA treatment was $0.25 \times 10^9/L$ (range $0.02-2.30 \times 10^9/L$) and $0.32 (0.02-1.81 \times 10^9/L)$ for treatment courses 1 and 2, respectively. Total lymphocyte counts increased to reach the lower limit of normal in approximately 40% of patients by 6 months after each LEMTRADA treatment course and approximately 80% of patients by 12 months after each course [see *Clinical Pharmacology (12.2)*].

6.3 Suicidal Behavior or Ideation

In clinical studies, 0.6% of patients in both the LEMTRADA and interferon beta-1a groups had events of attempted suicide or suicidal ideation. There were no completed suicides in either clinical study treatment group. Suicidal behavior or ideation occurred in patients with or without a history of a psychiatric or thyroid disorder. Advise patients to report immediately any symptoms of depression or suicidal ideation to the prescribing physician.

6.4 Immunogenicity

As with all therapeutic proteins, there is potential for immunogenicity. The incidence of antibodies is highly dependent on the sensitivity and specificity of the assay. Additionally, the observed incidence of antibody (including inhibitory antibody) positivity in an assay may be influenced by several factors including assay methodology, sample handling, timing of sample collection, concomitant medications, and underlying disease. For these reasons, comparison of the incidence of antibodies to LEMTRADA with the incidence of antibodies to other products may be misleading.

Using an enzyme-linked immunosorbent assay (ELISA) and a competitive binding assay, anti-alemtuzumab binding antibodies were detected in 62%, 67%, and 29% of LEMTRADA-treated

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patients, at months 1, 3, and 12 (Course 1) as well as 83%, 83%, and 75% of LEMTRADA-treated patients at months 13, 15, and 24 (Course 2). Samples that tested positive for binding antibodies were further evaluated for evidence of *in vitro* inhibition using a flow cytometry assay. Neutralizing antibodies were detected in 87%, 46%, and 5% of positive binding antibody patients at months 1, 3, and 12 (Course 1) as well as 94%, 88%, and 42% of positive binding antibody patients at months 13, 15, and 24 (Course 2). Anti-alemtuzumab antibodies were associated with decreased alemtuzumab concentration during Course 2, but not Course 1. Through 2 treatment courses, there was no evidence from clinical trials that the presence of binding or inhibitory anti-alemtuzumab antibodies had a significant effect on clinical outcomes, total lymphocyte count, or adverse events. High titer anti-alemtuzumab antibodies, which were observed in 13 patients, were associated with incomplete lymphocyte depletion following a third or fourth treatment course, but there was no clear effect of anti-alemtuzumab antibodies on the clinical efficacy or safety profile of LEMTRADA.

6.5 Postmarketing Experience

The following adverse reactions have been identified during post approval use of alemtuzumab. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Postmarketing Experience with LEMTRADA

Blood and Lymphatic System Disorders: Neutropenia, thrombocytopenia [see Warnings and Precautions (5.2)]

Cerebrovascular Disorders: Stroke, including hemorrhagic and ischemic stroke and cervicocephalic arterial dissection [see Warnings and Precautions (5.3)]

Gastrointestinal System Disorders: Cholecystitis, including acalculous cholecystitis and acute acalculous cholecystitis [see Warnings and Precautions (5.13)]

Hepatobiliary Disorders: Autoimmune hepatitis [see Warnings and Precautions (5.10)]

Infections and Infestations: Opportunistic infections [see Warnings and Precautions (5.11)], Progressive multifocal leukoencephalopathy [see Warnings and Precautions (5.12)]

Immune System Disorders: Autoimmune hepatitis, vasculitis, Guillain-Barré syndrome [see Warnings and Precautions (5.1)], hemophagocytic lymphohistiocytosis

Pulmonary System Disorders: Pulmonary alveolar hemorrhage [see Warnings and Precautions (5.2)]

Postmarketing Experience with CAMPATH

CAMPATH is approved for the treatment of B-cell chronic lymphocytic leukemia (B-CLL) and is generally administered at higher and more frequent doses (e.g., 30 mg) than recommended in the treatment of MS.

Cardiac Disorders: Congestive heart failure, cardiomyopathy, and decreased ejection fraction in non-MS patients previously treated with potentially cardiotoxic agents.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

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Pregnancy Exposure Registry

There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to LEMTRADA during pregnancy. Physicians are encouraged to register patients by calling 1-866-758-2990.

Risk Summary

There are no adequate data on the developmental risk associated with the use of LEMTRADA in pregnant women. LEMTRADA was embryolethal in pregnant huCD52 transgenic mice when administered during organogenesis [see *Animal data*]. Auto-antibodies may develop after administration of LEMTRADA. Placental transfer of anti-thyroid antibodies resulting in neonatal Graves' disease has been reported.

In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively. The background risk of major birth defects and miscarriage for the indicated population is unknown.

Clinical Considerations

LEMTRADA induces persistent thyroid disorders [see *Warnings and Precautions (5.8)*]. Untreated hypothyroidism in pregnant women increases the risk for miscarriage and may have effects on the fetus including mental retardation and dwarfism. In mothers with Graves' disease, maternal thyroid stimulating hormone receptor antibodies can be transferred to a developing fetus and can cause neonatal Graves' disease. In a patient who developed Graves' disease after treatment with alemtuzumab, placental transfer of anti-thyrotropin receptor antibodies resulted in neonatal Graves' Disease with thyroid storm in her infant who was born 1 year after alemtuzumab dosing [see *Warnings and Precautions (5.1)*].

Data

Animal data

When LEMTRADA was administered to pregnant huCD52 transgenic mice during organogenesis (gestation days [GD] 6-10 or GD 11-15) at doses of 3 or 10 mg/kg IV, no teratogenic effects were observed. However, there was an increase in embryolethality (increased postimplantation loss and the number of dams with all fetuses dead or resorbed) in pregnant animals dosed during GD 11-15. In a separate study in pregnant huCD52 transgenic mice, administration of LEMTRADA during organogenesis (GD 6-10 or GD 11-15) at doses of 3 or 10 mg/kg IV, decreases in B- and T-lymphocyte populations were observed in the offspring at both doses tested.

In pregnant huCD52 transgenic mice administered LEMTRADA at doses of 3 or 10 mg/kg/day IV throughout gestation and lactation, there was an increase in pup deaths during the lactation period at 10 mg/kg. Decreases in T- and B-lymphocyte populations and in antibody response were observed in offspring at both doses tested.

8.2 Lactation

Risk Summary

There are no data on the presence of alemtuzumab in human milk, the effects on the breastfed infant, or the effects of the drug on milk production. Alemtuzumab was detected in the milk of lactating huCD52 transgenic mice administered LEMTRADA [see *Animal data*].

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The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for LEMTRADA and any potential adverse effects on the breastfed child from LEMTRADA or from the underlying maternal conditions.

Data

Animal data

Alemtuzumab was detected in the milk of lactating huCD52 transgenic mice following intravenous administration of LEMTRADA at a dose of 10 mg/kg on postpartum days 8-12. Serum levels of alemtuzumab were similar in lactating mice and offspring on postpartum Day 13 and were associated with evidence of pharmacological activity (decrease in lymphocyte counts) in the offspring.

8.3 Females and Males of Reproductive Potential

Contraception

Before initiation of LEMTRADA treatment, women of childbearing potential should be counselled on the potential for a serious risk to the fetus. To avoid in utero exposure to LEMTRADA, women of childbearing potential should use effective contraceptive measures when receiving a course of treatment with LEMTRADA and for 4 months following that course of treatment [see Use in Specific Populations (8.1)].

Infertility

In huCD52 transgenic mice, administration of LEMTRADA prior to and during the mating period resulted in adverse effects on sperm parameters in males and reduced number of corpora lutea and implantations in females [see Nonclinical Toxicology (13.1)].

8.4 Pediatric Use

Safety and effectiveness in pediatric patients less than 17 years of age have not been established. Use of LEMTRADA is not recommended in pediatric patients due to the risks of autoimmunity, infusion reactions, and stroke, and because it may increase the risk of malignancies (thyroid, melanoma, lymphoproliferative disorders, and lymphoma) [see Warnings and Precautions (5.1, 5.2, 5.3, 5.4)].

8.5 Geriatric Use

Clinical studies of LEMTRADA did not include sufficient numbers of patients aged 65 and over to determine whether they respond differently than younger patients.

10 OVERDOSAGE

Two MS patients experienced serious reactions (headache, rash, and either hypotension or sinus tachycardia) after a single accidental infusion up to 60 mg of LEMTRADA. Doses of LEMTRADA greater than those recommended may increase the intensity and/or duration of infusion reactions or its immune effects. There is no known antidote for alemtuzumab overdosage.

11 DESCRIPTION

Alemtuzumab is a recombinant humanized IgG1 kappa monoclonal antibody directed against the cell surface glycoprotein, CD52. Alemtuzumab has an approximate molecular weight of 150 kD.

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Alemtuzumab is produced in mammalian cell (Chinese hamster ovary) suspension culture in a nutrient medium containing neomycin. Neomycin is not detectable in the final product.

LEMTRADA (alemtuzumab) injection is a sterile, clear and colorless to slightly yellow, solution (pH 7.2 ± 0.2) for intravenous infusion.

Each 1 mL of solution contains 10 mg alemtuzumab, dibasic sodium phosphate (1.15 mg), disodium edetate dihydrate (0.0187 mg), polysorbate 80 (0.1 mg), potassium chloride (0.2 mg), potassium dihydrogen phosphate (0.2 mg), sodium chloride (8 mg), and Water for Injection, USP.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

The precise mechanism by which alemtuzumab exerts its therapeutic effects in multiple sclerosis is unknown but is presumed to involve binding to CD52, a cell surface antigen present on T and B lymphocytes, and on natural killer cells, monocytes, and macrophages. Following cell surface binding to T and B lymphocytes, alemtuzumab results in antibody-dependent cellular cytotoxicity and complement-mediated lysis.

12.2 Pharmacodynamics

Effects of LEMTRADA on the Lymphocyte Population

LEMTRADA depletes circulating T and B lymphocytes after each treatment course. In clinical trials, the lowest cell counts occurred 1 month after a course of treatment at the time of the first post-treatment blood count. Lymphocyte counts then increased over time; B cell counts usually recovered within 6 months; T cell counts increased more slowly and usually remained below baseline 12 months after treatment. Approximately 60% of patients had total lymphocyte counts below the lower limit of normal 6 months after each treatment course and 20% had counts below the lower limit of normal after 12 months.

Reconstitution of the lymphocyte population varies for the different lymphocyte subtypes. At Month 1 in clinical trials, the mean CD4+ lymphocyte count was 40 cells per microliter, and, at Month 12, 270 cells per microliter. At 30 months, approximately half of patients had CD4+ lymphocyte counts that remained below the lower limit of normal.

Cardiac Electrophysiology

In a study of 53 MS patients, alemtuzumab 12 mg per day for 5 days caused no changes in the QTc interval greater than 20 ms. An average 22 to 26 beats-per-minute increase in heart rate was observed for at least 2 hours after the first but not subsequent infusions.

12.3 Pharmacokinetics

The pharmacokinetics of LEMTRADA were evaluated in a total of 148 patients with relapsing forms of MS who received 12 mg/day on 5 consecutive days, followed by 12 mg/day on 3 consecutive days 12 months following the first treatment course.

Absorption

Serum concentrations increased with each consecutive dose within a treatment course, with the highest observed concentrations occurring following the last infusion of a treatment course. The mean maximum concentration was 3014 ng/mL on Day 5 of the first treatment course, and 2276 ng/mL on Day 3 of the second treatment course.

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Distribution
LEMTRADA is largely confined to the blood and interstitial space with a central volume of distribution of 14.1 L.

Elimination
The elimination half-life was approximately 2 weeks and was comparable between courses. The serum concentrations were generally undetectable (<60 ng/mL) within approximately 30 days following each treatment course.

Specific Populations
Age, race, or gender had no effect on the pharmacokinetics of LEMTRADA.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility
Studies to assess the carcinogenic or genotoxic potential of LEMTRADA have not been conducted.

When LEMTRADA (3 or 10 mg/kg IV) was administered to huCD52 transgenic male mice on 5 consecutive days prior to cohabitation with untreated wild-type females, no effect on fertility or reproductive performance was observed. However, adverse effects on sperm parameters (including abnormal morphology [detached/no head] and reduced total count and motility) were observed at both doses tested.

When LEMTRADA (3 or 10 mg/kg IV) was administered to huCD52 transgenic female mice for 5 consecutive days prior to cohabitation with untreated wild-type males, there was a decrease in the average number of corpora lutea and implantation sites and an increase in postimplantation loss, resulting in fewer viable embryos at the higher dose tested.

14 CLINICAL STUDIES

The efficacy of LEMTRADA was demonstrated in two studies (Study 1 and 2) that evaluated LEMTRADA 12 mg in patients with relapsing-remitting multiple sclerosis (RRMS). LEMTRADA was administered by intravenous infusion once daily over a 5-day course, followed one year later by intravenous infusion once daily over a 3-day course. Both studies included patients who had experienced at least 2 relapses during the 2 years prior to trial entry and at least 1 relapse during the year prior to trial entry. Neurological examinations were performed every 12 weeks and at the time of suspected relapse. Magnetic resonance imaging (MRI) evaluations were performed annually.

Study 1
Study 1 was a 2-year randomized, open-label, rater-blinded, active comparator (interferon beta-1a 44 micrograms administered subcutaneously three times a week) controlled study in patients with RRMS. Patients entering Study 1 had Expanded Disability Status Scale (EDSS) scores of 5 or less and had to have experienced at least one relapse while on interferon beta or glatiramer acetate therapy.

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Patients were randomized to receive LEMTRADA (n=426) or interferon beta-1a (n=202). At baseline, the mean age was 35 years, the mean disease duration was 4.5 years, and the mean EDSS score was 2.7.

The clinical outcome measures were the annualized relapse rate (ARR) over 2 years and the time to confirmed disability progression. Confirmed disability progression was defined as at least a 1 point increase above baseline EDSS (1.5 point increase for patients with baseline EDSS of 0) sustained for 6 months. The MRI outcome measure was the change in T2 lesion volume.

The annualized relapse rate was significantly lower in patients treated with LEMTRADA than in patients who received interferon beta-1a. Time to onset of 6-month confirmed disability progression was significantly delayed with LEMTRADA treatment compared to interferon beta-1a. There was no significant difference between the treatment groups for the change in T2 lesion volume. The results of Study 1 are shown in Table 2 and Figure 1.

Table 2: Clinical and MRI Results of Study 1

	LEMTRADA (N=426)	interferon beta-1a 44 mcg (N=202)	p-value
Clinical Outcomes			
Annualized relapse rate	0.26	0.52	<0.0001
Relative reduction	49%		
Proportion of patients with disability progression at Year 2	13%	21%	0.0084
Relative risk reduction	42%		
Percent of patients remaining relapse-free at Year 2	65%	47%	<0.0001
MRI Outcomes			
Percent change in T2 lesion volume from baseline	-1.3	-1.2	0.14

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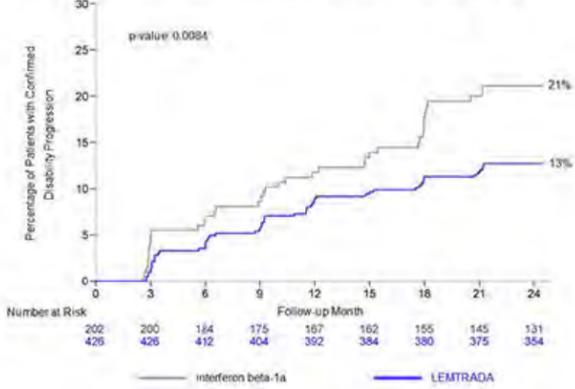
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Figure 1: Time to 6-month Confirmed Disability Progression (Study 1)



Study 2

Study 2 was a 2-year randomized, open-label, rater-blinded, active comparator (interferon beta-1a 44 micrograms administered subcutaneously three times a week) controlled study in patients with RRMS. Patients entering Study 2 had EDSS scores of 3 or less and no prior treatment for multiple sclerosis.

Patients were randomized to receive LEMTRADA (n=376) or interferon beta-1a (n=187). At baseline, the mean age was 33 years, the mean disease duration was 2 years, and the mean EDSS score was 2.

The clinical outcome measures were the annualized relapse rate (ARR) over 2 years and the time to confirmed disability progression, as defined in Study 1. The MRI outcome measure was the change in T2 lesion volume.

The annualized relapse rate was significantly lower in patients treated with LEMTRADA than in patients who received interferon beta-1a. There was no significant difference between the treatment groups for the time to confirmed disability progression and for the primary MRI endpoint (change in T2 lesion volume). The results for Study 2 are shown in Table 3.

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Table 3: Clinical and MRI Results of Study 2

	LEMTRADA (N=376)	interferon beta-1a 44 mg (N=187)	p-value
Clinical Outcomes			
Annualized relapse rate	0.18	0.39	<0.0001
Relative reduction	55%		
Proportion of patients with disability progression at Year 2	8%	11%	0.22
Relative risk reduction	30%		
Percent of patients remaining relapse-free at Year 2	78%	59%	<0.0001
MRI Outcomes			
Percent change in T2 lesion volume from baseline	-9.3	-6.5	0.31

16 HOW SUPPLIED/STORAGE AND HANDLING

16.1 How Supplied

LEMTRADA (alemtuzumab) injection is a sterile, clear and colorless to slightly yellow solution for intravenous infusion, containing no antimicrobial preservatives.

Each LEMTRADA carton (NDC: 58468-0200-1) contains one single-dose vial that delivers 12 mg/1.2 mL (10 mg/mL). The vial stopper is not made with natural rubber latex.

16.2 Storage and Handling

Store LEMTRADA vials at 2°C to 8°C (36°F to 46°F). Do not freeze or shake. Store in original carton to protect from light.

17 PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-approved patient labeling (Medication Guide).

Autoimmunity

- Advise patients to contact their healthcare provider promptly if they experience any symptoms of potential autoimmune disease. Give examples of important symptoms such as bleeding, easy bruising, petechiae, purpura, hematuria, edema, jaundice, or hemoptysis /see *Warnings and Precautions (5.1)*.
- Advise patients of the importance of monthly blood and urine tests for 48 months following the last course of LEMTRADA to monitor for signs of autoimmunity because early detection and prompt treatment can help prevent serious and potentially fatal outcomes associated with these events. Advise patients that monitoring may need to continue past 48 months if they have signs or symptoms of autoimmunity.

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- Advise patients that LEMTRADA may cause hyperthyroid or hypothyroid disorders.
- Advise patients to contact their healthcare provider if they experience symptoms reflective of a potential thyroid disorder such as unexplained weight loss or gain, fast heartbeat or palpitations, nervousness, worsening tiredness, eye swelling, constipation, or feeling cold.
- Advise women of childbearing potential of the risks of pregnancy with concomitant thyroid disease. Advise women of childbearing potential to discuss pregnancy planning with their doctor.
- Cases of autoimmune hepatitis have been reported in patients treated with LEMTRADA. Advise patients to contact their healthcare provider right away if they develop signs or symptoms suggestive of hepatic dysfunction such as unexplained nausea, vomiting, abdominal pain, fatigue, anorexia, jaundice and/or dark urine, or bleeding or bruising more easily than normal.

Infusion Reactions

- Advise patients that infusion reactions can occur at the time of infusion or after they leave the infusion center [see Warnings and Precautions (5.2)]. Educate patients that serious infusion reactions can occur at the time of infusion or within 48 hours after the last infusion. Advise patients to contact their healthcare provider promptly if they experience symptoms of an infusion reaction, including:
 - Swelling in the mouth or throat, difficulty breathing, weakness, abnormal heart rate (fast, slow, or irregular), rash, chest pain (or tightness or discomfort), or coughing up blood
- Instruct the patient to remain at the infusion center for 2 hours after each LEMTRADA infusion, or longer at the discretion of the physician.

Stroke and Cervicocephalic Arterial Dissection

- Educate patients on the symptoms and instruct patients to seek immediate medical attention if symptoms of stroke or cervicocephalic arterial dissection occur (e.g., neck pain, weakness on one side, facial droop, difficulty with speech, sudden severe headache) [see Warnings and Precautions (5.3)].

Malignancies

- Advise patients that LEMTRADA may increase their risk of malignancies including thyroid cancer and melanoma [see Warnings and Precautions (5.4)].
- Advise patients to report symptoms of thyroid cancer, including a new lump or swelling in the neck, pain in the front of the neck, hoarseness or other voice changes that do not go away, trouble swallowing or breathing, or a constant cough not due to a cold.
- Advise patients that they should have baseline and yearly skin examinations.

LEMTRADA REMS Program

- LEMTRADA is available only through a restricted program called the LEMTRADA REMS Program [see Warnings and Precautions (5.5)]. Inform the patient of the following notable requirements:
 - Patients and providers must be enrolled in the program.

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- Patients must comply with the ongoing monitoring requirements.
- Patients must report any side effects or symptoms to their doctor.
- LEMTRADA is available only at certified infusion centers participating in the program. Therefore, provide patients with information on the LEMTRADA REMS Program in order to locate an infusion center.
- Advise patients to read the LEMTRADA REMS material for patients, *What You Need to Know About LEMTRADA Treatment: A Patient Guide and What You Need to Know About LEMTRADA Treatment and Infusion Reactions: A Patient Guide*.
- Instruct patients to carry the LEMTRADA REMS Patient Safety Information Card with them in case of an emergency.

Infections

- Advise patients to contact their healthcare provider if they develop symptoms of serious infection such as fever or swollen glands [see Warnings and Precautions (5.11)].
- Advise patients to complete any necessary immunizations at least 6 weeks prior to treatment with LEMTRADA [see Dosage and Administration (2.1)]. Advise patients that they should talk to their healthcare provider before taking any vaccine after recent treatment with LEMTRADA [see Warnings and Precautions (5.11)].
- Advise patients to avoid or adequately heat foods that are potential sources of *Listeria monocytogenes* prior to receiving LEMTRADA and if they have had a recent course of LEMTRADA. The duration of increased risk for *Listeria* infection after LEMTRADA administration is not known. Inform patients that *Listeria* infection can lead to significant complications or death [see Warnings and Precautions (5.11)].
- Advise patients to take their prescribed medication for herpes prophylaxis as directed by their healthcare provider [see Warnings and Precautions (5.11)].
- Advise patients that yearly HPV screening is recommended [see Warnings and Precautions (5.11)].

Progressive Multifocal Leukoencephalopathy

- Inform patients that progressive multifocal leukoencephalopathy (PML) has occurred in a patient who received LEMTRADA. Inform the patient that PML is characterized by a progression of deficits and usually leads to death or severe disability over weeks or months. Instruct the patient of the importance of contacting their doctor if they develop any symptoms suggestive of PML. Inform the patient that typical symptoms associated with PML are diverse, progress over days to weeks, and include progressive weakness on one side of the body or clumsiness of limbs, disturbance of vision, and changes in thinking, memory, and orientation leading to confusion and personality changes [see Warnings and Precautions (5.12)].

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LEMTRADA
alemtuzumab 12mg iv

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- Advise patients to report symptoms of acute acalculous cholecystitis. These include abdominal pain, abdominal tenderness, fever, nausea, and vomiting [see Warnings and Precautions (5.13)].

Pneumonitis

- Advise patients that pneumonitis has been reported in patients treated with LEMTRADA [see Warnings and Precautions (5.14)]. Advise patients to report symptoms of lung disease such as shortness of breath, cough, wheezing, chest pain or tightness, and hemoptysis.

Concomitant Use of CAMPATH

- Advise patients that alemtuzumab is the same drug as CAMPATH for use in B-CLL. Patients should inform their healthcare provider if they have taken CAMPATH [see Warnings and Precautions (5.15)].

Pregnancy Exposure Registry

- Advise patients that there is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to LEMTRADA during pregnancy [see Use in Specific Populations (8.1)].

Fetal Risk

- Inform patients that LEMTRADA may cause fetal harm. Discuss with women of childbearing age whether they are pregnant, might be pregnant, or are trying to become pregnant. Advise women of childbearing age of the need for effective contraception during LEMTRADA treatment and for 4 months after a treatment course of LEMTRADA. Advise the patient that if she should nevertheless become pregnant, she should immediately inform her physician.

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LEMTRADA REMS PROGRAM OVERVIEW

What is the LEMTRADA REMS (Risk Evaluation and Mitigation Strategy)?

A REMS is a strategy to manage known or potential risks associated with a drug. It is required by the FDA to ensure that the benefits of the drug outweigh its risks. Due to serious risks of autoimmune conditions, infusion reactions, stroke and malignancies, LEMTRADA[®] (alemtuzumab) is only available through a restricted program called the LEMTRADA REMS.

LEMTRADA REMS Requirements

- **Prescribers** must be enrolled in the LEMTRADA REMS to be able to prescribe LEMTRADA.
- **Pharmacies** must be enrolled in the LEMTRADA REMS to be able to dispense LEMTRADA.
- **Healthcare Facilities** must be enrolled in the LEMTRADA REMS to be able to dispense and administer LEMTRADA.
- **Patients** must be enrolled and authorized in the LEMTRADA REMS in order to receive LEMTRADA.

PRESCRIBER ENROLLMENT INSTRUCTIONS

1. Complete the training program, which includes reviewing the following:
 - LEMTRADA Prescribing Information
 - LEMTRADA REMS Program Overview
 - LEMTRADA REMS Education Program for Prescribers
2. Successfully complete the 8-question LEMTRADA REMS Knowledge Assessment.
3. Enroll in the program by completing a LEMTRADA REMS Prescriber Enrollment Form.
4. Submit the completed and signed Forms to the LEMTRADA REMS.

PHARMACY ENROLLMENT INSTRUCTIONS

1. An authorized representative must enroll on behalf of the pharmacy by reviewing the LEMTRADA REMS Program Overview and completing the LEMTRADA REMS Pharmacy Enrollment Form, which acknowledges that the pharmacy agrees to follow the procedures outlined in the LEMTRADA REMS, including:
 - All relevant staff at the pharmacy who will be involved with the dispensing of LEMTRADA must be educated and trained.
 - The pharmacy will verify that a LEMTRADA REMS Prescription Ordering Form is received for each prescription.
 - The pharmacy will verify that prescribers and healthcare facilities are certified and patients are authorized to receive LEMTRADA prior to dispensing LEMTRADA.
 - Enrollment in the LEMTRADA REMS must be renewed every 2 years from initial enrollment.
2. Submit the completed and signed LEMTRADA REMS Pharmacy Enrollment Form to the LEMTRADA REMS.

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HEALTHCARE FACILITY ENROLLMENT INSTRUCTIONS

1. An authorized representative must enroll on behalf of the healthcare facility by reviewing the *LEMTRADA REMS Education Program for Healthcare Facilities* and completing the LEMTRADA REMS Healthcare Facility Enrollment Form, which acknowledges that the healthcare facility agrees to follow the procedures outlined in the LEMTRADA REMS, including:
 - All staff at the facility who will be involved with the dispensing and administration of LEMTRADA must be trained, and a written record of all staff REMS trainings must be kept on file.
 - The healthcare facility will verify that prescribers are certified and patients are authorized to receive LEMTRADA prior to dispensing or administering LEMTRADA.
 - The healthcare facility will provide a copy of *What You Need to Know About LEMTRADA Treatment and Infusion Reactions: A Patient Guide* to the patient on the first day of each treatment course when LEMTRADA is dispensed.
 - The healthcare facility will complete a LEMTRADA REMS Infusion Checklist for each patient at the conclusion of each treatment course and submit it to the LEMTRADA REMS within 5 business days.
 - Enrollment in the LEMTRADA REMS must be renewed every 2 years from initial enrollment.
2. Submit the completed and signed LEMTRADA REMS Healthcare Facility Enrollment Form to the LEMTRADA REMS.

PATIENT ENROLLMENT INSTRUCTIONS

1. Complete the LEMTRADA REMS Patient Enrollment Form, which contains information to be completed by both the prescriber and the patient.
2. Provide a copy of *What You Need to Know About LEMTRADA Treatment: A Patient Guide* and a LEMTRADA Patient Safety Information Card to each patient who will receive LEMTRADA. You must use *What You Need to Know About LEMTRADA Treatment: A Patient Guide* to counsel your patients on the serious risks and REMS requirements with the use of LEMTRADA.
3. Submit the completed and signed LEMTRADA REMS Patient Enrollment Form to the LEMTRADA REMS.
4. Provide the patient with a copy of the LEMTRADA REMS Patient Enrollment Form and keep a copy in the patient's medical record.

Where to Find REMS Information and Resources
To enroll in the LEMTRADA REMS, call 1-855-676-6326. For information related to enrollment in the LEMTRADA REMS, call 1-855-676-6326 or visit www.LemtradaREMS.com

Indication and Usage
LEMTRADA is indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include relapsing-remitting disease and active secondary progressive disease, in adults. Because of its safety profile, the use of LEMTRADA should generally be reserved for patients who have had an inadequate response to two or more drugs indicated for the treatment of MS.

Limitations of Use:
LEMTRADA is not recommended for use in patients with clinically isolated syndrome (CIS) because of its safety profile. The Prescribing Information includes a **BOXED WARNING** for LEMTRADA. Please see accompanying Prescribing Information for complete safety information, including **BOXED WARNING**.

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The screenshot shows a web browser window displaying the LEMTRADA REMS Training page. The browser's address bar shows a Google search. The page header includes the LEMTRADA logo (alemtozumab^{12mg} iv) and navigation links for Prescribing Information and Medication Guide. A user is logged in as Adam Smith, with links for My Profile and Log Out. A main navigation bar contains Home, Forms and FAQs, REMS Certified Prescriber & Healthcare Facility Locator, and About REMS. A progress bar shows the current step is Training, with previous steps Registration and Assessment, and a next step Enrollment. The main content area is titled 'LEMTRADA REMS Training' and indicates the user is on screen 1 of 12, with a total of 30 training screens. A large graphic titled 'LEMTRADA REMS Education Program for Prescribers' is displayed, with a 'For Prescribers' label in the top right corner. The graphic lists the topics covered in the education program: LEMTRADA REMS requirements, serious risks of autoimmune conditions, infusion reactions, stroke, and malignancies, and counseling and management of the patient. The LEMTRADA logo is at the bottom right of the graphic. Below the graphic are 'Previous' and 'Next' buttons, and a page indicator '(30 of 41)'. A call to action at the bottom of the graphic asks for questions about the program and provides a phone number (1-855-676-6326) and hours (Mon-Fri, 8:30 am - 8:00 pm ET). The footer contains links for Privacy Policy, Terms and Conditions, and Contact Us, along with copyright information for Genzyme Corporation (©2019) and the Sanofi Genzyme logo.

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What Is the LEMTRADA REMS?

A REMS (Risk Evaluation and Mitigation Strategy) is a strategy to manage known or potential risks associated with a drug, and is required by the FDA to ensure that the benefits of the drug outweigh its risks. Due to serious risks of autoimmune conditions, infusion reactions, stroke and malignancy, LEMTRADA is only available through a restricted program called the LEMTRADA REMS.

This brochure has been developed as part of the LEMTRADA REMS to help educate prescribers about the risks associated with LEMTRADA and how to help mitigate these risks through periodic monitoring for, and prompt identification of, signs and symptoms of these events.

- Prescribers must be enrolled in the LEMTRADA REMS to be able to prescribe LEMTRADA.
- Pharmacies must be enrolled in the LEMTRADA REMS to be able to dispense LEMTRADA.
- Healthcare Facilities must be enrolled in the LEMTRADA REMS to be able to dispense and administer LEMTRADA.
- Patients must be enrolled and authorized in the LEMTRADA REMS in order to receive LEMTRADA.

Steps for Prescriber Certification and Enrollment in the LEMTRADA REMS

1. Complete the training program, which includes reviewing the following materials:
 - LEMTRADA Prescribing Information
 - LEMTRADA REMS Program Overview
 - LEMTRADA REMS Education Program for Prescribers
2. Successfully complete the 8-question Knowledge Assessment.
3. Enroll in the program by completing a LEMTRADA REMS Prescriber Enrollment Form
4. Submit the completed and signed Forms to the LEMTRADA REMS

The LEMTRADA REMS Program Overview, Knowledge Assessment, LEMTRADA Prescribing Information, and other REMS materials are available online at www.LemtradaREMS.com or by contacting the LEMTRADA REMS at 1-855-676-6326.

To enroll in the LEMTRADA REMS Program, call 1-855-676-6326 or go to www.LemtradaREMS.com

Genzyme will send confirmation of a prescriber's enrollment in the LEMTRADA REMS, including the prescriber's assigned LEMTRADA REMS identification number.

You will not be able to prescribe LEMTRADA without completing your certification in the LEMTRADA REMS.

You should understand that if you fail to comply with the LEMTRADA REMS requirements, you may no longer be able to participate in the LEMTRADA REMS.



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Overview of Important Safety Information

INDICATION AND USAGE

LEMTRADA is indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include relapsing-remitting disease and active secondary progressive disease, in adults. Because of its safety profile, the use of LEMTRADA should generally be reserved for patients who have had an inadequate response to two or more drugs indicated for the treatment of MS.

Limitations of Use
LEMTRADA is not recommended for use in patients with clinically isolated syndrome (CIS) because of its safety profile.

The Prescribing Information includes a **BOXED WARNING** for LEMTRADA.
Please see the Prescribing Information for complete safety information, including **BOXED WARNING**.

SERIOUS RISKS ASSOCIATED WITH LEMTRADA

Autoimmune Conditions

LEMTRADA has been associated with risk of autoimmune conditions, including immune thrombocytopenia, other cytopenias (including neutropenia, hemolytic anemia, and pancytopenia), thyroid disorders and glomerular nephropathies, which may occur many years after treatment and may be serious or life-threatening. Early detection and treatment of these conditions may decrease the risk of poor outcomes.
Please review the sections that follow to gain a better understanding of the risks of autoimmune conditions.

Immune Thrombocytopenia (ITP)

Immune thrombocytopenia (ITP) occurred in 2% of LEMTRADA-treated patients in clinical studies (controlled and open-label extension) in MS. Immune thrombocytopenia is an autoimmune disorder usually associated with anti-platelet antibodies. Platelet depletion reduces the ability of the blood to clot. Symptoms of ITP could include (but are not limited to) easy bruising, petechiae, spontaneous mucocutaneous bleeding (epistaxis, hemoptysis), and heavier than normal or irregular menstrual bleeding. These clinical signs of ITP may be apparent before serious bleeding develops.
ITP can be a serious condition leading to morbidity and mortality, and may occur several years after dosing. It is important to monitor all patients for ITP as follows:

- Complete blood counts with differential should be obtained ≤30 days prior to initiation of treatment and at monthly intervals thereafter until 48 months after the patient's last infusion of LEMTRADA. After this period of time, testing should be performed based on clinical findings suggestive of ITP.
- Check the patient for clinical symptoms of ITP.
- Counsel the patient on the importance of complying with monthly monitoring of their blood and the need to continue for 48 months after their last infusion.
- Educate the patient on how to recognize ITP related symptoms, and emphasize the need to remain vigilant for them.
- If ITP is suspected, appropriate medical intervention should be promptly initiated, including immediate referral to a specialist. Severe or widespread bleeding is life-threatening and demands immediate care.

The potential risk associated with retreatment with LEMTRADA following the occurrence of ITP is unknown.

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Potential Clinical Presentations of ITP

Note: These pictures are only a guide in order to show examples of bruises or petechiae. The patient may have a less severe type of bruise or petechiae than these pictures and still have ITP.

		
<p>This is an example of a leg with petechiae.</p> <p>Petechiae are small, scattered, "pinprick" spots under the skin that are red, pink or purple.</p> <p>Petechiae can occur anywhere on the patient's body, not just the legs.</p>	<p>This is an example of easy or excessive bruising.</p> <p>This could occur anywhere on the patient's body.</p>	<p>This is an example of purpura under the tongue.</p> <p>Purpura could occur on any mucous membrane, including anywhere in the mouth (under the tongue, roof of the mouth, inner cheeks, tongue, gums).</p>

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Other Autoimmune Cytopenias (including neutropenia, hemolytic anemia, and pancytopenia)

Autoimmune cytopenias such as neutropenia, hemolytic anemia, and pancytopenia have been reported in clinical studies (controlled and open-label extension) in MS. One LEMTRADA-treated patient with autoimmune pancytopenia died from sepsis. Symptoms of autoimmune hemolytic anemia may include weakness, chest pain, jaundice, dark urine, and tachycardia. Use the monthly CBC results to monitor for cytopenias. If a cytopenia is confirmed, appropriate medical intervention should be promptly initiated.

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Glomerular Nephropathies

Glomerular nephropathies, including anti-glomerular basement membrane (GBM) disease, have been reported after treatment with LEMTRADA in multiple sclerosis patients in clinical trials. Cases of anti-GBM disease have been diagnosed up to 40 months after the last dose of LEMTRADA.

In postmarketing cases, some LEMTRADA-treated patients with anti-GBM disease developed end-stage renal disease requiring dialysis or renal transplantation. Urgent evaluation and treatment is required, because early treatment can improve the preservation of renal function. Anti-GBM disease can be life-threatening if left untreated.

Clinical manifestations of nephropathy may include elevation in serum creatinine, edema, hematuria, change in urine color, decreased urine output, fatigue, dyspnea, and/or proteinuria. While not observed in clinical trials, alveolar hemorrhage manifested as hemoptysis is a common component of anti-GBM disease. Since patients may be asymptomatic, it is important that the monthly tests are conducted.

- Serum creatinine levels, urinalysis with cell counts, and urine protein to creatinine ratio should be obtained ≤30 days prior to the first infusion of LEMTRADA. Serum creatinine and urinalysis with cell counts should be obtained at monthly intervals thereafter until 48 months after the patient's last infusion. After this period of time, testing should be performed based on clinical findings suggestive of nephropathies.
- In menstruating females, consider the timing of urinalysis to avoid false positives. The observation of clinically significant changes from baseline in serum creatinine, unexplained hematuria, and/or proteinuria, should prompt further evaluation for nephropathies, including referral to a specialist.
- Early detection and treatment of nephropathies may decrease the risk of poor outcomes.
- Immediate referral to a specialist for further assessment for patients with suspected nephropathy is strongly recommended.

Thyroid Disorders

During clinical trials, autoimmune thyroid disorders including Graves' disease, hyperthyroidism, hypothyroidism, autoimmune thyroiditis, and goiter were reported. Thyroid endocrine disorders, including autoimmune thyroid disorders occurred in 36.8% of LEMTRADA-treated patients in clinical studies (controlled and open-label extension).

Newly diagnosed thyroid disorders occurred throughout the uncontrolled clinical study follow-up period, more than 7 years after the first LEMTRADA dose. Serious thyroid events occurred in 5.2% of patients. Of all LEMTRADA-treated patients, 3.8% underwent thyroidectomy.

It is important to monitor all patients for thyroid disorders as follows:

- Thyroid function tests such as thyroid stimulating hormone (TSH) levels should be obtained ≤30 days prior to the first infusion of LEMTRADA and then every 3 months thereafter continuing until 48 months following the last infusion. Continue to test thyroid function after 48 months if clinically indicated.
- Additionally watch out for signs and symptoms of thyroid disorders, which may include excessive sweating, unexplained weight loss, eye swelling, nervousness and fast heartbeat (hyperthyroidism), or unexplained weight gain, feeling cold, worsening tiredness and newly occurring constipation (hypothyroidism).



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• Thyroid disease poses special risks in women who become pregnant. Untreated thyroid disease can cause harm to the unborn and newborn baby. Special caution should be taken for pregnant women with Graves' disease, as maternal thyroid stimulating hormone receptor antibodies can be transferred to a developing fetus and can cause transient neonatal Graves' disease. The HCP responsible for managing the patient's pregnancy must be made aware of the increased risk of thyroid disorders due to the patient's LEMTRADA treatment, and the need for these to be appropriately treated.

Autoimmune Hepatitis
Autoimmune hepatitis causing clinically significant liver injury, including acute liver failure requiring transplant, has been reported in patients treated with LEMTRADA in the postmarketing setting. If a patient develops clinical signs, including unexplained liver enzyme elevations or symptoms suggestive of hepatic dysfunction (e.g., unexplained nausea, vomiting, abdominal pain, fatigue, anorexia, or jaundice and/or dark urine), promptly measure serum transaminases and total bilirubin and interrupt or discontinue treatment with LEMTRADA, as appropriate.

Prior to starting treatment with LEMTRADA, obtain serum transaminases (ALT and AST) and total bilirubin levels. Obtain transaminase levels and total bilirubin levels periodically until 48 months after the last dose.

Strategies to Mitigate the Risk of Autoimmune Conditions
In order to minimize possible risks and side effects of LEMTRADA, prescribers and patients must commit to 48 months of follow-up after the last infusion of LEMTRADA. It is important that patients understand that they should continue with the monitoring, even if they are feeling well.

Creating a partnership between you and your patient, along with careful review of the patient education tool (*What You Need to Know About LEMTRADA Treatment: A Patient Guide*) with your patient, will help patients to:

- Comply with periodic tests
- Identify and report symptoms early
- Receive prompt and appropriate treatment if needed

To enhance your understanding of the duration of the effects of treatment and the length of required follow-up, please refer to the diagrams below titled *Overview of LEMTRADA Treatment and Overview of LEMTRADA Monitoring*.



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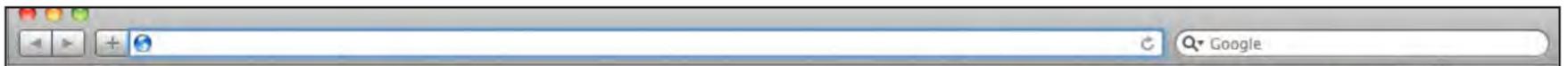
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Overview of LEMTRADA Treatment



Mandatory monthly laboratory testing is required until 4 years after the last infusion with LEMTRADA. If more than 2 courses are deemed necessary, administer subsequent course(s) at least 1 year after the prior treatment course. Mandatory monthly monitoring may extend beyond 5 years, until at least 4 years after the last infusion.

Overview of LEMTRADA Monitoring

Condition	Activity	Timing	
Immune Thrombocytopenia (ITP)	Complete blood count with differential	Prior to initiating LEMTRADA treatment	Monthly until 48 months after last infusion
Glomerular Nephropathies, including anti-GBM disease	Urine protein to creatinine ratio	Prior to initiating LEMTRADA treatment	
	Serum creatinine	Prior to initiating LEMTRADA treatment	Monthly until 48 months after last infusion
	Urinalysis with microscopy	Prior to initiating LEMTRADA treatment	Monthly until 48 months after last infusion
Thyroid Disorders	Thyroid function tests (such as TSH)	Prior to initiating LEMTRADA treatment	Every 3 months until 48 months after last infusion
Autoimmune Hepatitis	Serum transaminases (ALT and AST) and total bilirubin levels	Prior to initiating LEMTRADA treatment	Periodically until 48 months after last infusion
Melanoma	Skin examinations	Prior to initiating LEMTRADA treatment	Yearly

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LEMTRADA REMS Education Program for Prescribers (8 of 12) Total Training Screens: 37 of 41

Infusion Reactions

Most patients treated with LEMTRADA in controlled clinical trials in MS experienced infusion reactions during or after LEMTRADA administration. Some of these reactions were serious and life-threatening. In some patients, infusion reactions were reported more than 24 hours after LEMTRADA infusion. Serious reactions occurred in 3% of patients, including cases of anaphylaxis in 2 patients (including anaphylactic shock), angioedema, bronchospasm, hypotension, chest pain, bradycardia, tachycardia (including atrial fibrillation), transient neurologic symptoms, hypertension, headache, pyrexia, and rash. Other infusion reactions included nausea, urticaria, pruritus, insomnia, chills, flushing, fatigue, dyspnea, pulmonary infiltrates, dysgeusia, dyspepsia, dizziness and pain. In clinical studies, 0.6% of patients with infusion reactions received epinephrine or atropine.

Cases of pulmonary alveolar hemorrhage and myocardial ischemia have been reported with onset within 48 hours of LEMTRADA infusion.

Premedicate with high-dose corticosteroids (1000 mg of methylprednisolone or equivalent) immediately prior to LEMTRADA infusion and for the first 3 days of each treatment course. Consider pretreatment with antihistamines and/or antipyretics prior to LEMTRADA administration. Infusion reactions may occur in patients despite pretreatment.

Consider additional monitoring in patients with medical conditions which predispose them to cardiovascular or pulmonary compromise. Physicians should alert patients that an infusion reaction could occur within 48 hours of infusion.

LEMTRADA can only be administered in certified healthcare settings that have on-site access to equipment and personnel trained to manage infusion reactions (including anaphylaxis and cardiac and respiratory emergencies).

Patients must be observed for infusion reactions during and for at least 2 hours after each LEMTRADA infusion. Consider longer periods of observation if clinically indicated. Vital signs should be monitored before the infusion and periodically during the infusion. If an infusion reaction occurs, appropriate symptomatic treatment should be provided as needed. The duration of the infusion may be extended if clinically indicated. If severe infusion reactions occur, immediate discontinuation of the infusion should be considered.

Stroke and Cervicocephalic Arterial Dissection

Stroke
In the postmarketing setting, serious and life-threatening stroke (including ischemic and hemorrhagic stroke) has been reported within 3 days of LEMTRADA administration, with most cases occurring within 1 day.

Cervicocephalic Arterial Dissection
In the postmarketing setting, cases of cervicocephalic (e.g., vertebral, carotid) arterial dissection involving multiple arteries have been reported within 3 days of LEMTRADA administration. Ischemic stroke was reported in one of these cases.

Educate patients on the symptoms of stroke and cervicocephalic (e.g., carotid, vertebral) arterial dissection. Instruct patients to seek immediate medical attention if symptoms of stroke or cervicocephalic arterial dissection occur.

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Malignancies

LEMTRADA is an immunomodulatory therapy, and caution should be exercised in initiating LEMTRADA in patients with pre-existing or ongoing malignancies.

Thyroid Cancer
LEMTRADA may increase the risk of thyroid cancer. In controlled clinical studies, 0.3% of LEMTRADA-treated patients developed thyroid cancer, compared to none in the interferon beta-1a-treated group. However, screening for thyroid cancer was performed more frequently in the LEMTRADA-treated group, because of the higher incidence of autoimmune thyroid disorders in those patients. Two additional cases of thyroid cancer in LEMTRADA-treated patients occurred in uncontrolled studies.

Melanoma
LEMTRADA may increase the risk of melanoma. In clinical studies, including extension data, 0.3% LEMTRADA-treated patients developed melanoma or melanoma in situ. One of those patients had evidence of locally advanced disease.

Lymphoproliferative Disorders and Lymphoma
Cases of lymphoproliferative disorders and lymphoma have occurred in LEMTRADA-treated patients with MS, including a MALT lymphoma, Castleman's Disease, and a fatality following treatment of non-Epstein Barr Virus-associated Burkitt's lymphoma. There are postmarketing reports of Epstein Barr Virus-associated lymphoproliferative disorders in non-MS patients.

Monitoring for Malignancies
Patients and healthcare providers should monitor for symptoms of thyroid cancer, including a new lump or swelling in the neck, pain in the front of the neck, persistent hoarseness or other voice changes, trouble swallowing or breathing, or a constant cough not due to an upper respiratory tract infection.

Perform baseline and yearly skin examinations to monitor for melanoma in patients receiving LEMTRADA.

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The screenshot shows a web browser window displaying the LEMTRADA REMS Desktop interface. The page is titled "LEMTRADA REMS Training" and shows a progress bar with four steps: Registration, Training (highlighted), Assessment, and Enrollment. The current slide is titled "Patient Enrollment, Counseling, and Management" and contains the following text:

Patient Enrollment, Counseling, and Management

To enroll your patient in the LEMTRADA REMS, you must:

- Complete the LEMTRADA REMS Patient Enrollment Form for each patient and provide a completed copy to the patient. The completed form should be submitted to the LEMTRADA REMS and a copy stored in the patient's records.
- Enrollment forms can be obtained online (www.LemtradaREMS.com) or by phone (1-855-676-6326).
- Completed forms should be faxed to 1-855-557-2478.
- Genzyme will provide confirmation of patient enrollment.

As part of patient management and counseling, you must:

- Inform your patient about the risks associated with LEMTRADA, including the risks of autoimmune conditions, infusion reactions, stroke and malignancies, and the need for baseline and periodic monitoring. A patient-directed educational guide has been developed for you to use in counseling your patients on the risks associated with LEMTRADA (*What You Need to Know About LEMTRADA Treatment: A Patient Guide*). You should review this guide with your patient on an ongoing basis. You must provide each patient with a copy of this guide and a LEMTRADA Patient Safety Information Card.
- Perform the baseline and periodic monitoring described above and in the Prescribing Information for LEMTRADA.
- Complete the LEMTRADA REMS Patient Status Form 6 months after the patient's first infusion with LEMTRADA, and every 6 months thereafter, until 48 months after the completion of the patient's last infusion of LEMTRADA, and submit the completed form to the LEMTRADA REMS.
- Notify Genzyme if an enrolled patient who has received LEMTRADA within the last 48 months is no longer under your care.

Ordering LEMTRADA

To order LEMTRADA, you must submit a LEMTRADA REMS Prescription Ordering Form for each LEMTRADA prescription to the LEMTRADA REMS. The ordering form can be obtained online (www.LemtradaREMS.com) or by phone (1-855-676-6326).

Completed forms should be faxed to 1-855-557-2478.

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Navigation buttons: Previous, Next, (39 of 41)

Footer text: If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6326, Mon – Fri, 8:30 am – 8:00 pm ET.

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LEMTRADA REMS Training

LEMTRADA REMS Education Program for Prescribers (11 of 12) Total Training Screens: 40 of 41

Administering LEMTRADA

As part of the LEMTRADA REMS, a healthcare facility must be enrolled in the LEMTRADA REMS to be able to dispense/administer LEMTRADA. It is important that you select a healthcare facility that is enrolled and active in the LEMTRADA REMS for your patient's infusion. A database of certified healthcare facilities is available by phone at 1-855-676-6326.

Prior to your patient's infusion, you must submit a LEMTRADA REMS Patient Authorization and Baseline Lab Form to the LEMTRADA REMS indicating completion of each patient's baseline labs within 30 days of the infusion date.

PRIOR TO EACH TREATMENT COURSE OF LEMTRADA

- Administer corticosteroids (1000 mg methylprednisolone or equivalent) immediately prior to LEMTRADA administration for the first 3 days of any treatment course
- Administer anti-viral prophylaxis for herpetic viral infection starting on the first day of each treatment course and continuing for a minimum of 2 months following treatment with LEMTRADA or until the CD4+ lymphocyte count is ≥ 200 cells per microliter, whichever occurs later
- Consider pretreating patients with antihistamines and/or antipyretics prior to LEMTRADA administration as needed

Adverse Event Reporting

Report suspected adverse events to Genzyme Medical Information at 1-800-745-4447 (option 2) or to FDA at 1-800-FDA-1088 or www.FDA.gov/medwatch.

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The screenshot shows a web browser window displaying the LEMTRADA REMS Training page. At the top, the LEMTRADA logo (alemtozumab 12mg iv) is on the left, and navigation links for 'Prescribing Information' and 'Medication Guide' are on the right. A user greeting 'Welcome, Adam Smith!' is followed by 'My Profile' and 'Log Out' links. A horizontal menu contains 'Home', 'Forms and FAQs', 'REMS Certified Prescriber & Healthcare Facility Locator', and 'About REMS'. Below this is a progress bar with four steps: 'Registration', 'Training' (highlighted), 'Assessment', and 'Enrollment'. The main heading is 'LEMTRADA REMS Training', with a sub-heading 'LEMTRADA REMS Education Program for Prescribers (12 of 12) Total Training Screens: 41 of 41'. A large, mostly empty content area is shown, with a 'FOLD' label on the left side. At the bottom of this area are the Sanofi Genzyme logo, copyright information, and the LEMTRADA logo. Below the content area are 'Previous' and 'Next' buttons, and a page indicator '(41 of 41)'. A call to action box at the bottom states: 'If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6326, Mon - Fri, 8:30 am - 8:00 pm ET.' The footer contains links for 'Privacy Policy', 'Terms and Conditions', and 'Contact Us', along with a disclaimer: 'This site is intended for United States residents only. ©2019 Genzyme Corporation. All rights reserved. Lemtrada, MS One to One, Sanofi and Genzyme registered in U.S. Patent and Trademark Office US.MS.LEM.14.10.013-v7 Last Updated 09/19' and the Sanofi Genzyme logo.

The screenshot shows a web browser window displaying the LEMTRADA REMS website. The browser's address bar shows a Google search. The website header includes the LEMTRADA logo (alemftuzumab 12mg iv) and navigation links for Prescribing Information and Medication Guide. A user is logged in as Adam Smith, with links for My Profile and Log Out. A main navigation bar contains Home, Forms and FAQs, REMS Certified Prescriber & Healthcare Facility Locator, and About REMS. Below this is a progress bar with four steps: Registration, Training (highlighted), Assessment, and Enrollment. The main content area features a green banner with the heading "LEMTRADA REMS Training Complete" and a message: "You have completed your review of the training materials. You may now answer the Knowledge Assessment questions." A green button labeled "Answer Knowledge Assessment Questions" is positioned below the message. Further down, a text block states: "If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6326, Mon - Fri, 8:30 am - 8:00 pm ET." The footer is a dark purple bar containing links for Privacy Policy, Terms and Conditions, and Contact Us. It also includes a disclaimer: "This site is intended for United States residents only." and copyright information: "©2019 Genzyme Corporation. All rights reserved." The Sanofi Genzyme logo is located in the bottom right corner of the footer.

FOLD

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QUESTION 1 (select one)

Which of the following laboratory tests are required prior to initiating LEMTRADA treatment and within 30 days of the first infusion?

- A. Complete blood count (CBC) with differential
- B. Serum creatinine and urinalysis with urine cell counts
- C. Urine protein to creatinine ratio
- D. Thyroid function test
- E. All of the above

Submit

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QUESTION 2 (select one)

My patient must have monthly blood and urine tests for:

- A. 12 months after their last infusion
- B. 24 months after their last infusion
- C. 36 months after their last infusion
- D. 48 months after their last infusion

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QUESTION 3

I should assess my patient's compliance with required lab testing on an ongoing basis and document their compliance on the LEMTRADA REMS Patient Status Form every 6 months.

True
 False

Submit

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QUESTION 4 (select one)

Which of the following symptoms could be associated with immune thrombocytopenia (ITP)?

- A. Headache, rash, pyrexia, nausea
- B. Easy bruising, petechiae, purpura, spontaneous mucocutaneous bleeding
- C. Weight gain, fatigue, constipation
- D. Pyrexia, chills, swollen glands

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QUESTION 5 (select one)

Which of the following could be associated with glomerular nephropathy?

- A. Elevation in serum creatinine, hematuria, or proteinuria
- B. Easy bruising, petechiae, purpura, spontaneous mucocutaneous bleeding (e.g., epistaxis, hemoptysis), and heavier than normal or irregular menstrual bleeding
- C. Weight gain, fatigue, constipation
- D. Weight loss, tachycardia, nervousness

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QUESTION 6 (select one)

Prior to enrolling a patient in the LEMTRADA REMS, you should:

- A. Provide "What You Need to Know About LEMTRADA Treatment: A Patient Guide" to the patient
- B. Counsel the patient on the serious risks associated with LEMTRADA and how to mitigate these risks through periodic monitoring
- C. Provide a LEMTRADA Patient Safety Information Card to the patient
- D. All of the above

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QUESTION 7

Cases of serious and life-threatening stroke (including ischemic and hemorrhagic stroke) have been reported within 3 days of LEMTRADA administration, with most cases occurring within 1 day.

True
 False

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QUESTION 8

The healthcare facility that will administer LEMTRADA infusions to my patient is required to be REMS certified and enrolled, and should have the necessary equipment and personnel to manage serious infusion reactions (including anaphylaxis, and cardiac and respiratory emergencies).

True
 False

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Please Review the Training Materials Again

Score: X / 8

You only answered X out of 8 questions correctly. In order to become certified in the LEMTRADA REMS, you must answer ALL 8 questions correctly. Please review the training materials again.

[View Training Materials](#) [Take Assessment Again](#)

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Registration Training Assessment Enrollment

LEMTRADA REMS Knowledge Assessment

To confirm that prescribers understand the LEMTRADA REMS requirements, you must successfully complete the Knowledge Assessment below. You must answer **ALL 8** questions correctly in order to become enrolled in the LEMTRADA REMS. Please note that you will have 3 attempts to successfully complete the Knowledge Assessment or you will have to view the training materials again.

Please Go Back to Training

You have failed to successfully complete the assessment 3 times. You will need to review the online training module before you can try again.

[Go Back to Training](#)

If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6326, Mon – Fri, 8:30 am – 8:00 pm ET.

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SANOFI GENZYME

The screenshot shows a web browser window displaying the LEMTRADA REMS website. The browser's address bar shows a Google search. The website header includes the LEMTRADA logo (alemfuzumab 12mg iv) and navigation links for Prescribing Information and Medication Guide. A user is logged in as Adam Smith, with links for My Profile and Log Out. A main navigation bar contains Home, Forms and FAQs, REMS Certified Prescriber & Healthcare Facility Locator, and About REMS. A progress bar below the navigation bar shows four steps: Registration, Training, Assessment (highlighted in purple), and Enrollment. The main content area is titled "LEMTRADA REMS Knowledge Assessment" and contains a message stating that the user has reached the maximum number of attempts (3) to complete the assessment. A red-bordered box contains the text: "Please Contact a Genzyme Representative", "You have reached the maximum number of attempts to complete the Knowledge Assessment. Please contact a Genzyme representative.", and "Please call 1-855-676-6326 to speak with a Genzyme representative." Below this message, there is a call to action: "If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6326, Mon - Fri, 8:30 am - 8:00 pm ET." The footer contains links for Privacy Policy, Terms and Conditions, and Contact Us, along with copyright information for Genzyme Corporation (©2019) and the Sanofi Genzyme logo.

FOLD

The screenshot shows a web browser window displaying the LEMTRADA REMS website. The browser's address bar shows a Google search engine. The website header includes the LEMTRADA logo (alemftuzumab 12mg iv) and navigation links for Prescribing Information and Medication Guide. A user is logged in as Adam Smith, with links for My Profile and Log Out. A main navigation bar contains Home, Forms and FAQs, REMS Certified Prescriber & Healthcare Facility Locator, and About REMS. A progress bar below the navigation bar shows four steps: Registration, Training, Assessment (highlighted in purple), and Enrollment. The main content area features a heading "LEMTRADA REMS Knowledge Assessment Complete" and a message stating that the user has successfully completed all assessment questions and can now review and submit their enrollment form. A green button labeled "Go to Enrollment" is positioned below the message. A call to action section follows, stating: "If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6326, Mon - Fri, 8:30 am - 8:00 pm ET." The footer contains links for Privacy Policy, Terms and Conditions, and Contact Us. It also includes a disclaimer: "This site is intended for United States residents only." and copyright information: "©2019 Genzyme Corporation. All rights reserved." The footer also lists "Lemtrada, MS One to One, Sanofi and Genzyme registered in U.S. Patent and Trademark Office US.MS.LEM.14.10.013-v7 Last Updated 09/19" and the SANOFI GENZYME logo.

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LEMTRADA REMS PRESCRIBER ENROLLMENT FORM

LEMTRADA is available only through the LEMTRADA REMS, a restricted distribution program. Only prescribers, healthcare facilities, and patients enrolled in the program are able to prescribe, dispense, administer, and receive LEMTRADA. Please review the following information and submit to Genzyme using the button below. Complete any missing information and correct any errors prior to submission.

*Required

PRESCRIBER INFORMATION

First Name*	<input type="text" value="Adam"/>
Last Name*	<input type="text" value="Smith"/>
Degree*	<input type="text" value="Medical Doctor"/>
Name of Institution or Healthcare Facility*	<input type="text" value="Massachusetts Institute"/>
Street Address*	<input type="text" value="72-04 Maple Lane"/>
City*	<input type="text" value="Boston"/>
State*	<input type="text" value="Massachusetts"/>
ZIP Code*	<input type="text" value="012314"/>
Office Phone Number*	<input type="text" value="555 555 5555"/>
Fax Number*	<input type="text" value="555 555 5555"/>
Mobile Phone Number	<input type="text" value="555 555 5555"/>
Email Address*	<input type="text" value="asmith@abc123.com"/>
National Provider Identification (NPI) Number*	<input type="text" value="0123456789"/>

If you are dispensing LEMTRADA from your clinic, a LEMTRADA REMS Healthcare Facility Enrollment Form must also be completed and submitted.

PRESCRIBER AGREEMENT

By completing this form, I attest that:

- I understand that LEMTRADA is indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include relapsing-remitting disease and active secondary progressive disease, in adults. Because of its safety profile, the use of LEMTRADA should generally be reserved for patients who have had an inadequate response to two or more drugs indicated for the treatment of MS. LEMTRADA is not recommended for use in patients with clinically isolated syndrome (CIS) because of its safety profile.
- I understand that LEMTRADA is only available through the LEMTRADA REMS and that I must comply with the program requirements in order to prescribe LEMTRADA.
- I have completed the LEMTRADA REMS Education Program for Prescribers, including a review of the LEMTRADA Prescribing Information, and successfully completed the LEMTRADA REMS Knowledge Assessment.
- I understand that by completing the training program and signing this LEMTRADA REMS Prescriber Enrollment Form, I will be enrolled in the LEMTRADA REMS and can prescribe LEMTRADA.
- I understand that I am responsible for reviewing *What You Need to Know About LEMTRADA Treatment: A Patient Guide* with each patient, and counseling each patient on an ongoing basis about the serious risks associated with the use of LEMTRADA and how to mitigate these risks through periodic monitoring.
- I understand that I must enroll all patients being treated with LEMTRADA into the LEMTRADA REMS prior to initiating the patient on treatment with LEMTRADA. I am responsible for completing a LEMTRADA REMS Patient Enrollment Form with the patient (or patient's legal representative), obtaining the patient's (or patient's legal representative's) signature on the form, and submitting the signed form to the LEMTRADA REMS. A completed copy should be provided to the patient and another copy should be stored in the patient's records.
- I will provide enrolled patients with a LEMTRADA Patient Safety Information Card and instruct patients to carry this card with them at all times in case of an emergency.
- I understand that I must submit a LEMTRADA REMS Prescription Ordering Form for each LEMTRADA prescription.
- I understand that I am responsible for completing baseline lab monitoring within 30 days prior to infusion of LEMTRADA.
- I understand that I must submit a LEMTRADA REMS Patient Authorization and Baseline Lab Form indicating completion of each patient's baseline labs within 30 days prior to the patient's infusion date.
- I understand the risks of autoimmune conditions and malignancies associated with the use of LEMTRADA, and the need for periodic monitoring in order to identify and mitigate these risks:
 - Complete blood counts with differential obtained within 30 days prior to initiation of treatment and at monthly intervals thereafter until 48 months after the last infusion.
 - Serum creatinine levels obtained within 30 days prior to initiation of treatment and at monthly intervals thereafter until 48 months after the last infusion.
 - Urinalysis with urine cell counts obtained within 30 days prior to initiation of treatment and at monthly intervals thereafter until 48 months after the last infusion.
 - Measure the urine protein to creatinine ratio within 30 days prior to initiation of treatment
 - Thyroid function tests, such as thyroid stimulating hormone (TSH) level, obtained within 30 days prior to initiation of treatment and every 3 months thereafter until 48 months after the last infusion.
 - Baseline and yearly skin examinations.
- I understand the risk of stroke during and following the administration of LEMTRADA
- I will report any adverse events of autoimmune conditions, infusion reactions, or malignancies to Genzyme.
- I will complete the LEMTRADA REMS Patient Status Form 6 months after the patient's first infusion and every 6 months thereafter, until 48 months after the completion of the patient's last infusion.
- I understand that I will notify Genzyme if a patient is no longer under my care.
- I understand that if I fail to comply with the requirements of the LEMTRADA REMS, I may no longer be able to participate in the program.
- I understand Genzyme and its agents may contact me via phone, mail, fax, or email to support administration of the LEMTRADA REMS.

I understand that the LEMTRADA REMS will publish my name, business address and phone number ("Contact Information") on its website in a directory of physicians certified to prescribe and administer LEMTRADA and consent to the foregoing. I understand that I am waiving the right to inspect my Contact Information prior to its inclusion on the website, and I agree to hold harmless and release the LEMTRADA REMS and Genzyme and its affiliates from any and all actions, claims, or demands arising out of or in connection with the use of my Contact Information on the website. I understand that I can request the removal of my Contact Information from the LEMTRADA REMS website at any time by contacting the LEMTRADA REMS at 1-855-676-6326.

Yes No

I have verified that all details are correct.

By providing my e-signature, I attest that I have completed the educational training about LEMTRADA for prescribers and that I understand the benefits and risks of LEMTRADA. I understand that my e-signature will be used to verify my enrollment in the LEMTRADA REMS.

By entering my name, NPI number, and password, I confirm that I have completed the LEMTRADA REMS training and that I will comply with the requirements of the program.

Full Name*

NPI Number*

Password*

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*Required

PRESCRIBER INFORMATION

First Name*	<input type="text" value="Adam"/>
Last Name*	<input type="text" value="Smith"/>
Degree*	<div style="border: 1px solid #ccc; padding: 2px;"> Select Doctor of Osteopathy Doctor of Pharmacy Medical Doctor Nurse Practitioner Physician Assistant Registered Nurse Registered Pharmacist </div>
Name of Institution or Healthcare Facility*	<input type="text" value="Institute"/>
Street Address*	<input type="text"/>
City*	<input type="text"/>
State*	<input type="text"/>
ZIP Code*	<input type="text" value="012314"/>
Office Phone Number*	<input type="text" value="555 555 5555"/>
Fax Number*	<input type="text" value="555 555 5555"/>
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- 7 I will provide enrolled patients with a LEMTRADA Patient Safety Information Card and instruct patients to carry this card with them at all times in case of an emergency.
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- 10 I understand that I must submit a LEMTRADA REMS Patient Authorization and Baseline Lab Form indicating completion of each patient's baseline labs within 30 days prior to the patient's infusion date.
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- 12 I will report any adverse events of autoimmune conditions, infusion reactions, or malignancies to Genzyme.
- 13 I will complete the LEMTRADA REMS Patient Status Form 6 months after the patient's first infusion and every 6 months thereafter, until 48 months after the completion of the patient's last infusion.
- 14 I understand that I will notify Genzyme if a patient is no longer under my care.
- 15 I understand that if I fail to comply with the requirements of the LEMTRADA REMS, I may no longer be able to participate in the program.
- 16 I understand Genzyme and its agents may contact me via phone, mail, fax, or email to support administration of the LEMTRADA REMS.

I understand that the LEMTRADA REMS will publish my name, business address and phone number ("Contact Information") on its website in a directory of physicians certified to prescribe and administer LEMTRADA and consent to the foregoing. I understand that I am waiving the right to inspect my Contact Information prior to its inclusion on the website, and I agree to hold harmless and release the LEMTRADA REMS and Genzyme and its affiliates from any and all actions, claims, or demands arising out of or in connection with the use of my Contact Information on the website. I understand that I can request the removal of my Contact Information from the LEMTRADA REMS website at any time by contacting the LEMTRADA REMS at 1-855-676-6326.

Yes No

I have verified that all details are correct.

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Full Name*	<input type="text"/>
NPI Number*	<input type="text"/>
Password*	<input type="password"/>

Cancel
Submit

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First Name*	<input type="text" value="Adam"/>
Last Name*	<input type="text" value="Smith"/>
Degree*	<input type="text" value="Medical Doctor"/>
Name of Institution or Healthcare Facility*	<input type="text" value="Massachusetts Institute"/>
Street Address*	<input type="text" value="72-04 Maple Lane"/>
City*	<input type="text" value="Boston"/>
State*	<div style="border: 1px solid #ccc; padding: 2px;"> Select Alabama Alaska American Samoa Arizona Arkansas California Colorado Connecticut Delaware District of Columbia Florida Georgia Guam Hawaii Idaho Illinois Indiana Iowa Kansas Kentucky Louisiana Maine Maryland Massachusetts Michigan Minnesota Mississippi Missouri Montana Nebraska Nevada New Hampshire New Jersey New Mexico New York North Carolina North Dakota Northern Mariana Islands Ohio Oklahoma Oregon Pennsylvania Puerto Rico Rhode Island South Carolina South Dakota Tennessee Texas Utah Vermont Virginia Virgin Islands Washington West Virginia Wisconsin Wyoming </div>
ZIP Code*	<input type="text"/>
Office Phone Nu	<input type="text"/>
Fax Number*	<input type="text"/>
Mobile Phone Nu	<input type="text"/>
Email Address*	<input type="text" value="@com"/>
National Provide Identification (NI	<input type="text"/>

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By completing th

- I understand that L relapsing forms of relapsing-remitting disease, in adults. LEMTRADA should had an inadequate the treatment of M patients with clinic safety profile.
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- I will provide enroll Information Card a them at all times ir
- I understand that I Prescription Order
- I understand that I monitoring within

I understand that information") on i to the foregoing. website, and I agt all actions, claims understand that I by contacting the LEMTRADA REMS at 1-855-676-6326.

Yes No

LEMTRADA REMS Healthcare Facility Enrollment Form must also

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I will complete the LEMTRADA REMS Patient Status Form 6 months after the patient's first infusion and every 6 months thereafter, until 48 months after the completion of the patient's last infusion.

I understand that I will notify Genzyme if a patient is no longer under my care.

I understand that if I fail to comply with the requirements of the LEMTRADA REMS. I may no longer be able to participate in the program.

I understand Genzyme and its agents may contact me via phone, mail, fax, or email to support administration of the LEMTRADA REMS.

I have verified that all details are correct.

By providing my e-signature, I attest that I have completed the educational training about LEMTRADA for prescribers and that I understand the benefits and risks of LEMTRADA. I understand that my e-signature will be used to verify my enrollment in the LEMTRADA REMS.

By entering my name, NPI number, and password, I confirm that I have completed the LEMTRADA REMS training and that I will comply with the requirements of the program.

Full Name*	<input type="text"/>
NPI Number*	<input type="text"/>
Password*	<input type="password"/>

Cancel
Submit

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VV-REG-0833078 0.1

Reference ID: 4512344



LEMTRADA
alemtuzumab^{12mg}

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Last Name*	<input type="text"/>	<small>Please enter your last name.</small>
Degree*	<input type="text"/>	<small>Please select degree.</small>
Name of Institution or Healthcare Facility*	<input type="text"/>	<small>Please enter name of institution or healthcare facility.</small>
Street Address*	<input type="text"/>	<small>Please enter your street address.</small>
City*	<input type="text"/>	<small>Please enter city.</small>
State*	<input type="text"/>	<small>Please select a state.</small>
ZIP Code*	<input type="text"/>	<small>Please enter a 5-digit ZIP Code.</small>
Office Phone Number*	<input type="text"/>	<small>Please enter a 10-digit phone number.</small>
Fax Number*	<input type="text"/>	<small>Please enter a 10-digit fax number.</small>
Mobile Phone Number	<input type="text"/>	
Email Address*	<input type="text"/>	<small>Please enter a valid email address.</small>
National Provider Identification (NPI) Number*	<input type="text"/>	<small>Please enter a valid NPI number.</small>

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Yes No Please make a selection.

I have verified that all details are correct.
Please indicate information has been verified.

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Full Name*

Please enter your full name.

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The screenshot shows a web browser window displaying the LEMTRADA REMS website. The browser's address bar shows a Google search. The website header includes the LEMTRADA logo (alemfuzumab 12mg) and navigation links for Prescribing Information and Medication Guide. A user is logged in as Adam Smith, with links for My Profile and Log Out. A main navigation bar contains Home, Forms and FAQs, REMS Certified Prescriber & Healthcare Facility Locator, and About REMS. A progress bar below the navigation bar shows four steps: Registration, Training, Assessment, and Enrollment, with Enrollment being the active and highlighted step. The main content area features a heading "Enrollment Is Complete!" followed by a paragraph explaining that the user has successfully completed online enrollment and will receive a confirmation email. It also provides contact information for a LEMTRADA REMS Specialist if a confirmation email is not received. A call to action links to download and print a copy of the Prescriber Enrollment Form. A "FOLD" label is present on the left side of the page. The footer contains links for Privacy Policy, Terms and Conditions, and Contact Us, along with copyright information for Genzyme Corporation (©2019) and the Sanofi Genzyme logo.

The screenshot shows a web browser window displaying the LEMTRADA REMS desktop interface. The browser's address bar shows a Google search engine. The page header includes the LEMTRADA logo (alemTuzumab 12mg iv) and navigation links for 'Prescribing Information' and 'Medication Guide'. A user greeting 'Welcome, Adam Smith!' is followed by 'My Profile' and 'Log Out' links. A main navigation bar contains 'Home', 'Forms & FAQs', 'REMS Certified Prescriber & Healthcare Facility Locator', and 'About REMS'. The main content area features a section titled 'LEMTRADA REMS (Risk Evaluation and Mitigation Strategy)' with sub-sections: 'What is the LEMTRADA REMS?', 'AUTOIMMUNE CONDITIONS', 'INFUSION REACTIONS', 'STROKE', and 'MALIGNANCIES'. To the right, a 'LEMTRADA REMS Requirements' box highlights 'PRESCRIBERS' and states that prescribers must be enrolled to prescribe LEMTRADA for patients with multiple sclerosis, with a link to 'Learn about Prescriber Enrollment'. Below this, two interactive cards are shown: 'Complete Enrollment in the LEMTRADA REMS' with a 'Review Training Materials' button, and 'Find a REMS Certified Prescriber or Healthcare Facility' with a search form including a ZIP code field, radio buttons for 'REMS Certified Prescriber' (selected) and 'REMS Certified Healthcare Facility', and a 'Find' button. A disclaimer states: 'This site is provided as a resource for prescribers and is not intended as medical advice. Information on the site is updated periodically (approximately every 12 hours)'. A contact section provides the phone number '1-855-676-6326' for questions. The footer contains links for 'Privacy Policy', 'Terms and Conditions', and 'Contact Us', along with copyright information for Genzyme Corporation (©2019) and the Sanofi Genzyme logo.

FOLD

LEMTRADA
alemtuzumab^{12mg} iv

Prescribing Information Medication Guide

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LEMTRADA REMS (Risk Evaluation and Mitigation Strategy)

What is the LEMTRADA REMS?
A REMS is a strategy to manage known or potential serious risks associated with a drug product and is required by the FDA to ensure the benefits of a drug outweigh its risks. The purpose of the LEMTRADA REMS is to inform prescribers, pharmacies, healthcare facilities, and patients about the risks of:

AUTOIMMUNE CONDITIONS
LEMTRADA causes serious, sometimes fatal, autoimmune conditions such as immune thrombocytopenia and anti-glomerular basement membrane disease. Monitor complete blood counts with differential, serum creatinine levels, and urinalysis with urine cell counts at periodic intervals for 48 months after the last dose of LEMTRADA.

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Serious and life-threatening stroke (including ischemic and hemorrhagic stroke) has been reported within 3 days of LEMTRADA administration. Instruct patients to seek immediate medical attention if symptoms of stroke occur.

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LEMTRADA may cause an increased risk of malignancy including thyroid cancer, melanoma, and lymphoproliferative disorders. Perform baseline and yearly exams.

LEMTRADA REMS Requirements

PRESCRIBERS

Prescribers must be enrolled in the LEMTRADA REMS to prescribe LEMTRADA for patients with multiple sclerosis.
[Learn about Prescriber Enrollment](#)

Complete Enrollment in the LEMTRADA REMS

You have not completed answering the LEMTRADA REMS Knowledge Assessment questions.

[Continue Assessment](#)

Find a REMS Certified Prescriber or Healthcare Facility

Search for prescribers or healthcare facilities that are certified by the LEMTRADA REMS to prescribe, dispense, or administer LEMTRADA.

Enter ZIP Code

REMS Certified Prescriber
 REMS Certified Healthcare Facility

[Find](#)

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[Learn about Prescriber Enrollment](#)

Complete Enrollment in the LEMTRADA REMS

You must review the training materials in order to complete your enrollment in the LEMTRADA REMS. Please call *MS One to One*® at 1-855-676-6326 to speak with a Genzyme representative.

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[Learn about Prescriber Enrollment](#)

Complete Enrollment in the LEMTRADA REMS

You have not completed your review and submission of the LEMTRADA REMS Prescriber Enrollment Form.

Complete your enrollment and gain access to the online tools and resources available to help you manage your LEMTRADA patients.

[Review Enrollment Form](#)

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[Learn about Prescriber Enrollment](#) ▶

LEMTRADA REMS Enrollment Complete



You have successfully completed online enrollment in the LEMTRADA REMS. You will receive a confirmation email with your LEMTRADA REMS Identification Number. A Genzyme representative will also follow up with you to schedule your appointment to verify enrollment.

Once your enrollment is verified, you gain access to the online tools and resources available to help you manage your LEMTRADA patients.

Review Training Materials Again

Find a REMS Certified Prescriber or Healthcare Facility



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About REMS

LEMTRADA REMS Training

Full Prescribing Information (1 of 27) Total Training Screens: 1 of 41

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use LEMTRADA safely and effectively. See full prescribing information for LEMTRADA.

LEMTRADA® (alemtuzumab) injection, for intravenous use
Initial U.S. Approval: 2001

WARNING: AUTOIMMUNITY, INFUSION REACTIONS, STROKE, AND MALIGNANCIES

See full prescribing information for complete boxed warning.

- LEMTRADA causes serious, sometimes fatal, autoimmune conditions such as immune thrombocytopenia and anti-glomerular basement membrane disease. Monitor complete blood counts with differential, serum creatinine levels, and urinalysis with urine counts at periodic intervals for 48 months after the last dose. (5.1)
- LEMTRADA causes serious and life-threatening infusion reactions. LEMTRADA must be administered in a setting with appropriate equipment and personnel to manage anaphylaxis or serious infusion reactions. Monitor patients for two hours after each infusion. Make patients aware that serious infusion reactions can also occur after the 2-hour monitoring period. (5.2)
- Serious and life-threatening stroke has been reported within 3 days of LEMTRADA administration. Instruct patients to seek immediate medical attention if symptoms of stroke occur. (5.3)
- LEMTRADA may cause an increased risk of malignancies, including thyroid cancer, melanoma, and lymphoproliferative disorders. Perform baseline and yearly skin exams. (5.4)
- LEMTRADA is available only through a restricted distribution program. (5.5)

RECENT MAJOR CHANGES

Boxed Warning	11/2018
Indications and Usage (1)	8/2018
Dosage and Administration (2.3)	11/2018
Dosage and Administration (2.6)	01/2019
Warnings and Precautions (5.1, 5.3, 5.7)	11/2018
Warnings and Precautions (5.2)	xx/2019
Warnings and Precautions, Autoimmune Hepatitis (5.10)	01/2019
Warnings and Precautions, Infections (5.11)	01/2019
Warnings and Precautions, PML (5.12)	07/2019

INDICATIONS AND USAGE

- LEMTRADA is a CD52-directed cytolytic monoclonal antibody indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include relapsing-remitting disease and active secondary progressive disease, in adults. Because of its safety profile, the use of LEMTRADA should generally be reserved for patients who have had an inadequate response to two or more drugs indicated for the treatment of MS [see Warnings and Precautions (5.7)]. (1)

Limitations of Use

LEMTRADA is not recommended for use in patients with clinically isolated syndrome (CIS) because of its safety profile [see Warnings and Precautions (5.7)]. (3)

DOSAGE AND ADMINISTRATION

- Baseline laboratory tests are required prior to treatment. (2.1)
- Administer LEMTRADA by intravenous infusion over 4 hours for 2 or more treatment courses:

Initial treatment of 2 courses:

- First course: 12 mg/day on 5 consecutive days. (2.3)
- Second course: 12 mg/day on 3 consecutive days 12 months after first treatment course. (2.3)

Subsequent treatment courses of 12 mg per day on 3 consecutive days (36-mg total dose) may be administered, as needed, at least 12 months after the last dose of any prior treatment course. (2.3)

- Premedicate with corticosteroids prior to LEMTRADA infusion for the first 3 days of each treatment course. (2.2)
- Administer antiviral agents for herpetic prophylaxis starting on the first day of LEMTRADA dosing and continuing for a minimum of two months after completion of LEMTRADA dosing or until CD4+ lymphocyte count is more than 200 cells per microliter, whichever occurs later. (2.2)
- Must be diluted prior to administration. (2.4)

DOSAGE FORMS AND STRENGTHS

Injection: 12 mg/1.2 mL (10 mg/mL) in a single-dose vial. (3)

CONTRAINDICATIONS

Infection with Human Immunodeficiency Virus (4)

WARNINGS AND PRECAUTIONS

- **Immune Thrombocytopenia:** Obtain complete blood counts (CBCs) with differential prior to initiation of treatment and at monthly intervals thereafter until 48 months after the last infusion. (5.6)
- **Glomerular Nephropathies:** Obtain serum creatinine levels, urinalysis with cell counts and urine protein to creatinine ratio prior to initiation of treatment. Monitor serum creatinine levels and urinalysis with cell counts at monthly intervals thereafter until 48 months after the last infusion. (5.7)
- **Thyroid Disorders:** Obtain thyroid function tests prior to initiation of treatment and every 3 months until 48 months after the last infusion. (5.8)
- **Other Autoimmune Conditions:** Monitor CBCs monthly until 48 months after the last infusion. (2.6, 5.9)
- **Autoimmune Hepatitis:** If signs of hepatic dysfunction occur, promptly measure serum transaminases and total bilirubin and interrupt or discontinue treatment. (5.10)
- **Infectious:** Consider delaying initiation of LEMTRADA in patients with active infections until the infection is fully controlled. Do not administer live viral vaccines following a course of LEMTRADA. (5.11)
- **Progressive Multifocal Leukoencephalopathy (PML):** Withhold LEMTRADA at the first sign or symptom suggestive of PML. (5.12)

ADVERSE REACTIONS

Most common adverse reactions (incidence ≥10% and > interferon beta-1a): rash, headache, pyrexia, nasopharyngitis, nausea, urinary tract infection, fatigue, insomnia, upper respiratory tract infection, herpes viral infection, urticaria, pruritus, thyroid gland disorders, fungal infection, arthralgia, pain in extremity, back pain, diarrhea, sinusitis, oropharyngeal pain, paresthesia, dizziness, abdominal pain, flushing, and vomiting. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Genzyme Corporation at 1-800-745-4447 (option 2) or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

USE IN SPECIFIC POPULATIONS

Pregnancy: May cause fetal harm. (8.1)

Women of childbearing potential should use effective contraception during and for 4 months after a course of treatment with LEMTRADA. (8.3)

See 17 for PATIENT COUNSELING INFORMATION and Medication Guide.

Revised: XX/2019

[Next](#) (1 of 41)

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VV-REG-0833078 0.1

Reference ID: 4512344

PRESCRIBER DASHBOARD PAGES



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REMS Certified Prescriber & Healthcare Facility Locator

About REMS

LEMTRADA REMS Support Tools

View individual profiles of your LEMTRADA patients and the healthcare facilities they visit. These resources can help you learn more about patients' authorization status, infusion records, and monitoring program activity.

LEMTRADA REMS Support Tools

You have 10 LEMTRADA patients ?

!	Last Name	First Name	Year of Birth	REMS ID	Last Infusion	Checklist	REMS Status
	Doe	John	1980	129684352	3/16/2013	View Checklist	Authorized
	Doe	John	1980	129684352	3/16/2013	View Checklist	Authorized
	Doe	John	1980	129684352	3/16/2013	View Checklist	Authorized
	Doe	John	1980	129684352	3/16/2012	View Checklist	Authorized
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About REMS

!
You have 4 patient alerts!
▼

You have **4 patients** who have authorization requirements.

- **1 patient** is overdue for authorization by the LEMTRADA REMS Patient Status Form.
- **3 patients** need to be authorized by the LEMTRADA Patient Status Form in 1 month.

[Manage my patient alert email preferences](#)

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	Doe	John	1980	129684352	3/16/2013	View Checklist	Authorized	
!	Doe	John	1980	129684352	—	—	Patient Status Form	Baseline Lab Form
	Doe	John	1980	129684352	3/16/2013	View Checklist	Authorized	
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[Manage my patient alert email preferences](#)

You have 10 LEMTRADA patients ?

Search, sort, and navigate information about your patients below. Click on a form to complete authorization requirements.

	Last Name	First Name				Checklist	REMS Status
	Doe	John				View Checklist	Authorized
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!	Doe	John	1980	129684352	3/16/2012	View Checklist	Baseline Lab Form
	Doe	John	1980	129684352	3/16/2013	View Checklist	Authorized
!	Doe	John	1980	129684352	—	—	Patient Status Form Baseline Lab Form
	Doe	John	1980	129684352	3/16/2013	View Checklist	Authorized
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The screenshot shows a web browser window displaying the LEMTRADA REMS Prescriber Dashboard. The page header includes the LEMTRADA logo, navigation links for Prescribing Information and Medication Guide, and a user greeting: "Welcome, Adam Smith! My Profile | Log Out". A main navigation bar contains links for Home, Forms & FAQs, REMS Certified Prescriber & Healthcare Facility Locator, and About REMS.

A prominent alert box at the top left states: "You have 4 patient alerts!". Below this, a list of alerts is visible:

- You have 4 patients who have authorization requirements.
- 1 patient is overdue for authorization by the LEMTRADA REMS Patient Status Form
- 3 patients need to be enrolled in the LEMTRADA REMS program.

 A "Manage my patient" link is also present.

The main content area features a "LEMTRADA REMS Support Tools" section with a description: "View individual profiles of your LEMTRADA patients and the healthcare facilities they visit. These resources can help you learn more about patients' authorization status, infusion records, and monitoring program activity." A "LEM Support Tools" button is located below this section.

A modal dialog box is overlaid on the page with the following text:

You Are Now Entering the LEMTRADA REMS Online Support Center

The information you are about to view is to support you in managing your LEMTRADA patients, and is not a mandatory part of the LEMTRADA REMS.

Buttons for "Go Back" and "Continue" are provided at the bottom of the dialog.

Below the dialog, a table lists 10 LEMTRADA patients. The table columns include Last Name, First Name, DOB, SSN, Enrollment Date, and REMS Status. Some rows include "View Checklist" links and buttons for "Patient Status Form" and "Baseline Lab Form".

At the bottom of the page, a disclaimer states: "This site is provided as a resource for prescribers and is not intended as medical advice. Information on the site is updated periodically (approximately every 12 hours)."

Contact information is provided: "If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6326, Mon - Fri, 8:30 am - 8:00 pm ET."

The footer contains links for Privacy Policy, Terms and Conditions, and Contact Us, along with copyright information for Sanofi Genzyme (©2013) and the company logo.

The screenshot displays a web browser window with the LEMTRADA REMS Prescriber Dashboard. The page title is "My Profile". At the top, there is a navigation bar with links for "Prescribing Information" and "Medication Guide". Below this, a welcome message reads "Welcome, Adam Smith!" followed by "My Profile" and "Log Out" links. A purple navigation bar contains buttons for "Home", "Forms & FAQs", "REMS Certified Prescriber & Healthcare Facility Locator", and "About REMS".

The main content area is titled "My Profile" and features a dark grey header with the name "Adam Smith". Below the name, the user's REMS ID is listed as "(REMS ID 123456)". Contact information includes the address "7776 Golden Blossom Run, Zook, IL 62056-3630", office phone "xxx-xxx-xxxx", mobile phone "xxx-xxx-xxxx", and fax "xxx-xxx-xxxx". A note states: "If any of your information is incorrect or has recently changed, please call 1-855-676-6326, Mon - Fri, 8:30 am - 8:00 pm ET, so we can make the appropriate updates."

The "Manage My Alert Preferences" section allows users to customize email alerts. It includes a "Patient Alert Emails" section with three radio button options: "Please provide a monthly summary of alerts", "Please provide a weekly summary of alerts" (which is selected), and "Please do not provide a summary of alerts". A green "Update Alert Preferences" button is located below these options.

The "Change Your Password" section provides instructions: "Passwords must be at least 8 characters in length and contain a minimum of 3 out of the following: A number, an upper-case letter, a lower-case letter, a special character (e.g. !, ", #, \$, etc.)". It contains three input fields for "Current Password", "New Password", and "Confirm Password", followed by a green "Change Password" button.

A disclaimer at the bottom of the main content area reads: "This site is provided as a resource for prescribers and is not intended as medical advice. Information on the site is updated periodically (approximately every 12 hours)."

Below the disclaimer, a call to action states: "If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6326, Mon - Fri, 8:30 am - 8:00 pm ET."

The footer contains links for "Privacy Policy", "Terms and Conditions", and "Contact Us". It also includes a disclaimer: "This site is intended for United States residents only." and copyright information: "©2019 Genzyme Corporation. All rights reserved." The footer also lists "Lemtrada, MS One to One, Sanofi and Genzyme registered in U.S. Patent and Trademark Office US.MS.LEM.14.10.013-v7 Last Updated 09/19" and the "SANOFI GENZYME" logo.

The screenshot shows a web browser window displaying the LEMTRADA REMS Prescriber Dashboard. The page features a purple header with the LEMTRADA logo and navigation links. The main content area is titled "My Profile" and displays the user's name, "Adam Smith", along with their REMS ID and contact information. Below this, there is a section for "Manage My Alert Preferences" with radio buttons for selecting the frequency of alert emails. A "Change Your Password" section follows, with input fields for current, new, and confirm passwords. The footer contains a disclaimer, contact information, and the Sanofi Genzyme logo.

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Prescribing Information Medication Guide

Welcome, Adam Smith! [My Profile](#) | [Log Out](#)

Home Forms & FAQs REMS Certified Prescriber & Healthcare Facility Locator About REMS

My Profile

Adam Smith

(REMS ID 123456)

7776 Golden Blossom Run
Zook, IL 62056-3630
Office Phone: xxx-xxx-xxxx
Mobile Phone: xxx-xxx-xxxx
Fax: xxx-xxx-xxxx

If any of your information is incorrect or has recently changed, please call **1-855-676-6326**, Mon – Fri, 8:30 am – 8:00 pm ET, so we can make the appropriate updates.

Manage My Alert Preferences

Customize how often you would like to receive emails about the status of your LEMTRADA patients. Please note that you will continue to receive important communications from Genzyme, if warranted.

FOLD

Patient Alert Emails

As part of the LEMTRADA REMS, you will automatically receive emails to update you on the status of your LEMTRADA patients. How often would you like to receive emails regarding patient alert summaries?

Please provide a monthly summary of alerts

Please provide a weekly summary of alerts

Please do not provide a summary of alerts

Update Alert Preferences

Change Your Password

Passwords must be at least 8 characters in length and contain a minimum of 3 out of the following: A number, an upper-case letter, a lower-case letter, a special character (e.g. !, ", #, \$, etc.)

Current Password

Please enter password.

New Password

Please enter a valid password.

Confirm Password

Please confirm new password.

Change Password

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Information on the site is updated periodically (approximately every 12 hours).

If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6326, Mon – Fri, 8:30 am – 8:00 pm ET.

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The screenshot shows a web browser window displaying the LEMTRADA REMS Prescriber Dashboard. The page header includes the LEMTRADA logo (alemantuzumab 12mg iv) and navigation links for Prescribing Information and Medication Guide. A user is logged in as Adam Smith, with links for My Profile and Log Out. A navigation bar contains Home, Forms & FAQs, REMS Certified Prescriber & Healthcare Facility Locator, and About REMS. The main content area is titled 'My Profile' and shows Adam Smith's profile with a REMS ID of 123456 and contact information. Below this is a 'Manage My Alert Preferences' section with a 'Patient Alert Emails' form where the user has selected 'Please provide a weekly summary of alerts'. The 'Change Your Password' section shows three password input fields with error messages: 'Password is incorrect', 'Password does not meet strength requirements', and 'Passwords do not match'. A 'Change Password' button is visible. A disclaimer states the site is not medical advice. A footer contains links for Privacy Policy, Terms and Conditions, and Contact Us, along with copyright information and the Sanofi Genzyme logo.

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Prescribing Information Medication Guide

Welcome, Adam Smith! [My Profile](#) | [Log Out](#)

Home Forms & FAQs REMS Certified Prescriber & Healthcare Facility Locator About REMS

My Profile

Adam Smith
(REMS ID 123456)
7776 Golden Blossom Run
Zook, IL 62056-3630
Office Phone: xxx-xxx-xxxx
Mobile Phone: xxx-xxx-xxxx
Fax: xxx-xxx-xxxx

If any of your information is incorrect or has recently changed, please call **1-855-676-6326**, Mon – Fri, 8:30 am – 8:00 pm ET, so we can make the appropriate updates.

Manage My Alert Preferences

Customize how often you would like to receive emails about the status of your LEMTRADA patients. Please note that you will continue to receive important communications from Genzyme, if warranted.

FOLD

Patient Alert Emails

As part of the LEMTRADA REMS, you will automatically receive emails to update you on the status of your LEMTRADA patients. How often would you like to receive emails regarding patient alert summaries?

Please provide a monthly summary of alerts

Please provide a weekly summary of alerts

Please do not provide a summary of alerts

[Update Alert Preferences](#)

Change Your Password

Passwords must be at least 8 characters in length and contain a minimum of 3 out of the following: A number, an upper-case letter, a lower-case letter, a special character (e.g. !, ", #, \$, etc.)

Current Password

Password is incorrect.

New Password

Password does not meet strength requirements.

Confirm Password

Passwords do not match.

[Change Password](#)

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Support for You

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Required LEMTRADA REMS Forms & Materials

Refer to these materials for information about the safe use of LEMTRADA through the LEMTRADA REMS.

- [Online](#) | [PDF](#) LEMTRADA REMS Program Overview
- [Online](#) | [PDF](#) LEMTRADA REMS Education Program for Prescribers
- [PDF](#) LEMTRADA REMS Prescriber Enrollment Form
- [Online](#) | [PDF](#) LEMTRADA REMS Patient Authorization and Baseline Lab Form
- [PDF](#) LEMTRADA REMS Patient Enrollment Form
- [PDF](#) LEMTRADA REMS Prescription Ordering Form
- [Online](#) | [PDF](#) LEMTRADA REMS Patient Status Form
- [PDF](#) What You Need to Know About LEMTRADA Treatment: A Patient Guide

Adobe® Reader® is required to view all of these PDFs. If you do not have it installed, [download it free here](#).

If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6326, Mon – Fri, 8:30 am – 8:00 pm ET.

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LEMTRADA REMS PATIENT STATUS FORM

This form must be completed every 6 months for each LEMTRADA patient under your care. Please complete this form 6 months after your patient's first infusion with LEMTRADA, and every 6 months thereafter, until 48 months after the patient's last infusion. Please complete the form and submit to Genzyme using the button below.

All fields are required.

PRESCRIBER INFORMATION	PATIENT INFORMATION
<p>First Name <input type="text" value="Prefilled Doctor's first name"/></p> <p>Last Name <input type="text" value="Prefilled Doctor's last name"/></p> <p>Office Phone Number <input type="text" value="Prefilled Doctor's phone number"/></p> <p>Address Line 1 <input type="text" value="Prefilled Doctor's address"/></p> <p>Address Line 2 <input type="text" value="Prefilled Doctor's address"/></p> <p>City <input type="text" value="Prefilled Doctor's city"/></p> <p>State <input type="text" value="Prefilled Doctor's state"/> ZIP Code <input type="text" value="Prefilled Doctor's ZIP Code"/></p>	<p>First Name <input type="text" value="Prefilled Patient's first name"/></p> <p>Last Name <input type="text" value="Prefilled Patient's last name"/></p> <p>Patient LEMTRADA REMS Identification Number <input type="text" value="Prefilled Patient's REMS ID"/></p> <p>Date of Birth (MM/DD/YYYY) <input type="text" value="Prefilled Patient's birthdate"/></p> <p>Date of Last LEMTRADA Infusion (MM/DD/YYYY) <input type="text" value="Prefilled Patient's last infusion"/></p>
<p style="text-align: center; color: #4a4a8a;">Is the above-named patient still under your care?</p> <p style="text-align: center;"> <input checked="" type="radio"/> Yes <input type="radio"/> No </p>	

IF YES, please complete the following information

The patient has completed the periodic monitoring within the last 6 months:
 Yes No

Since submitting the last LEMTRADA REMS Patient Status Form, has the patient been diagnosed with any of the following?

<p>Autoimmune conditions <input type="radio"/> Yes <input type="radio"/> No</p>	<p>Infusion reactions <input type="radio"/> Yes <input type="radio"/> No</p>
<p>Stroke <input type="radio"/> Yes <input type="radio"/> No</p>	<p>Malignancies <input type="radio"/> Yes <input type="radio"/> No</p>

This adverse event has already been reported to Genzyme (specify date of report):

Report all adverse events to Genzyme Medical Information at 1-800-745-4447 (option 2) or the FDA at 1-800-FDA-1088 (1-800-332-1088) or www.FDA.gov/medwatch

In signing this form, I acknowledge that I have reviewed *What You Need to Know About LEMTRADA Treatment: A Patient Guide* with this patient and counseled the patient about the serious risks associated with the use of LEMTRADA, and how to mitigate these risks through periodic monitoring.

By providing my e-signature, I attest that I have filled out the Patient Status Form to the best of my knowledge. I understand that my e-signature will be used to verify my enrollment in the LEMTRADA REMS.

By entering my name, NPI number, and password, I confirm that I have completed the LEMTRADA REMS training and that I will comply with the requirements of the program.

Full Name

National Provider Identification (NPI) Number

Password

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VV-REG-0833078 0.1

Reference ID: 4512344



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LEMTRADA REMS PATIENT STATUS FORM

This form must be completed every 6 months for each LEMTRADA patient under your care. Please complete this form 6 months after your patient's first infusion with LEMTRADA, and every 6 months thereafter, until 48 months after the patient's last infusion. Please complete the form and submit to Genzyme using the button below.

All fields are required.

PRESCRIBER INFORMATION	PATIENT INFORMATION
<p>First Name</p> <input type="text" value="Prefilled Doctor's first name"/> <small style="color: red;">Please enter first name.</small>	<p>First Name</p> <input type="text" value="Prefilled Patient's first name"/> <small style="color: red;">Please enter first name.</small>
<p>Last Name</p> <input type="text" value="Prefilled Doctor's last name"/> <small style="color: red;">Please enter last name.</small>	<p>Last Name</p> <input type="text" value="Prefilled Patient's last name"/> <small style="color: red;">Please enter last name.</small>
<p>Office Phone Number</p> <input type="text" value="Prefilled Doctor's phone number"/> <small style="color: red;">Please enter a 10-digit phone number.</small>	<p>Patient LEMTRADA REMS Identification Number</p> <input type="text" value="Prefilled Patient's REMS ID"/> <small style="color: red;">Please enter LEMTRADA REMS identification number.</small>
<p>Address Line 1</p> <input type="text" value="Prefilled Doctor's address"/> <small style="color: red;">Please enter address.</small>	<p>Date of Birth (MM/DD/YYYY)</p> <input type="text" value="Prefilled Patient's birthdate"/> <small style="color: red;">Please enter valid date of birth.</small>
<p>Address Line 2</p> <input type="text" value="Prefilled Doctor's address"/> <small style="color: red;">Please enter address.</small>	<p>Date of Last LEMTRADA Infusion (MM/DD/YYYY)</p> <input type="text" value="Prefilled Patient's last infusion"/> <small style="color: red;">Please enter valid date.</small>
<p>City</p> <input type="text" value="Prefilled Doctor's city"/> <small style="color: red;">Please enter city.</small>	<div style="border: 1px solid #ccc; padding: 5px;"> <p style="text-align: center; color: #4a4a8a; font-weight: bold;">Is the above-named patient still under your care?</p> <p style="text-align: center;"> <input checked="" type="radio"/> Yes <input type="radio"/> No </p> <small style="color: red;">Please make a selection.</small> </div>
<p>State</p> <input type="text" value="Prefilled Doctor's state"/> <small style="color: red;">Please select state.</small>	
<p>ZIP Code</p> <input type="text" value="Prefilled Doctor's ZIP Code"/> <small style="color: red;">Please enter a 5-digit ZIP Code.</small>	

IF YES, please complete the following information

The patient has completed the periodic monitoring within the last 6 months:

Yes No Please make a selection.

Since submitting the last LEMTRADA REMS Patient Status Form, has the patient been diagnosed with any of the following?

<p>Autoimmune conditions</p> <p style="text-align: center;"> <input type="radio"/> Yes <input type="radio"/> No <small style="color: red;">Please make a selection.</small> </p>	<p>Infusion reactions</p> <p style="text-align: center;"> <input type="radio"/> Yes <input type="radio"/> No <small style="color: red;">Please make a selection.</small> </p>
<p>Stroke</p> <p style="text-align: center;"> <input type="radio"/> Yes <input type="radio"/> No <small style="color: red;">Please make a selection.</small> </p>	<p>Malignancies</p> <p style="text-align: center;"> <input type="radio"/> Yes <input type="radio"/> No <small style="color: red;">Please make a selection.</small> </p>

This adverse event has already been reported to Genzyme (specify date of report):

Report all adverse events to Genzyme Medical Information at 1-800-745-4447 (option 2) or the FDA at 1-800-FDA-1088 (1-800-332-1088) or www.FDA.gov/medwatch

In signing this form, I acknowledge that I have reviewed *What You Need to Know About LEMTRADA Treatment: A Patient Guide* with this patient and counseled the patient about the serious risks associated with the use of LEMTRADA, and how to mitigate these risks through periodic monitoring.

By providing my e-signature, I attest that I have filled out the Patient Status Form to the best of my knowledge. I understand that my e-signature will be used to verify my enrollment in the LEMTRADA REMS.

By entering my name, NPI number, and password, I confirm that I have completed the LEMTRADA REMS training and that I will comply with the requirements of the program.

Full Name

Please enter your name.

National Provider Identification (NPI) Number

Please enter a valid NPI number.

Password

Please enter your password.

Cancel
Submit

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VV-REG-0833078 0.1

Reference ID: 4512344



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LEMTRADA REMS PATIENT STATUS FORM

This form must be completed every 6 months for each LEMTRADA patient under your care. Please complete this form 6 months after your patient's first infusion with LEMTRADA, and every 6 months thereafter, until 48 months after the patient's last infusion. Please complete the form and submit to Genzyme using the button below.

All fields are required.

PRESCRIBER INFORMATION	PATIENT INFORMATION
<p>First Name <input type="text" value="Prefilled Doctor's first name"/></p> <p>Last Name <input type="text" value="Prefilled Doctor's last name"/></p> <p>Office Phone Number <input type="text" value="Prefilled Doctor's phone number"/></p> <p>Address Line 1 <input type="text" value="Prefilled Doctor's address"/></p> <p>Address Line 2 <input type="text" value="Prefilled Doctor's address"/></p> <p>City <input type="text" value="Prefilled Doctor's city"/></p> <p>State <input type="text" value="Prefilled Doctor's state"/> ZIP Code <input type="text" value="Prefilled Doctor's ZIP Code"/></p>	<p>First Name <input type="text" value="Prefilled Patient's first name"/></p> <p>Last Name <input type="text" value="Prefilled Patient's last name"/></p> <p>Patient LEMTRADA REMS Identification Number <input type="text" value="Prefilled Patient's REMS ID"/></p> <p>Date of Birth (MM/DD/YYYY) <input type="text" value="Prefilled Patient's birthdate"/></p> <p>Date of Last LEMTRADA Infusion (MM/DD/YYYY) <input type="text" value="Prefilled Patient's last infusion"/></p>
<p>Is the above-named patient still under your care?</p> <p><input type="radio"/> Yes <input checked="" type="radio"/> No</p>	

IF NO, please indicate the name of the healthcare provider now responsible for this patient's care.

Healthcare Provider's Name

- OR -

Healthcare Provider's Phone Number

Patient's Current Healthcare Provider Is Unknown

In signing this form, I acknowledge that I have reviewed *What You Need to Know About LEMTRADA Treatment: A Patient Guide* with this patient and counseled the patient about the serious risks associated with the use of LEMTRADA, and how to mitigate these risks through periodic monitoring.

By providing my e-signature, I attest that I have filled out the Patient Status Form to the best of my knowledge. I understand that my e-signature will be used to verify my enrollment in the LEMTRADA REMS.

By entering my name, NPI number, and password, I confirm that I have completed the LEMTRADA REMS training and that I will comply with the requirements of the program.

Full Name

National Provider Identification (NPI) Number

Password

[Cancel](#) [Submit](#)

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LEMTRADA REMS PATIENT STATUS FORM

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All fields are required.

PRESCRIBER INFORMATION

First Name

Please enter first name.

Last Name

Please enter last name.

Office Phone Number

Please enter a 10-digit phone number.

Address Line 1

Please enter address.

Address Line 2

City

Please enter city.

State **ZIP Code**

Please select state. Please enter a 5-digit ZIP Code.

PATIENT INFORMATION

First Name

Please enter first name.

Last Name

Please enter last name.

Patient LEMTRADA REMS Identification Number

Please enter LEMTRADA REMS identification number.

Date of Birth (MM/DD/YYYY)

Please enter valid date of birth.

Date of Last LEMTRADA Infusion (MM/DD/YYYY)

Please enter valid date.

Is the above-named patient still under your care?

Yes No

Please make a selection.

IF NO, please indicate the name of the healthcare provider now responsible for this patient's care.

Healthcare Provider's Name

Please enter healthcare provider's name.

- OR -

Patient's Current Healthcare Provider Is Unknown

Healthcare Provider's Phone Number

Please enter healthcare provider's 10-digit phone number.

In signing this form, I acknowledge that I have reviewed *What You Need to Know About LEMTRADA Treatment: A Patient Guide* with this patient and counseled the patient about the serious risks associated with the use of LEMTRADA, and how to mitigate these risks through periodic monitoring.

By providing my e-signature, I attest that I have filled out the Patient Status Form to the best of my knowledge. I understand that my e-signature will be used to verify my enrollment in the LEMTRADA REMS.

By entering my name, NPI number, and password, I confirm that I have completed the LEMTRADA REMS training and that I will comply with the requirements of the program.

Full Name

Please enter your name.

National Provider Identification (NPI) Number

Please enter a valid NPI number.

Password

Please enter your password.

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SANOFI GENZYME 

VV-REG-0833078 0.1

Reference ID: 4512344

The screenshot shows a web browser window displaying the LEMTRADA REMS Patient Status Form Confirmation page. The browser's address bar shows a Google search engine. The page header includes the LEMTRADA logo (alemntuzumab^{12mg} iv) and navigation links for Prescribing Information and Medication Guide. A user is logged in as Adam Smith, with links for My Profile and Log Out. A navigation menu contains Home, Forms & FAQs, REMS Certified Prescriber & Healthcare Facility Locator, and About REMS. The main content area features a green heading: "LEMTRADA REMS Patient Status Form Complete." Below this, a message states: "Please allow 1-2 business days for the form to be processed. If you have questions about your form submission, please contact the LEMTRADA REMS at 1-855-676-6326, Mon - Fri, 8:30 am - 8:00 pm ET." A link is provided to "Download and print a copy of the LEMTRADA REMS Patient Status Form for your records." A green "Back" button is visible. A callout box with a dashed border says "If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6326, Mon - Fri, 8:30 am - 8:00 pm ET." The footer contains links for Privacy Policy, Terms and Conditions, and Contact Us. It also includes a disclaimer: "This site is intended for United States residents only." Copyright information: "©2019 Genzyme Corporation. All rights reserved." and registration details: "Lemtrada, MS One to One, Sanofi and Genzyme registered in U.S. Patent and Trademark Office US.MS.LEM.14.10.013-v7 Last Updated 09/19". The Sanofi Genzyme logo is in the bottom right corner. A pink dashed line labeled "FOLD" is on the left side of the footer area.



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LEMTRADA REMS PATIENT AUTHORIZATION AND BASELINE LAB FORM

This form must be completed within 30 days prior to the first infusion date of each LEMTRADA patient's treatment course. Please complete the form and submit to Genzyme using the button below.

All fields are required.

PRESCRIBER INFORMATION

First Name

Last Name

Office Phone Number

Address Line 1

Address Line 2

City

State **ZIP Code**

Prescriber LEMTRADA REMS Identification Number

PATIENT INFORMATION

First Name

Last Name

Patient LEMTRADA REMS Identification Number

Date of Birth (MM/DD/YYYY)

PRESCRIPTION INFORMATION

Select one

Initial course (1 vial [12 mg/day]) X 5 consecutive days
Total number of vials ordered

Subsequent course (1 vial [12 mg/day]) X 3 consecutive days
Total number of vials ordered

AUTHORIZATION AND BASELINE LABS

Do you authorize LEMTRADA treatment for the above-referenced patient?
 Yes No

Do you attest that required baseline laboratory testing has been completed prior to LEMTRADA treatment and within 30 days of the patient's first infusion?
 Yes No

By providing my e-signature, I attest that I have filled out the Patient Authorization and Baseline Lab Form to the best of my knowledge. I understand that my e-signature will be used to verify my enrollment in the LEMTRADA REMS.

By entering my name, NPI number, and password, I confirm that I have completed the LEMTRADA REMS training and that I will comply with the requirements of the program.

Full Name

National Provider Identification (NPI) Number

Password

[Cancel](#)
Submit

This site is provided as a resource for prescribers and is not intended as medical advice. Information on the site is updated periodically (approximately every 12 hours).

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If you have questions about the LEMTRADA REMS or need help enrolling, call **1-855-676-6326**, Mon - Fri, 8:30 am - 8:00 pm ET.

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LEMTRADA
alemtuzumab^{12mg} iv

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LEMTRADA REMS PATIENT AUTHORIZATION AND BASELINE LAB FORM

This form must be completed within 30 days prior to the first infusion date of each LEMTRADA patient's treatment course. Please complete the form and submit to Genzyme using the button below.

All fields are required.

PRESCRIBER INFORMATION

First Name

Please enter first name.

Last Name

Please enter last name.

Office Phone Number

Please enter a 10-digit phone number.

Address Line 1

Address Line 2

Please enter address.

City

Please enter city.

State **ZIP Code**

Please select a state. *Please enter a 5-digit ZIP Code.*

Prescriber LEMTRADA REMS Identification Number

Please enter LEMTRADA REMS Identification Number.

PATIENT INFORMATION

First Name

Please enter first name.

Last Name

Please enter last name.

Patient LEMTRADA REMS Identification Number

Please enter LEMTRADA REMS identification number.

Date of Birth (MM/DD/YYYY)

Please enter valid date of birth.

PRESCRIPTION INFORMATION

Select one
Please make a selection.

Initial course (1 vial [12 mg/day]) X 5 consecutive days
Total number of vials ordered:
Please enter number of vials.

Subsequent course (1 vial [12 mg/day]) X 3 consecutive days
Total number of vials ordered:
Please enter number of vials.

AUTHORIZATION AND BASELINE LABS

Do you authorize LEMTRADA treatment for the above-referenced patient?

Yes No
Please make a selection.

Do you attest that required baseline laboratory testing has been completed prior to LEMTRADA treatment and within 30 days of the patient's first infusion?

Yes No
Please make a selection.

By providing my e-signature, I attest that I have filled out the Patient Authorization and Baseline Lab Form to the best of my knowledge. I understand that my e-signature will be used to verify my enrollment in the LEMTRADA REMS.

By entering my name, NPI number, and password, I confirm that I have completed the LEMTRADA REMS training and that I will comply with the requirements of the program.

Full Name

Please enter your name.

National Provider Identification (NPI) Number

Please enter a valid NPI number.

Password

Please enter a valid password.

Cancel
Submit

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The screenshot shows a web browser window displaying the LEMTRADA REMS Patient Authorization and Baseline Lab Form Complete page. The browser's address bar shows a Google search engine. The page header includes the LEMTRADA logo (alemtozumab^{12mg} iv) and navigation links for Prescribing Information and Medication Guide. A user is logged in as Adam Smith, with links for My Profile and Log Out. A navigation menu contains Home, Forms & FAQs, REMS Certified Prescriber & Healthcare Facility Locator, and About REMS. The main content area features a green heading: "LEMTRADA REMS Patient Authorization and Baseline Lab Form Complete." Below this, a message states: "Please allow 1-2 business days for the form to be processed. If you have questions about your form submission, please contact the LEMTRADA REMS at 1-855-676-6326, Mon - Fri, 8:30 am - 8:00 pm ET." A link is provided to "Download and print a copy of the LEMTRADA REMS Patient Authorization and Baseline Lab Form for your records." A green "Back" button is visible. A call to action states: "If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6326, Mon - Fri, 8:30 am - 8:00 pm ET." The footer contains links for Privacy Policy, Terms and Conditions, and Contact Us. It also includes a disclaimer: "This site is intended for United States residents only." Copyright information: "©2019 Genzyme Corporation. All rights reserved." and "Lemtrada, MS One to One, Sanofi and Genzyme registered in U.S. Patent and Trademark Office US.MS.LEM.14.10.013-v7 Last Updated 09/19". The Sanofi Genzyme logo is in the bottom right corner. A pink dashed line labeled "FOLD" is on the left side of the footer area.

LEMTRADA
alemtuzumab^{12mg}_{iv}

Prescribing Information Medication Guide

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Support for You

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Frequently Asked Questions

Use the following FAQs to answer your questions about the LEMTRADA REMS. If you cannot find an answer to your question, or if you have additional questions, contact a LEMTRADA REMS Specialist at **1-855-676-6326**, Mon – Fri, 8:30 am – 8:00 pm.

[Expand](#)

1. How do I add a patient to this website?

This site displays information about patients enrolled in the LEMTRADA REMS. REMS certified prescribers can enroll new patients in the LEMTRADA REMS by submitting a completed LEMTRADA Patient Enrollment Form to Genzyme. A PDF of the LEMTRADA Patient Enrollment Form is available in the [Forms & FAQs](#) section. Once patients are enrolled in the program, their information will be available.

Please contact the LEMTRADA REMS at 1-855-676-6326 if you have questions about the enrollment process or if an enrolled patient's information is missing or incorrect.

2. How can a healthcare facility be added to this portal? ▶

3. How can I find an infusion center for my patients? ▶

4. What is the LEMTRADA REMS Patient Authorization and Baseline Lab Form? ▶

5. What is the LEMTRADA REMS Patient Status Form? ▶

6. Why do I have an alert that my patient is "Not REMS Authorized"? ▶

7. What are Patient Alerts and how do I view them? ▶

8. How can I change the frequency of Patient Alert emails? ▶

9. How can I access my profile? ▶

10. How can I update contact information on this site? ▶

11. How do I reset my password? ▶

If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6326, Mon – Fri, 8:30 am – 8:00 pm ET.

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Frequently Asked Questions

Use the following FAQs to answer your questions about the LEMTRADA REMS. If you cannot find an answer to your question, or if you have additional questions, contact a LEMTRADA REMS Specialist at **1-855-676-6326**, Mon – Fri, 8:30 am – 8:00 pm. [Collapse](#)

- 1. How do I add a patient to this website?**

This site displays information about patients enrolled in the LEMTRADA REMS. REMS certified prescribers can enroll new patients in the LEMTRADA REMS by submitting a completed LEMTRADA Patient Enrollment Form to Genzyme. A PDF of the LEMTRADA Patient Enrollment Form is available in the [Forms & FAQs](#) section. Once patients are enrolled in the program, their information will be available.

Please contact the LEMTRADA REMS at 1-855-676-6326 if you have questions about the enrollment process or if an enrolled patient's information is missing or incorrect.
- 2. How can a healthcare facility be added to this portal?**

An authorized representative of the healthcare facility must register with the LEMTRADA REMS Training Center. After registration, the representative must review the *LEMTRADA REMS Education Program for Healthcare Facilities*, complete the online module, complete and sign the LEMTRADA REMS Healthcare Facility Enrollment Form, and implement the necessary staff training and processes.

For further information, contact a LEMTRADA REMS Specialist at 1-855-676-6326.
- 3. How can I find an infusion center for my patients?**

Use the [REMS Certified Prescriber & Healthcare Facility Locator](#) to find infusion centers and healthcare facilities for your patients. You can search by state, address, or ZIP Code to find a center that is certified by the LEMTRADA REMS to dispense/administer LEMTRADA. You can also contact the LEMTRADA REMS at 1-855-676-6326 to speak with a LEMTRADA REMS Specialist.
- 4. What is the LEMTRADA REMS Patient Authorization and Baseline Lab Form?**

The LEMTRADA REMS Patient Authorization and Baseline Lab Form is a **mandatory form** that must be filled out within 30 days prior to the first infusion date of each LEMTRADA patient's treatment course. The form can be found in the [Forms](#) section.
- 5. What is the LEMTRADA REMS Patient Status Form?**

The LEMTRADA REMS Patient Status Form is a **mandatory form** that must be filled out every 6 months after a patient's first infusion with LEMTRADA, and until 48 months after a patient's final infusion. The form can be found in the [Forms](#) section.
- 6. Why do I have an alert that my patient is "Not REMS Authorized"?**

Alerts are generated when patients are overdue for authorization by the LEMTRADA REMS Patient Authorization Form and/or the LEMTRADA REMS Patient Status Form. Authorization forms that have not been received by the LEMTRADA REMS are available for submission next to the patient's name.

For more information about why your patient is "Not REMS Authorized," click the link to the [LEMTRADA REMS Support](#) tools to view the individual Patient Profile page.
- 7. What are Patient Alerts and how do I view them?**

Patient Alerts notify prescribers when a patient is behind on their authorization requirements. You can view a summarized version of all of your Patient Alerts from any page by clicking the [My Patients](#) tab. To see alerts for a specific patient, click the link to the LEMTRADA REMS Support Tools to view the individual's Patient Profile page.
- 8. How can I change the frequency of Patient Alert emails?**

To change the frequency of Patient Alert emails, first click [My Profile](#) in the navigation bar. Under the "Manage My Alert Preferences" section, you may choose the new frequency you would like. To complete the change, click the "Update Alert Preferences" button.
- 9. How can I access my profile?**

You can access your profile from any page by clicking on [My Profile](#) in the top right corner of the site.
- 10. How can I update contact information on this site?**

To update your contact information, contact the LEMTRADA REMS at 1-855-676-6326.
- 11. How do I reset my password?**

To change your password, visit the [My Profile](#) page and find the "Change Password" section. Enter and confirm a new password. To complete the change, click the "Change Password" button.

If you have questions about the LEMTRADA REMS or need help enrolling, call **1-855-676-6326, Mon – Fri, 8:30 am – 8:00 pm ET.**

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REMS Certified Prescriber & Healthcare Facility Locator

About REMS

REMS Certified Prescriber & Healthcare Facility Locator

Search for prescribers or healthcare facilities that are enrolled and certified in the LEMTRADA REMS and able to prescribe or dispense/administer LEMTRADA.

Please enter street address, city, state, or ZIP Code you would like to search for.

New Search: 🔍

REMS Certified Prescribers

REMS Certified Healthcare Facilities

📍

Certified Prescriber Name

Address

P: (888) - 888 - 8888

📍

Certified Prescriber Name

Address

P: (888) - 888 - 8888

📍

Certified Prescriber Name

Address

P: (888) - 888 - 8888

📍

Certified Prescriber Name

Address

P: (888) - 888 - 8888

📍

Certified Prescriber Name

Address

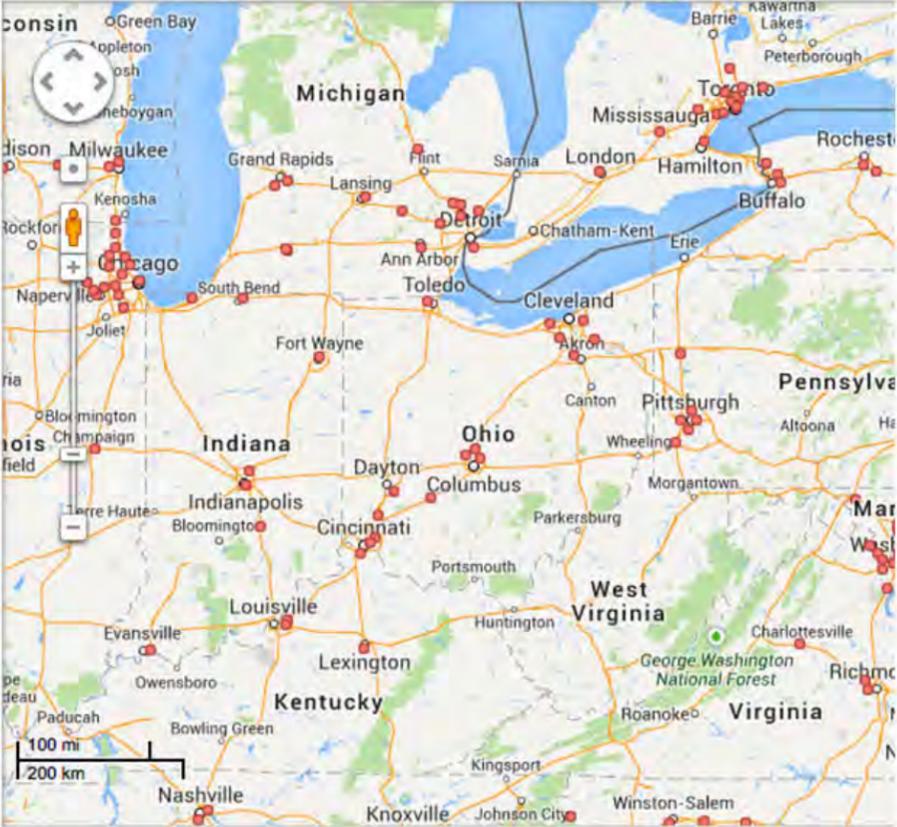
P: (888) - 888 - 8888

📍

Certified Prescriber Name

Address

P: (888) - 888 - 8888



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VV-REG-0833078 0.1

Reference ID: 4512344



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Search for prescribers or healthcare facilities that are enrolled and certified in the LEMTRADA REMS and able to prescribe or dispense/administer LEMTRADA.

Please enter street address, city, state, or ZIP Code you would like to search for.

New Search: 🔍

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REMS Certified Healthcare Facilities

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Certified Center Name

Address

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Certified Center Name

Address

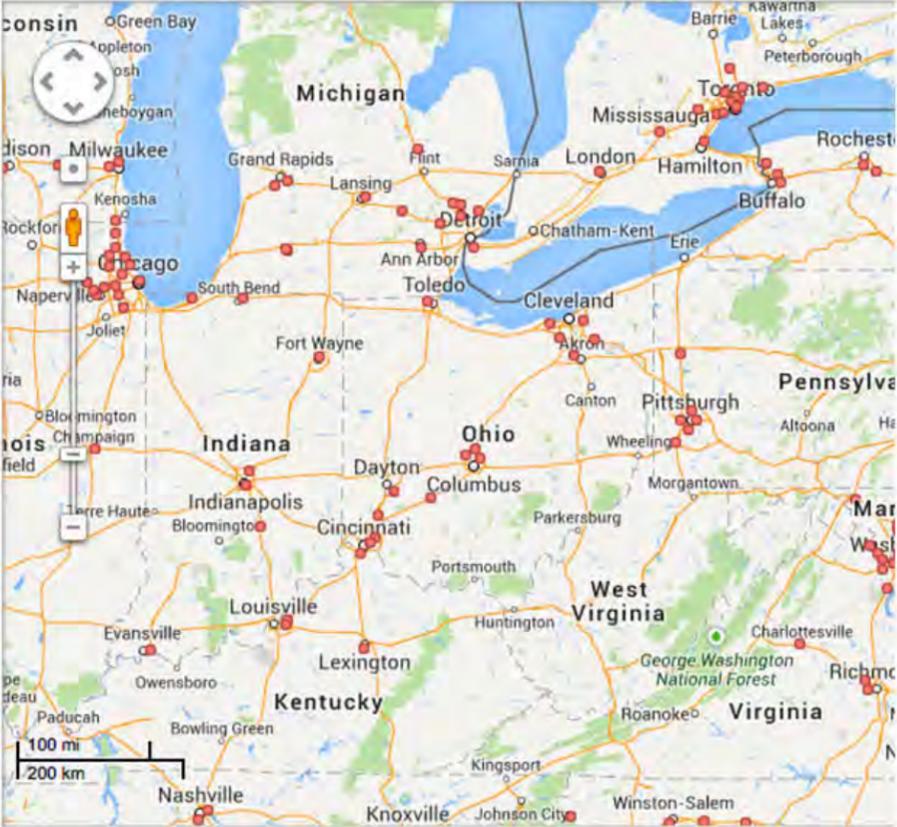
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Certified Center Name

Address

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VV-REG-0833078 0.1

Reference ID: 4512344

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LEMTRADA REMS Requirements

Welcome to the LEMTRADA REMS. Here you can:

- Retrain and enroll in the LEMTRADA REMS when indicated by a Genzyme representative
- Manage and/or track your progress through the LEMTRADA REMS training and enrollment
- Download materials to help inform your patients about treatment with LEMTRADA

LEMTRADA REMS Activity

Steps	Activity	Progress
1.	Account Registration	Completed
2.	Training	Completed
3.	Assessment Test	Completed
4.	Enrollment Form Submission	Completed
5.	Enrollment Processed	Completed
6.	REMS ID Assigned	Completed

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or need help enrolling, call 1-855-676-6326, Mon - Fri, 8:30 am - 8:00 pm ET.**

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LEMTRADA REMS Prescriber Enrollment

- Prescribers must be enrolled in the LEMTRADA REMS to be able to prescribe LEMTRADA for patients with relapsing forms of multiple sclerosis (MS). Because of its safety profile, the use of LEMTRADA should generally be reserved for patients who have had an inadequate response to two or more drugs indicated for the treatment of MS
- Note that your healthcare facility must be separately enrolled in the LEMTRADA REMS to dispense/administer LEMTRADA

To enroll in the program, prescribers must complete the following steps:

1	Register with the LEMTRADA REMS Online Training Center
2	Review the <i>LEMTRADA REMS Education Program for Prescribers</i> , including the LEMTRADA REMS Program Overview and the LEMTRADA full Prescribing Information in the online module on this site
3	Successfully complete the 8-question Knowledge Assessment at the end of the module
4	After completing the assessment, complete and sign the LEMTRADA REMS Prescriber Enrollment Form

[Review Online Training](#)

If you have questions about the LEMTRADA REMS or need help enrolling, call **1-855-676-6326**, Mon - Fri, 8:30 am - 8:00 pm ET.

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The screenshot shows a web browser window displaying the LEMTRADA REMS desktop interface. The browser's address bar shows a Google search. The website header includes the LEMTRADA logo (alemtezumab^{12mg} iv) and navigation links for Prescribing Information and Medication Guide. A user is logged in as Adam Smith, with links for My Profile and Log Out. A main navigation bar contains Home, Forms & FAQs, REMS Certified Prescriber & Healthcare Facility Locator, and About REMS. Below this, there are buttons for REMS Activity, Prescriber Enrollment, and Patient Guides. The Patient Guides section is active, displaying the heading "LEMTRADA Patient Guides" and a list of two PDF guides: "What You Need to Know About LEMTRADA Treatment: A Patient Guide" and "What You Need to Know About LEMTRADA Treatment and Infusion Reactions: A Patient Guide". A note indicates that Adobe Reader is required to view these PDFs. A call to action banner states: "If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6326, Mon - Fri, 8:30 am - 8:00 pm ET." The footer contains links for Privacy Policy, Terms and Conditions, and Contact Us, along with copyright information for Genzyme Corporation (©2019) and the Sanofi Genzyme logo.

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BOTH PRESCRIBER AND HEALTHCARE FACILITY USER

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[Prescriber](#) [Healthcare Facility](#)

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LEMTRADA REMS Support Tools

View individual profiles of your LEMTRADA patients and the healthcare facilities they visit. These resources can help you learn more about patients' authorization status, infusion records, and monitoring program activity.

[LEMTRADA REMS Support Tools](#)

You have 10 LEMTRADA patients ?

ⓘ	Last Name	First Name	Year of Birth	REMS ID	Last Infusion	Checklist	REMS Status
	Doe	John	1980	129684352	3/16/2013	View Checklist	Authorized
	Doe	John	1980	129684352	3/16/2013	View Checklist	Authorized
	Doe	John	1980	129684352	3/16/2013	View Checklist	Authorized
	Doe	John	1980	129684352	3/16/2012	View Checklist	Authorized
	Doe	John	1980	129684352	3/16/2013	View Checklist	Authorized
	Doe	John	1980	129684352	3/16/2013	View Checklist	Authorized
	Doe	John	1980	129684352	3/16/2013	View Checklist	Authorized
	Doe	John	1980	129684352	3/16/2013	View Checklist	Authorized
	Doe	John	1980	129684352	3/16/2013	View Checklist	Authorized
	Doe	John	1980	129684352	3/16/2013	View Checklist	Authorized
	Doe	John	1980	129684352	3/16/2013	View Checklist	Authorized

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LEMTRADA REMS DESKTOP

REMS Certified Healthcare Facility Pages Only

HEALTHCARE FACILITY TRAINING PAGES

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Registration for LEMTRADA REMS Training

To register as a new user, select whether you would like to complete enrollment as a prescriber, or authorized representative of a healthcare facility or pharmacy. Enrolled prescribers who would like to enroll their affiliated healthcare facility should also register as a new healthcare facility user.

Select the option which best describes you:

I am a Prescriber

I represent a Healthcare Facility

I represent a Pharmacy

[Already Registered? Log In](#)

If you are already certified by the LEMTRADA REMS, or have recently completed training and have not received your log-in information, please call **1-855-676-6326**.

[Cancel](#) [Next](#)

If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6326, Mon – Fri, 8:30 am – 8:00 pm ET.

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Registration Training Enrollment

Healthcare Facility Registration for LEMTRADA REMS Training

To complete your training for the LEMTRADA REMS, please set up an account.

*Required

Email Address*

Create a Password* Passwords must be at least 8 characters in length and contain a minimum of 3 out of the following: A number, an upper-case letter, a lower-case letter, a special character (e.g. !, ", #, \$, etc.)

Confirm Password*

Name of Institution or Healthcare Facility*

National Provider Identification (NPI) Number*

Infusion Facility Address*

City*

State* ZIP Code*

Phone Number*

Fax Number*

Site Affiliation*

Ship-to is the same as facility address

Ship-to Address*

City*

State* ZIP Code*

Name of Authorized Healthcare Facility Representative

First Name*

Last Name*

Title*

*By checking this box, you indicate you will comply with our [terms and conditions](#).

[Cancel](#)

If you have questions about the LEMTRADA REMS or need help enrolling, call **1-855-676-6326**, Mon - Fri, 8:30 am - 8:00 pm ET.

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LEMTRADA
alemtuzumab^{12mg}iv

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Registration | Training | Enrollment

Healthcare Facility Registration for LEMTRADA REMS Training

To complete your training for the LEMTRADA REMS, please set up an account.

*Required

Email Address*

Create a Password* Passwords must be at least 8 characters in length and contain a minimum of 3 out of the following: A number, an upper-case letter, a lower-case letter, a special character (e.g. !, *, #, \$, etc.)

Confirm Password*

Name of Institution or Healthcare Facility*

National Provider Identification (NPI) Number*

Infusion Facility Address*

City*

State* ZIP Code*

- ✓ Select
- Alabama
- Alaska
- American Samoa
- Arizona
- Arkansas
- California
- Colorado
- Connecticut
- Delaware
- District of Columbia
- Florida
- Georgia
- Guam
- Hawaii
- Idaho
- Illinois
- Indiana
- Iowa
- Kansas
- Kentucky
- Louisiana
- Maine
- Maryland
- Massachusetts
- Michigan
- Minnesota
- Mississippi
- Missouri
- Montana
- Nebraska
- Nevada
- New Hampshire
- New Jersey
- New Mexico
- New York
- North Carolina
- North Dakota
- Northern Mariana Islands
- Ohio
- Oklahoma
- Oregon
- Pennsylvania
- Puerto Rico
- Rhode Island
- South Carolina
- South Dakota
- Tennessee
- Texas
- Utah
- Vermont
- Virginia
- Virgin Islands
- Washington
- West Virginia
- Wisconsin
- Wyoming

Register

the LEMTRADA REMS
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Confirm Password*

Name of Institution or Healthcare Facility*

National Provider Identification (NPI) Number*

Infusion Facility Address*

City*

State* **ZIP Code***

Phone Number*

Fax Number*

Site Affiliation*

- Select
- Academic
- Government
- Ambulatory/Free Standing
- Hospital Based
- Private Practice (in office)

City*

State* **ZIP Code***

Name of Authorized Healthcare Facility Representative

First Name*

Last Name*

Title*

*By checking this box, you indicate you will comply with our [terms and conditions](#).

[Cancel](#)

Register

If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6326, Mon - Fri, 8:30 am - 8:00 pm ET.

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Confirm Password*

Name of Institution or Healthcare Facility*

National Provider Identification (NPI) Number*

Infusion Facility Address*

City*

State* ZIP Code*

Phone Number*

Fax Number*

Site Affiliation*

I am not a facility address

- ✓ Select
- Alabama
- Alaska
- American Samoa
- Arizona
- Arkansas
- California
- Colorado
- Connecticut
- Delaware
- District of Columbia
- Florida
- Georgia
- Guam
- Hawaii
- Idaho
- Illinois
- Indiana
- Iowa
- Kansas
- Kentucky
- Louisiana
- Maine
- Maryland
- Massachusetts
- Michigan
- Minnesota
- Mississippi
- Missouri
- Montana
- Nebraska
- Nevada
- New Hampshire
- New Jersey
- New Mexico
- New York
- North Carolina
- North Dakota
- Northern Mariana Islands
- Ohio
- Oklahoma
- Oregon
- Pennsylvania
- Puerto Rico
- Rhode Island
- South Carolina
- South Dakota
- Tennessee
- Texas
- Utah
- Vermont
- Virginia
- Virgin Islands
- Washington
- West Virginia
- Wisconsin
- Wyoming

Healthcare Facility Representative

I agree with the terms and conditions.

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Get the LEMTRADA REMS

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Name of Institution or Healthcare Facility*

Please enter name of institution or healthcare facility.

National Provider Identification (NPI) Number*

Please enter a valid NPI number.

Infusion Facility Address*

Please enter infusion facility address.

City*

Please enter city.

State* **ZIP Code***

Please select a state.

Please enter a 5-digit ZIP Code.

Phone Number*

Please enter a 10-digit phone number.

Fax Number*

Please enter a 10-digit fax number.

Site Affiliation*

Please select a site affiliation.

Ship-to is the same as facility address

Ship-to Address*

Please enter ship-to address.

City*

Please enter city.

State* **ZIP Code***

Please select a state.

Please enter a 5-digit ZIP Code.

Name of Authorized Healthcare Facility Representative

First Name*

Please enter first name.

Last Name*

Please enter last name.

Title*

Please enter title.

*By checking this box, you indicate you will comply with our [terms and conditions](#).

Terms and conditions not selected.

[Cancel](#)

If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6326, Mon – Fri, 8:30 am – 8:00 pm ET.

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Healthcare Facility Registration for LEMTRADA REMS Training

To complete your training for the LEMTRADA REMS, please set up an account.

*Required

Email Address*

Please enter a valid email address.

Create a Password*

Password does not meet strength requirements.

Confirm Password*

Please confirm password.

Name of Institution or Healthcare Facility*

Please enter name of institution or healthcare facility.

National Provider Identification (NPI) Number*

Please enter a valid NPI number.

Infusion Facility Address*

Please enter infusion facility address.

City*

Please enter city.

State* ZIP Code*

Please select a state. Please enter a 5-digit ZIP Code.

Phone Number*

Please enter a 10-digit phone number.

Fax Number*

Please enter a 10-digit fax number.

Site Affiliation*

Please select a site affiliation.

Ship-to is the same as facility address

Ship-to Address*

Please enter ship-to address.

City*

Please enter city.

State* ZIP Code*

Please select a state. Please enter a 5-digit ZIP Code.

Name of Authorized Healthcare Facility Representative

First Name*

Please enter first name.

Last Name*

Please enter last name.

Title*

Please enter title.

*By checking this box, you indicate you will comply with our terms and conditions.
Terms and conditions not selected.

[Cancel](#)

If you have questions about the LEMTRADA REMS
 or need help enrolling, call 1-855-676-6326, Mon - Fri, 8:30 am - 8:00 pm ET.

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The screenshot shows a web browser window displaying the LEMTRADA REMS registration confirmation page. The browser's address bar shows a Google search engine. The page features the LEMTRADA logo (alemtezumab 12mg iv) and navigation links for Prescribing Information and Medication Guide. A user is logged in as Robert Clark, with links for My Profile and Log Out. A navigation bar includes Home, Forms & FAQs, REMS Certified Prescriber & Healthcare Facility Locator, and About REMS. A progress bar highlights the current step: Registration, followed by Training and Enrollment. The main content area says "Thank You for Registering" and provides instructions to complete training. A green button labeled "Review Training Materials" is present. A contact number (1-855-676-6326) is provided for questions. The footer contains legal disclaimers, copyright information (©2019 Genzyme Corporation), and the Sanofi Genzyme logo. A pink dashed line labeled "FOLD" is visible on the left side of the page.



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Welcome, Robert Clark! [My Profile](#) | [Log Out](#)

- Home
- Forms & FAQs
- REMS Certified Prescriber & Healthcare Facility Locator
- About REMS



Thank You for Registering

Your account is your personal online center for LEMTRADA REMS training, resources, and support. Please complete training to become certified to dispense/administer LEMTRADA.

[Review Training Materials](#)

If you have questions about the LEMTRADA REMS or need help enrolling, call **1-855-676-6326**, Mon – Fri, 8:30 am – 8:00 pm ET.

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Registration Training Enrollment

LEMTRADA REMS Online Training Module

If inactive on the training module for 20 minutes, you will be automatically logged off the LEMTRADA website and lose your training progress.

- Please review the LEMTRADA REMS Training Materials, including the LEMTRADA REMS Program Overview, and the *LEMTRADA REMS Education Program for Healthcare Facilities*. You may review the material at your own pace and go back to any point of the presentation at your discretion
- After reviewing the material in the module, you will be asked to review and sign the LEMTRADA REMS Healthcare Facility Enrollment Form to complete your enrollment
- All staff at your site who will be involved with the dispensing/administration of LEMTRADA must be trained on the information in the module and adhere to the requirements of the LEMTRADA REMS

Online training will take approximately 20 minutes. Please allow enough time to view the entire module. You will be automatically logged out after 20 minutes of inactivity and your training progress may be lost.

Continue

If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6326, Mon – Fri, 8:30 am – 8:00 pm ET.

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The screenshot shows a web browser window displaying the LEMTRADA REMS website. At the top left is the LEMTRADA logo (alemftuzumab^{12mg} iv). To the right are links for 'Prescribing Information' and 'Medication Guide'. Below these is a welcome message 'Welcome, Robert Clark!' and links for 'My Profile' and 'Log Out'. A navigation bar contains 'Home', 'Forms & FAQs', 'REMS Certified Prescriber & Healthcare Facility Locator', and 'About REMS'. A modal dialog box is centered on the screen with the title 'Are You Sure You Want to Exit?' and the message 'You will lose your session and will need to begin again.' It has two buttons: 'Yes' and 'No, Continue'. Below the dialog box, a green 'Continue' button is visible. The page also contains a 'FOLD' label on the left, a paragraph about online training duration, and a footer with contact information and the Sanofi Genzyme logo.

The screenshot shows a web browser window displaying the LEMTRADA REMS desktop interface. The browser's address bar shows a Google search. The page header includes the LEMTRADA logo (alemfuzumab 12mg iv) and navigation links for Prescribing Information and Medication Guide. A user is logged in as Robert Clark, with links for My Profile and Log Out. A dark purple navigation bar contains links for Home, Forms & FAQs, REMS Certified Prescriber & Healthcare Facility Locator, and About REMS. A white modal window titled "Inactivity Alert" is centered on the screen, indicating 15 minutes of inactivity and a 15-minute session expiration. A green "Continue" button is visible in the modal. The background content is partially obscured but includes a "FOLD" label on the left and a "Continue" button below the modal. At the bottom, there is a contact number (1-855-676-6326) and the Sanofi Genzyme logo.

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alemfuzumab 12mg iv

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Inactivity Alert

There has been no activity for 15 minutes. You will be logged out if there is no activity before your session expires.

00:04:39

[Continue](#)

FOLD

[Continue](#)

If you have questions about the LEMTRADA REMS or need help enrolling, call **1-855-676-6326**, Mon - Fri, 8:30 am - 8:00 pm ET.

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The screenshot shows a web browser window displaying the LEMTRADA REMS website. The browser's address bar shows a Google search engine. The website header features the LEMTRADA logo (alemfuzumab 12mg iv) and navigation links for Prescribing Information, Medication Guide, Register, and Log In. A dark purple navigation bar contains links for Home, Prescriber Enrollment, Healthcare Facility Enrollment, Pharmacy Enrollment, Patient Guides, Forms & Resources, and REMS Certified Prescriber & Healthcare Facility Locator. The main content area displays a 'Your Session Has Timed Out' message with a 'Restart' button. Below this, a message provides contact information for questions or enrollment help. The footer includes links for Privacy Policy, Terms and Conditions, and Contact Us, along with a disclaimer, copyright notice, and the Sanofi Genzyme logo.

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Your Session Has Timed Out

There has been no activity for 20 minutes, so you have been timed out.

[Restart](#)

If you have questions about the LEMTRADA REMS or need help enrolling, call **1-855-676-6326**, Mon - Fri, 8:30 am - 8:00 pm ET.

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LEMTRADA REMS Training

LEMTRADA REMS Program Overview (1 of 2)
Total Training Screens: 1 of 10



LEMTRADA REMS PROGRAM OVERVIEW

What Is the LEMTRADA REMS (Risk Evaluation and Mitigation Strategy)?

A REMS is a strategy to manage known or potential risks associated with a drug. It is required by the FDA to ensure that the benefits of the drug outweigh its risks. Due to serious risks of autoimmune conditions, infusion reactions, stroke and malignancies, LEMTRADA[®] (alemtuzumab) is only available through a restricted program called the LEMTRADA REMS.

LEMTRADA REMS Requirements

- **Prescribers** must be enrolled in the LEMTRADA REMS to be able to prescribe LEMTRADA.
- **Pharmacies** must be enrolled in the LEMTRADA REMS to be able to dispense LEMTRADA.
- **Healthcare Facilities** must be enrolled in the LEMTRADA REMS to be able to dispense and administer LEMTRADA.
- **Patients** must be enrolled and authorized in the LEMTRADA REMS in order to receive LEMTRADA.

PRESCRIBER ENROLLMENT INSTRUCTIONS

1. Complete the training program, which includes reviewing the following:
 - LEMTRADA Prescribing Information
 - LEMTRADA REMS Program Overview
 - LEMTRADA REMS Education Program for Prescribers
2. Successfully complete the 8-question LEMTRADA REMS Knowledge Assessment.
3. Enroll in the program by completing a LEMTRADA REMS Prescriber Enrollment Form.
4. Submit the completed and signed Forms to the LEMTRADA REMS.

PHARMACY ENROLLMENT INSTRUCTIONS

1. An authorized representative must enroll on behalf of the pharmacy by reviewing the LEMTRADA REMS Program Overview and completing the LEMTRADA REMS Pharmacy Enrollment Form, which acknowledges that the pharmacy agrees to follow the procedures outlined in the LEMTRADA REMS, including:
 - All relevant staff at the pharmacy who will be involved with the dispensing of LEMTRADA must be educated and trained.
 - The pharmacy will verify that a LEMTRADA REMS Prescription Ordering Form is received for each prescription.
 - The pharmacy will verify that prescribers and healthcare facilities are certified and patients are authorized to receive LEMTRADA prior to dispensing LEMTRADA.
 - Enrollment in the LEMTRADA REMS must be renewed every 2 years from initial enrollment.
2. Submit the completed and signed LEMTRADA REMS Pharmacy Enrollment Form to the LEMTRADA REMS.

Next

(1 of 10)

If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6326, Mon – Fri, 8:30 am – 8:00 pm ET.

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VV-REG-0833078 0.1

Reference ID: 4512344



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LEMTRADA REMS Training

LEMTRADA REMS Program Overview (2 of 2)
Total Training Screens: 2 of 10

HEALTHCARE FACILITY ENROLLMENT INSTRUCTIONS

1. An authorized representative must enroll on behalf of the healthcare facility by reviewing the *LEMTRADA REMS Education Program for Healthcare Facilities* and completing the LEMTRADA REMS Healthcare Facility Enrollment Form, which acknowledges that the healthcare facility agrees to follow the procedures outlined in the LEMTRADA REMS, including:
 - All staff at the facility who will be involved with the dispensing and administration of LEMTRADA must be trained, and a written record of all staff REMS trainings must be kept on file.
 - The healthcare facility will verify that prescribers are certified and patients are authorized to receive LEMTRADA prior to dispensing or administering LEMTRADA.
 - The healthcare facility will provide a copy of *What You Need to Know About LEMTRADA Treatment and Infusion Reactions: A Patient Guide* to the patient on the first day of each treatment course when LEMTRADA is dispensed.
 - The healthcare facility will complete a LEMTRADA REMS Infusion Checklist for each patient at the conclusion of each treatment course and submit it to the LEMTRADA REMS within 5 business days.
 - Enrollment in the LEMTRADA REMS must be renewed every 2 years from initial enrollment.
2. Submit the completed and signed LEMTRADA REMS Healthcare Facility Enrollment Form to the LEMTRADA REMS.

PATIENT ENROLLMENT INSTRUCTIONS

1. Complete the LEMTRADA REMS Patient Enrollment Form, which contains information to be completed by both the prescriber and the patient.
2. Provide a copy of *What You Need to Know About LEMTRADA Treatment: A Patient Guide* and a LEMTRADA Patient Safety Information Card to each patient who will receive LEMTRADA. You must use *What You Need to Know About LEMTRADA Treatment: A Patient Guide* to counsel your patients on the serious risks and REMS requirements with the use of LEMTRADA.
3. Submit the completed and signed LEMTRADA REMS Patient Enrollment Form to the LEMTRADA REMS.
4. Provide the patient with a copy of the LEMTRADA REMS Patient Enrollment Form and keep a copy in the patient's medical record.

Where to Find REMS Information and Resources
To enroll in the LEMTRADA REMS, call 1-855-676-6326. For information related to enrollment in the LEMTRADA REMS, call 1-855-676-6326 or visit www.LemtradaREMS.com

Indication and Usage
LEMTRADA is indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include relapsing-remitting disease and active secondary progressive disease, in adults. Because of its safety profile, the use of LEMTRADA should generally be reserved for patients who have had an inadequate response to two or more drugs indicated for the treatment of MS.

Limitations of Use:
LEMTRADA is not recommended for use in patients with clinically isolated syndrome (CIS) because of its safety profile. The Prescribing Information includes a **BOXED WARNING** for LEMTRADA.
Please see accompanying Prescribing Information for complete safety information, including **BOXED WARNING**.

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VV-REG-0833078 0.1

Reference ID: 4512344

The screenshot shows a web browser window displaying the LEMTRADA REMS Training page. The browser's address bar shows a Google search. The page header includes the LEMTRADA logo (alemfuzumab 12mg iv) and navigation links for Prescribing Information and Medication Guide. A user is logged in as Robert Clark, with links for My Profile and Log Out. A main navigation bar contains Home, Forms & FAQs, REMS Certified Prescriber & Healthcare Facility Locator, and About REMS. A progress bar shows Registration, Training (current), and Enrollment. The main content area is titled 'LEMTRADA REMS Training' and 'LEMTRADA REMS Education Program for Healthcare Facilities (1 of 8)'. A large graphic features the title 'LEMTRADA REMS Education Program for Healthcare Facilities' and a list of topics: LEMTRADA REMS requirements, serious risks, and proper administration. Navigation buttons for Previous, Next, and (3 of 10) are visible. A contact number is provided for questions. The footer contains Privacy Policy, Terms and Conditions, Contact Us, copyright information, and the Sanofi Genzyme logo.

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LEMTRADA REMS Training
LEMTRADA REMS Education Program for Healthcare Facilities (1 of 8) Total Training Screens: 3 of 10

For Healthcare Facilities

LEMTRADA REMS Education Program for Healthcare Facilities

This Educational Piece Includes Information About:

- The LEMTRADA REMS requirements to implement in your healthcare facility
- Serious risks of autoimmune conditions, infusion reactions, stroke and malignancies
- Proper administration of LEMTRADA[®] (alemfuzumab)

LEMTRADA[®]
alemfuzumab^{12mg} iv

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If you have questions about the LEMTRADA REMS or need help enrolling, call **1-855-676-6326**, Mon - Fri, 8:30 am - 8:00 pm ET.

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LEMTRADA REMS Education Program for Healthcare Facilities (2 of 8) Total Training Screens: 4 of 10

STEPS FOR HEALTHCARE FACILITY CERTIFICATION

What Is the LEMTRADA REMS (Risk Evaluation and Mitigation Strategy)?

A REMS is a strategy to manage known or potential risks associated with a drug and is required by the FDA to ensure that the benefits of the drug outweigh its risks. LEMTRADA is only available under a restricted program called the LEMTRADA REMS because of the risks of infusion reactions, autoimmune conditions, stroke and malignancies. The *LEMTRADA REMS Education Program for Healthcare Facilities* is designed to educate and train healthcare facilities' authorized representatives on the serious risks associated with LEMTRADA, the LEMTRADA REMS requirements, and how to properly administer LEMTRADA.

- **Prescribers** must be enrolled in the LEMTRADA REMS to be able to prescribe LEMTRADA.
- **Pharmacies** must be enrolled in the LEMTRADA REMS to be able to dispense LEMTRADA.
- **Healthcare Facilities** must be enrolled in the LEMTRADA REMS to be able to dispense and administer LEMTRADA.
- **Patients** must be certified and authorized in the LEMTRADA REMS in order to receive LEMTRADA.

#	Step
1	Designate an authorized representative.
2	Review the <i>LEMTRADA REMS Education Program for Healthcare Facilities</i> , including the Prescribing Information.
3	Complete and sign the LEMTRADA REMS Healthcare Facility Enrollment Form. This enrollment must be renewed every 2 years.
4	Implement the necessary staff training and processes to comply with the LEMTRADA REMS requirements.

The *LEMTRADA REMS Education Program for Healthcare Facilities*, LEMTRADA REMS Healthcare Facility Enrollment Form, and other LEMTRADA REMS tools are available online at www.LemtradaREMS.com or by contacting the LEMTRADA REMS at 1-855-676-6326. To enroll in the LEMTRADA REMS, call 1-855-676-6326 or enroll online at www.LemtradaREMS.com.

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Who Can Be An Authorized Representative?

An authorized representative at the healthcare facility can be a:

- Pharmacist
- Director of infusion center
- Prescriber
- Nurse
- Or any responsible individual in the healthcare facility

Please check with your manager to ensure the appropriate person represents the healthcare facility and attests to the enrollment requirements as stated on the LEMTRADA REMS Healthcare Facility Enrollment Form.

- One representative needs to enroll per healthcare facility (the "authorized representative"). One authorized representative can manage more than one healthcare facility.
- Please note, there are no LEMTRADA REMS requirements for staff at a healthcare facility who will not be involved with dispensing or administering LEMTRADA.

Overview of Important Safety Information

INDICATION AND USAGE

LEMTRADA is indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include relapsing-remitting disease and active secondary progressive disease, in adults. Because of its safety profile, the use of LEMTRADA should generally be reserved for patients who have had an inadequate response to two or more drugs indicated for the treatment of MS.

Limitations of Use:

LEMTRADA is not recommended for use in patients with clinically isolated syndrome (CIS) because of its safety profile.

The Prescribing Information includes a **BOXED WARNING** for LEMTRADA.

Please see the Prescribing Information for complete safety information, including **BOXED WARNING**.

SERIOUS RISKS ASSOCIATED WITH LEMTRADA

Infusion Reactions

Most patients treated with LEMTRADA in controlled clinical trials in MS experienced infusion reactions during or after LEMTRADA administration. Some of these reactions were serious and life-threatening. In some patients, infusion reactions were reported more than 24 hours after LEMTRADA infusion. Serious reactions occurred in 3% of patients, including cases of anaphylaxis in 2 patients (including anaphylactic shock), angioedema, bronchospasm, hypotension, chest pain, bradycardia, tachycardia (including atrial fibrillation), transient neurologic symptoms, hypertension, headache, pyrexia, and rash. Other infusion reactions included nausea, urticaria, pruritus, insomnia, chills, flushing, fatigue, dyspnea, pulmonary infiltrates, dysgeusia, dyspepsia, dizziness, and pain. In clinical studies, 0.6% of patients with infusion reactions received epinephrine or atropine. Cases of pulmonary alveolar hemorrhage and myocardial ischemia have been reported with onset within 48 hours of LEMTRADA infusion.

Premedicate patients with high-dose corticosteroids (1000 mg of methylprednisolone or equivalent) immediately prior to LEMTRADA infusion for the first 3 days of each treatment course. Consider pretreatment with antihistamines and/or antipyretics prior to LEMTRADA administration. Infusion reactions may occur in patients despite pretreatment.



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Consider additional monitoring in patients with medical conditions which predispose them to cardiovascular or pulmonary compromise. Prescribers should alert patients that an infusion reaction could occur within 48 hours of infusion.

LEMTRADA can only be administered in certified healthcare settings that have on-site access to equipment and personnel trained to manage infusion reactions (including anaphylaxis and cardiac and respiratory emergencies).

Patients must be observed for infusion reactions during and for at least 2 hours after each LEMTRADA infusion. Consider longer periods of observation if clinically indicated. Vital signs should be monitored before and periodically during the infusion. If an infusion reaction occurs, appropriate symptomatic treatment should be provided as needed. If the infusion is not well tolerated, the duration of the infusion may be extended. If severe infusion reactions occur, immediate discontinuation of the infusion should be considered.

Stroke and Cervicocephalic Arterial Dissection

Stroke
In the postmarketing setting, serious and life-threatening stroke (including ischemic and hemorrhagic stroke) has been reported within 3 days of LEMTRADA administration, with most cases occurring within 1 day.

Cervicocephalic Arterial Dissection
In the postmarketing setting, cases of cervicocephalic (e.g., vertebral, carotid) arterial dissection involving multiple arteries have been reported within 3 days of LEMTRADA administration. Ischemic stroke was reported in one of these cases.
Educate patients on the symptoms of stroke and cervicocephalic (e.g., carotid, vertebral) arterial dissection. Instruct patients to seek immediate medical attention if symptoms of stroke or cervicocephalic arterial dissection occur.

Autoimmune Conditions

LEMTRADA has been associated with risk of autoimmune conditions, including immune thrombocytopenia, other cytopenias (including neutropenia, hemolytic anemia, and pancytopenia), thyroid disorders, and glomerular nephropathies, which may occur many years after treatment and may be serious or life-threatening. Early detection and prompt treatment can help prevent serious and potentially fatal outcomes associated with these events.
Please review the sections that follow to gain a better understanding of the risks of autoimmune conditions.

Immune Thrombocytopenia (ITP)
Immune thrombocytopenia (ITP) is an autoimmune disorder usually associated with anti-platelet antibodies. Platelet depletion reduces the ability of the blood to clot.
ITP was reported in 2% of patients in clinical trials in MS. ITP can be a serious condition leading to morbidity and mortality, and may occur several years after dosing. Prescribers are required to monitor all patients for ITP by obtaining complete blood counts with differential \leq 30 days prior to initiation of treatment and at monthly intervals thereafter until 48 months after the patient's last infusion of LEMTRADA. After this period of time, testing should be performed based on clinical findings suggestive of ITP. Patients should also be monitored for clinical symptoms of ITP. Symptoms of ITP could include (but are not limited to) easy bruising, petechiae, spontaneous mucocutaneous bleeding (epistaxis, hemoptysis), and heavier than normal or

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irregular menstrual bleeding. These clinical signs of ITP may be apparent before serious bleeding develops.

POTENTIAL CLINICAL PRESENTATIONS OF ITP

Note: These pictures are only a guide in order to show examples of bruises or petechiae. The patient may have a less severe type of bruise or petechiae than these pictures and still have ITP.



This is an example of a leg with petechiae.

Petechiae are small, scattered, "pinpoint" spots under the skin that are red, pink, or purple. Petechiae can occur anywhere on the patient's body, not just the legs.



This is an example of easy or excessive bruising. This could occur anywhere on the patient's body.



This is an example of purpura under the tongue. Purpura could occur on any mucous membrane including anywhere in the mouth (under the tongue, roof of the mouth, inner cheeks, tongue, gums).

Images © 2015 Genzyme Corporation.

Other Autoimmune Cytopenias (including neutropenia, hemolytic anemia, and pancytopenia)

Autoimmune cytopenias such as neutropenia, hemolytic anemia, and pancytopenia have been reported in clinical studies in MS. One LEMTRADA-treated patient with autoimmune pancytopenia died from sepsis. Symptoms of autoimmune hemolytic anemia may include weakness, chest pain, jaundice, dark urine, and tachycardia. Monthly CBC results will also be used to monitor for cytopenias. If a cytopenia is confirmed, appropriate medical intervention should be promptly initiated.

Glomerular Nephropathies

Glomerular nephropathies, including anti-glomerular basement membrane (anti-GBM) disease, have been reported after treatment with LEMTRADA in MS patients in clinical trials. In postmarketing cases, some LEMTRADA-treated patients with anti-GBM disease developed end-stage renal disease requiring dialysis or renal transplantation. Urgent evaluation and treatment is required, because early treatment can improve the preservation of renal function. Anti-GBM disease can be life-threatening if left untreated. Cases of anti-GBM disease have been diagnosed up to 40 months after the last dose of LEMTRADA. Clinical manifestations of nephropathy may include elevation in serum creatinine, hematuria, and/or proteinuria. While not observed in clinical trials, alveolar hemorrhage manifested as hemoptysis may occur with anti-GBM disease. Since patients may be asymptomatic, prescribers are required to monitor patients by obtaining serum creatinine levels, urinalysis with cell counts, and urine protein to creatinine ratio prior to

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initiation of treatment. Obtain serum creatinine levels and urinalysis with cell counts at monthly intervals thereafter until 48 months after the patient's last infusion. After this period of time, testing should be performed based on clinical findings suggestive of nephropathies.

Thyroid Disorders

Thyroid endocrine disorders, including autoimmune thyroid disorders occurred in 26.8% of LEMTRADA-treated patients in clinical studies (controlled and open-label extension). Newly diagnosed thyroid disorders occurred throughout the uncontrolled clinical study follow-up period, more than 7 years after the first LEMTRADA dose. Serious thyroid events occurred in 5.2% of patients. Prescribers are required to monitor all patients for thyroid disorders by obtaining thyroid function tests, such as thyroid-stimulating hormone (TSH) levels ≤ 30 days prior to the first infusion of LEMTRADA, and then every 3 months thereafter continuing until 48 months following the last infusion. Continue to test thyroid function after 48 months if clinically indicated. Prescribers should also monitor for signs and symptoms of thyroid disorders, which may include excessive sweating, unexplained weight loss, eye swelling, nervousness and fast heartbeat (hyperthyroidism), or unexplained weight gain, feeling cold, worsening tiredness, and newly occurring constipation (hypothyroidism).

Autoimmune Hepatitis

Autoimmune hepatitis causing clinically significant liver injury, including acute liver failure requiring transplant, has been reported in patients treated with LEMTRADA in the postmarketing setting. If a patient develops clinical signs, including unexplained liver enzyme elevations or symptoms suggestive of hepatic dysfunction (e.g., unexplained nausea, vomiting, abdominal pain, fatigue, anorexia, or jaundice and/or dark urine), prescribers should promptly measure serum transaminases and total bilirubin and interrupt or discontinue treatment with LEMTRADA, as appropriate.

Prior to starting treatment with LEMTRADA, prescribers are to obtain serum transaminases (ALT and AST) and total bilirubin levels. Prescribers should obtain transaminase levels and total bilirubin levels periodically until 48 months after the last dose.

Malignancies

LEMTRADA may increase the risk of thyroid cancer. Patients and prescribers should monitor for symptoms of thyroid cancer, including a new lump or swelling in the neck, pain in the front of the neck, persistent hoarseness or other voice changes, trouble swallowing or breathing, or a constant cough not due to an upper respiratory tract infection.

LEMTRADA may increase the risk of melanoma. Prescribers should perform baseline and yearly skin examinations to monitor for melanoma in patients receiving LEMTRADA. Cases of lymphoproliferative disorders and lymphoma have occurred in LEMTRADA-treated patients with MS.



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Strategies to Implement in Your Healthcare Facility to Mitigate Risk of Infusion Reactions

- Ensure the infusion site is equipped with the necessary equipment and personnel to manage infusion reactions (including anaphylaxis and cardiac and respiratory emergencies).
- Premedicate patients with high-dose corticosteroids (1000 mg of methylprednisolone or equivalent) immediately prior to LEMTRADA infusion for the first 3 days of each LEMTRADA treatment course. Consider pretreatment with antihistamines and/or antipyretics prior to LEMTRADA administration. Infusion reactions may occur despite pretreatment.
- Observe patients for infusion reactions during and for at least 2 hours after each LEMTRADA infusion.
- Consider longer periods of observation if clinically indicated. Monitor vital signs before and periodically during the infusion.
- Provide appropriate symptomatic treatment as needed if an infusion reaction occurs.
- Consider extending the duration of the infusion if the infusion is not well tolerated.
- Consider immediate discontinuation of the infusion if severe infusion reactions occur.
- Do not administer LEMTRADA outside of the authorized representative's certified healthcare facility.

Proper Storage and Administration

STORAGE OF LEMTRADA

- LEMTRADA is packaged in 12 mg/1.2 mL (10 mg/mL) single-dose vials.
- LEMTRADA vials should be stored at 2° to 8° C (36° to 46° F). Do not freeze or shake. Protect from light.

PRIOR TO EACH TREATMENT COURSE OF LEMTRADA

- Confirm prescriber is certified and patient is enrolled and authorized to receive LEMTRADA.
- Counsel each patient about the risk for infusion reactions.
- Provide the patient with *What You Need to Know About LEMTRADA Treatment and Infusion Reactions: A Patient Guide* prior to dispensing LEMTRADA.
- Administer corticosteroids immediately prior to LEMTRADA administration for the first 3 days of each treatment course.
- Ensure oral prophylaxis for herpes infection is available or has been prescribed to start on the first day of each treatment course. Consider pretreating patients with antihistamines and/or antipyretics prior to LEMTRADA administration as needed.
- Monitor vital signs before and periodically during the infusion.

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ADMINISTRATION OF LEMTRADA

1. Inspect vial for particulate matter/discoloration prior to use.
2. Withdraw 1.2 mL of LEMTRADA from the vial into a syringe using aseptic technique.
3. Inject into 100 mL sterile 0.9% Sodium Chloride, USP or 5% Dextrose in Water, USP. Gently invert the bag to mix the solution.
4. Cover IV solution bag to protect from light.
5. Administer 12 mg/day over approximately 4 hours.
6. Do not administer as IV push or bolus.
7. If infusion is not well tolerated, infusion duration may be extended.
8. Use the LEMTRADA diluted product within 8 hours after dilution. LEMTRADA diluted product may be stored at room temperature (15° to 25° C) or refrigerated conditions (2° to 8° C). Protect from light. Do not administer as IV push or bolus.
9. Monitor patient vital signs before and periodically during the infusion, and provide appropriate symptomatic treatment for infusion reactions as needed.
10. Monitor patients for at least 2 hours after each LEMTRADA infusion or longer if clinically indicated.

FOLLOWING THE CONCLUSION OF EACH LEMTRADA TREATMENT COURSE

- Complete a LEMTRADA REMS Infusion Checklist for each patient at the conclusion of each treatment course and fax (1-855-557-2478) to the LEMTRADA REMS or submit online at www.LemtradaREMS.com within 5 business days of the last infusion.
- Return unused vials of LEMTRADA to Genzyme within 50 days of receipt of the LEMTRADA REMS Patient Authorization and Baseline Lab Form.

Adverse Event Reporting

Report suspected adverse events to Genzyme Medical Information at 1-800-745-4447 (option 2) or to FDA at 1-800-FDA-1088 or www.FDA.gov/medwatch.

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The screenshot shows a web browser window displaying the LEMTRADA REMS Training Confirmation page. The browser's address bar shows a Google search engine. The page header includes the LEMTRADA logo (alemtezumab 12mg iv) and navigation links for Prescribing Information and Medication Guide. A user is logged in as Robert Clark, with links for My Profile and Log Out. A main navigation bar contains Home, Forms & FAQs, REMS Certified Prescriber & Healthcare Facility Locator, and About REMS. A progress bar shows Registration, Training (highlighted), and Enrollment. The main content area features the heading "LEMTRADA REMS Training Complete" and a message: "You have completed your review of the training materials." Below this is a green button labeled "Go To Enrollment". A contact information section states: "If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6326, Mon - Fri, 8:30 am - 8:00 pm ET." The footer contains links for Privacy Policy, Terms and Conditions, and Contact Us. It also includes a disclaimer: "This site is intended for United States residents only." and copyright information: "©2019 Genzyme Corporation. All rights reserved." The footer also mentions "Lemtrada, MS One to One, Sanofi and Genzyme registered in U.S. Patent and Trademark Office US.MS.LEM.14.10.013-v7 Last Updated 09/19" and the SANOFI GENZYME logo.

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LEMTRADA REMS HEALTHCARE FACILITY ENROLLMENT FORM

LEMTRADA is only available through the LEMTRADA REMS, a restricted distribution program. Only prescribers, pharmacies, healthcare facilities, and patients enrolled in the program are able to prescribe, dispense, administer, and receive LEMTRADA. An authorized representative of the healthcare facility must enroll the facility in the LEMTRADA REMS.

Please review the following information and submit to Genzyme by clicking the button below. Complete any missing information and correct any errors prior to submission.

All fields are required.

HEALTHCARE FACILITY INFORMATION

Name of Institution or Healthcare Facility	<input type="text" value="Extrophy Institute"/>
National Provider Identification (NPI) Number	<input type="text" value="0123456789"/>
Infusion Facility Address	<input type="text" value="43 Eleanor St"/> <input type="text"/>
City	<input type="text" value="Los Angeles"/>
State	<input type="text" value="California"/>
ZIP Code	<input type="text" value="90212"/>
Phone Number	<input type="text" value="555-555-5555"/>
Fax Number	<input type="text" value="555-555-5555"/>
Site Affiliation	<input type="text" value="Academic"/>
<input type="checkbox"/> Ship-to is the same as facility address	
Ship-to Address	<input type="text" value="43 Eleanor St"/> <input type="text"/>
City	<input type="text" value="Los Angeles"/>
State	<input type="text" value="California"/>
ZIP Code	<input type="text" value="90212"/>
Name of Authorized Healthcare Facility Representative	
First Name	<input type="text" value="John"/>
Last Name	<input type="text" value="Doe"/>
Email Address	<input type="text" value="jdoe@abc123.com"/>
Title	<input type="text" value="MD"/>

HEALTHCARE FACILITY AGREEMENT

I am the authorized representative designated by my healthcare facility to coordinate the activities of the LEMTRADA REMS. By signing this form, I agree to comply with the following requirements:

- I understand that my healthcare facility must be certified with the LEMTRADA REMS to receive or administer LEMTRADA.
- I have completed the review of the LEMTRADA REMS Education Program for Healthcare Facilities and the LEMTRADA REMS Program Overview.
- I understand that my healthcare facility must confirm that the patient is authorized to receive LEMTRADA by contacting the LEMTRADA REMS or verifying online at www.LemtradaREMS.com prior to initiation of each treatment course.
- I understand the risk of serious infusion reactions during and following the administration of LEMTRADA
- I understand the risk of stroke during and following the administration of LEMTRADA
- I understand the need to monitor patients for infusion reactions during and for at least 2 hours after each LEMTRADA infusion.
 - To include the monitoring of patient vital signs before the infusion and periodically during the infusion.
- I understand that my healthcare facility must be equipped with the necessary on-site equipment and personnel to manage anaphylaxis or serious infusion reactions.
- I understand that my healthcare facility must renew enrollment in the LEMTRADA REMS every 2 years from initial enrollment.
- This healthcare facility will establish procedures and protocols that are subject to audit, to help ensure compliance with the safe-use conditions required in the LEMTRADA REMS, including the following:
 - Ensure that a LEMTRADA REMS Prescription Ordering Form is received for each prescription.
 - Ensure that the prescriber is certified and the patient is enrolled and authorized by either calling the LEMTRADA REMS or verifying this information via the LEMTRADA REMS website prior to dispensing and administering LEMTRADA.
 - Ensure that the infusion site is equipped to manage infusion reactions.

- Ensure that the infusion site is equipped to manage infusion reactions.
- Ensure that LEMTRADA is not dispensed outside of the authorized representative's certified healthcare facility.
- Prior to the first day of each treatment course, counsel and provide a copy of *What You Need to Know About LEMTRADA Treatment and Infusion Reactions: A Patient Guide* to each patient to inform them about the risk of serious infusion reactions.
- Observe each patient administered LEMTRADA at my healthcare facility during and for at least 2 hours after each LEMTRADA infusion, in order to provide appropriate medical treatment in the event of serious infusion reactions following LEMTRADA infusion.
- For each patient, complete and return the LEMTRADA REMS Infusion Checklist to the LEMTRADA REMS within 5 business days from the patient's last infusion of LEMTRADA within a specific treatment course.
- Renew enrollment into the LEMTRADA REMS every 2 years from the initial enrollment.
- To make available to Genzyme documentation to verify understanding of, and adherence to, the requirements of the LEMTRADA REMS.
- To return to Genzyme any unused vials of LEMTRADA within 50 days from the submission date of the LEMTRADA REMS Patient Authorization and Baseline Lab Form.
- To ensure that a LEMTRADA REMS Patient Authorization and Baseline Lab Form is received for each prescription by either calling the LEMTRADA REMS or verifying this information via the LEMTRADA REMS website.
- To ensure that all non-prescribing HCPs who administer LEMTRADA in my healthcare setting are trained using the LEMTRADA REMS Program Overview and the LEMTRADA REMS Education Program for Healthcare Facilities, and a record regarding such training must be maintained.

I have verified that all details are correct.

By providing my e-signature, I acknowledge that I have completed the educational training required for LEMTRADA for healthcare facilities and I understand the benefits and risks of LEMTRADA. I acknowledge that all staff members from my site must be trained on the information in the module and adhere to the requirements of the LEMTRADA REMS. I understand that I must complete this LEMTRADA REMS Healthcare Facility Enrollment Form in order to complete this enrollment process.

By entering my name, NPI number, and password, I confirm that I have completed the LEMTRADA REMS training and that I will comply with the requirements of the program.

Full Name

NPI Number

Password

Cancel
Submit

If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6326, Mon - Fri, 8:30 am - 8:00 pm ET.

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Please review the following information and submit to Genzyme by clicking the button below. Complete any missing information and correct any errors prior to submission.

All fields are required.

HEALTHCARE FACILITY INFORMATION

Name of Institution or Healthcare Facility	<input type="text" value="Extrophy Institute"/>
National Provider Identification (NPI) Number	<input type="text" value="0123456789"/>
Infusion Facility Address	<input type="text" value="43 Eleanor St"/>
City	<input type="text" value="Los Angeles"/>
State	<div style="border: 1px solid gray; padding: 2px;"> <div style="display: flex; align-items: center;"> v Select <div style="flex-grow: 1;"> <ul style="list-style-type: none"> Alabama Alaska American Samoa Arizona Arkansas California Colorado Connecticut Delaware District of Columbia Florida Georgia Guam Hawaii Idaho Illinois Indiana Iowa Kansas Kentucky Louisiana Maine Maryland Massachusetts Michigan Minnesota Mississippi Missouri Montana Nebraska Nevada New Hampshire New Jersey New Mexico New York North Carolina North Dakota Northern Mariana Islands Ohio Oklahoma Oregon Pennsylvania Puerto Rico Rhode Island South Carolina South Dakota Tennessee Texas Utah Vermont Virginia Virgin Islands Washington West Virginia Wisconsin Wyoming </div> </div> </div>
ZIP Code	<input type="text"/>
Phone Number	<input type="text"/>
Fax Number	<input type="text"/>
Site Affiliation	<input type="text"/>
<input type="checkbox"/> Ship-to is the same as	
Ship-to Address	<input type="text"/>
City	<input type="text"/>
State	<input type="text"/>
ZIP Code	<input type="text"/>
Name of Authorized Health Professional	<input type="text"/>
First Name	<input type="text"/>
Last Name	<input type="text"/>
Email Address	<input type="text"/>
Title	<input type="text"/>

HEALTHCARE FACILITY

I am the authorized representative of this facility. I agree to comply with the following conditions:

- I understand that my healthcare facility is authorized to receive LEMTRADA REMS to receive LEMTRADA.
- I have completed the review of the LEMTRADA REMS Patient Authorization and Baseline Lab Form.
- I understand that my healthcare facility is authorized to receive LEMTRADA REMS or verifying online at the time of each treatment course.
- I understand the risk of serious infusion reactions following the administration of LEMTRADA.
- I understand the need to monitor patients during and for at least 2 hours following the administration of LEMTRADA.
- To include the monitoring and periodically during the treatment course.
- I understand that my healthcare facility has necessary on-site equipment to manage serious infusion reactions.
- I understand that my healthcare facility will be subject to audit, to help ensure the quality of care and adherence to the requirements of the LEMTRADA REMS.
- This healthcare facility will be subject to audit, to help ensure the quality of care and adherence to the requirements of the LEMTRADA REMS.
- Ensure that a LEMTRADA REMS Patient Authorization and Baseline Lab Form is received for each prescription.
- Ensure that the prescriber is certified and the patient is enrolled and authorized by either calling the LEMTRADA REMS or verifying this information via the LEMTRADA REMS website prior to dispensing and administering LEMTRADA.
- Ensure that the infusion site is equipped to manage infusion reactions.

I have verified that all details are correct.

By providing my e-signature, I acknowledge that I have completed the educational training required for LEMTRADA for healthcare facilities and I understand the benefits and risks of LEMTRADA. I acknowledge that all staff members from my site must be trained on the information in the module and adhere to the requirements of the LEMTRADA REMS. I understand that I must complete this LEMTRADA REMS Healthcare Facility Enrollment Form in order to complete this enrollment process.

By entering my name, NPI number, and password, I confirm that I have completed the LEMTRADA REMS training and that I will comply with the requirements of the program.

Full Name

NPI Number

Password

Cancel

Submit

If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6326, Mon - Fri, 8:30 am - 8:00 pm ET.

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LEMTRADA
alemtuzumab 12mg IV

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LEMTRADA REMS HEALTHCARE FACILITY ENROLLMENT FORM

LEMTRADA is only available through the LEMTRADA REMS, a restricted distribution program. Only prescribers, pharmacies, healthcare facilities, and patients enrolled in the program are able to prescribe, dispense, administer, and receive LEMTRADA. An authorized representative of the healthcare facility must enroll the facility in the LEMTRADA REMS.

Please review the following information and submit to Genzyme by clicking the button below. Complete any missing information and correct any errors prior to submission.

All fields are required.

HEALTHCARE FACILITY INFORMATION

Name of Institution or Healthcare Facility	<input type="text" value="Extrophy Institute"/>
National Provider Identification (NPI) Number	<input type="text" value="0123456789"/>
Infusion Facility Address	<input type="text" value="43 Eleanor St"/>
City	<input type="text" value="Los Angeles"/>
State	<input type="text" value="California"/>
ZIP Code	<input type="text" value="90212"/>
Phone Number	<input type="text" value="555-555-5555"/>
Fax Number	<input type="text" value="555-555-5555"/>
Site Affiliation	<div style="border: 1px solid gray; padding: 2px;"> Select <input checked="" type="checkbox"/> Academic <input type="checkbox"/> Government <input type="checkbox"/> Ambulatory/Free Standing <input type="checkbox"/> Hospital Based <input type="checkbox"/> Private Practice (in office) </div>
<input type="checkbox"/> Ship-to is the same as facility address	
Ship-to Address	<input type="text"/>
City	<input type="text" value="Los Angeles"/>
State	<input type="text" value="California"/>
ZIP Code	<input type="text" value="90212"/>
Name of Authorized Healthcare Facility Representative	
First Name	<input type="text" value="John"/>
Last Name	<input type="text" value="Doe"/>
Email Address	<input type="text" value="jdoe@abc123.com"/>
Title	<input type="text" value="MD"/>

HEALTHCARE FACILITY AGREEMENT

I am the authorized representative designated by my healthcare facility to coordinate the activities of the LEMTRADA REMS. By signing this form, I agree to comply with the following requirements:

- I understand that my healthcare facility must be certified with the LEMTRADA REMS to receive or administer LEMTRADA.
- I have completed the review of the LEMTRADA REMS Education Program for Healthcare Facilities and the LEMTRADA REMS Program Overview.
- I understand that my healthcare facility must confirm that the patient is authorized to receive LEMTRADA by contacting the LEMTRADA REMS or verifying online at www.LemtradaREMS.com prior to initiation of each treatment course.
- I understand the risk of serious infusion reactions during and following the administration of LEMTRADA
- I understand the risk of stroke during and following the administration of LEMTRADA
- I understand the need to monitor patients for infusion reactions during and for at least 2 hours after each LEMTRADA infusion.
 - To include the monitoring of patient vital signs before the infusion and periodically during the infusion.
- I understand that my healthcare facility must be equipped with the necessary on-site equipment and personnel to manage anaphylaxis or serious infusion reactions.
- I understand that my healthcare facility must renew enrollment in the LEMTRADA REMS every 2 years from initial enrollment.
- This healthcare facility will establish procedures and protocols that are subject to audit, to help ensure compliance with the safe-use conditions required in the LEMTRADA REMS, including the following:
 - Ensure that a LEMTRADA REMS Prescription Ordering Form is received for each prescription.
 - Ensure that the prescriber is certified and the patient is enrolled and authorized by either calling the LEMTRADA REMS or verifying this information via the LEMTRADA REMS website prior to dispensing and administering LEMTRADA.
 - Ensure that the infusion site is equipped to manage infusion reactions.

- Ensure that the infusion site is equipped to manage infusion reactions.
- Ensure that LEMTRADA is not dispensed outside of the authorized representative's certified healthcare facility.
- Prior to the first day of each treatment course, counsel and provide a copy of *What You Need to Know About LEMTRADA Treatment and Infusion Reactions: A Patient Guide* to each patient to inform them about the risk of serious infusion reactions.
- Observe each patient administered LEMTRADA at my healthcare facility during and for at least 2 hours after each LEMTRADA infusion, in order to provide appropriate medical treatment in the event of serious infusion reactions following LEMTRADA infusion.
- For each patient, complete and return the LEMTRADA REMS Infusion Checklist to the LEMTRADA REMS within 5 business days from the patient's last infusion of LEMTRADA within a specific treatment course.
- Renew enrollment into the LEMTRADA REMS every 2 years from the initial enrollment.
- To make available to Genzyme documentation to verify understanding of, and adherence to, the requirements of the LEMTRADA REMS.
- To return to Genzyme any unused vials of LEMTRADA within 50 days from the submission date of the LEMTRADA REMS Patient Authorization and Baseline Lab Form.
- To ensure that a LEMTRADA REMS Patient Authorization and Baseline Lab Form is received for each prescription by either calling the LEMTRADA REMS or verifying this information via the LEMTRADA REMS website.
- To ensure that all non-prescribing HCPs who administer LEMTRADA in my healthcare setting are trained using the LEMTRADA REMS Program Overview and the LEMTRADA REMS Education Program for Healthcare Facilities, and a record regarding such training must be maintained.

I have verified that all details are correct.

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By entering my name, NPI number, and password, I confirm that I have completed the LEMTRADA REMS training and that I will comply with the requirements of the program.

Full Name

NPI Number

Password

Cancel
Submit

If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6326, Mon - Fri, 8:30 am - 8:00 pm ET.

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VV-REG-0833078 0.1

Reference ID: 4512344



LEMTRADA[®]
alemtuzumab 12mg
iv

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Please review the following information and submit to Genzyme by clicking the button below. Complete any missing information and correct any errors prior to submission.

All fields are required.

HEALTHCARE FACILITY INFORMATION

Name of Institution or Healthcare Facility	<input type="text"/>	<i>Please enter name of institution or healthcare facility.</i>
National Provider Identification (NPI) Number	<input type="text"/>	<i>Please enter a valid NPI number.</i>
Infusion Facility Address	<input type="text"/>	<i>Please enter infusion facility address.</i>
City	<input type="text"/>	<i>Please enter city.</i>
State	<input type="text" value="Select"/>	<i>Please select state.</i>
ZIP Code	<input type="text"/>	<i>Please enter a 5-digit ZIP Code.</i>
Phone Number	<input type="text"/>	<i>Please enter a 10-digit phone number.</i>
Fax Number	<input type="text"/>	<i>Please enter a 10-digit fax number.</i>
Site Affiliation	<input type="text" value="Select"/>	<i>Please select a site affiliation.</i>
<input type="checkbox"/> Ship-to is the same as facility address		
Ship-to Address	<input type="text"/>	<i>Please enter ship-to address.</i>
City	<input type="text"/>	<i>Please enter city.</i>
State	<input type="text" value="Select"/>	<i>Please select state.</i>
ZIP Code	<input type="text"/>	<i>Please enter a 5-digit ZIP Code.</i>
Name of Authorized Healthcare Facility Representative		
First Name	<input type="text"/>	<i>Please enter first name.</i>
Last Name	<input type="text"/>	<i>Please enter last name.</i>
Email Address	<input type="text"/>	<i>Please enter a valid email address.</i>
Title	<input type="text"/>	<i>Please enter title.</i>

HEALTHCARE FACILITY AGREEMENT

I am the authorized representative designated by my healthcare facility to coordinate the activities of the LEMTRADA REMS. By signing this form, I agree to comply with the following requirements:

- I understand that my healthcare facility must be certified with the LEMTRADA REMS to receive or administer LEMTRADA.
- I have completed the review of the LEMTRADA REMS Education Program for Healthcare Facilities and the LEMTRADA REMS Program Overview.
- I understand that my healthcare facility must confirm that the patient is authorized to receive LEMTRADA by contacting the LEMTRADA REMS or verifying online at www.LemtradaREMS.com prior to initiation of each treatment course.
- I understand the risk of serious infusion reactions during and following the administration of LEMTRADA
- I understand the risk of stroke during and following the administration of LEMTRADA
- I understand the need to monitor patients for infusion reactions during and for at least 2 hours after each LEMTRADA infusion.
 - To include the monitoring of patient vital signs before the infusion and periodically during the infusion.
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- Observe each patient administered LEMTRADA at my healthcare facility during and for at least 2 hours after each LEMTRADA infusion, in order to provide appropriate medical treatment in the event of serious infusion reactions following LEMTRADA infusion.
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- Renew enrollment into the LEMTRADA REMS every 2 years from the initial enrollment.
- To make available to Genzyme documentation to verify understanding of, and adherence to, the requirements of the LEMTRADA REMS.
- To return to Genzyme any unused vials of LEMTRADA within 50 days from the submission date of the LEMTRADA REMS Patient Authorization and Baseline Lab Form.
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- To ensure that all non-prescribing HCPs who administer LEMTRADA in my healthcare setting are trained using the LEMTRADA REMS Program Overview and the *LEMTRADA REMS Education Program for Healthcare Facilities*, and a record regarding such training must be maintained.

I have verified that all details are correct.
Please indicate information has been verified.

By providing my e-signature, I acknowledge that I have completed the educational training required for LEMTRADA for healthcare facilities and I understand the benefits and risks of LEMTRADA. I acknowledge that all staff members from my site must be trained on the information in the module and adhere to the requirements of the LEMTRADA REMS. I understand that I must complete this LEMTRADA REMS Healthcare Facility Enrollment Form in order to complete this enrollment process.

By entering my name, NPI number, and password, I confirm that I have completed the LEMTRADA REMS training and that I will comply with the requirements of the program.

Full Name

Please enter your full name.

NPI Number

Please enter a valid NPI number.

Password

Please enter a password.

Cancel
Submit

If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6326, Mon - Fri, 8:30 am - 8:00 pm ET.

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VV-REG-0833078 0.1

Reference ID: 4512344

The screenshot shows a web browser window displaying the LEMTRADA REMS website. The browser's address bar shows a Google search engine. The website header includes the LEMTRADA logo (alemfuzumab 12mg iv) and navigation links for Prescribing Information and Medication Guide. A user is logged in as Robert Clark, with links for My Profile and Log Out. A main navigation bar contains Home, Forms & FAQs, REMS Certified Prescriber & Healthcare Facility Locator, and About REMS. A progress bar indicates the user has completed the Enrollment step, following Registration and Training. The main content area features a heading 'Enrollment Is Complete!' and a paragraph stating that the user has successfully completed online enrollment and will receive a confirmation email. It also provides contact information for a LEMTRADA REMS Specialist at 1-855-676-6326. A note mentions access to an online support center. A link is provided to download and print a copy of the LEMTRADA REMS Healthcare Facility Enrollment Form. A call to action at the bottom of the main content area asks for help enrolling and provides the phone number 1-855-676-6326, Mon - Fri, 8:30 am - 8:00 pm ET. The footer contains links for Privacy Policy, Terms and Conditions, and Contact Us, along with copyright information for Genzyme Corporation (©2019) and the Sanofi Genzyme logo.

FOLD

LEMTRADA
alemtuzumab^{12mg} iv

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LEMTRADA REMS (Risk Evaluation and Mitigation Strategy)

What is the LEMTRADA REMS?
A REMS is a strategy to manage known or potential serious risks associated with a drug product and is required by the FDA to ensure the benefits of a drug outweigh its risks. The purpose of the LEMTRADA REMS is to inform prescribers, pharmacies, healthcare facilities, and patients about the risks of:

AUTOIMMUNE CONDITIONS
LEMTRADA causes serious, sometimes fatal, autoimmune conditions such as immune thrombocytopenia and anti-glomerular basement membrane disease. Monitor complete blood counts with differential, serum creatinine levels, and urinalysis with urine cell counts at periodic intervals for 48 months after the last dose of LEMTRADA.

INFUSION REACTIONS
LEMTRADA causes serious and life threatening infusion reactions. LEMTRADA must be administered in a setting with appropriate equipment and personnel to manage anaphylaxis or serious infusion reactions.

STROKE
Serious and life-threatening stroke (including ischemic and hemorrhagic stroke) has been reported within 3 days of LEMTRADA administration. Instruct patients to seek immediate medical attention if symptoms of stroke occur.

MALIGNANCIES
LEMTRADA may cause an increased risk of malignancy including thyroid cancer, melanoma, and lymphoproliferative disorders. Perform baseline and yearly exams.

LEMTRADA REMS Requirements

HEALTHCARE FACILITIES

Healthcare facilities must be enrolled in the LEMTRADA REMS to dispense/administer LEMTRADA for patients with multiple sclerosis. One representative needs to enroll per healthcare setting.
[Learn about Healthcare Facility Enrollment](#) ▶

Complete Enrollment in the LEMTRADA REMS

You have not completed your review of the training materials. You must review the training materials in order to complete your enrollment in the LEMTRADA REMS.

[Review Training Materials](#)

Find a REMS Certified Prescriber or Healthcare Facility

Search for prescribers or healthcare facilities that are certified by the LEMTRADA REMS to prescribe, dispense, or administer LEMTRADA.

Enter ZIP Code

REMS Certified Prescriber
 REMS Certified Healthcare Facility

[Find](#)

This site is provided as a resource for prescribers and is not intended as medical advice. Information on the site is updated periodically (approximately every 12 hours).

If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6326, Mon – Fri, 8:30 am – 8:00 pm ET.

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[Learn about Healthcare Facility Enrollment](#) ▶

Complete Enrollment in the LEMTRADA REMS



You must review the training materials in order to complete your enrollment in the LEMTRADA REMS. Please call *MS One to One*® at 1-855-676-6326 to speak with a Genzyme representative.

Find a REMS Certified Prescriber or Healthcare Facility



Search for prescribers or healthcare facilities that are certified by the LEMTRADA REMS to prescribe, dispense, or administer LEMTRADA.

Enter ZIP Code

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[Learn about Healthcare Facility Enrollment](#) ▶

Complete Enrollment in the LEMTRADA REMS



You have not completed your review and submission of the LEMTRADA REMS Healthcare Facility Enrollment Form.

Review Enrollment Form

Find a REMS Certified Prescriber or Healthcare Facility



Search for prescribers or healthcare facilities that are certified by the LEMTRADA REMS to prescribe, dispense, or administer LEMTRADA.

Enter ZIP Code

REMS Certified Prescriber
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Find

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LEMTRADA
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[Learn about Healthcare Facility Enrollment](#) ▶

LEMTRADA REMS Enrollment Complete



You have successfully completed online enrollment in the LEMTRADA REMS. You will receive a confirmation email with your LEMTRADA REMS Identification Number. A Genzyme representative will also follow up with you to schedule your appointment to verify enrollment.

Once your enrollment is verified, you gain access to the online tools and resources available to help you manage your LEMTRADA patients.

Review Training Materials Again

Find a REMS Certified Prescriber or Healthcare Facility



Search for prescribers or healthcare facilities that are certified by the LEMTRADA REMS to prescribe, dispense, or administer LEMTRADA.

Enter ZIP Code

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LEMTRADA
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LEMTRADA REMS Training

LEMTRADA REMS Program Overview (1 of 2) Total Training Screens: 1 of 10

LEMTRADA
alemtuzumab^{12mg} iv **LEMTRADA REMS PROGRAM OVERVIEW**

What Is the LEMTRADA REMS (Risk Evaluation and Mitigation Strategy)?
A REMS is a strategy to manage known or potential risks associated with a drug. It is required by the FDA to ensure that the benefits of the drug outweigh its risks. Due to serious risks of autoimmune conditions, infusion reactions, stroke and malignancies, LEMTRADA[®] (alemtuzumab) is only available through a restricted program called the LEMTRADA REMS.

LEMTRADA REMS Requirements

- **Prescribers** must be enrolled in the LEMTRADA REMS to be able to prescribe LEMTRADA.
- **Pharmacies** must be enrolled in the LEMTRADA REMS to be able to dispense LEMTRADA.
- **Healthcare Facilities** must be enrolled in the LEMTRADA REMS to be able to dispense and administer LEMTRADA.
- **Patients** must be enrolled and authorized in the LEMTRADA REMS in order to receive LEMTRADA.

PRESCRIBER ENROLLMENT INSTRUCTIONS

1. Complete the training program, which includes reviewing the following:
 - LEMTRADA Prescribing Information
 - LEMTRADA REMS Program Overview
 - LEMTRADA REMS Education Program for Prescribers
2. Successfully complete the 8-question LEMTRADA REMS Knowledge Assessment.
3. Enroll in the program by completing a LEMTRADA REMS Prescriber Enrollment Form.
4. Submit the completed and signed Forms to the LEMTRADA REMS.

PHARMACY ENROLLMENT INSTRUCTIONS

1. An authorized representative must enroll on behalf of the pharmacy by reviewing the LEMTRADA REMS Program Overview and completing the LEMTRADA REMS Pharmacy Enrollment Form, which acknowledges that the pharmacy agrees to follow the procedures outlined in the LEMTRADA REMS, including:
 - All relevant staff at the pharmacy who will be involved with the dispensing of LEMTRADA must be educated and trained.
 - The pharmacy will verify that a LEMTRADA REMS Prescription Ordering Form is received for each prescription.
 - The pharmacy will verify that prescribers and healthcare facilities are certified and patients are authorized to receive LEMTRADA prior to dispensing LEMTRADA.
 - Enrollment in the LEMTRADA REMS must be renewed every 2 years from initial enrollment.
2. Submit the completed and signed LEMTRADA REMS Pharmacy Enrollment Form to the LEMTRADA REMS.

[Next](#) (1 of 10)

If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6326, Mon - Fri, 8:30 am - 8:00 pm ET.

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REMS CERTIFIED HEALTHCARE FACILITY DASHBOARD PAGES



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About REMS

🚨 You have 5 patient alerts! ▶

Our Patients

Prescribers

Manage Users

Use the list below to search and sort information about patients using your healthcare facility to receive LEMTRADA. Only patients enrolled in the LEMTRADA REMS are eligible to receive infusions. Click on a patient's name to view their full profile.

You have 10 LEMTRADA patients ?

🚨	Last Name	First Name	Year of Birth	REMS ID	Prescriber (REMS ID)	REMS Status
	Doe	John	1980	129684352	Adam Smith (01234567)	Authorized
	Doe	John	1980	129684352	Adam Smith (01234567)	Authorized
🚨	Doe	John	1980	129684352	Adam Smith (01234567)	Not Authorized
🚨	Doe	John	1980	129684352	Adam Smith (01234567)	Not Authorized
	Doe	John	1980	129684352	Adam Smith (01234567)	Authorized
🚨	Doe	John	1980	129684352	Adam Smith (01234567)	Not Authorized
	Doe	John	1980	129684352	Adam Smith (01234567)	Authorized
	Doe	John	1980	129684352	Adam Smith (01234567)	Authorized
	Doe	John	1980	129684352	Adam Smith (01234567)	Infusion Verification
	Doe	John	1980	129684352	Adam Smith (01234567)	Authorized

Re-enroll in the LEMTRADA REMS

Healthcare Facilities must renew their enrollment every 2 years, and authorized representatives must renew their enrollment every year.

Re-enroll Now

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The screenshot displays the LEMTRADA REMS Desktop interface. At the top, there is a navigation bar with links for "Prescribing Information" and "Medication Guide". Below this, a welcome message reads "Welcome, Robert Clark!" with links for "My Profile" and "Log Out". The main navigation menu includes "Home", "Forms & FAQs", "REMS Certified Prescriber & Healthcare Facility Locator", and "About REMS".

A prominent alert banner at the top of the main content area states "You have 5 patient alerts!". Below this, there are tabs for "Our Patients", "Prescribers", and "Manage Users". A large white popup window is centered on the screen, containing the text "Your Re-enrollment Is Due in Less Than a Month" and two buttons: "Re-enroll Now" and "Return to Dashboard".

The main content area features a table of patients with the following columns: Last Name, First Name, Birth Date, Facility ID, Prescriber Name, and REMS Status. The table contains 10 rows of data. The first two rows are "Authorized", the next two are "Not Authorized" (highlighted in red), the next two are "Authorized", the next two are "Not Authorized" (highlighted in red), and the final two are "Authorized". The last row has an "Infusion Verification" button next to it.

Below the table, there is a section titled "Re-enroll in the LEMTRADA REMS" with a "Re-enroll Now" button. A disclaimer states: "This site is provided as a resource for prescribers and is not intended as medical advice. Information on the site is updated periodically (approximately every 12 hours)."

At the bottom, there is contact information: "If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6326, Mon - Fri, 8:30 am - 8:00 pm ET." The footer includes links for "Privacy Policy", "Terms and Conditions", and "Contact Us", along with copyright information for Sanofi Genzyme.



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About REMS

LEMTRADA REMS (Risk Evaluation and Mitigation Strategy)

What is the LEMTRADA REMS?
A REMS is a strategy to manage known or potential serious risks associated with a drug product and is required by the FDA to ensure the benefits of a drug outweigh its risks. The purpose of the LEMTRADA REMS is to inform prescribers, pharmacies, healthcare facilities, and patients about the risks of:

AUTOIMMUNE CONDITIONS
LEMTRADA causes serious, sometimes fatal, autoimmune conditions such as immune thrombocytopenia and anti-glomerular basement membrane disease. Monitor complete blood counts with differential, serum creatinine levels, and urinalysis with urine cell counts at periodic intervals for 48 months after the last dose of LEMTRADA.

INFUSION REACTIONS
LEMTRADA causes serious and life threatening infusion reactions. LEMTRADA must be administered in a setting with appropriate equipment and personnel to manage anaphylaxis or serious infusion reactions.

STROKE
Serious and life-threatening stroke (including ischemic and hemorrhagic stroke) has been reported within 3 days of LEMTRADA administration. Instruct patients to seek immediate medical attention if symptoms of stroke occur.

MALIGNANCIES
LEMTRADA may cause an increased risk of malignancy including thyroid cancer, melanoma, and lymphoproliferative disorders. Perform baseline and yearly exams.

LEMTRADA REMS Requirements

HEALTHCARE FACILITIES

Healthcare facilities must be enrolled in the LEMTRADA REMS to dispense/administer LEMTRADA for patients with multiple sclerosis. *One representative needs to enroll per healthcare setting.*

[Learn about Healthcare Facility Enrollment](#) ▶

Re-enroll in the LEMTRADA REMS



You have been locked out due to incomplete re-enrollment. Please click the link below to re-enroll in the LEMTRADA REMS.

Re-enroll Now

Find a REMS Certified Prescriber or Healthcare Facility



Search for prescribers or healthcare facilities that are certified by the LEMTRADA REMS to prescribe, dispense, or administer LEMTRADA.

Enter ZIP Code

REMS Certified Prescriber
 REMS Certified Healthcare Facility

Find

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About REMS

⚠ You have 5 patient alerts!

You have **5 patients** who have authorization requirements.

- **2 patients** are overdue for the LEMTRADA REMS Patient Status Form.
- **2 patients** need to be authorized by the LEMTRADA REMS Patient Status Form in 1 month.
- **1 patient** needs to be verified before their infusion.

[Manage my patient alert email preferences](#)

Our Patients

Prescribers

Manage Users

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LEMTRADA REMS INFUSION VERIFICATION

Patients cannot be infused until the patient, their prescriber, and the healthcare facility are verified under the LEMTRADA REMS. **John Doe** is scheduled to be infused on **XX/XX/XXXX**. If this date is incorrect or the date changes, please contact the LEMTRADA REMS at 1-855-676-6326.

Check marks indicate that verification has been completed.

Patient	✓
Certified Prescriber	✓
Certified Healthcare Facility	✓

✓ - Verified

Yes, I have verified my patient is ready for infusion.

Confirm

FOLD

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Check marks indicate that verification has been completed.

Patient	✓
Certified Prescriber	✓
Certified Healthcare Facility	✓

✓ - Verified

Yes, I have verified my patient is ready for infusion.
Please indicate verification.

Confirm

FOLD

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John Doe
(REMS ID 129684352)
REMS Authorized
Year of Birth: 1982
7776 Golden Blossom Run
Zook, IL 62056-3630
Home Phone: xxx-xxx-xxxx
Mobile Phone: xxx-xxx-xxxx

LEMTRADA REMS Infusion Checklist

Insurance	
Provider: BlueCross BlueShield of Kansas City	Coverage: Completed (View)

Infusion Information	
Next Infusion Date: 6/10/12	Infusion Facility: Facility 01

Prescriber Information	
Prescriber: Adam Smith , MD	REMS ID: 0123456789

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LEMTRADA REMS INFUSION CHECKLIST

As a condition of your healthcare facility's authorization to infuse LEMTRADA® (alemtuzumab), this Infusion Checklist **must** be completed for each patient by the last day of each patient's treatment course and submitted within **5 business days**. **This Infusion Checklist must also be completed and returned even if LEMTRADA is not infused.** Keep a copy of this checklist in the patient's medical record.

Please complete the form and submit to Genzyme by clicking the button below.

All fields are required.

PATIENT INFORMATION

Patient First Name

Patient Last Name

Patient LEMTRADA REMS Identification Number

DOB (MM/DD/YYYY)
 [Full Patient Record](#)

PRESCRIBER INFORMATION

Prescriber First Name

Prescriber Last Name

Prescriber LEMTRADA REMS Identification Number

HEALTHCARE FACILITY INFORMATION

Healthcare Facility Name

Healthcare Facility LEMTRADA REMS Identification Number

Step 1: CONFIRM that the patient is authorized to receive LEMTRADA

You must complete the LEMTRADA REMS infusion verification online or contact the LEMTRADA REMS by phone (1-855-676-6326) prior to initiation of each treatment course.

Is the patient authorized to receive LEMTRADA? Yes No

Step 2: CONFIRM that the patient has been counseled and has received *What You Need to Know About LEMTRADA Treatment and Infusion Reactions: A Patient Guide*

The patient must be counseled about the risk for infusion reactions and provided with *What You Need to Know About LEMTRADA Treatment and Infusion Reactions: A Patient Guide* prior to the first infusion of each treatment course.

Has the patient been counseled and received the guide?
 Yes No

Step 3: CONFIRM appropriate medical measures available for infusion

Appropriate medical support measures are available:

1. In case of serious infusion reactions.
2. To monitor patient's vital signs before, during, and post-infusion.

Are the appropriate medical measures listed above available?
 Yes No

Step 4: RECORD infusion information

Was patient infused with LEMTRADA? Yes No

Step 5: RETURN of unused vials of LEMTRADA

Unused vials of LEMTRADA must be returned within 50 days of submission of the LEMTRADA REMS Patient Authorization and Lab Form. Contact the LEMTRADA REMS at 1-855-676-6326 for additional information.

Step 6: SIGNATURE

By providing my e-signature, I attest that I have filled out the Infusion Checklist to the best of my knowledge. I understand that my e-signature will be used to verify my enrollment in the LEMTRADA REMS. By entering my name, NPI number, and password, I confirm my e-signature of this form.

Name of staff member completing checklist:

Password

NPI Number

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[Cancel](#) Save Submit

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LEMTRADA REMS INFUSION CHECKLIST

As a condition of your healthcare facility's authorization to infuse LEMTRADA® (alemtuzumab), this Infusion Checklist **must** be completed for each patient by the last day of each patient's treatment course and submitted within 5 business days. **This Infusion Checklist must also be completed and returned even if LEMTRADA is not infused.** Keep a copy of this checklist in the patient's medical record.

Please complete the form and submit to Genzyme by clicking the button below.

All fields are required.

PATIENT INFORMATION

Patient First Name

Patient Last Name

Patient LEMTRADA REMS Identification Number

DOB (MM/DD/YYYY)
 [Full Patient Record](#)

PRESCRIBER INFORMATION

Prescriber First Name

Prescriber Last Name

Prescriber LEMTRADA REMS Identification Number

HEALTHCARE FACILITY INFORMATION

Healthcare Facility Name

Healthcare Facility LEMTRADA REMS Identification Number

Step 1: CONFIRM that the patient is authorized to receive LEMTRADA

You must complete the LEMTRADA REMS infusion verification online or contact the LEMTRADA REMS by phone (1-855-676-6326) prior to initiation of each treatment course.

Is the patient authorized to receive LEMTRADA? Yes No

Alert!

STOP – DO NOT INFUSE.
Refer patient back to the LEMTRADA prescriber.

Step 2: CONFIRM that the patient has been counseled and has received *What You Need to Know About LEMTRADA Treatment and Infusion Reactions: A Patient Guide*

The patient must be counseled about the risk for infusion reactions and provided with *What You Need to Know About LEMTRADA Treatment and Infusion Reactions: A Patient Guide* prior to the first infusion of each treatment course.

Has the patient been counseled and received the guide?
 Yes No

Step 3: CONFIRM appropriate medical measures available for infusion

Appropriate medical support measures are available:

- In case of serious infusion reactions.
- To monitor patient's vital signs before, during, and post-infusion.

Are the appropriate medical measures listed above available?
 Yes No

Step 4: RECORD infusion information

Was patient infused with LEMTRADA? Yes No

Step 5: RETURN of unused vials of LEMTRADA

Unused vials of LEMTRADA must be returned within 50 days of submission of the LEMTRADA® REMS Patient Authorization and Lab Form. Contact the LEMTRADA REMS at 1-855-676-6326 for additional information.

Step 6: SIGNATURE

By providing my e-signature, I attest that I have filled out the Infusion Checklist to the best of my knowledge. I understand that my e-signature will be used to verify my enrollment in the LEMTRADA REMS. By entering my name, NPI number, and password, I confirm my e-signature of this form.

Name of staff member completing checklist:

Password

NPI Number

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[Cancel](#)

Save

Submit

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If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6326, Mon – Fri, 8:30 am – 8:00 pm ET.

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LEMTRADA
alemtuzumab^{12mg}_{iv}

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LEMTRADA REMS INFUSION CHECKLIST

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Please complete the form and submit to Genzyme by clicking the button below.

All fields are required.

PATIENT INFORMATION

Patient First Name

Please enter patient's first name.

Patient Last Name

Please enter patient's last name.

Patient LEMTRADA REMS Identification Number

Please enter patient's LEMTRADA REMS Identification Number.

DOB (MM/DD/YYYY)

Full Patient Record

Please enter patient's valid date of birth.

PRESCRIBER INFORMATION

Prescriber First Name

Please enter prescriber's first name.

Prescriber Last Name

Please enter prescriber's last name.

Prescriber LEMTRADA REMS Identification Number

Please enter prescriber's LEMTRADA REMS Identification Number.

HEALTHCARE FACILITY INFORMATION

Healthcare Facility Name

Please enter healthcare facility name.

Healthcare Facility LEMTRADA REMS Identification Number

Please enter Healthcare Facility LEMTRADA REMS Identification Number.

Step 1: CONFIRM that the patient is authorized to receive LEMTRADA

You must complete the LEMTRADA REMS infusion verification online or contact the LEMTRADA REMS by phone (1-855-676-6326) prior to initiation of each treatment course.

Is the patient authorized to receive LEMTRADA? Yes No

Alert!

STOP – DO NOT INFUSE. Refer patient back to the LEMTRADA prescriber.

Step 2: CONFIRM that the patient has been counseled and has received *What You Need to Know About LEMTRADA Treatment and Infusion Reactions: A Patient Guide*

The patient must be counseled about the risk for infusion reactions and provided with *What You Need to Know About LEMTRADA Treatment and Infusion Reactions: A Patient Guide* prior to the first infusion of each treatment course.

Has the patient been counseled and received the guide?
 Yes No

Alert!

STOP – Provide the patient guide. Proceed to the next question after the patient has received the guide and has been counseled.

Step 3: CONFIRM appropriate medical measures available during infusion

Appropriate medical support measures are available:

- In case of serious infusion reactions.
- To monitor patient's vital signs during and post-infusion.

Are the appropriate medical measures listed above available?
 Yes No

Alert!

STOP – DO NOT INFUSE until appropriate medical support measures are available. Please contact the LEMTRADA REMS additional information.

Step 4: RECORD infusion information

Was patient infused with LEMTRADA? Yes No

Alert!

Proceed to Step 5

Step 5: RETURN of unused vials of LEMTRADA

Unused vials of LEMTRADA must be returned within 50 days of submission of the LEMTRADA REMS Patient Authorization and Lab Form. Contact the LEMTRADA REMS at 1-855-676-6326 for additional information.

Step 6: SIGNATURE

By providing my e-signature, I attest that I have filled out the Infusion Checklist to the best of my knowledge. I understand that my e-signature will be used to verify my enrollment in the LEMTRADA REMS. By entering my name, NPI number, and password, I confirm my e-signature of this form.

Name of staff member completing checklist

Please enter name of staff member completing checklist.

Password

Please enter password.

NPI Number

Please enter a valid NPI number.

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Please complete the form and submit to Genzyme by clicking the button below.

All fields are required.

PATIENT INFORMATION

Patient First Name

Patient Last Name

Patient LEMTRADA REMS Identification Number

DOB (MM/DD/YYYY)
 [Full Patient Record](#)

PRESCRIBER INFORMATION

Prescriber First Name

Prescriber Last Name

Prescriber LEMTRADA REMS Identification Number

HEALTHCARE FACILITY INFORMATION

Healthcare Facility Name

Healthcare Facility LEMTRADA REMS Identification Number

Step 1: CONFIRM that the patient is authorized to receive LEMTRADA

You must complete the LEMTRADA REMS infusion verification online or contact the LEMTRADA REMS by phone (1-855-676-6326) prior to initiation of each treatment course.

Is the patient authorized to receive LEMTRADA? Yes No

Step 2: CONFIRM that the patient has been counseled and has received *What You Need to Know About LEMTRADA Treatment and Infusion Reactions: A Patient Guide*

The patient must be counseled about the risk for infusion reactions and provided with *What You Need to Know About LEMTRADA Treatment and Infusion Reactions: A Patient Guide* prior to the first infusion of each treatment course.

Has the patient been counseled and received the guide? Yes No

Step 3: CONFIRM appropriate medical measures available during infusion

Appropriate medical support measures are available:

- In case of serious infusion reactions.
- To monitor patient's vital signs during and post-infusion.

Are the appropriate medical measures listed above available? Yes No

Step 4: RECORD infusion information

Was patient infused with LEMTRADA? Yes No

Fill in Dates of Infusion below and then proceed to Step 5.

LEMTRADA Infusions

Dates of Infusion:

Date:

Date:

Date:

Step 5: RETURN of unused vials of LEMTRADA

Unused vials of LEMTRADA must be returned within 50 days of submission of the LEMTRADA REMS Patient Authorization and Lab Form. Contact the LEMTRADA REMS at 1-855-676-6326 for additional information.

Step 6: SIGNATURE

By providing my e-signature, I attest that I have filled out the Infusion Checklist to the best of my knowledge. I understand that my e-signature will be used to verify my enrollment in the LEMTRADA REMS. By entering my name, NPI number, and password, I confirm my e-signature of this form.

Name of staff member completing checklist

Password

NPI Number

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Submit

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LEMTRADA REMS INFUSION CHECKLIST

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Please complete the form and submit to Genzyme by clicking the button below.

All fields are required.

PATIENT INFORMATION

Patient First Name

Patient Last Name

Patient LEMTRADA REMS Identification Number

DOB (MM/DD/YYYY)
 [Full Patient Record](#)

PRESCRIBER INFORMATION

Prescriber First Name

Prescriber Last Name

Prescriber LEMTRADA REMS Identification Number

HEALTHCARE FACILITY INFORMATION

Healthcare Facility Name

Healthcare Facility LEMTRADA REMS Identification Number

Step 1: CONFIRM that the patient is authorized to receive LEMTRADA

You must complete the LEMTRADA REMS infusion verification online or contact the LEMTRADA REMS by phone (1-855-676-6326) prior to initiation of each treatment course.

Is the patient authorized to receive LEMTRADA? Yes No

Step 2: CONFIRM that the patient has been counseled and has received *What You Need to Know About LEMTRADA Treatment and Infusion Reactions: A Patient Guide*

The patient must be counseled about the risk for infusion reactions and provided with *What You Need to Know About LEMTRADA Treatment and Infusion Reactions: A Patient Guide* prior to the first infusion of each treatment course.

Has the patient been counseled and received the guide? Yes No

Step 3: CONFIRM appropriate medical measures available during infusion

Appropriate medical support measures are available:
1. In case of serious infusion reactions.
2. To monitor patient's vital signs during and post-infusion.

Are the appropriate medical measures listed above available? Yes No

Step 4: RECORD infusion information

Was patient infused with LEMTRADA? Yes No

Fill in Dates of Infusion below and then proceed to Step 5.

LEMTRADA Infusions

Dates of Infusion:

Date:

Date:

Date:

Step 5: RETURN of unused vials of LEMTRADA

Unused vials of LEMTRADA must be returned within 50 days of submission of the LEMTRADA REMS Patient Authorization and Lab Form. Contact the LEMTRADA REMS at 1-855-676-6326 for additional information.

Step 6: SIGNATURE

By providing my e-signature, I attest that I have filled out the Infusion Checklist to the best of my knowledge. I understand that my e-signature will be used to verify my enrollment in the LEMTRADA REMS. By entering my name, NPI number, and password, I confirm my e-signature of this form.

Name of staff member completing checklist

Password

NPI Number

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LEMTRADA REMS INFUSION CHECKLIST

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Please complete the form and submit to Genzyme by clicking the button below.

All fields are required.

PATIENT INFORMATION

Patient First Name

Patient Last Name

Patient LEMTRADA REMS Identification Number

DOB (MM/DD/YYYY)
 [Full Patient Record](#)

PRESCRIBER INFORMATION

Prescriber First Name

Prescriber Last Name

Prescriber LEMTRADA REMS Identification Number

HEALTHCARE FACILITY INFORMATION

Healthcare Facility Name

Healthcare Facility LEMTRADA REMS Identification Number

Step 1: CONFIRM that the patient is authorized to receive LEMTRADA

You must complete the LEMTRADA REMS infusion verification online or contact the LEMTRADA REMS by phone (1-855-676-6326) prior to initiation of each treatment course.

Is the patient authorized to receive LEMTRADA? Yes No

Step 2: CONFIRM that the patient has been counseled and has received *What You Need to Know About LEMTRADA Treatment and Infusion Reactions: A Patient Guide*

The patient must be counseled about the risk for infusion reactions and provided with *What You Need to Know About LEMTRADA Treatment and Infusion Reactions: A Patient Guide* prior to the first infusion of each treatment course.

Has the patient been counseled and received the guide? Yes No

Step 3: CONFIRM appropriate medical measures available during infusion

Appropriate medical support measures are available:

- In case of serious infusion reactions.
- To monitor patient's vital signs during and post-infusion.

Are the appropriate medical measures listed above available? Yes No

Step 4: RECORD infusion information

Was patient infused with LEMTRADA? Yes No

Fill in Dates of Infusion below and then proceed to Step 5.

LEMTRADA Infusions

Dates of Infusion: *Please enter valid date (MM/DD/YYYY).*

Date: Date:

Date: Date:

Date:

Step 5: RETURN of unused vials of LEMTRADA

Unused vials of LEMTRADA must be returned within 50 days of submission of the LEMTRADA REMS Patient Authorization and Lab Form. Contact the LEMTRADA REMS at 1-855-676-6326 for additional information.

Step 6: SIGNATURE

By providing my e-signature, I attest that I have filled out the Infusion Checklist to the best of my knowledge. I understand that my e-signature will be used to verify my enrollment in the LEMTRADA REMS. By entering my name, NPI number, and password, I confirm my e-signature of this form.

Name of staff member completing checklist

Password

NPI Number

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Save

Submit

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LEMTRADA
alemtuzumab

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LEMTRADA REMS INFUSION CHECKLIST

Do you wish to submit this form?

Yes
No

PATIENT INFORMATION

<p>Patient First Name: <input type="text" value="John"/></p> <p>Patient Last Name: <input type="text" value="Doe"/></p> <p>Patient LEMTRADA REMS Identification Number: <input type="text" value="125698909"/></p> <p>DOB (MM/DD/YYYY): <input type="text" value="06/10/1965"/> Full Patient Record</p>	<p>Prescriber First Name: <input type="text" value="Adam"/></p> <p>Prescriber Last Name: <input type="text" value="Smith"/></p> <p>Prescriber LEMTRADA REMS Identification Number: <input type="text" value="125698909"/></p>
---	---

HEALTHCARE FACILITY INFORMATION

<p>Healthcare Facility Name: <input type="text" value="Facility 01"/></p>	<p>Healthcare Facility LEMTRADA REMS Identification Number: <input type="text" value="098789678"/></p>
---	--

Step 1: CONFIRM that the patient is authorized to receive LEMTRADA

You must complete the LEMTRADA REMS infusion verification online or contact the LEMTRADA REMS by phone (1-855-676-6326) prior to initiation of each treatment course.

Is the patient authorized to receive LEMTRADA? Yes No

Step 2: CONFIRM that the patient has been counseled and has received *What You Need to Know About LEMTRADA Treatment and Infusion Reactions: A Patient Guide*

The patient must be counseled about the risk for infusion reactions and provided with *What You Need to Know About LEMTRADA Treatment and Infusion Reactions: A Patient Guide* prior to the first infusion of each treatment course.

Has the patient been counseled and received the guide? Yes No

Step 3: CONFIRM appropriate medical measures available during infusion

Appropriate medical support measures are available:

1. In case of serious infusion reactions.
2. To monitor patient's vital signs during and post-infusion.

Are the appropriate medical measures listed above available? Yes No

Step 4: RECORD infusion information

Was patient infused with LEMTRADA? Yes No

Fill in Dates of Infusion below and then proceed to Step 5.

LEMTRADA Infusions

Dates of infusion:

Date: <input type="text" value="10 / 1 / 2007"/> <input type="text" value="10 / 4 / 2007"/>
Date: <input type="text" value="10 / 2 / 2007"/> <input type="text" value="10 / 5 / 2007"/>
Date: <input type="text" value="10 / 3 / 2007"/>

Step 5: RETURN of unused vials of LEMTRADA

Unused vials of LEMTRADA must be returned within 50 days of submission of the LEMTRADA REMS Patient Authorization and Lab Form. Contact the LEMTRADA REMS at 1-855-676-6326 for additional information.

Step 6: SIGNATURE

By providing my e-signature, I attest that I have filled out the Infusion Checklist to the best of my knowledge. I understand that my e-signature will be used to verify my enrollment in the LEMTRADA REMS. By entering my name, NPI number, and password, I confirm my e-signature of this form.

Name of staff member completing checklist:

Password:

NPI Number:

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[Cancel](#)
Save
Submit

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The screenshot shows a web browser window with the following content:

- Browser Header:** Includes navigation arrows, a search bar with "Google", and window control buttons.
- Page Header:** Features the LEMTRADA logo (alem^{12mg}tuzumab^{iv}) on the left and links for "Prescribing Information" and "Medication Guide" on the right. Below this is a personalized welcome message: "Welcome, Robert Clark!" with links for "My Profile" and "Log Out".
- Navigation Bar:** A horizontal bar with four buttons: "Home", "Forms & FAQs", "REMS Certified Prescriber & Healthcare Facility Locator", and "About REMS".
- Main Content Area:**
 - Section Header:** "LEMTRADA REMS INFUSION CHECKLIST COMPLETE"
 - Text:** "Please allow 1-2 business days for the form to be processed. If you have questions about your form submission, please contact the LEMTRADA REMS at 1-855-676-6326, Mon - Fri, 8:30 am - 8:00 pm ET."
 - Action:** "Download and print a copy of the LEMTRADA REMS Infusion Checklist for the patient's medical record."
 - Button:** A green "Back" button.
 - Text:** "If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6326, Mon - Fri, 8:30 am - 8:00 pm ET."
- Footer:** A dark purple footer containing:
 - Links: "Terms and Conditions | Privacy Policy | Contact Us"
 - Disclaimer: "This site is intended for United States residents only."
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 - Legal: "Lemtrada, MS One to One, Sanofi and Genzyme registered in U.S. Patent and Trademark Office US.MS.LEM.14.10.013-v7 Last Updated 09/19"
 - Logo: "SANOFI GENZYME" with the company logo.

FOLD

LEMTRADA
alemtuzumab^{12mg} iv

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John Doe
(REMS ID 129684352)
REMS Authorized
Year of Birth: 1982
7776 Golden Blossom Run
Zook, IL 62056-3630
Home Phone: xxx-xxx-xxxx
Mobile Phone: xxx-xxx-xxxx

LEMTRADA REMS INFUSION CHECKLIST
Your progress on the LEMTRADA REMS Infusion Checklist has been saved. The checklist must be completed by the last day of the patient's treatment course.
[View Checklist](#)

Insurance	
Provider: BlueCross BlueShield of Kansas City	Coverage: Completed (View)

Infusion Information	
First Course: 6/10/12 - 6/14/12 (View Checklist)	Infusion Facility: Facility 01

Prescriber Information	
Prescriber: Adam Smith , MD	REMS ID: 0123456789

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The screenshot shows a web browser window displaying the LEMTRADA REMS desktop interface. The browser's address bar shows a Google search engine. The page header includes the LEMTRADA logo (alemfuzumab 12mg iv) and navigation links for 'Prescribing Information' and 'Medication Guide'. A personalized welcome message for 'Robert Clark' is displayed, along with links for 'My Profile' and 'Log Out'. A purple navigation bar contains links for 'Home', 'Forms & FAQs', 'REMS Certified Prescriber & Healthcare Facility Locator', and 'About REMS'. The main content area features a 'Previous Page' section for 'John Doe' (REMS ID 129684352), a green 'REMS Authorized' badge, and contact information. Below this are three data tables: 'Insurance' (Provider: BlueCross BlueShield of Kansas City, Coverage: Completed), 'Infusion Information' (First Course: 6/10/12 - 6/14/12, Infusion Facility: Facility 01), and 'Prescriber Information' (Prescriber: Adam Smith, MD, REMS ID: 0123456789). A disclaimer states the site is for prescribers and is updated every 12 hours. A call to action provides a phone number for questions. The footer contains links for 'Privacy Policy', 'Terms and Conditions', and 'Contact Us', along with copyright information and the Sanofi Genzyme logo.

LEMTRADA[®]
alemfuzumab^{12mg}_{iv}

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John Doe
(REMS ID 129684352)
REMS Authorized
Year of Birth: 1982
7776 Golden Blossom Run
Zook, IL 62056-3630
Home Phone: xxx-xxx-xxxx
Mobile Phone: xxx-xxx-xxxx

Insurance	
Provider: BlueCross BlueShield of Kansas City	Coverage: Completed (View)

Infusion Information	
First Course: 6/10/12 - 6/14/12 (View Checklist)	Infusion Facility: Facility 01

Prescriber Information	
Prescriber: Adam Smith , MD	REMS ID: 0123456789

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The screenshot shows a web browser window displaying the LEMTRADA REMS website. The browser's address bar shows a Google search engine. The website header includes the LEMTRADA logo (alemtezumab 12mg iv) and navigation links for 'Prescribing Information' and 'Medication Guide'. A user is logged in as 'Robert Clark', with links for 'My Profile' and 'Log Out'. A purple navigation bar contains 'Home', 'Forms & FAQs', 'REMS Certified Prescriber & Healthcare Facility Locator', and 'About REMS'. The main content area features a 'Previous Page' link, the patient's name 'John Doe' (REMS ID 129684352), and a green 'REMS Authorized' badge. Patient details include birth year (1982), address (7776 Golden Blossom Run, Zook, IL 62056-3630), and phone numbers. A 'LEMTRADA REMS Infusion Checklist' link is present. Three data tables are shown: 'Insurance' (Provider: BlueCross BlueShield of Kansas City, Coverage: Completed), 'Infusion Information' (First Course: 6/10/12 - 6/14/12, Infusion Facility: Facility 01), and 'Prescriber Information' (Prescriber: Adam Smith, MD, REMS ID: 0123456789). A disclaimer states the site is for prescribers and not medical advice. A call to action provides a phone number (1-855-676-6326) for questions. The footer contains 'Privacy Policy | Terms and Conditions | Contact Us', copyright information (©2019 Genzyme Corporation), and the SANOFI GENZYME logo.

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Prescribing Information Medication Guide

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John Doe
(REMS ID 129684352)

REMS Authorized

Year of Birth: 1982
7776 Golden Blossom Run
Zook, IL 62056-3630
Home Phone: xxx-xxx-xxxx
Mobile Phone: xxx-xxx-xxxx

[LEMTRADA REMS Infusion Checklist](#)

Insurance	
Provider: BlueCross BlueShield of Kansas City	Coverage: Completed (View)

Infusion Information	
First Course: 6/10/12 - 6/14/12 (View Checklist)	Infusion Facility: Facility 01

Prescriber Information	
Prescriber: Adam Smith , MD	REMS ID: 0123456789

This site is provided as a resource for prescribers and is not intended as medical advice.
Information on the site is updated periodically (approximately every 12 hours).

If you have questions about the LEMTRADA REMS
or need help enrolling, call **1-855-676-6326**, Mon - Fri, 8:30 am - 8:00 pm ET.

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◀ Previous Page
John Doe
(REMS ID 129684352)
Not REMS Authorized
Year of Birth: 1982
7776 Golden Blossom Run
Zook, IL 62056-3630
Home Phone: xxx-xxx-xxxx
Mobile Phone: xxx-xxx-xxxx

Alert
This patient is overdue for authorization by the LEMTRADA REMS Patient Status Form. Please contact the prescriber, who must complete the necessary form.

[LEMTRADA REMS Infusion Checklist](#)

Insurance	
Provider: BlueCross BlueShield of Kansas City	Coverage: Completed (View)

Infusion Information	
First Course: 6/10/12 - 6/14/12 (View Checklist)	Infusion Facility: Facility 01
Next Infusion Date: 6/10/13	Infusion Facility: Facility 01

Prescriber Information	
Prescriber: Adam Smith, MD	REMS ID: 0123456789

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The screenshot shows a web browser window displaying the LEMTRADA REMS Desktop HCF Dashboard. The page features a purple header with the LEMTRADA logo and navigation links. A patient profile for John Doe is shown, including contact information and a 'REMS Authorized' status. Below this are three data tables: Insurance, Infusion Information, and Prescriber Information. A disclaimer and contact information are also present. The footer contains legal notices and the Sanofi Genzyme logo.

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John Doe
(REMS ID 129684352)
REMS Authorized
Year of Birth: 1982
7776 Golden Blossom Run
Zook, IL 62056-3630
Home Phone: xxx-xxx-xxxx
Mobile Phone: xxx-xxx-xxxx

Insurance	
Provider: BlueCross BlueShield of Kansas City	Coverage: Completed (View)

Infusion Information	
First Course: 6/10/12 - 6/14/12 (View Checklist)	Infusion Facility: Facility 01
Second Course: 6/10/13 - 6/12/13 (View Checklist)	Infusion Facility: Facility 01

Prescriber Information	
Prescriber: Adam Smith , MD	REMS ID: 0123456789

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About REMS

🔔 You have 5 patient alerts!
▶

Our Patients

Prescribers

Manage Users

You have 13 LEMTRADA prescribers associated with your patients ?

Last Name	First Name	REMS ID	REMS Status	Patient Alerts
Smith	Adam	0123456789	Certified	
Smith	Adam	0123456789	Certified	
Smith	Adam	0123456789	Certified	
Smith	Adam	0123456789	Not Certified	🔔
Smith	Adam	0123456789	Certified	
Smith	Adam	0123456789	Certified	
Smith	Adam	0123456789	Certified	
Smith	Adam	0123456789	Certified	
Smith	Adam	0123456789	Not Certified	
Smith	Adam	0123456789	Certified	
Smith	Adam	0123456789	Certified	
Smith	Adam	0123456789	Not Certified	🔔
Smith	Adam	0123456789	Certified	

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The screenshot shows a web browser window displaying the LEMTRADA REMS Desktop HCF Dashboard. The page features a navigation bar with links for 'Prescribing Information' and 'Medication Guide'. A user is logged in as Robert Clark, with links for 'My Profile' and 'Log Out'. A notification bar indicates 'You have 5 patient alerts!'. Below this, there are tabs for 'Our Patients', 'Prescribers', and 'Manage Users'. The 'Prescribers' tab is active, showing a list of 13 prescribers associated with the user's patients. A tooltip is expanded over the first row of the table, providing instructions on how to search, sort, and navigate the information.

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🔔 You have 5 patient alerts!

Our Patients Prescribers Manage Users

You have 13 LEMTRADA prescribers associated with your patients

Last Name	First Name	Address	Phone Number	Status	Patient Alerts
Smith	Adam			Certified	
Smith	Adam		0123456789	Certified	
Smith	Adam		0123456789	Certified	
Smith	Adam		0123456789	Not Certified	🔔
Smith	Adam		0123456789	Certified	
Smith	Adam		0123456789	Certified	
Smith	Adam		0123456789	Certified	
Smith	Adam		0123456789	Certified	
Smith	Adam		0123456789	Not Certified	
Smith	Adam		0123456789	Certified	
Smith	Adam		0123456789	Certified	
Smith	Adam		0123456789	Not Certified	🔔
Smith	Adam		0123456789	Certified	

Search, sort, and navigate information about your prescribers below. Click on a name to view their individual profile.

FOLD

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Adam Smith, MD
(REMS ID 129684352)

REMS Certified

7776 Golden Blossom Run
Zook, IL 62056-3630
Office Phone: xxx-xxx-xxxx
Mobile Phone: xxx-xxx-xxxx
Fax: xxx-xxx-xxxx



[View Map](#)

Patients Seeing This Prescriber

🚨 You have 1 patient alerts!
▶

You have 10 LEMTRADA patients associated with this prescriber ? 🔍

🚨	Last Name	First Name	Year of Birth	REMS ID	REMS Status
	Doe	John	1980	129684352	Authorized
	Doe	John	1980	129684352	Authorized
🚨	Doe	John	1980	129684352	Not Authorized
	Doe	John	1980	129684352	Not Authorized
	Doe	John	1980	129684352	Authorized
	Doe	John	1980	129684352	Not Authorized
	Doe	John	1980	129684352	Authorized
	Doe	John	1980	129684352	Authorized
	Doe	John	1980	129684352	Authorized
	Doe	John	1980	129684352	Authorized

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Adam Smith, MD
(REMS ID 129684352)

REMS Certified

7776 Golden Blossom Run
Zook, IL 62056-3630
Office Phone: xxx-xxx-xxxx
Mobile Phone: xxx-xxx-xxxx
Fax: xxx-xxx-xxxx



[View Map](#)

Patients Seeing This Prescriber

🚨 You have 1 patient alerts!
▶

You have 10 LEMTRADA patients associated with this prescriber 🔍

	Last Name	First Name	Birth Date	REMS ID	REMS Status
	Doe			129684352	Authorized
	Doe	John	1980	129684352	Authorized
🚨	Doe	John	1980	129684352	Not Authorized
	Doe	John	1980	129684352	Not Authorized
	Doe	John	1980	129684352	Authorized
	Doe	John	1980	129684352	Not Authorized
	Doe	John	1980	129684352	Authorized
	Doe	John	1980	129684352	Authorized
	Doe	John	1980	129684352	Authorized
	Doe	John	1980	129684352	Authorized

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VV-REG-0833078 0.1

Reference ID: 4512344



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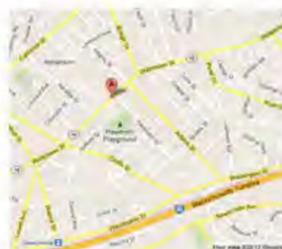
About REMS

◀ Previous Page

Adam Smith, MD
(REMS ID 129684352)

REMS Certified

7776 Golden Blossom Run
Zook, IL 62056-3630
Office Phone: xxx-xxx-xxxx
Mobile Phone: xxx-xxx-xxxx
Fax: xxx-xxx-xxxx



[View Map](#)

Patients Seeing This Prescriber

🚨 You have 1 patient alerts!
▼

You have **1 patient** who has authorization requirements.

- **1 patient** is due for the LEMTRADA REMS Patient Status Form in 1 month.

[Manage my patient alert email preferences](#)

You have 10 LEMTRADA patients associated with this prescriber ? 🔍

	Last Name	First Name	Year of Birth	REMS ID	REMS Status
	Doe	John	1980	129684352	Authorized
	Doe	John	1980	129684352	Authorized
🚨	Doe	John	1980	129684352	Not Authorized
	Doe	John	1980	129684352	Not Authorized
	Doe	John	1980	129684352	Authorized
	Doe	John	1980	129684352	Not Authorized
	Doe	John	1980	129684352	Authorized
	Doe	John	1980	129684352	Authorized
	Doe	John	1980	129684352	Authorized
	Doe	John	1980	129684352	Authorized

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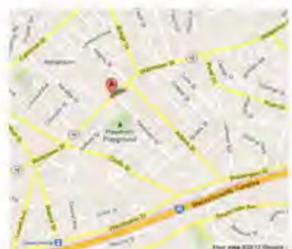
About REMS

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Adam Smith, MD
(REMS ID 129684352)

Not REMS Certified

7776 Golden Blossom Run
Zook, IL 62056-3630
Office Phone: xxx-xxx-xxxx
Mobile Phone: xxx-xxx-xxxx
Fax: xxx-xxx-xxxx



[View Map](#)

Patients Seeing This Prescriber

🚨 You have 1 patient alerts!
▶

You have 10 LEMTRADA patients associated with this prescriber ? 🔍

🚨	Last Name	First Name	Year of Birth	REMS ID	REMS Status
	Doe	John	1980	129684352	Authorized
	Doe	John	1980	129684352	Authorized
🚨	Doe	John	1980	129684352	Not Authorized
	Doe	John	1980	129684352	Not Authorized
	Doe	John	1980	129684352	Authorized
	Doe	John	1980	129684352	Not Authorized
	Doe	John	1980	129684352	Authorized
	Doe	John	1980	129684352	Authorized
	Doe	John	1980	129684352	Authorized
	Doe	John	1980	129684352	Authorized

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ⓘ You have 5 patient alerts!

Our Patients Prescribers **Manage Users**

As a Facilities Manager, you have access to LEMTRADA REMS certified facility staff profiles. Use the list below to search and sort staff members enrolled in the LEMTRADA REMS at your healthcare facility. Click on a name to update a user's information, or delete a user.

+ Add New User

You have 6 certified users **?**

Last Name	First Name	Last Logged In	Edit	Delete
Clark	Robert	10/14/2014	Edit	Delete
Clark	Robert	10/14/2014	Edit	Delete
Clark	Robert	10/14/2014	Edit	Delete
Clark	Robert	10/14/2014	Edit	Delete
Clark	Robert	10/14/2014	Edit	Delete
Clark	Robert	10/14/2014	Edit	Delete

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You have 5 patient alerts!

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+ Add New User

You have 6 certified users

Last Name			Edit	Delete
Clark			Edit	Delete
Clark	Robert	10/14/2014	Edit	Delete
Clark	Robert	10/14/2014	Edit	Delete
Clark	Robert	10/14/2014	Edit	Delete
Clark	Robert	10/14/2014	Edit	Delete
Clark	Robert	10/14/2014	Edit	Delete

FOLD

All users below must have completed LEMTRADA REMS training. Click on a name to update user information or remove users who have access to your facility's account.

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SANOFI GENZYME

The screenshot displays the LEMTRADA REMS Desktop HCF Dashboard. At the top, the LEMTRADA logo is visible, along with navigation links for 'Prescribing Information' and 'Medication Guide'. A user is logged in as 'Robert Clark', with links for 'My Profile' and 'Log Out'. The dashboard includes a navigation menu with 'Home', 'Forms & FAQs', 'REMS Certified Prescriber & Healthcare Facility Locator', and 'About REMS'. A notification states 'You have 5 patient'. Below this, there's a section for 'Our Patients' with an 'Add New User' button. A table shows a list of users, with the last row containing 'Clark', 'Robert', and '10/14/2014'. A modal window titled 'Add New User' is open, containing the following text: 'Only healthcare facilities enrolled in the LEMTRADA REMS can dispense and administer LEMTRADA. All new users must be appropriately trained to administer LEMTRADA before being added to this system. All fields are required.' The form includes input fields for 'First Name', 'Last Name', 'Email', and 'Confirm Email'. A checkbox is labeled 'User has received the required LEMTRADA REMS training.' The modal has 'Cancel' and 'Save' buttons.

Add New User

Only healthcare facilities enrolled in the LEMTRADA REMS can dispense and administer LEMTRADA. All new users must be appropriately trained to administer LEMTRADA before being added to this system.

All fields are required.

First Name

Last Name

Email

Confirm Email

User has received the required LEMTRADA REMS training.

[Cancel](#) [Save](#)

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The screenshot shows a web browser window displaying the LEMTRADA REMS Desktop HCF Dashboard. The dashboard header includes the LEMTRADA logo, navigation links for 'Prescribing Information' and 'Medication Guide', and a user greeting 'Welcome, Robert Clark!' with links for 'My Profile' and 'Log Out'. The main navigation bar contains 'Home', 'Forms & FAQs', 'REMS Certified Prescriber & Healthcare Facility Locator', and 'About REMS'. A notification banner at the top left states 'You have 5 patient'. Below this, there are sections for 'Our Patients' and 'Add New User'. A table lists certified users with columns for 'Last Name', 'First Name', 'Date', and 'Action'. The 'Add New User' modal is open, containing the following text and form fields:

Add New User

Only healthcare facilities enrolled in the LEMTRADA REMS can dispense and administer LEMTRADA. All new users must be appropriately trained to administer LEMTRADA before being added to this system.

All fields are required.

First Name

Please enter first name.

Last Name

Please enter last name.

Email

Please enter email.

Confirm Email

Please confirm email.

User has received the required LEMTRADA REMS training.
Please confirm that user has been trained.

[Cancel](#) [Save](#)

At the bottom of the page, there is a disclaimer: 'This site is provided as a resource for prescribers and is not intended as medical advice. Information on the site is updated periodically (approximately every 12 hours).', contact information for questions, and a footer with 'SANOFI GENZYME' logo and copyright information.

The screenshot shows a web browser window displaying the LEMTRADA REMS HCF Dashboard. The dashboard header includes the LEMTRADA logo, navigation links for 'Prescribing Information' and 'Medication Guide', and a user greeting: 'Welcome, Robert Clark! My Profile | Log Out'. A main navigation bar contains 'Home', 'Forms & FAQs', 'REMS Certified Prescriber & Healthcare Facility Locator', and 'About REMS'. A notification banner states 'You have 5 patient alerts!'. Below this are buttons for 'Our Patients' and 'Prescribers'. A text block explains that as a Facilities Manager, users can sort, add, or delete staff members. A green 'Add New User' button is present. A section titled 'You have 6 certified users' features a table with columns for 'Last Name', 'First Name', and a date. Below the table are 'Edit' and 'Delete' buttons for each user. An 'Edit User' modal form is open in the center, containing input fields for 'First Name' (Robert), 'Last Name' (Clark), and 'Email' (rclark@abc123.com). It also has two checkboxes: 'User has received the required LEMTRADA REMS training.' and 'Require password reset.', along with 'Cancel' and 'Save' buttons. At the bottom of the page, there is a disclaimer: 'This site is provided as a resource for prescribers and is not intended as medical advice. Information on the site is updated periodically (approximately every 12 hours).', contact information for questions, and a footer with 'SANOFI GENZYME' logo and copyright information.

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Prescribing Information Medication Guide

Welcome, Robert Clark! My Profile | Log Out

Home Forms & FAQs REMS Certified Prescriber & Healthcare Facility Locator About REMS

You have 5 patient alerts!

Our Patients Prescribers

As a Facilities Manager, you have access to sort staff members enrolled in the LEMTRADA REMS program, add new users, or delete a user.

Add New User

You have 6 certified users

Last Name	First Name	Date	Edit	Delete
Clark	Robert	10/14/2014	Edit	Delete
Clark	Robert	10/14/2014	Edit	Delete
Clark	Robert	10/14/2014	Edit	Delete
Clark	Robert	10/14/2014	Edit	Delete
Clark	Robert	10/14/2014	Edit	Delete
Clark	Robert	10/14/2014	Edit	Delete

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SANOFI GENZYME

LEMTRADA
alemtuzumab ORIG

Prescribing Information Medication Guide

Welcome, Robert Clark! [My Profile](#) | [Log Out](#)

Home Forms & FAQs REMS Certified Prescriber & Healthcare Facility Locator About REMS

You have 5 patient alerts!

Our Patients Prescriptions

As a Facilities Manager, you have access to...
sort staff members enrolled in the LEMTRADA...
or delete a user.

[Add New User](#)

You have 6 certified users

Last Name	First Name		
Clark	Robert	10/14/2014	Edit Delete
Clark	Robert	10/14/2014	Edit Delete
Clark	Robert	10/14/2014	Edit Delete
Clark	Robert	10/14/2014	Edit Delete
Clark	Robert	10/14/2014	Edit Delete
Clark	Robert	10/14/2014	Edit Delete

Edit User

First Name
Robert

Last Name
Clark

Email
rclark@abc123.com

User has received the required LEMTRADA REMS training.
Please confirm that user has been trained.

Require password reset.

[Cancel](#) [Save](#)

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Information on the site is updated periodically (approximately every 12 hours).

If you have questions about the LEMTRADA REMS
or need help enrolling, call 1-855-676-6326. Mon - Fri, 8:30 am - 8:00 pm ET.

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The screenshot shows a web browser window displaying the LEMTRADA REMS HCF Dashboard. A modal dialog box is centered on the screen, asking for confirmation to delete a user. The dialog has a white background, a close button (X) in the top right, and two buttons at the bottom: a red 'Delete' button and a 'Cancel' link.

The background dashboard includes the LEMTRADA logo, navigation tabs (Home, Forms & FAQs, REMS Certified Prescriber & Healthcare Facility Locator, About REMS), and a table of certified users. The table has columns for Last Name, First Name, Last Logged In, Edit, and Delete. There are six rows of data, all with 'Clark' as the last name and 'Robert' as the first name.

Below the table, there is a disclaimer: "This site is provided as a resource for prescribers and is not intended as medical advice. Information on the site is updated periodically (approximately every 12 hours)." and contact information: "If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6326. Mon - Fri, 8:30 am - 8:00 pm ET."

The footer contains links for Privacy Policy, Terms and Conditions, and Contact Us, along with copyright information for Sanofi Genzyme (©2019 Genzyme Corporation) and the LEMTRADA logo.

The screenshot shows a web browser window displaying the LEMTRADA REMS HCF Dashboard. A white modal box is centered on the screen with the text "User Successfully Deleted" and a green "Back" button. The background is dimmed but shows a navigation menu with "Home", "Forms & FAQs", "REMS Certified Prescriber & Healthcare Facility Locator", and "About REMS". A header area includes "Prescribing Information" and "Medication Guide", and a user greeting "Welcome, Robert Clark!" with links for "My Profile" and "Log Out". A notification bar at the top left says "You have 5 patient". Below the modal, a section titled "Our Patients" contains a table of certified users. The table has columns for "Last Name", "First Name", and "Last Logged In", with each row containing "Clark", "Robert", and "10/14/2014" respectively, and "Edit" and "Delete" buttons. A "FOLD" button is visible on the left side of the table. At the bottom of the page, there is a disclaimer: "This site is provided as a resource for prescribers and is not intended as medical advice. Information on the site is updated periodically (approximately every 12 hours)." and contact information: "If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6326. Mon - Fri, 8:30 am - 8:00 pm ET." The footer includes "Privacy Policy | Terms and Conditions | Contact Us", "©2019 Genzyme Corporation. All rights reserved.", and the "SANOFI GENZYME" logo.

LEMTRADA[®]
alemtuzumab^{12mg} iv

Prescribing Information Medication Guide

Welcome, Robert Clark! [My Profile](#) | [Log Out](#)

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My Profile

Robert Clark
(REMS ID 123456)
7776 Golden Blossom Run
Zook, IL 62056-3630
Office Phone: xxx-xxx-xxxx
Fax: xxx-xxx-xxxx

If any of your information is incorrect or has recently changed, please call **1-855-676-6326**, Mon – Fri, 8:30 am – 8:00 pm ET, so we can make appropriate updates.

Manage My Alert Preferences

Customize how often you would like to receive emails about the status of your LEMTRADA patients. Please note that you will continue to receive important communications from Genzyme, if warranted.

Patient Alert Emails

As a part of the LEMTRADA REMS you will automatically receive emails to update you on the status of your LEMTRADA patients. How often would you like to receive emails regarding patient alert summaries?

Please provide a monthly summary of alerts

Please provide a weekly summary of alerts

Please do not provide a summary of alerts

[Update Alert Preferences](#)

Change Your Password

Passwords must be at least 8 characters in length and contain a minimum of 3 out of the following: A number, an upper-case letter, a lower-case letter, a special character (e.g. !, ", #, \$, etc.)

Current Password

New Password

Confirm Password

[Change Password](#)

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The screenshot shows a web browser window displaying the LEMTRADA REMS desktop interface. The browser's address bar shows a Google search. The page header includes the LEMTRADA logo (alemfuzumab 12mg iv) and navigation links for Prescribing Information and Medication Guide. A user greeting reads "Welcome, Robert Clark!" with links for My Profile and Log Out. A purple navigation bar contains buttons for Home, Forms & FAQs, REMS Certified Prescriber & Healthcare Facility Locator, and About REMS. The main content area is titled "My Profile" and features a dark header with the name "Robert Clark" and "(REMS ID 123456)". Below this, contact information is listed: "7776 Golden Blossom Run, Zook, IL 62056-3630, Office Phone: xxx-xxx-xxxx, Fax: xxx-xxx-xxxx". A note states: "If any of your information is incorrect or has recently changed, please call 1-855-676-6326, Mon - Fri, 8:30 am - 8:00 pm ET, so we can make appropriate updates." The next section is "Manage My Alert Preferences" with a sub-header "Patient Alert Emails". It explains that users will receive emails about patient status and asks how often they want to receive summaries. Three radio button options are provided: "Please provide a monthly summary of alerts", "Please provide a weekly summary of alerts" (which is selected), and "Please do not provide a summary of alerts". A green "Update Alert Preferences" button is at the bottom of this section. The following section is "Change Your Password", which includes instructions on password requirements (at least 8 characters, including a number, upper-case letter, lower-case letter, and special character). It contains three input fields: "Current Password", "New Password", and "Confirm Password", each with a red error message below it: "Please enter password.", "Please enter a valid password.", and "Please confirm new password." respectively. A green "Change Password" button is at the bottom. A disclaimer states: "This site is provided as a resource for prescribers and is not intended as medical advice. Information on the site is updated periodically (approximately every 12 hours)." A call to action at the bottom reads: "If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6326, Mon - Fri, 8:30 am - 8:00 pm ET." The footer contains links for Privacy Policy, Terms and Conditions, and Contact Us. It also includes a disclaimer: "This site is intended for United States residents only. ©2019 Genzyme Corporation. All rights reserved. Lemtrada, MS One to One, Sanofi and Genzyme registered in U.S. Patent and Trademark Office US.MS.LEM.14.10.013-v7 Last Updated 09/19" and the SANOFI GENZYME logo.

The screenshot shows a web browser window displaying the LEMTRADA REMS desktop interface. The browser's address bar shows a Google search engine. The page header includes the LEMTRADA logo (alemTuzumab^{12mg} iv) and navigation links for Prescribing Information and Medication Guide. A user greeting reads "Welcome, Robert Clark!" with links for My Profile and Log Out. A purple navigation bar contains buttons for Home, Forms & FAQs, REMS Certified Prescriber & Healthcare Facility Locator, and About REMS.

The main content area is titled "My Profile" and features a dark header with the name "Robert Clark" and "(REMS ID 123456)". Below this, the user's address is listed: "7776 Golden Blossom Run, Zook, IL 62056-3630, Office Phone: xxx-xxx-xxxx, Fax: xxx-xxx-xxxx". A note states: "If any of your information is incorrect or has recently changed, please call 1-855-676-6326, Mon - Fri, 8:30 am - 8:00 pm ET, so we can make appropriate updates."

The next section is "Manage My Alert Preferences", with a sub-section "Patient Alert Emails". It asks, "How often would you like to receive emails regarding patient alert summaries?" and provides three radio button options: "Please provide a monthly summary of alerts", "Please provide a weekly summary of alerts" (which is selected), and "Please do not provide a summary of alerts". A green "Update Alert Preferences" button is at the bottom of this section.

The "Change Your Password" section follows, with instructions: "Passwords must be at least 8 characters in length and contain a minimum of 3 out of the following: A number, an upper-case letter, a lower-case letter, a special character (e.g. !, *, #, \$, etc.)". It contains three input fields: "Current Password" (with a red error message "Password is incorrect."), "New Password" (with a red error message "Password does not meet strength requirements"), and "Confirm Password" (with a red error message "Passwords do not match."). A green "Change Password" button is at the bottom.

A disclaimer states: "This site is provided as a resource for prescribers and is not intended as medical advice. Information on the site is updated periodically (approximately every 12 hours)."

A call to action reads: "If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6326, Mon - Fri, 8:30 am - 8:00 pm ET."

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The screenshot shows a web browser window displaying the LEMTRADA REMS website. The browser's address bar shows a Google search. The website header includes the LEMTRADA logo (alemtozumab^{12mg} iv) and navigation links for Prescribing Information and Medication Guide. A user is logged in as Robert Clark, with links for My Profile and Log Out. A main navigation bar contains Home, Forms & FAQs (highlighted), REMS Certified Prescriber & Healthcare Facility Locator, and About REMS. Below this, a sub-navigation bar has Forms and FAQs (highlighted). The main content area is titled "Required LEMTRADA REMS Forms & Materials" and includes a sub-header "Refer to these materials for information about the safe use of LEMTRADA through the LEMTRADA REMS." A list of resources follows, each with an ONLINE or PDF link and a title: LEMTRADA REMS Program Overview, LEMTRADA REMS Education Program for Healthcare Facilities, LEMTRADA REMS Healthcare Facility Enrollment Form, LEMTRADA REMS Infusion Checklist, and What You Need to Know About LEMTRADA Treatment and Infusion Reactions: A Patient Guide. A note at the bottom of the list states that Adobe Reader is required to view the PDFs. A call to action section below the list provides contact information: "If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6326, Mon - Fri, 8:30 am - 8:00 pm ET." The footer contains links for Privacy Policy, Terms and Conditions, and Contact Us, along with copyright information for Genzyme Corporation (©2019) and the Sanofi Genzyme logo.

FOLD



LEMTRADA
alemtuzumab^{12mg} iv

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LEMTRADA REMS INFUSION CHECKLIST

As a condition of your healthcare facility's authorization to infuse LEMTRADA® (alemtuzumab), this Infusion Checklist **must** be completed for each patient by the last day of each patient's treatment course and submitted within **5 business days**. This Infusion Checklist **must also be completed and returned even if LEMTRADA is not infused**. Keep a copy of this checklist in the patient's medical record.

Please complete the form and submit to Genzyme by clicking the button below.

All fields are required.

PATIENT INFORMATION

Patient First Name

Patient Last Name

Patient LEMTRADA REMS Identification Number

DOB (MM/DD/YYYY)
 [Full Patient Record](#)

PRESCRIBER INFORMATION

Prescriber First Name

Prescriber Last Name

Prescriber LEMTRADA REMS Identification Number

HEALTHCARE FACILITY INFORMATION

Healthcare Facility Name

Healthcare Facility LEMTRADA REMS Identification Number

Step 1: CONFIRM that the patient is authorized to receive LEMTRADA

You must complete the LEMTRADA REMS infusion verification online or contact the LEMTRADA REMS by phone (1-855-676-6326) prior to initiation of each treatment course.

Is the patient authorized to receive LEMTRADA? Yes No

Step 2: CONFIRM that the patient has been counseled and has received *What You Need to Know About LEMTRADA Treatment and Infusion Reactions: A Patient Guide*

The patient must be counseled about the risk for infusion reactions and provided with *What You Need to Know About LEMTRADA Treatment and Infusion Reactions: A Patient Guide* prior to the first infusion of each treatment course.

Has the patient been counseled and received the guide?
 Yes No

Step 3: CONFIRM appropriate medical measures available for infusion

Appropriate medical support measures are available:

1. In case of serious infusion reactions.
2. To monitor patient's vital signs before, during, and post-infusion.

Are the appropriate medical measures listed above available?
 Yes No

Step 4: RECORD infusion information

Was patient infused with LEMTRADA? Yes No

Step 5: RETURN of unused vials of LEMTRADA

Unused vials of LEMTRADA must be returned within 50 days of submission of the LEMTRADA REMS Patient Authorization and Lab Form. Contact the LEMTRADA REMS at 1-855-676-6326 for additional information.

Step 6: SIGNATURE

By providing my e-signature, I attest that I have filled out the Infusion Checklist to the best of my knowledge. I understand that my e-signature will be used to verify my enrollment in the LEMTRADA REMS. By entering my name, NPI number, and password, I confirm my e-signature of this form.

Name of staff member completing checklist:

Password

NPI Number

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alemtuzumab^{12mg} iv

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Please complete the form and submit to Genzyme by clicking the button below.

All fields are required.

PATIENT INFORMATION

Patient First Name

Patient Last Name

Patient LEMTRADA REMS Identification Number

DOB (MM/DD/YYYY)
 [Full Patient Record](#)

PRESCRIBER INFORMATION

Prescriber First Name

Prescriber Last Name

Prescriber LEMTRADA REMS Identification Number

HEALTHCARE FACILITY INFORMATION

Healthcare Facility Name

Healthcare Facility LEMTRADA REMS Identification Number

Step 1: CONFIRM that the patient is authorized to receive LEMTRADA

You must complete the LEMTRADA REMS infusion verification online or contact the LEMTRADA REMS by phone (1-855-676-6326) prior to initiation of each treatment course.

Is the patient authorized to receive LEMTRADA? Yes No

Alert!

STOP – DO NOT INFUSE.
Refer patient back to the LEMTRADA prescriber.

Step 2: CONFIRM that the patient has been counseled and has received *What You Need to Know About LEMTRADA Treatment and Infusion Reactions: A Patient Guide*

The patient must be counseled about the risk for infusion reactions and provided with *What You Need to Know About LEMTRADA Treatment and Infusion Reactions: A Patient Guide* prior to the first infusion of each treatment course.

Has the patient been counseled and received the guide?
 Yes No

Step 3: CONFIRM appropriate medical measures available for infusion

Appropriate medical support measures are available:

- In case of serious infusion reactions.
- To monitor patient's vital signs before, during, and post-infusion.

Are the appropriate medical measures listed above available?
 Yes No

Step 4: RECORD infusion information

Was patient infused with LEMTRADA? Yes No

Step 5: RETURN of unused vials of LEMTRADA

Unused vials of LEMTRADA must be returned within 50 days of submission of the LEMTRADA REMS Patient Authorization and Lab Form. Contact the LEMTRADA REMS at 1-855-676-6326 for additional information.

Step 6: SIGNATURE

By providing my e-signature, I attest that I have filled out the Infusion Checklist to the best of my knowledge. I understand that my e-signature will be used to verify my enrollment in the LEMTRADA REMS. By entering my name, NPI number, and password, I confirm my e-signature of this form.

Name of staff member completing checklist:

Password

NPI Number

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[Cancel](#)

Submit

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Please complete the form and submit to Genzyme by clicking the button below.

All fields are required.

PATIENT INFORMATION

Patient First Name

Please enter patient's first name.

Patient Last Name

Please enter patient's last name.

Patient LEMTRADA REMS Identification Number

Please enter patient's LEMTRADA REMS Identification Number.

DOB (MM/DD/YYYY)

[Full Patient Record](#)

Please enter patient's valid date of birth.

PRESCRIBER INFORMATION

Prescriber First Name

Please enter prescriber's first name.

Prescriber Last Name

Please enter prescriber's last name.

Prescriber LEMTRADA REMS Identification Number

Please enter prescriber's LEMTRADA REMS Identification Number.

HEALTHCARE FACILITY INFORMATION

Healthcare Facility Name

Please enter healthcare facility name.

Healthcare Facility LEMTRADA REMS Identification Number

Please enter Healthcare Facility LEMTRADA REMS Identification Number.

Step 1: CONFIRM that the patient is authorized to receive LEMTRADA

You must complete the LEMTRADA REMS infusion verification online or contact the LEMTRADA REMS by phone (1-855-676-6326) prior to initiation of each treatment course.

Is the patient authorized to receive LEMTRADA? Yes No

Alert!

STOP – DO NOT INFUSE. Refer patient back to the LEMTRADA prescriber.

Step 2: CONFIRM that the patient has been counseled and has received *What You Need to Know About LEMTRADA Treatment and Infusion Reactions: A Patient Guide*

The patient must be counseled about the risk for infusion reactions and provided with *What You Need to Know About LEMTRADA Treatment and Infusion Reactions: A Patient Guide* prior to the first infusion of each treatment course.

Has the patient been counseled and received the guide?
 Yes No

Alert!

STOP – Provide the patient guide. Proceed to the next question after the patient has received the guide and has been counseled.

Step 3: CONFIRM appropriate medical measures available during infusion

Appropriate medical support measures are available:

1. In case of serious infusion reactions.
2. To monitor patient's vital signs during and post-infusion.

Are the appropriate medical measures listed above available?
 Yes No

Alert!

STOP – DO NOT INFUSE until appropriate medical support measures are available. Please contact the LEMTRADA REMS for additional information.

Step 4: RECORD infusion information

Was patient infused with LEMTRADA? Yes No

Alert!

Proceed to Step 5

Step 5: RETURN of unused vials of LEMTRADA

Unused vials of LEMTRADA must be returned within 50 days of submission of the LEMTRADA REMS Patient Authorization and Lab Form. Contact the LEMTRADA REMS at 1-855-676-6326 for additional information.

Step 6: SIGNATURE

By providing my e-signature, I attest that I have filled out the Infusion Checklist to the best of my knowledge. I understand that my e-signature will be used to verify my enrollment in the LEMTRADA REMS. By entering my name, NPI number, and password, I confirm my e-signature of this form.

Name of staff member completing checklist

Please enter name of staff member completing checklist.

Password

Please enter password.

NPI Number

Please enter a valid NPI number.

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VV-REG-0833078 0-1

Reference ID: 4512344



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Please complete the form and submit to Genzyme by clicking the button below.

All fields are required.

PATIENT INFORMATION

Patient First Name

Patient Last Name

Patient LEMTRADA REMS Identification Number

DOB (MM/DD/YYYY)
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PRESCRIBER INFORMATION

Prescriber First Name

Prescriber Last Name

Prescriber LEMTRADA REMS Identification Number

HEALTHCARE FACILITY INFORMATION

Healthcare Facility Name

Healthcare Facility LEMTRADA REMS Identification Number

Step 1: CONFIRM that the patient is authorized to receive LEMTRADA

You must complete the LEMTRADA REMS infusion verification online or contact the LEMTRADA REMS by phone (1-855-676-6326) prior to initiation of each treatment course.

Is the patient authorized to receive LEMTRADA? Yes No

Step 2: CONFIRM that the patient has been counseled and has received *What You Need to Know About LEMTRADA Treatment and Infusion Reactions: A Patient Guide*

The patient must be counseled about the risk for infusion reactions and provided with *What You Need to Know About LEMTRADA Treatment and Infusion Reactions: A Patient Guide* prior to the first infusion of each treatment course.

Has the patient been counseled and received the guide? Yes No

Step 3: CONFIRM appropriate medical measures available during infusion

Appropriate medical support measures are available:

- In case of serious infusion reactions.
- To monitor patient's vital signs during and post-infusion.

Are the appropriate medical measures listed above available? Yes No

Step 4: RECORD infusion information

Was patient infused with LEMTRADA? Yes No

Fill in Dates of Infusion below and then proceed to Step 5.

LEMTRADA Infusions

Dates of Infusion:

Date:

Step 5: RETURN of unused vials of LEMTRADA

Unused vials of LEMTRADA must be returned within 50 days of submission of the LEMTRADA REMS Patient Authorization and Lab Form. Contact the LEMTRADA REMS at 1-855-676-6326 for additional information.

Step 6: SIGNATURE

By providing my e-signature, I attest that I have filled out the Infusion Checklist to the best of my knowledge. I understand that my e-signature will be used to verify my enrollment in the LEMTRADA REMS. By entering my name, NPI number, and password, I confirm my e-signature of this form.

Name of staff member completing checklist

Password

NPI Number

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LEMTRADA REMS INFUSION CHECKLIST

As a condition of your healthcare facility's authorization to infuse LEMTRADA® (alemtezumab), this Infusion Checklist must be completed for each patient by the last day of each patient's treatment course and submitted within 5 business days. This Infusion Checklist must also be completed and returned even if LEMTRADA is not infused. Keep a copy of this checklist in the patient's medical record.

Please complete the form and submit to Genzyme by clicking the button below.

All fields are required.

PATIENT INFORMATION

Patient First Name

Patient Last Name

Patient LEMTRADA REMS Identification Number

DOB (MM/DD/YYYY)
 [Full Patient Record](#)

PRESCRIBER INFORMATION

Prescriber First Name

Prescriber Last Name

Prescriber LEMTRADA REMS Identification Number

HEALTHCARE FACILITY INFORMATION

Healthcare Facility Name

Healthcare Facility LEMTRADA REMS Identification Number

Step 1: CONFIRM that the patient is authorized to receive LEMTRADA

You must complete the LEMTRADA REMS infusion verification online or contact the LEMTRADA REMS by phone (1-855-676-6326) prior to initiation of each treatment course.

Is the patient authorized to receive LEMTRADA? Yes No

Step 2: CONFIRM that the patient has been counseled and has received *What You Need to Know About LEMTRADA Treatment and Infusion Reactions: A Patient Guide*

The patient must be counseled about the risk for infusion reactions and provided with *What You Need to Know About LEMTRADA Treatment and Infusion Reactions: A Patient Guide* prior to the first infusion of each treatment course.

Has the patient been counseled and received the guide? Yes No

Step 3: CONFIRM appropriate medical measures available during infusion

Appropriate medical support measures are available:

- In case of serious infusion reactions.
- To monitor patient's vital signs during and post-infusion.

Are the appropriate medical measures listed above available? Yes No

Step 4: RECORD infusion information

Was patient infused with LEMTRADA? Yes No

Fill in Dates of Infusion below and then proceed to Step 5.

LEMTRADA Infusions

Dates of Infusion:

Date:

Date:

Date:

Step 5: RETURN of unused vials of LEMTRADA

Unused vials of LEMTRADA must be returned within 50 days of submission of the LEMTRADA REMS Patient Authorization and Lab Form. Contact the LEMTRADA REMS at 1-855-676-6326 for additional information.

Step 6: SIGNATURE

By providing my e-signature, I attest that I have filled out the Infusion Checklist to the best of my knowledge. I understand that my e-signature will be used to verify my enrollment in the LEMTRADA REMS. By entering my name, NPI number, and password, I confirm my e-signature of this form.

Name of staff member completing checklist

Password

NPI Number

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LEMTRADA
alemtuzumab^{12mg}
iv

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LEMTRADA REMS INFUSION CHECKLIST

As a condition of your healthcare facility's authorization to infuse LEMTRADA® (alemtuzumab), this Infusion Checklist must be completed for each patient by the last day of each patient's treatment course and submitted within 5 business days. This Infusion Checklist must also be completed and returned even if LEMTRADA is not infused. Keep a copy of this checklist in the patient's medical record.

Please complete the form and submit to Genzyme by clicking the button below.

All fields are required.

PATIENT INFORMATION

Patient First Name

Patient Last Name

Patient LEMTRADA REMS Identification Number

DOB (MM/DD/YYYY)
 [Full Patient Record](#)

PRESCRIBER INFORMATION

Prescriber First Name

Prescriber Last Name

Prescriber LEMTRADA REMS Identification Number

HEALTHCARE FACILITY INFORMATION

Healthcare Facility Name

Healthcare Facility LEMTRADA REMS Identification Number

Step 1: CONFIRM that the patient is authorized to receive LEMTRADA

You must complete the LEMTRADA REMS infusion verification online or contact the LEMTRADA REMS by phone (1-855-676-6326) prior to initiation of each treatment course.

Is the patient authorized to receive LEMTRADA? Yes No

Step 2: CONFIRM that the patient has been counseled and has received *What You Need to Know About LEMTRADA Treatment and Infusion Reactions: A Patient Guide*

The patient must be counseled about the risk for infusion reactions and provided with *What You Need to Know About LEMTRADA Treatment and Infusion Reactions: A Patient Guide* prior to the first infusion of each treatment course.

Has the patient been counseled and received the guide?
 Yes No

Step 3: CONFIRM appropriate medical measures available during infusion

Appropriate medical support measures are available:

- In case of serious infusion reactions.
- To monitor patient's vital signs during and post-infusion.

Are the appropriate medical measures listed above available?
 Yes No

Step 4: RECORD infusion information

Was patient infused with LEMTRADA? Yes No

Fill in Dates of Infusion below and then proceed to Step 5.

LEMTRADA Infusions

Dates of Infusion: *Please enter valid date (MM/DD/YYYY).*

Date: Date:

Date: Date:

Date:

Step 5: RETURN of unused vials of LEMTRADA

Unused vials of LEMTRADA must be returned within 50 days of submission of the LEMTRADA REMS Patient Authorization and Lab Form. Contact the LEMTRADA REMS at 1-855-676-6326 for additional information.

Step 6: SIGNATURE

By providing my e-signature, I attest that I have filled out the Infusion Checklist to the best of my knowledge. I understand that my e-signature will be used to verify my enrollment in the LEMTRADA REMS. By entering my name, NPI number, and password, I confirm my e-signature of this form.

Name of staff member completing checklist

Password

NPI Number

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LEMTRADA REMS INFUSION CHECKLIST

Do you wish to submit this form?

PATIENT INFORMATION

Patient First Name: John
Patient Last Name: Doe
Patient LEMTRADA REMS Identification Number: 125698909
DOB (MM/DD/YYYY): 06/10/1965 [Full Patient Record](#)

Prescriber First Name: Adam
Prescriber Last Name: Smith
Prescriber LEMTRADA REMS Identification Number: 125698909

HEALTHCARE FACILITY INFORMATION

Healthcare Facility Name: Facility 01
Healthcare Facility LEMTRADA REMS Identification Number: 098789678

Step 1: CONFIRM that the patient is authorized to receive LEMTRADA

You must complete the LEMTRADA REMS infusion verification online or contact the LEMTRADA REMS by phone (1-855-676-6326) prior to initiation of each treatment course.

Is the patient authorized to receive LEMTRADA? Yes No

Step 2: CONFIRM that the patient has been counseled and has received *What You Need to Know About LEMTRADA Treatment and Infusion Reactions: A Patient Guide*

The patient must be counseled about the risk for infusion reactions and provided with *What You Need to Know About LEMTRADA Treatment and Infusion Reactions: A Patient Guide* prior to the first infusion of each treatment course.

Has the patient been counseled and received the guide? Yes No

Step 3: CONFIRM appropriate medical measures available during infusion

Appropriate medical support measures are available:

- In case of serious infusion reactions.
- To monitor patient's vital signs during and post-infusion.

Are the appropriate medical measures listed above available? Yes No

Step 4: RECORD infusion information

Was patient infused with LEMTRADA? Yes No

Fill in Dates of Infusion below and then proceed to Step 5.

LEMTRADA Infusions

Dates of infusion:

Date: 10 / 1 / 2007 Date: 10 / 4 / 2007
Date: 10 / 2 / 2007 Date: 10 / 5 / 2007
Date: 10 / 3 / 2007

Step 5: RETURN of unused vials of LEMTRADA

Unused vials of LEMTRADA must be returned within 50 days of submission of the LEMTRADA REMS Patient Authorization and Lab Form. Contact the LEMTRADA REMS at 1-855-676-6326 for additional information.

Step 6: SIGNATURE

By providing my e-signature, I attest that I have filled out the Infusion Checklist to the best of my knowledge. I understand that my e-signature will be used to verify my enrollment in the LEMTRADA REMS. By entering my name, NPI number, and password, I confirm my e-signature of this form.

Name of staff member completing checklist: Robert Clark
Password: *****
NPI Number: 1234567890

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SANOFI GENZYME

VV-REG-0833078-0.1

The screenshot shows a web browser window displaying the LEMTRADA REMS website. The browser's address bar shows a Google search engine. The website header includes the LEMTRADA logo (alemfuzumab^{12mg} iv) and navigation links for Prescribing Information and Medication Guide. A user is logged in as Robert Clark, with links for My Profile and Log Out. A navigation menu contains Home, Forms & FAQs, REMS Certified Prescriber & Healthcare Facility Locator, and About REMS. The main content area features a confirmation message: "LEMTRADA REMS INFUSION CHECKLIST COMPLETE". Below this, it states: "Please allow 1-2 business days for the form to be processed. If you have questions about your form submission, please contact the LEMTRADA REMS at 1-855-676-6326, Mon - Fri, 8:30 am - 8:00 pm ET." A link is provided to "Download and print a copy of the LEMTRADA REMS Infusion Checklist for the patient's medical record." A green "Back" button is visible. The footer contains links for Terms and Conditions, Privacy Policy, and Contact Us. A "FOLD" label is present on the left side of the footer area. The footer also includes a disclaimer: "This site is intended for United States residents only." and copyright information: "©2019 Genzyme Corporation. All rights reserved." The Sanofi Genzyme logo is in the bottom right corner.

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LEMTRADA REMS INFUSION CHECKLIST COMPLETE

Please allow 1-2 business days for the form to be processed. If you have questions about your form submission, please contact the LEMTRADA REMS at 1-855-676-6326, Mon - Fri, 8:30 am - 8:00 pm ET.

[Download and print a copy of the LEMTRADA REMS Infusion Checklist for the patient's medical record.](#)

[Back](#)

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The screenshot shows a web browser window displaying the LEMTRADA REMS HCF Dashboard. The page features a navigation bar with links for Home, Forms & FAQs, REMS Certified Prescriber & Healthcare Facility Locator, and About REMS. A secondary navigation bar includes Prescribing Information, Medication Guide, and a user greeting: "Welcome, Robert Clark! My Profile | Log Out". The main content area is titled "Frequently Asked Questions" and includes an introductory paragraph and a list of 11 questions with expandable answers. The first question is "How do I add a patient to this website?". The footer contains links for Privacy Policy, Terms and Conditions, and Contact Us, along with copyright information and the Sanofi Genzyme logo.

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Prescribing Information Medication Guide

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Home Forms & FAQs REMS Certified Prescriber & Healthcare Facility Locator About REMS

Forms FAQs

Frequently Asked Questions

Use the following FAQs to answer your questions about the LEMTRADA REMS. If you cannot find an answer to your question, or if you have additional questions, contact the LEMTRADA REMS at **1-855-676-6326**, Mon - Fri, 8:30 am - 8:00 pm ET.

[Expand](#)

1. How do I add a patient to this website?
This site displays information about patients enrolled in the LEMTRADA REMS. REMS certified prescribers can enroll new patients in the LEMTRADA REMS by submitting a completed LEMTRADA Patient Enrollment Form to Genzyme. A PDF of the LEMTRADA Patient Enrollment Form is available in the [Forms & FAQs](#) section. Once patients are enrolled in the program, their information will be available.
Please contact the LEMTRADA REMS at 1-855-676-6326 if you have questions about the enrollment process or if an enrolled patient's information is missing or incorrect.
2. How can I verify that prescribers are eligible to prescribe LEMTRADA?
3. How do I verify that patients are authorized to receive a LEMTRADA infusion?
4. Why do I have an alert that my patient is "Not REMS Authorized"?
5. What is the LEMTRADA REMS Infusion Checklist and how do I access it?
6. What do I do if a patient or prescriber that is associated with a request for a prescription for LEMTRADA is "Not REMS Authorized" or "Not REMS Certified" on my dashboard?
7. How can I access my profile?
8. How can I update contact information on this site?
9. How do I reset my password?
10. How do I add a new user to my healthcare facility's LEMTRADA REMS dashboard?
11. What do I do if the Healthcare Facility account manager (HCF REMS authorized representative) needs to change?

If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6326, Mon - Fri, 8:30 am - 8:00 pm ET.

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Forms & FAQs

REMS Certified Prescriber & Healthcare Facility Locator

About REMS

Forms

FAQs

Frequently Asked Questions

Use the following FAQs to answer your questions about the LEMTRADA REMS. If you cannot find an answer to your question, or if you have additional questions, contact the LEMTRADA REMS at **1-855-676-6326**. Mon - Fri, 8:30 am - 8:00 pm ET.

[Collapse](#)

- 1. How do I add a patient to this website?**

This site displays information about patients enrolled in the LEMTRADA REMS. REMS certified prescribers can enroll new patients in the LEMTRADA REMS by submitting a completed LEMTRADA Patient Enrollment Form to Genzyme. A PDF of the LEMTRADA Patient Enrollment Form is available in the [Forms & FAQs](#) section. Once patients are enrolled in the program, their information will be available.

Please contact the LEMTRADA REMS at 1-855-676-6326 if you have questions about the enrollment process or if an enrolled patient's information is missing or incorrect.
- 2. How can I verify that prescribers are eligible to prescribe LEMTRADA?**

"REMS Certified" prescribers are enrolled in the LEMTRADA REMS and eligible to prescribe LEMTRADA. You can view whether a prescriber is "REMS Certified" or "Not REMS Certified" by viewing the "Prescribers" tab on your dashboard.
- 3. How do I verify that patients are authorized to receive a LEMTRADA infusion?**

Prior to your patient's treatment course, you will receive a notification on your dashboard with instructions to verify that your patient is authorized to receive LEMTRADA. Patients cannot be infused until the patient, their prescriber, and the healthcare facility are verified under the LEMTRADA REMS.

When you receive a verification alert, click the "Infusion Verification" button on your patient dashboard and follow the infusion verification instructions.
- 4. Why do I have an alert that my patient is "Not REMS Authorized"?**

If your patient is "Not REMS Authorized," please check the individual's Patient Profile for more details about their status. Alerts are generated when patients are overdue for authorization by the LEMTRADA REMS Patient Authorization Form and/or the LEMTRADA REMS Patient Status Form. Prescribers must complete both forms in order to authorize patients for an infusion.

Contact the LEMTRADA REMS at 1-855-676-6326 to speak with a LEMTRADA REMS Specialist if you have questions about a patient's eligibility.
- 5. What is the LEMTRADA REMS Infusion Checklist and how do I access it?**

After a patient completes a treatment course with LEMTRADA, healthcare facilities are required to complete a [LEMTRADA REMS Infusion Checklist](#). The LEMTRADA REMS Infusion Checklist is intended to capture a patient's infusion history. You can view a PDF of a patient's completed post-infusion checklist by clicking "View Checklist" on the patient's profile page.
- 6. What do I do if a patient or prescriber that is associated with a request for a prescription for LEMTRADA is "Not REMS Authorized" or "Not REMS Certified" on my dashboard?**

If a patient or the patient's prescriber is identified as "Not REMS Authorized" or "Not REMS Certified," **DO NOT** administer LEMTRADA vials to that patient or dispense LEMTRADA prescriptions from that prescriber. Contact a LEMTRADA REMS Specialist at 1-855-676-6326 if you have questions about the LEMTRADA REMS eligibility.
- 7. How can I access my profile?**

You can access your profile from any page by clicking on [My Profile](#) in the top right corner of the site.
- 8. How can I update contact information on this site?**

To update your contact information, contact the LEMTRADA REMS at 1-855-676-6326.
- 9. How do I reset my password?**

Facilities Managers can change the password of the account by visiting the "Change Password" section on the [My Profile](#) page. To change the password, enter and confirm a new password and click the "Change Password" button.
- 10. How do I add a new user to my healthcare facility's LEMTRADA REMS dashboard?**

Facilities Managers can add new users to the account by visiting the [Manage User](#) tab on your dashboard, and clicking the "Add New User" button to allow a staff member access to the account. Ensure that all users have been appropriately trained on the [LEMTRADA REMS requirements](#).
- 11. What do I do if the Healthcare Facility account manager (HCF REMS authorized representative) needs to change?**

Please contact the LEMTRADA REMS at 1-855-676-6326.

If you have questions about the LEMTRADA REMS or need help enrolling, call **1-855-676-6326, Mon – Fri, 8:30 am – 8:00 pm ET.**

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REMS Certified Prescriber & Healthcare Facility Locator

About REMS

REMS Certified Prescriber & Healthcare Facility Locator

Search for prescribers or healthcare facilities that are enrolled and certified in the LEMTRADA REMS and able to prescribe or dispense/administer LEMTRADA.

Please enter street address, city, state, or ZIP Code you would like to search for.

New Search: 🔍

REMS Certified Prescribers

REMS Certified Healthcare Facilities

📍

Certified Prescriber Name

Address

Address

P: (888) - 888 - 8888

📍

Certified Prescriber Name

Address

Address

P: (888) - 888 - 8888

📍

Certified Prescriber Name

Address

Address

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Certified Prescriber Name

Address

Address

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VV-REG-0833078 0.1

Reference ID: 4512344



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About REMS

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Search for prescribers or healthcare facilities that are enrolled and certified in the LEMTRADA REMS and able to prescribe or dispense/administer LEMTRADA.

Please enter street address, city, state, or ZIP Code you would like to search for.

New Search: 🔍

REMS Certified Prescribers

REMS Certified Healthcare Facilities

📍 **Certified Center Name**
Address
Address
P: (888) - 888 - 8888

📍 **Certified Center Name**
Address
Address
P: (888) - 888 - 8888

📍 **Certified Center Name**
Address
Address
P: (888) - 888 - 8888

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REMS Activity Healthcare Facility Enrollment Patient Guides

Welcome to the LEMTRADA REMS. Here you can:

- Retrain and enroll in the LEMTRADA REMS every 2 years
- Manage and/or track your progress through the LEMTRADA REMS training and enrollment
- Download materials to help support implementation of the LEMTRADA REMS

LEMTRADA REMS Activity

Steps	Activity	Progress
1.	Account Registration	Completed
2.	Training	Completed
3.	Enrollment Form Submission	Completed
4.	Enrollment Processed	Completed
5.	REMS ID Assigned	Completed

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REMS Activity Healthcare Facility Enrollment Patient Guides

LEMTRADA REMS Requirements

- Healthcare facilities must be enrolled in the LEMTRADA REMS to be able to dispense/administer LEMTRADA for patients with relapsing forms of multiple sclerosis (MS). Because of its safety profile, the use of LEMTRADA should generally be reserved for patients who have had an inadequate response to two or more drugs indicated for the treatment of MS

LEMTRADA REMS Healthcare Facility Enrollment

To enroll in the program, an authorized representative of the healthcare facility must complete the following steps:

- 1 Designate an authorized representative
- 2 Register the authorized representative with the LEMTRADA REMS Training Center
- 3 Authorized representative must review the LEMTRADA REMS Education Program for Healthcare Facilities and the LEMTRADA REMS Program Overview through the online module on this site
- 4 After completing the online module, complete and sign the LEMTRADA REMS Healthcare Facility Enrollment Form. This enrollment must be renewed every 2 years
- 5 Implement the necessary staff training and processes to comply with the LEMTRADA REMS requirements

[Review Online Training](#)

If you have questions about the LEMTRADA REMS or need help enrolling, call **1-855-676-6326**, Mon - Fri, 8:30 am - 8:00 pm ET.

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REMS Activity Healthcare Facility Enrollment Patient Guides

LEMTRADA Patient Guides

Below are materials that help inform patients about treatment with LEMTRADA.

[PDF](#) What You Need to Know About LEMTRADA Treatment: A Patient Guide

[PDF](#) What You Need to Know About LEMTRADA Treatment and Infusion Reactions: A Patient Guide

Adobe® Reader® is required to view all of these PDFs. If you do not have it installed, download it free here.

If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6326, Mon - Fri, 8:30 am - 8:00 pm ET.

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DASHBOARD PAGES FOR HCF USERS WHO ARE NON-MANAGERS



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About REMS

! You have 5 patient alerts!
 ▶

Our Patients
Prescribers

Use the list below to search and sort information about patients using your healthcare facility to receive LEMTRADA. Only patients enrolled in the LEMTRADA REMS are eligible to receive infusions. Click on a patient's name to view their full profile.

You have 10 LEMTRADA patients ?

!	Last Name	First Name	Year of Birth	REMS ID	Prescriber (REMS ID)	REMS Status
	Doe	John	1980	129684352	Adam Smith (01234567)	Authorized
	Doe	John	1980	129684352	Adam Smith (01234567)	Authorized
!	Doe	John	1980	129684352	Adam Smith (01234567)	Not Authorized
!	Doe	John	1980	129684352	Adam Smith (01234567)	Not Authorized
	Doe	John	1980	129684352	Adam Smith (01234567)	Authorized
!	Doe	John	1980	129684352	Adam Smith (01234567)	Not Authorized
	Doe	John	1980	129684352	Adam Smith (01234567)	Authorized
	Doe	John	1980	129684352	Adam Smith (01234567)	Authorized
	Doe	John	1980	129684352	Adam Smith (01234567)	Infusion Verification
	Doe	John	1980	129684352	Adam Smith (01234567)	Authorized

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If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6326, Mon - Fri, 8:30 am - 8:00 pm ET.

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SANOFI GENZYME



LEMTRADA
alemtuzumab^{12mg}_{iv}

[Prescribing Information](#) [Medication Guide](#)

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Home

Forms & FAQs

REMS Certified Prescriber & Healthcare Facility Locator

About REMS

🔔 You have 5 patient alerts!
▶

Our Patients
Prescribers

Use the list below to search and sort information about patients using your healthcare facility to receive LEMTRADA. Only patients enrolled in the LEMTRADA REMS are eligible to receive infusions. Click on a patient's name to view their full profile.

You have 10 LEMTRADA patients ?

🔔	Last Name	First Name	DOB	S ID	Prescriber (REMS ID)	REMS Status
	Doe			4352	Adam Smith (01234567)	Authorized
	Doe	John	1980	129684352	Adam Smith (01234567)	Authorized
🔔	Doe	John	1980	129684352	Adam Smith (01234567)	Not Authorized
🔔	Doe	John	1980	129684352	Adam Smith (01234567)	Not Authorized
	Doe	John	1980	129684352	Adam Smith (01234567)	Authorized
🔔	Doe	John	1980	129684352	Adam Smith (01234567)	Not Authorized
	Doe	John	1980	129684352	Adam Smith (01234567)	Authorized
	Doe	John	1980	129684352	Adam Smith (01234567)	Authorized
	Doe	John	1980	129684352	Adam Smith (01234567)	Infusion Verification
	Doe	John	1980	129684352	Adam Smith (01234567)	Authorized

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REMS Certified Prescriber & Healthcare Facility Locator

About REMS

LEMTRADA REMS (Risk Evaluation and Mitigation Strategy)

What is the LEMTRADA REMS?
A REMS is a strategy to manage known or potential serious risks associated with a drug product and is required by the FDA to ensure the benefits of a drug outweigh its risks. The purpose of the LEMTRADA REMS is to inform prescribers, pharmacies, healthcare facilities, and patients about the risks of:

AUTOIMMUNE CONDITIONS
LEMTRADA causes serious, sometimes fatal, autoimmune conditions such as immune thrombocytopenia and anti-glomerular basement membrane disease. Monitor complete blood counts with differential, serum creatinine levels, and urinalysis with urine cell counts at periodic intervals for 48 months after the last dose of LEMTRADA.

INFUSION REACTIONS
LEMTRADA causes serious and life threatening infusion reactions. LEMTRADA must be administered in a setting with appropriate equipment and personnel to manage anaphylaxis or serious infusion reactions.

STROKE
Serious and life-threatening stroke (including ischemic and hemorrhagic stroke) has been reported within 3 days of LEMTRADA administration. Instruct patients to seek immediate medical attention if symptoms of stroke occur.

MALIGNANCIES
LEMTRADA may cause an increased risk of malignancy including thyroid cancer, melanoma, and lymphoproliferative disorders. Perform baseline and yearly exams.

Re-enroll in the LEMTRADA REMS



You have been locked out due to incomplete re-enrollment. Please have the Healthcare Facility manager re-enroll in the LEMTRADA REMS in order for you to gain access to your profile information.

Find a REMS Certified Prescriber or Healthcare Facility



Search for prescribers or healthcare facilities that are certified by the LEMTRADA REMS to prescribe, dispense, or administer LEMTRADA.

Enter ZIP Code

REMS Certified Prescriber
 REMS Certified Healthcare Facility

Find

This site is provided as a resource for prescribers and is not intended as medical advice. Information on the site is updated periodically (approximately every 12 hours).

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Home

Forms & FAQs

REMS Certified Prescriber & Healthcare Facility Locator

About REMS

⚠ You have 5 patient alerts!

You have **5 patients** who have authorization requirements.

- **2 patients** are overdue for the LEMTRADA REMS Patient Status Form.
- **2 patients** need to be authorized by the LEMTRADA REMS Patient Status Form in 1 month.
- **1 patient** needs to be verified before their infusion.

[Manage my patient alert email preferences](#)

Our Patients

Prescribers

Use the list below to search and sort information about patients using your healthcare facility to receive LEMTRADA. Only patients enrolled in the LEMTRADA REMS are eligible to receive infusions. Click on a patient's name to view their full profile.

You have 10 LEMTRADA patients ?

⚠	Last Name	First Name	Year of Birth	REMS ID	Prescriber (REMS ID)	REMS Status
	Doe	John	1980	129684352	Adam Smith (01234567)	Authorized
	Doe	John	1980	129684352	Adam Smith (01234567)	Authorized
⚠	Doe	John	1980	129684352	Adam Smith (01234567)	Not Authorized
⚠	Doe	John	1980	129684352	Adam Smith (01234567)	Not Authorized
	Doe	John	1980	129684352	Adam Smith (01234567)	Authorized
⚠	Doe	John	1980	129684352	Adam Smith (01234567)	Not Authorized
	Doe	John	1980	129684352	Adam Smith (01234567)	Authorized
	Doe	John	1980	129684352	Adam Smith (01234567)	Authorized
	Doe	John	1980	129684352	Adam Smith (01234567)	Infusion Verification
	Doe	John	1980	129684352	Adam Smith (01234567)	Authorized

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LEMTRADA
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REMS Certified Prescriber & Healthcare Facility Locator

About REMS

🔔 You have 5 patient alerts!
▶

Our Patients

Prescribers

You have 13 LEMTRADA prescribers associated with your patients ?

Last Name	First Name	REMS ID	REMS Status	Patient Alerts
Smith	Adam	0123456789	Certified	
Smith	Adam	0123456789	Certified	
Smith	Adam	0123456789	Certified	
Smith	Adam	0123456789	Not Certified	🔔
Smith	Adam	0123456789	Certified	
Smith	Adam	0123456789	Certified	
Smith	Adam	0123456789	Certified	
Smith	Adam	0123456789	Certified	
Smith	Adam	0123456789	Not Certified	
Smith	Adam	0123456789	Certified	
Smith	Adam	0123456789	Certified	
Smith	Adam	0123456789	Not Certified	🔔
Smith	Adam	0123456789	Certified	

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The screenshot shows a web browser window displaying the LEMTRADA REMS desktop interface. At the top left is the LEMTRADA logo (alemtozumab 12mg iv). To the right are links for 'Prescribing Information' and 'Medication Guide'. Below the logo is a navigation bar with buttons for 'Home', 'Forms & FAQs', 'REMS Certified Prescriber & Healthcare Facility Locator', and 'About REMS'. A red alert banner at the top states 'You have 5 patient alerts!'. The main content area has tabs for 'Our Patients' and 'Prescribers'. Under 'Prescribers', it says 'You have 13 LEMTRADA prescribers associated with your patients' and includes a search bar. A table lists prescribers with columns for Last Name, First Name, ID, Status, and Patient Alerts. A tooltip is expanded over the table, providing instructions: 'Search, sort, and navigate information about your prescribers below. Click on a name to view their individual profile.' The table contains 13 rows, with some rows highlighted in red to indicate 'Not Certified' status. At the bottom, there is a disclaimer, contact information, and the Sanofi Genzyme logo.

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Prescribing Information Medication Guide

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Home Forms & FAQs REMS Certified Prescriber & Healthcare Facility Locator About REMS

You have 5 patient alerts!

Our Patients Prescribers

You have 13 LEMTRADA prescribers associated with your patients

Last Name	First Name	ID	Status	Patient Alerts
Smith	Adam	0123456789	Certified	
Smith	Adam	0123456789	Certified	
Smith	Adam	0123456789	Certified	
Smith	Adam	0123456789	Not Certified	1
Smith	Adam	0123456789	Certified	
Smith	Adam	0123456789	Certified	
Smith	Adam	0123456789	Certified	
Smith	Adam	0123456789	Certified	
Smith	Adam	0123456789	Not Certified	
Smith	Adam	0123456789	Certified	
Smith	Adam	0123456789	Certified	
Smith	Adam	0123456789	Not Certified	1
Smith	Adam	0123456789	Certified	

This site is provided as a resource for prescribers and is not intended as medical advice. Information on the site is updated periodically (approximately every 12 hours).

If you have questions about the LEMTRADA REMS or need help enrolling, call **1-855-676-6326**, Mon - Fri, 8:30 am - 8:00 pm ET.

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SANOFI GENZYME

BOTH A PRESCRIBER AND HEALTHCARE FACILITY USER



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Prescriber
Healthcare Facility

Home

Forms & FAQs

REMS Certified Prescriber & Healthcare Facility Locator

About REMS

🚨 You have 5 patient alerts!
▶

Our Patients

Prescribers
Manage Users

Use the list below to search and sort information about patients using your healthcare facility to receive LEMTRADA. Only patients enrolled in the LEMTRADA REMS are eligible to receive infusions. Click on a patient's name to view their full profile.

You have 10 LEMTRADA patients ?

🔍

	Last Name	First Name	Year of Birth	REMS ID	Prescriber (REMS ID)	REMS Status
	Doe	John	1980	129684352	Adam Smith (01234567)	Authorized
	Doe	John	1980	129684352	Adam Smith (01234567)	Authorized
🚨	Doe	John	1980	129684352	Adam Smith (01234567)	Not Authorized
🚨	Doe	John	1980	129684352	Adam Smith (01234567)	Not Authorized
	Doe	John	1980	129684352	Adam Smith (01234567)	Authorized
🚨	Doe	John	1980	129684352	Adam Smith (01234567)	Not Authorized
	Doe	John	1980	129684352	Adam Smith (01234567)	Authorized
	Doe	John	1980	129684352	Adam Smith (01234567)	Authorized
	Doe	John	1980	129684352	Adam Smith (01234567)	Infusion Verification
	Doe	John	1980	129684352	Adam Smith (01234567)	Authorized

Re-enroll in the LEMTRADA REMS

Healthcare Facilities must renew their enrollment every 2 years, and authorized representatives must renew their enrollment every year.

Re-enroll Now

This site is provided as a resource for prescribers and is not intended as medical advice. Information on the site is updated periodically (approximately every 12 hours).

If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6326, Mon – Fri, 8:30 am – 8:00 pm ET.

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FROM:
The LEMTRADA REMS
1-855-557-2478

TO:

«healthcare facility_site_name»
«healthcare facility_site_address»
«healthcare facility_site_city», «site_state» «site_zip»

RE: LEMTRADA® (alemtuzumab) Enrollment Confirmation and Authorization Verification for <<Patient_First_Name>> <<Patient_Last_Name>> REMS ID <<Patient_REMS_ID>> under care of Dr. <<Treating_Prescriber_Last_Name>>

This letter is to confirm that I, <<Representative_Name>> <<Representative_Last_Initial>> spoke to <<Insert contact name>> on <<Date>> and <<Time>> and confirmed that <<Patient_First_Name>> <<Patient_Last_Name>> REMS ID <<Patient_REMS_ID>> is enrolled and authorized to receive LEMTRADA at this time.

Attached you will find copies of the patient's *LEMTRADA REMS Prescription Ordering Form* and *LEMTRADA REMS Authorization and Baseline Lab Form* for your records.

If you have any questions regarding this information, or if there is a change in the patient's LEMTRADA treatment date, please contact the LEMTRADA REMS at 1-855-676-6326.

Please note that receipt of this document is not a guarantee of payment for medication.

Please see accompanying full Prescribing Information, including boxed WARNING, for Important Safety Information.

Sincerely,

The LEMTRADA REMS



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LEMTRADA REMS DESKTOP

Pharmacy Desktop Pages Only

PHARMACY TRAINING PAGES

The screenshot shows a web browser window displaying the LEMTRADA REMS Desktop Pharmacy Training Registration Home Selection page. The browser's address bar shows a Google search engine. The page features the LEMTRADA logo (alemftuzumab 12mg iv) and navigation links for Prescribing Information, Medication Guide, Register, and Log In. A horizontal menu contains links for Home, Prescriber Enrollment, Healthcare Facility Enrollment, Pharmacy Enrollment, Patient Guides, Forms & Resources, and REMS Certified Prescriber & Healthcare Facility Locator. The main content area is titled "Registration for LEMTRADA REMS Training" and includes instructions for new users. It offers three radio button options: "I am a Prescriber", "I represent a Healthcare Facility", and "I represent a Pharmacy", with the third option selected. A "Next" button is visible. A "Log In" link is also present. A call to action states: "If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6326, Mon - Fri, 8:30 am - 8:00 pm ET." The footer contains links for Privacy Policy, Terms and Conditions, and Contact Us, along with copyright information for Genzyme Corporation and the Sanofi Genzyme logo.

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Prescribing Information Medication Guide
Register | Log In

Home Prescriber Enrollment Healthcare Facility Enrollment Pharmacy Enrollment Patient Guides Forms & Resources REMS Certified Prescriber & Healthcare Facility Locator

Registration for LEMTRADA REMS Training

To register as a new user, select whether you would like to complete enrollment as a prescriber, or authorized representative of a healthcare facility or pharmacy. Enrolled prescribers who would like to enroll their affiliated healthcare facility should also register as a new healthcare facility user.

Select the option which best describes you:

I am a Prescriber

I represent a Healthcare Facility

I represent a Pharmacy

Already Registered? [Log In](#)

If you are already certified by the LEMTRADA REMS, or have recently completed training and have not received your log-in information, please call **1-855-676-6326**.

[Cancel](#) [Next](#)

If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6326, Mon - Fri, 8:30 am - 8:00 pm ET.

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Prescribing Information Medication Guide
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Registration Training Enrollment

Pharmacy Registration for LEMTRADA REMS Training

To complete your training for the LEMTRADA REMS, please set up an account.

*Required

Email Address*

Create a Password*

Confirm Password*

Name of Pharmacy*

National Provider Identification (NPI) Number*

Pharmacy Address*

City*

State* ZIP Code*

Name of Authorized Pharmacy Representative*

Title*

Phone Number*

Fax Number*

*By checking this box, you indicate you will comply with our [terms and conditions](#).

[Cancel](#)

If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6326, Mon - Fri, 8:30 am - 8:00 pm ET.

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FOLD

The screenshot shows a web browser window displaying the LEMTRADA REMS Pharmacy Registration form. The browser's address bar shows a Google search. The LEMTRADA logo (alemfuzumab 12mg iv) is in the top left. Navigation links include 'Prescribing Information', 'Medication Guide', 'Register', and 'Log In'. A menu bar contains: Home, Prescriber Enrollment, Healthcare Facility Enrollment, Pharmacy Enrollment, Patient Guides, Forms & Resources, and REMS Certified Prescriber & Healthcare Facility Locator. A progress bar shows 'Registration' as the active step, followed by 'Training' and 'Enrollment'.

The main heading is 'Pharmacy Registration for LEMTRADA REMS Training'. Below it, instructions state: 'To complete your training for the LEMTRADA REMS, please set up an account.' A note indicates '*Required' fields. The form includes input boxes for: Email Address*, Create a Password* (with a password strength note: 'Passwords must be at least 8 characters in length and contain a minimum of 3 out of the following: A number, an upper-case letter, a lower-case letter, a special character (e.g. !, ", #, \$, etc.)'), Confirm Password*, Name of Pharmacy*, National Provider Identification (NPI) Number*, and ZIP Code*. A dropdown menu for state selection is open, listing all 50 states and DC. Below the dropdown is a 'Pharmacy Representative*' field. A checkbox with the text 'By checking this box, you indicate you will accept the Terms and Conditions.' is present. A green 'Register' button is at the bottom of the form.

At the bottom of the page, there is a banner for 'the LEMTRADA REMS' with the phone number '1-855-676-6326, Mon - Fri, 8:30 am - 8:00 pm ET.' and the SANOFI GENZYME logo.

FOLD

- ✓ Select
- Alabama
- Alaska
- American Samoa
- Arizona
- Arkansas
- California
- Colorado
- Connecticut
- Delaware
- District of Columbia
- Florida
- Georgia
- Guam
- Hawaii
- Idaho
- Illinois
- Indiana
- Iowa
- Kansas
- Kentucky
- Louisiana
- Maine
- Maryland
- Massachusetts
- Michigan
- Minnesota
- Mississippi
- Missouri
- Montana
- Nebraska
- Nevada
- New Hampshire
- New Jersey
- New Mexico
- New York
- North Carolina
- North Dakota
- Northern Mariana Islands
- Ohio
- Oklahoma
- Oregon
- Pennsylvania
- Puerto Rico
- Rhode Island
- South Carolina
- South Dakota
- Tennessee
- Texas
- Utah
- Vermont
- Virginia
- Virgin Islands
- Washington
- West Virginia
- Wisconsin
- Wyoming

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Prescribing Information Medication Guide
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Registration Training Enrollment

Pharmacy Registration for LEMTRADA REMS Training

To complete your training for the LEMTRADA REMS, please set up an account.

*Required

Email Address*

Please enter a valid email address.

Create a Password*
 Passwords must be at least 8 characters in length and contain a minimum of 3 out of the following: A number, an upper-case letter, a lower-case letter, a special character (e.g. !, ", #, \$, etc.)

Confirm Password*

Please confirm password.

Name of Pharmacy*

Please enter name of pharmacy.

National Provider Identification (NPI) Number*

Please enter a valid NPI number.

Pharmacy Address*

Please enter pharmacy address.

City*

Please enter city.

State* ZIP Code*

Please select a state. Please enter a 5-digit ZIP Code.

Name of Authorized Pharmacy Representative*

Please enter name of authorized pharmacy representative.

Title*

Please enter title.

Phone Number*

Please enter a 10-digit phone number.

Fax Number*

Please enter a 10-digit fax number.

*By checking this box, you indicate you will comply with our [terms and conditions](#).
Terms and conditions not selected.

[Cancel](#) [Register](#)

If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6326, Mon - Fri, 8:30 am - 8:00 pm ET.

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Prescribing Information Medication Guide
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Home Prescriber Enrollment Healthcare Facility Enrollment Pharmacy Enrollment Patient Guides Forms & Resources REMS Certified Prescriber & Healthcare Facility Locator

Registration Training Enrollment

Pharmacy Registration for LEMTRADA REMS Training

To complete your training for the LEMTRADA REMS, please set up an account.

*Required

Email Address*

Please enter a valid email address.

Create a Password*

Password does not meet strength requirements.

Confirm Password*

Please confirm password.

Name of Pharmacy*

Please enter name of pharmacy.

National Provider Identification (NPI) Number*

Please enter a valid NPI number.

Pharmacy Address*

Please enter pharmacy address.

City*

Please enter city.

State* ZIP Code*

Please select a state. Please enter a 5-digit ZIP Code.

Name of Authorized Pharmacy Representative*

Please enter name of authorized pharmacy representative.

Title*

Please enter title.

Phone Number*

Please enter a 10-digit phone number.

Fax Number*

Please enter a 10-digit fax number.

*By checking this box, you indicate you will comply with our [terms and conditions](#).
Terms and conditions not selected.

[Cancel](#) [Register](#)

If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6326, Mon - Fri, 8:30 am - 8:00 pm ET.

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The screenshot shows a web browser window displaying the LEMTRADA REMS website. The browser's address bar shows a Google search engine. The website header includes the LEMTRADA logo (alemzufumab 12mg iv) and navigation links for Prescribing Information and Medication Guide. A personalized welcome message for Patricia Washington is displayed, along with links for My Profile and Log Out. A navigation menu contains Home, Forms & FAQs, REMS Certified Prescriber & Healthcare Facility Locator, and About REMS. A progress bar indicates the user has completed Registration and is currently in the Training phase, with Enrollment next. The main content area features a 'Thank You for Registering' message, explaining that the account is a personal online center for training and support, and a green button labeled 'Review Training Materials'. A contact information section provides a phone number (1-855-676-6326) for questions or enrollment help. The footer contains links for Privacy Policy, Terms and Conditions, and Contact Us, along with copyright information for Genzyme Corporation (©2019) and the Sanofi Genzyme logo.

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The screenshot shows a web browser window displaying the LEMTRADA REMS Online Training Module registration page. The page features a navigation bar with links for Home, Forms & FAQs, REMS Certified Prescriber & Healthcare Facility Locator, and About REMS. A progress indicator shows three steps: Registration, Training, and Enrollment, with Training currently selected. The main content area includes a warning about inactivity, a list of instructions for the training module, and a 'Continue' button. The footer contains legal disclaimers, copyright information, and the Sanofi Genzyme logo.

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Prescribing Information Medication Guide

Welcome, Patricia Washington! [My Profile](#) | [Log Out](#)

Home Forms & FAQs REMS Certified Prescriber & Healthcare Facility Locator About REMS

Registration Training Enrollment

LEMTRADA REMS Online Training Module

If inactive on the training module for 20 minutes, you will be automatically logged off the LEMTRADA website and lose your training progress.

- Please review the LEMTRADA REMS Training Materials, including the LEMTRADA REMS Program Overview in the module. You may review the material at your own pace and go back to any point of the presentation at your discretion
- After reviewing the material in the module, you will be asked to review and sign the LEMTRADA REMS Pharmacy Enrollment Form to complete your enrollment
- All staff at your site who will be involved with the dispensing/administrating of LEMTRADA must be trained on the information in the module and adhere to the requirements of the LEMTRADA REMS

Online training will take approximately 20 minutes. Please allow enough time to view the entire module. You will be automatically logged out after 20 minutes of inactivity and your training progress may be lost.

[Continue](#)

If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6326, Mon - Fri, 8:30 am - 8:00 pm ET.

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SANOFI GENZYME

The screenshot shows a web browser window displaying the LEMTRADA REMS website. The browser's address bar shows a Google search. The website header includes the LEMTRADA logo (alemtezumab 12mg IV) and navigation links for Prescribing Information and Medication Guide. A user is logged in as Patricia Washington, with links for My Profile and Log Out. A dark purple navigation bar contains links for Home, Forms & FAQs, REMS Certified Prescriber & Healthcare Facility Locator, and About REMS. A white modal dialog box is centered on the screen, titled "Are You Sure You Want to Exit?". The dialog contains the text "You will lose your session and will need to begin again." and two buttons: "Yes" and "No, Continue". The background content is partially obscured by the dialog. Below the dialog, a green "Continue" button is visible. Further down, there is a section titled "If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6326, Mon - Fri, 8:30 am - 8:00 pm ET." The footer contains links for Privacy Policy, Terms and Conditions, and Contact Us, along with copyright information for Genzyme Corporation (©2019) and the Sanofi Genzyme logo.

The screenshot shows a web browser window displaying the LEMTRADA REMS desktop interface. At the top left is the LEMTRADA logo with 'alemtuzumab 12mg IV' below it. To the right, there are links for 'Prescribing Information' and 'Medication Guide', and a user greeting 'Welcome, Patricia Washington!' with 'My Profile' and 'Log Out' links. A navigation bar contains 'Home', 'Forms & FAQs', 'REMS Certified Prescriber & Healthcare Facility Locator', and 'About REMS'. A modal window titled 'Inactivity Alert' is centered on the screen, stating 'There has been no activity for 15 minutes. You will be logged out if there is no activity before your session expires.' and showing a timer at '00:04:39'. A green 'Continue' button is visible in the modal. The background content is partially obscured but includes a 'Continue' button and a section titled 'If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6326, Mon - Fri, 8:30 am - 8:00 pm ET.' The footer contains 'Privacy Policy | Terms and Conditions | Contact Us', copyright information for Genzyme Corporation, and the Sanofi Genzyme logo.

The screenshot shows a web browser window displaying the LEMTRADA REMS website. The browser's address bar shows a Google search engine. The website header features the LEMTRADA logo (alem tuzumab 12mg iv) and navigation links for Prescribing Information, Medication Guide, Register, and Log In. A dark purple navigation bar contains links for Home, Prescriber Enrollment, Healthcare Facility Enrollment, Pharmacy Enrollment, Patient Guides, Forms & Resources, and REMS Certified Prescriber & Healthcare Facility Locator. The main content area displays a message: "Your Session Has Timed Out" with a sub-message: "There has been no activity for 20 minutes, so you have been timed out." Below this is a green "Restart" button. A call to action states: "If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6326, Mon - Fri, 8:30 am - 8:00 pm ET." The footer is dark purple and includes links for Privacy Policy, Terms and Conditions, and Contact Us. It also contains the text: "This site is intended for United States residents only. ©2019 Genzyme Corporation. All rights reserved. Lemtrada, MS One to One, Sanofi and Genzyme registered in U.S. Patent and Trademark Office US.MS.LEM.14.10.013-v7 Last Updated 09/19" and the SANOFI GENZYME logo.

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LEMTRADA REMS Program Overview (1 of 2)
Total Training Screens: 1 of 2



LEMTRADA REMS PROGRAM OVERVIEW

What is the LEMTRADA REMS (Risk Evaluation and Mitigation Strategy)?

A REMS is a strategy to manage known or potential risks associated with a drug. It is required by the FDA to ensure that the benefits of the drug outweigh its risks. Due to serious risks of autoimmune conditions, infusion reactions, stroke and malignancies, LEMTRADA[®] (alemtuzumab) is only available through a restricted program called the LEMTRADA REMS.

LEMTRADA REMS Requirements

- **Prescribers** must be enrolled in the LEMTRADA REMS to be able to prescribe LEMTRADA.
- **Pharmacies** must be enrolled in the LEMTRADA REMS to be able to dispense LEMTRADA.
- **Healthcare Facilities** must be enrolled in the LEMTRADA REMS to be able to dispense and administer LEMTRADA.
- **Patients** must be enrolled and authorized in the LEMTRADA REMS in order to receive LEMTRADA.

PRESCRIBER ENROLLMENT INSTRUCTIONS

1. Complete the training program, which includes reviewing the following:
 - LEMTRADA Prescribing Information
 - LEMTRADA REMS Program Overview
 - LEMTRADA REMS Education Program for Prescribers
2. Successfully complete the 8-question LEMTRADA REMS Knowledge Assessment.
3. Enroll in the program by completing a LEMTRADA REMS Prescriber Enrollment Form.
4. Submit the completed and signed Forms to the LEMTRADA REMS.

PHARMACY ENROLLMENT INSTRUCTIONS

1. An authorized representative must enroll on behalf of the pharmacy by reviewing the LEMTRADA REMS Program Overview and completing the LEMTRADA REMS Pharmacy Enrollment Form, which acknowledges that the pharmacy agrees to follow the procedures outlined in the LEMTRADA REMS, including:
 - All relevant staff at the pharmacy who will be involved with the dispensing of LEMTRADA must be educated and trained.
 - The pharmacy will verify that a LEMTRADA REMS Prescription Ordering Form is received for each prescription.
 - The pharmacy will verify that prescribers and healthcare facilities are certified and patients are authorized to receive LEMTRADA prior to dispensing LEMTRADA.
 - Enrollment in the LEMTRADA REMS must be renewed every 2 years from initial enrollment.
2. Submit the completed and signed LEMTRADA REMS Pharmacy Enrollment Form to the LEMTRADA REMS.

Next

(1 of 2)

If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6326, Mon – Fri, 8:30 am – 8:00 pm ET.

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VV-REG-0833078 0.1

Reference ID: 4512344



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LEMTRADA REMS Program Overview (2 of 2)
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HEALTHCARE FACILITY ENROLLMENT INSTRUCTIONS

1. An authorized representative must enroll on behalf of the healthcare facility by reviewing the *LEMTRADA REMS Education Program for Healthcare Facilities* and completing the LEMTRADA REMS Healthcare Facility Enrollment Form, which acknowledges that the healthcare facility agrees to follow the procedures outlined in the LEMTRADA REMS, including:
 - All staff at the facility who will be involved with the dispensing and administration of LEMTRADA must be trained, and a written record of all staff REMS trainings must be kept on file.
 - The healthcare facility will verify that prescribers are certified and patients are authorized to receive LEMTRADA prior to dispensing or administering LEMTRADA.
 - The healthcare facility will provide a copy of *What You Need to Know About LEMTRADA Treatment and Infusion Reactions: A Patient Guide* to the patient on the first day of each treatment course when LEMTRADA is dispensed.
 - The healthcare facility will complete a LEMTRADA REMS infusion Checklist for each patient at the conclusion of each treatment course and submit it to the LEMTRADA REMS within 5 business days.
 - Enrollment in the LEMTRADA REMS must be renewed every 2 years from initial enrollment.
2. Submit the completed and signed LEMTRADA REMS Healthcare Facility Enrollment Form to the LEMTRADA REMS.

PATIENT ENROLLMENT INSTRUCTIONS

1. Complete the LEMTRADA REMS Patient Enrollment Form, which contains information to be completed by both the prescriber and the patient.
2. Provide a copy of *What You Need to Know About LEMTRADA Treatment: A Patient Guide* and a LEMTRADA Patient Safety Information Card to each patient who will receive LEMTRADA. You must use *What You Need to Know About LEMTRADA Treatment: A Patient Guide* to counsel your patients on the serious risks and REMS requirements with the use of LEMTRADA.
3. Submit the completed and signed LEMTRADA REMS Patient Enrollment Form to the LEMTRADA REMS.
4. Provide the patient with a copy of the LEMTRADA REMS Patient Enrollment Form and keep a copy in the patient's medical record.

Where to Find REMS Information and Resources

To enroll in the LEMTRADA REMS, call 1-855-676-6326. For information related to enrollment in the LEMTRADA REMS, call 1-855-676-6326 or visit www.LemtradaREMS.com

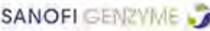
Indication and Usage

LEMTRADA is indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include relapsing-remitting disease and active secondary progressive disease, in adults. Because of its safety profile, the use of LEMTRADA should generally be reserved for patients who have had an inadequate response to two or more drugs indicated for the treatment of MS.

Limitations of Use:

LEMTRADA is not recommended for use in patients with clinically isolated syndrome (CIS) because of its safety profile. The Prescribing Information includes a **BOXED WARNING** for LEMTRADA. Please see accompanying Prescribing Information for complete safety information, including **BOXED WARNING**.

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VV-REG-0833078 0.1

Reference ID: 4512344

The screenshot shows a web browser window displaying the LEMTRADA REMS Training Complete page. The browser's address bar shows a Google search engine. The page header includes the LEMTRADA logo (alemfuzumab 12mg iv) and navigation links for Prescribing Information and Medication Guide. A personalized welcome message for Patricia Washington is displayed, along with links for My Profile and Log Out. A navigation bar contains Home, Forms & FAQs, REMS Certified Prescriber & Healthcare Facility Locator, and About REMS. A progress indicator shows three steps: Registration, Training (highlighted), and Enrollment. The main content area features the heading "LEMTRADA REMS Training Complete" and a message: "You have completed your review of the training materials." A green button labeled "Go To Enrollment" is positioned below the message. A call to action states: "If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6326, Mon - Fri, 8:30 am - 8:00 pm ET." The footer contains links for Privacy Policy, Terms and Conditions, and Contact Us. It also includes a disclaimer: "This site is intended for United States residents only." and copyright information: "©2019 Genzyme Corporation. All rights reserved." The footer also lists "Lemtrada, MS One to One, Sanofi and Genzyme registered in U.S. Patent and Trademark Office US.MS.LEM.14.10.013-v7 Last Updated 09/19" and the SANOFI GENZYME logo.

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LEMTRADA REMS Pharmacy Enrollment Form

LEMTRADA is only available through the LEMTRADA REMS, a restricted distribution program. Only prescribers, pharmacies, healthcare facilities, and patients enrolled in the program are able to prescribe, dispense, administer, and receive LEMTRADA. An authorized representative of the pharmacy must enroll the pharmacy in the LEMTRADA REMS.

Please review the following information and submit to Genzyme by clicking the button below. Complete any missing information and correct any errors prior to submission.

All fields are required.

PHARMACY INFORMATION

Name of Pharmacy	<input type="text" value="Zebra Pharmacy"/>
National Provider Identification (NPI) Number	<input type="text" value="0123456789"/>
Pharmacy Address	<input type="text" value="70 Oak Street"/>
	<input type="text" value="Apartment 7C"/>
City	<input type="text" value="Santa Monica"/>
State	<input type="text" value="California"/>
ZIP Code	<input type="text" value="90212"/>
Name of Authorized Pharmacy Representative	<input type="text" value="Charles Brown"/>
Title	<input type="text" value="MD"/>
Phone Number	<input type="text" value="555-555-5555"/>
Fax Number	<input type="text" value="555-555-5555"/>
Email Address	<input type="text" value="123@abc1234.com"/>

PHARMACY AGREEMENT

I am the authorized representative designated by my pharmacy to coordinate the activities of the LEMTRADA REMS. By signing this form, I agree to comply with the following program requirements:

- I understand that my pharmacy must be certified with the LEMTRADA REMS to dispense LEMTRADA.
- I will oversee implementation and compliance with the LEMTRADA REMS requirements.
- I have reviewed the LEMTRADA REMS Program Overview.
- I will ensure that all relevant staff involved in the dispensing of LEMTRADA are educated and trained using the LEMTRADA REMS.
- I will put processes and procedures in place, and follow such processes and procedures, to ensure the following verifications are met prior to dispensing LEMTRADA:
 - The LEMTRADA REMS Prescription Ordering Form is received for each prescription.
- The prescriber is certified, the infusion site is certified, and the patient is enrolled and authorized to receive LEMTRADA by contacting the LEMTRADA REMS prior to dispensing LEMTRADA.
- Ensuring LEMTRADA is only dispensed to a certified infusion center.
- This pharmacy will establish procedures and protocols that are subject to audit, to help ensure compliance with the requirements of the LEMTRADA REMS.
- I understand that my pharmacy must renew enrollment in the LEMTRADA REMS every 2 years from initial enrollment.
- To make available to Genzyme, documentation to verify understanding of, and adherence to, the requirements of the LEMTRADA REMS.

I have verified that all details are correct.

By providing my e-signature, I attest that I have completed the educational training about LEMTRADA for pharmacies and I understand the benefits and risks of LEMTRADA. I understand that all staff members from my site must be trained on the information in the module and adhere to the requirements of the LEMTRADA REMS. I understand that I must complete this LEMTRADA REMS Pharmacy Enrollment Form in order to complete the enrollment process.

By entering my name, NPI number, and password, I confirm that I have completed the LEMTRADA REMS training and that I will comply with the requirements of the program.

Full Name

NPI Number

Password

[Cancel](#)
Submit

If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6326, Mon – Fri, 8:30 am – 8:00 pm ET.

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LEMTRADA REMS Pharmacy Enrollment Form

LEMTRADA is only available through the LEMTRADA REMS, a restricted distribution program. Only prescribers, pharmacies, healthcare facilities, and patients enrolled in the program are able to prescribe, dispense, administer, and receive LEMTRADA. An authorized representative of the pharmacy must enroll the pharmacy in the LEMTRADA REMS.

Please review the following information and submit to Genzyme by clicking the button below. Complete any missing information and correct any errors prior to submission.

All fields are required.

PHARMACY INFORMATION

Name of Pharmacy	<input type="text" value="Zebra Pharmacy"/>
National Provider Identification (NPI) Number	<input type="text" value="0123456789"/>
Pharmacy Address	<input type="text" value="70 Oak Street"/>
	<input type="text" value="Apartment 7C"/>
City	<input type="text" value="Santa Monica"/>
State	<div style="border: 1px solid gray; padding: 5px;"> <div style="display: flex; align-items: center;"> ✓ Select <div style="flex-grow: 1;"> <ul style="list-style-type: none"> Alabama Alaska American Samoa Arizona Arkansas California Colorado Connecticut Delaware District of Columbia Florida Georgia Guam Hawaii Idaho Illinois Indiana Iowa Kansas Kentucky Louisiana Maine Maryland Massachusetts Michigan Minnesota Mississippi Missouri Montana Nebraska Nevada New Hampshire New Jersey New Mexico New York North Carolina North Dakota Northern Mariana Islands Ohio Oklahoma Oregon Pennsylvania Puerto Rico Rhode Island South Carolina South Dakota Tennessee Texas Utah Vermont Virginia Virgin Islands Washington West Virginia Wisconsin Wyoming </div> </div> </div>
ZIP Code	<input type="text"/>
Name of Authorized Pharmacy Representative	<input type="text"/>
Title	<input type="text"/>
Phone Number	<input type="text"/>
Fax Number	<input type="text"/>
Email Address	<input type="text"/>

PHARMACY AGREEMENT

I am the authorized representative of the pharmacy. By signing this form, I agree to the following terms and conditions:

- I understand that my pharmacy is required to participate in the LEMTRADA REMS program.
- I will oversee implementation of the LEMTRADA REMS requirements.
- I have reviewed the LEMTRADA REMS Overview.
- I will ensure that all requirements for dispensing of LEMTRADA using the LEMTRADA REMS are met.
- I will put processes in place to ensure that all requirements are met prior to receiving LEMTRADA for each pharmacy.

I have verified that all dispensing requirements are met.

By providing my e-signature, I understand the benefits of the information in the requirements and I agree to complete this LEMTRADA REMS enrollment form.

By entering my name, NPI number, and password, I will comply with the requirements of the LEMTRADA REMS program.

[Cancel](#)

pharmacy to coordinate the activities of the LEMTRADA REMS. By providing my e-signature, I agree to the following requirements:

- The prescriber is certified, the infusion site is certified, and the patient is enrolled and authorized to receive LEMTRADA by contacting the LEMTRADA REMS prior to dispensing LEMTRADA.
- Ensuring LEMTRADA is only dispensed to a certified infusion center.
- This pharmacy will establish procedures and protocols that are subject to audit, to help ensure compliance with the requirements of the LEMTRADA REMS.
- I understand that my pharmacy must renew enrollment in the LEMTRADA REMS every 2 years from initial enrollment.
- To make available to Genzyme, documentation to verify understanding of, and adherence to, the requirements of the LEMTRADA REMS.

I have completed the educational training about LEMTRADA for pharmacies and understand that all staff members from my site must be trained on the requirements of the LEMTRADA REMS. I understand that I must complete this LEMTRADA REMS enrollment form in order to complete the enrollment process.

I understand that I have completed the LEMTRADA REMS training and that

If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6326, Mon – Fri, 8:30 am – 8:00 pm ET.

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Registration Training Enrollment

LEMTRADA REMS Pharmacy Enrollment Form

LEMTRADA is only available through the LEMTRADA REMS, a restricted distribution program. Only prescribers, pharmacies, healthcare facilities, and patients enrolled in the program are able to prescribe, dispense, administer, and receive LEMTRADA. An authorized representative of the pharmacy must enroll the pharmacy in the LEMTRADA REMS.

Please review the following information and submit to Genzyme by clicking the button below. Complete any missing information and correct any errors prior to submission.

All fields are required.

PHARMACY INFORMATION

Name of Pharmacy
Please enter name of pharmacy.

National Provider Identification (NPI) Number
Please enter a valid NPI number.

Pharmacy Address

Please enter pharmacy address.

City
Please enter city.

State
Please select a state.

ZIP Code
Please enter a 5-digit ZIP Code.

Name of Authorized Pharmacy Representative
Please enter name of Authorized Pharmacy Representative.

Title
Please enter title.

Phone Number
Please enter a 10-digit phone number.

Fax Number
Please enter a 10-digit fax number.

Email Address
Please enter a valid email address.

PHARMACY AGREEMENT

I am the authorized representative designated by my pharmacy to coordinate the activities of the LEMTRADA REMS. By signing this form, I agree to comply with the following program requirements:

- I understand that my pharmacy must be certified with the LEMTRADA REMS to dispense LEMTRADA.
- I will oversee implementation and compliance with the LEMTRADA REMS requirements.
- I have reviewed the LEMTRADA REMS Program Overview.
- I will ensure that all relevant staff involved in the dispensing of LEMTRADA are educated and trained using the LEMTRADA REMS.
- I will put processes and procedures in place, and follow such processes and procedures, to ensure the following verifications are met prior to dispensing LEMTRADA:
 - The LEMTRADA REMS Prescription Ordering Form is received for each prescription.
 - The prescriber is certified, the infusion site is certified, and the patient is enrolled and authorized to receive LEMTRADA by contacting the LEMTRADA REMS prior to dispensing LEMTRADA.
 - Ensuring LEMTRADA is only dispensed to a certified infusion center.
- This pharmacy will establish procedures and protocols that are subject to audit, to help ensure compliance with the requirements of the LEMTRADA REMS.
- I understand that my pharmacy must renew enrollment in the LEMTRADA REMS every 2 years from initial enrollment.
- To make available to Genzyme, documentation to verify understanding of, and adherence to, the requirements of the LEMTRADA REMS.

I have verified that all details are correct.
Please indicate information has been verified.

By providing my e-signature, I attest that I have completed the educational training about LEMTRADA for pharmacies and I understand the benefits and risks of LEMTRADA. I understand that all staff members from my site must be trained on the information in the module and adhere to the requirements of the LEMTRADA REMS. I understand that I must complete this LEMTRADA REMS Pharmacy Enrollment Form in order to complete the enrollment process.

By entering my name, NPI number, and password, I confirm that I have completed the LEMTRADA REMS training and that I will comply with the requirements of the program.

Full Name
Please enter your full name.

NPI Number
Please enter your NPI number.

Password
Please enter a password.

[Cancel](#) [Submit](#)

If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6326, Mon – Fri, 8:30 am – 8:00 pm ET.

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The screenshot shows a web browser window displaying the LEMTRADA REMS website. The browser's address bar shows a Google search engine. The website header includes the LEMTRADA logo (alem tuzumab 12mg iv) and navigation links for Prescribing Information and Medication Guide. A personalized welcome message reads "Welcome, Patricia Washington!" with links for My Profile and Log Out. A main navigation bar contains Home, Forms & FAQs, REMS Certified Prescriber & Healthcare Facility Locator, and About REMS. A progress bar below the navigation bar shows three steps: Registration, Training, and Enrollment, with Enrollment being the active step. The main content area features a heading "Enrollment Is Complete!" followed by a paragraph stating that the user has successfully completed online enrollment and will receive a confirmation email. It also mentions that a Genzyme representative will follow up to schedule an appointment. A bolded instruction states: "If you do not receive a confirmation email after the representative's visit, please contact a LEMTRADA REMS Specialist at 1-855-676-6326." Below this, it explains that once enrollment is verified, the user will have access to an online support center. A link is provided to "Download and print a copy of your LEMTRADA REMS Pharmacy Enrollment Form for your records." A section titled "If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6326, Mon - Fri, 8:30 am - 8:00 pm ET." is also present. The footer contains links for Privacy Policy, Terms and Conditions, and Contact Us, along with a disclaimer that the site is for United States residents only, copyright information for 2019 Genzyme Corporation, and the Sanofi Genzyme logo.

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LEMTRADA REMS (Risk Evaluation and Mitigation Strategy)

What is the LEMTRADA REMS?
A REMS is a strategy to manage known or potential serious risks associated with a drug product and is required by the FDA to ensure the benefits of a drug outweigh its risks. The purpose of the LEMTRADA REMS is to inform prescribers, pharmacies, healthcare facilities, and patients about the risks of:

AUTOIMMUNE CONDITIONS
LEMTRADA causes serious, sometimes fatal, autoimmune conditions such as immune thrombocytopenia and anti-glomerular basement membrane disease. Monitor complete blood counts with differential, serum creatinine levels, and urinalysis with urine cell counts at periodic intervals for 48 months after the last dose of LEMTRADA.

INFUSION REACTIONS
LEMTRADA causes serious and life threatening infusion reactions. LEMTRADA must be administered in a setting with appropriate equipment and personnel to manage anaphylaxis or serious infusion reactions.

STROKE
Serious and life-threatening stroke (including ischemic and hemorrhagic stroke) has been reported within 3 days of LEMTRADA administration. Instruct patients to seek immediate medical attention if symptoms of stroke occur.

MALIGNANCIES
LEMTRADA may cause an increased risk of malignancy including thyroid cancer, melanoma, and lymphoproliferative disorders. Perform baseline and yearly exams.

LEMTRADA REMS Requirements

PHARMACIES

Pharmacies must be enrolled in the LEMTRADA REMS to be able to dispense LEMTRADA for patients with multiple sclerosis.

[Learn about Pharmacy Enrollment](#)

Complete Enrollment in the LEMTRADA REMS

You have not completed your review of the training materials. You must review the training materials in order to complete your enrollment in the LEMTRADA REMS.

[Review Training Materials](#)

Find a REMS Certified Prescriber or Healthcare Facility

Search for prescribers or healthcare facilities that are certified by the LEMTRADA REMS to prescribe, dispense, or administer LEMTRADA.

Enter ZIP Code

REMS Certified Prescriber
 REMS Certified Healthcare Facility

[Find](#)

This site is provided as a resource for prescribers and is not intended as medical advice. Information on the site is updated periodically (approximately every 12 hours).

If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6326, Mon – Fri, 8:30 am – 8:00 pm ET.

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A REMS is a strategy to manage known or potential serious risks associated with a drug product and is required by the FDA to ensure the benefits of a drug outweigh its risks. The purpose of the LEMTRADA REMS is to inform prescribers, pharmacies, healthcare facilities, and patients about the risks of:

AUTOIMMUNE CONDITIONS
LEMTRADA causes serious, sometimes fatal, autoimmune conditions such as immune thrombocytopenia and anti-glomerular basement membrane disease. Monitor complete blood counts with differential, serum creatinine levels, and urinalysis with urine cell counts at periodic intervals for 48 months after the last dose of LEMTRADA.

INFUSION REACTIONS
LEMTRADA causes serious and life threatening infusion reactions. LEMTRADA must be administered in a setting with appropriate equipment and personnel to manage anaphylaxis or serious infusion reactions.

STROKE
Serious and life-threatening stroke (including ischemic and hemorrhagic stroke) has been reported within 3 days of LEMTRADA administration. Instruct patients to seek immediate medical attention if symptoms of stroke occur.

MALIGNANCIES
LEMTRADA may cause an increased risk of malignancy including thyroid cancer, melanoma, and lymphoproliferative disorders. Perform baseline and yearly exams.

LEMTRADA REMS Requirements

PHARMACIES

Pharmacies must be enrolled in the LEMTRADA REMS to be able to dispense LEMTRADA for patients with multiple sclerosis.

[Learn about Pharmacy Enrollment](#) ▶

Complete Enrollment in the LEMTRADA REMS



You must review the training materials in order to complete your enrollment in the LEMTRADA REMS. Please call *MS One to One*[®] at 1-855-676-6326 to speak with a Genzyme representative.

Find a REMS Certified Prescriber or Healthcare Facility



Search for prescribers or healthcare facilities that are certified by the LEMTRADA REMS to prescribe, dispense, or administer LEMTRADA.

Enter ZIP Code

 REMS Certified Prescriber
 REMS Certified Healthcare Facility

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If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6326, Mon – Fri, 8:30 am – 8:00 pm ET.

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LEMTRADA REMS (Risk Evaluation and Mitigation Strategy)

What is the LEMTRADA REMS?
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[Learn about Pharmacy Enrollment](#)

Complete Enrollment in the LEMTRADA REMS

You have not completed your review and submission of the LEMTRADA REMS Pharmacy Enrollment Form.

[Review Enrollment Form](#)

Find a REMS Certified Prescriber or Healthcare Facility

Search for prescribers or healthcare facilities that are certified by the LEMTRADA REMS to prescribe, dispense, or administer LEMTRADA.

Enter ZIP Code

REMS Certified Prescriber
 REMS Certified Healthcare Facility

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[Learn about Pharmacy Enrollment](#)

LEMTRADA REMS Enrollment Complete

You have successfully completed online enrollment in the LEMTRADA REMS. You will receive a confirmation email with your LEMTRADA REMS Identification Number. A Genzyme representative will also follow up with you to schedule your appointment to verify enrollment.

[Review Training Materials Again](#)

Find a REMS Certified Prescriber or Healthcare Facility

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Enter ZIP Code

REMS Certified Prescriber
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About REMS

LEMTRADA REMS Training

LEMTRADA REMS Program Overview (1 of 2)
Total Training Screens: 1 of 2



LEMTRADA REMS PROGRAM OVERVIEW

What is the LEMTRADA REMS (Risk Evaluation and Mitigation Strategy)?

A REMS is a strategy to manage known or potential risks associated with a drug. It is required by the FDA to ensure that the benefits of the drug outweigh its risks. Due to serious risks of autoimmune conditions, infusion reactions, stroke and malignancies, LEMTRADA[®] (alemtuzumab) is only available through a restricted program called the LEMTRADA REMS.

LEMTRADA REMS Requirements

- **Prescribers** must be enrolled in the LEMTRADA REMS to be able to prescribe LEMTRADA.
- **Pharmacies** must be enrolled in the LEMTRADA REMS to be able to dispense LEMTRADA.
- **Healthcare Facilities** must be enrolled in the LEMTRADA REMS to be able to dispense and administer LEMTRADA.
- **Patients** must be enrolled and authorized in the LEMTRADA REMS in order to receive LEMTRADA.

PRESCRIBER ENROLLMENT INSTRUCTIONS

1. Complete the training program, which includes reviewing the following:
 - LEMTRADA Prescribing Information
 - LEMTRADA REMS Program Overview
 - LEMTRADA REMS Education Program for Prescribers
2. Successfully complete the 8-question LEMTRADA REMS Knowledge Assessment.
3. Enroll in the program by completing a LEMTRADA REMS Prescriber Enrollment Form.
4. Submit the completed and signed Forms to the LEMTRADA REMS.

PHARMACY ENROLLMENT INSTRUCTIONS

1. An authorized representative must enroll on behalf of the pharmacy by reviewing the LEMTRADA REMS Program Overview and completing the LEMTRADA REMS Pharmacy Enrollment Form, which acknowledges that the pharmacy agrees to follow the procedures outlined in the LEMTRADA REMS, including:
 - All relevant staff at the pharmacy who will be involved with the dispensing of LEMTRADA must be educated and trained.
 - The pharmacy will verify that a LEMTRADA REMS Prescription Ordering Form is received for each prescription.
 - The pharmacy will verify that prescribers and healthcare facilities are certified and patients are authorized to receive LEMTRADA prior to dispensing LEMTRADA.
 - Enrollment in the LEMTRADA REMS must be renewed every 2 years from initial enrollment.
2. Submit the completed and signed LEMTRADA REMS Pharmacy Enrollment Form to the LEMTRADA REMS.

Next

(1 of 2)

If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6326, Mon – Fri, 8:30 am – 8:00 pm ET.

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VV-REG-0833078 0.1

Reference ID: 4512344

PHARMACY DASHBOARD PAGES

LEMTRADA[®]
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LEMTRADA REMS Pharmacy Dashboard

Authorized representatives of pharmacies can use this site to coordinate fulfilling the LEMTRADA REMS requirements.

Have you verified all prescription requests?

Please call 1-855-676-6326, Mon - Fri, 8:30 am - 8:00 pm ET to verify:

- 1) the prescriber is REMS certified to prescribe LEMTRADA
- 2) the healthcare facility is REMS certified to administer LEMTRADA
- 3) the patient is enrolled and authorized by the LEMTRADA REMS

> Re-enroll in the LEMTRADA REMS
Pharmacies must renew their enrollment every 2 years and authorized representatives must renew their enrollment every year.

[Re-enroll Now](#)

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The screenshot shows a web browser window displaying the LEMTRADA REMS Pharmacy Dashboard. The browser's address bar shows a Google search. The page header includes the LEMTRADA logo (alemtezumabiv 12mg) and navigation links for Prescribing Information and Medication Guide. A user is logged in as Patricia Washington, with links for My Profile and Log Out. The main navigation bar contains Home, Forms & FAQs, REMS Certified Prescriber & Healthcare Facility Locator, and About REMS. A central overlay box with a close button (X) displays the message: "Your Re-enrollment Is Due in Less Than a Month". Below this message are two buttons: "Re-enroll Now" and "Return to Dashboard". The background content includes a section titled "LEMTRADA REMS" with a "Re-enroll Now" button and a "FOLD" label. At the bottom, there is a footer with links for Privacy Policy, Terms and Conditions, and Contact Us, along with copyright information for Genzyme Corporation and the SANOFI GENZYME logo.



LEMTRADA
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PHARMACIES

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[Learn about Pharmacy Enrollment](#) ▶

Re-enroll in the LEMTRADA REMS



You have been locked out due to incomplete re-enrollment. Please click the link below to re-enroll in the LEMTRADA REMS.

Re-enroll Now

Find a REMS Certified Prescriber or Healthcare Facility



Search for prescribers or healthcare facilities that are certified by the LEMTRADA REMS to prescribe, dispense, or administer LEMTRADA.

Enter ZIP Code

REMS Certified Prescriber
 REMS Certified Healthcare Facility

Find

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My Profile

Patricia Washington

(REMS ID 123456)

7776 Golden Blossom Run
Zook, IL 62056-3630
Office Phone: xxx-xxx-xxxx
Fax: xxx-xxx-xxxx

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Change Your Password

Passwords must be at least 8 characters in length and contain a minimum of 3 out of the following: A number, an upper-case letter, a lower-case letter, a special character (e.g. !, ", #, \$, etc.)

FOLD

Current Password

New Password

Confirm Password

Change Password

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My Profile

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Current Password

Please enter password.

New Password

Please enter valid password.

Confirm Password

Please confirm new password.

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Forms **FAQs**

Required LEMTRADA REMS Forms & Materials

Refer to these materials for information about the safe use of LEMTRADA through the LEMTRADA REMS.

[Online](#) | [PDF](#) LEMTRADA REMS Program Overview

[PDF](#) LEMTRADA REMS Pharmacy Enrollment Form

Adobe® Reader® is required to view all of these PDFs. If you do not have it installed, [download it free here](#).

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Forms FAQs

Frequently Asked Questions

Use the following FAQs to answer your questions about the LEMTRADA REMS. If you cannot find an answer to your question, or if you have additional questions, contact the LEMTRADA REMS at **1-855-676-6326**, Mon – Fri, 8:30 am – 8:00 pm ET.

[Expand](#)

1. How can I verify that prescribers are eligible to prescribe LEMTRADA?
Please call the LEMTRADA REMS at 1-855-676-6326 to verify if a prescriber is REMS certified to prescribe LEMTRADA.
2. How can I verify that a healthcare facility is eligible to dispense/administer LEMTRADA?
3. How do I verify that patients are authorized to receive a LEMTRADA infusion?
4. What do I do if a patient, prescriber, or healthcare facility that is associated with a request for a prescription for LEMTRADA is "Not REMS Authorized" or "Not REMS Certified"?
5. How can I access my profile?
6. How can I update contact information on this site?
7. How do I reset my password?
8. What do I do if the Pharmacy account manager (Pharmacy authorized representative) needs to change?

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[Collapse](#)

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- 3. How do I verify that patients are authorized to receive a LEMTRADA infusion?**
Please call the LEMTRADA REMS at 1-855-676-6326 to verify if a patient is eligible for a LEMTRADA infusion.
- 4. What do I do if a patient, prescriber, or healthcare facility that is associated with a request for a prescription for LEMTRADA is "Not REMS Authorized" or "Not REMS Certified"?**
If a patient is identified as "Not REMS Authorized," **DO NOT** dispense vials for that patient. If a prescriber or healthcare facility is identified as "Not REMS Certified," **DO NOT** dispense LEMTRADA vials to that healthcare facility or prescriber. Contact the LEMTRADA REMS at 1-855-676-6326, which can assist with how to manage each unauthorized request.
- 5. How can I access my profile?**
You can access your profile from any page by clicking on [My Profile](#) in the top right corner of the site.
- 6. How can I update contact information on this site?**
To update your contact information, contact the LEMTRADA REMS at 1-855-676-6326.
- 7. How do I reset my password?**
Pharmacy Managers can change the password of the account by visiting the "Change Password" section on the [My Profile](#) page. To change the password, enter and confirm a new password and click the "Change Password" button.
- 8. What do I do if the Pharmacy account manager (Pharmacy authorized representative) needs to change?**
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REMS Certified Prescriber & Healthcare Facility Locator

About REMS

REMS Certified Prescriber & Healthcare Facility Locator

Search for prescribers or healthcare facilities that are enrolled and certified in the LEMTRADA REMS and able to prescribe or dispense/administer LEMTRADA.

Please enter street address, city, state, or ZIP Code you would like to search for.

New Search: 🔍

REMS Certified Prescribers

REMS Certified Healthcare Facilities

📍

Certified Prescriber Name

Address

P. (888) - 888 - 8888

📍

Certified Prescriber Name

Address

P. (888) - 888 - 8888

📍

Certified Prescriber Name

Address

P. (888) - 888 - 8888

📍

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Genzyme is providing this search feature to help patients find prescribers and healthcare facilities that have been certified by the LEMTRADA REMS. Genzyme does not receive payment for providing this feature, and does not endorse, recommend, have jurisdiction over, or accept responsibility for the actions of any of the prescribers or healthcare facilities listed herein.

This site is provided as a resource for prescribers and is not intended as medical advice. Information on the site is updated periodically (approximately every 12 hours).

If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6326, Mon - Fri, 8:30 am - 8:00 pm ET.

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VV-REG-0833078 0.1

Reference ID: 4512344



LEMTRADA
alemtuzumab^{12mg} iv

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REMS Certified Prescriber & Healthcare Facility Locator

About REMS

REMS Certified Prescriber & Healthcare Facility Locator

Search for prescribers or healthcare facilities that are enrolled and certified in the LEMTRADA REMS and able to prescribe or dispense/administer LEMTRADA.

Please enter street address, city, state, or ZIP Code you would like to search for.

New Search: 🔍

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REMS Activity Pharmacy Enrollment Patient Guides

LEMTRADA REMS Requirements

Welcome to the LEMTRADA REMS. Here you can:

- Retrain and enroll in the LEMTRADA REMS every 2 years.
- Manage and/or track your progress through the LEMTRADA REMS training and enrollment
- Download materials to help support implementation of the LEMTRADA REMS

LEMTRADA REMS Activity

Steps	Activity	Progress
1.	Account Registration	Completed
2.	Training	Completed
3.	Enrollment Form Submission	Completed
4.	Enrollment Processed	Completed
5.	REMS ID Assigned	Completed

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REMS Activity Pharmacy Enrollment Patient Guides

LEMTRADA REMS Pharmacy Enrollment

- Pharmacies must be enrolled in the LEMTRADA REMS to be able to dispense LEMTRADA for patients with multiple sclerosis

To enroll in the program, an authorized representative of the pharmacy must complete the following steps:

1	Designate an authorized representative
2	Register the authorized representative with the LEMTRADA REMS Training Center
3	Authorized representative must review the LEMTRADA REMS Program Overview
4	After reviewing the material, complete and sign the LEMTRADA REMS Pharmacy Enrollment Form. This enrollment must be renewed every 2 years
5	Implement the necessary staff and training processes to comply with the LEMTRADA REMS

[Review Online Training](#)

If you have questions about the LEMTRADA REMS or need help enrolling, call **1-855-676-6326**, Mon - Fri, 8:30 am - 8:00 pm ET.

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LEMTRADA Patient Guides

Below are materials that help inform patients about treatment with LEMTRADA.

[PDF](#) What You Need to Know About LEMTRADA Treatment: A Patient Guide

[PDF](#) What You Need to Know About LEMTRADA Treatment and Infusion Reactions: A Patient Guide

Adobe® Reader® is required to view all of these PDFs. If you do not have it installed, download it free here.

If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6326, Mon - Fri, 8:30 am - 8:00 pm ET.

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LEMTRADA REMS MOBILE

PUBLIC and Prescriber Pages Only

PUBLIC FACING PAGES

8:45 PM

Google

PRESCRIBING INFORMATION
MEDICATION GUIDE



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LEMTRADA REMS (Risk Evaluation and Mitigation Strategy)

What is the LEMTRADA REMS?

A REMS is a strategy to manage known or potential serious risks associated with a drug product and is required by the FDA to ensure the benefits of a drug outweigh its risks. The purpose of the LEMTRADA REMS is to inform prescribers, pharmacies, healthcare facilities, and patients about the risks of:

AUTOIMMUNE CONDITIONS
LEMTRADA causes serious, sometimes fatal, autoimmune conditions such as immune thrombocytopenia and anti-glomerular basement membrane disease. Monitor complete blood counts with differential, serum creatinine levels, and urinalysis with urine cell counts at periodic intervals for 48 months after the last dose of LEMTRADA.

INFUSION REACTIONS
LEMTRADA causes serious and life threatening infusion reactions. LEMTRADA must be administered in a setting with appropriate equipment and personnel to manage anaphylaxis or serious infusion reactions.

STROKE
Serious and life-threatening stroke (including ischemic and hemorrhagic stroke) has been reported within 3 days of LEMTRADA administration. Instruct patients to seek immediate medical attention if symptoms of stroke occur.

MALIGNANCIES
LEMTRADA may cause an increased risk of malignancy including thyroid cancer, melanoma, and lymphoproliferative disorders. Perform baseline and yearly skin exams.

Enroll in the LEMTRADA REMS



Prescribers, healthcare facilities, pharmacies, and patients must be enrolled in the LEMTRADA REMS to be able to dispense, administer, or receive LEMTRADA, respectively. Enroll in the program and gain access to the online tools and resources available to help you manage your LEMTRADA patients.

[Information for Prescribers >](#)

[Information for Healthcare Facilities >](#)

[Information for Pharmacies >](#)

[Already registered? Log In >](#)

Enroll Now

Find a REMS Certified Prescriber or Healthcare Facility



Search for prescribers or healthcare facilities that are certified by the LEMTRADA REMS to prescribe, dispense, or administer LEMTRADA.

Enter ZIP Code

REMS Certified Prescriber

REMS Certified Healthcare Facility

Find

LEMTRADA REMS Requirements

PRESCRIBERS

Prescribers must be enrolled in the LEMTRADA REMS to prescribe LEMTRADA for patients with multiple sclerosis. [Learn about Prescriber Enrollment >](#)

HEALTHCARE FACILITIES

Healthcare facilities must be enrolled in the LEMTRADA REMS to dispense/administer LEMTRADA for patients with multiple sclerosis. *One representative needs to enroll per healthcare setting.* [Learn about Healthcare Facility Enrollment >](#)

PHARMACIES

Pharmacies must be enrolled in the LEMTRADA REMS to be able to dispense LEMTRADA for patients with multiple sclerosis. [Learn about Pharmacy Enrollment >](#)

If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6326.

Mon – Fri, 8:30 am – 8:00 pm ET.

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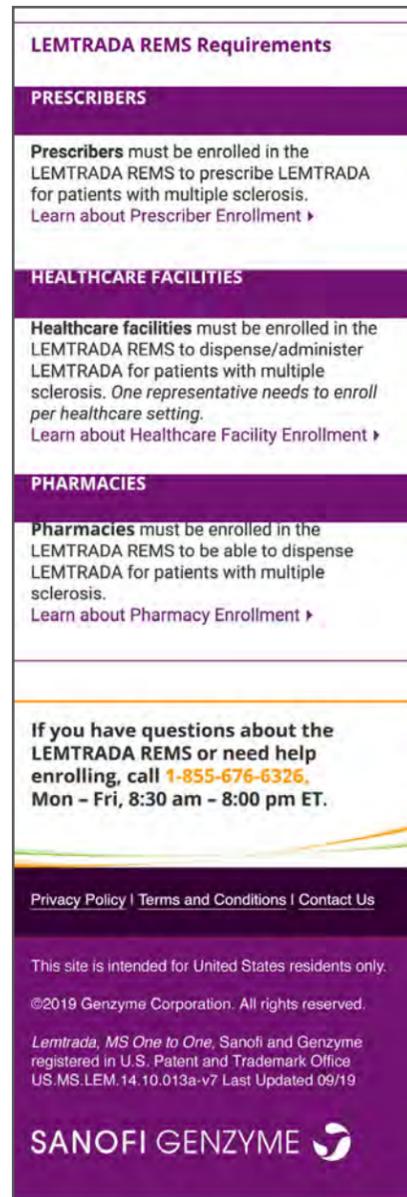
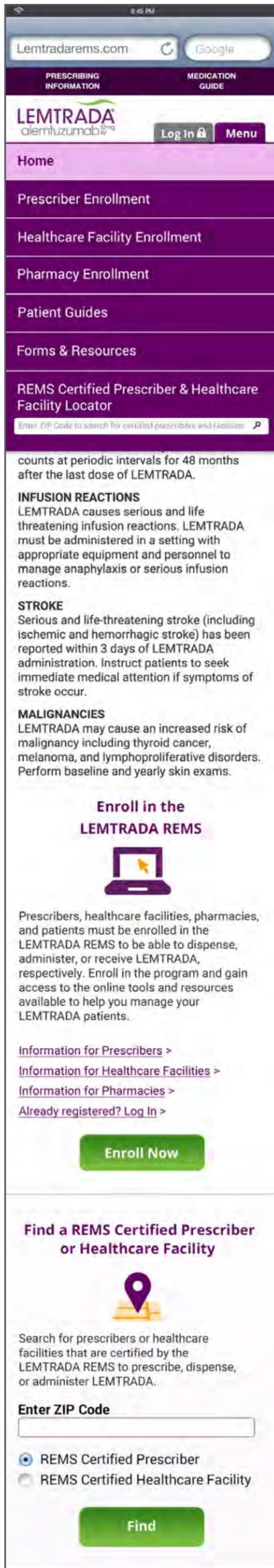
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Enroll in the LEMTRADA REMS

Prescribers, healthcare facilities, pharmacies, and patients must be enrolled in the LEMTRADA REMS to be able to dispense, administer, or receive LEMTRADA, respectively. Enroll in the program and gain access to the online tools and resources available to help you manage your LEMTRADA patients.

[Information for Prescribers >](#)
[Information for Healthcare Facilities >](#)
[Information for Pharmacies >](#)
[Already registered? Log In >](#)

Enroll Now

Find a REMS Certified Prescriber or Healthcare Facility

Search for prescribers or healthcare facilities that are certified by the LEMTRADA REMS to prescribe, dispense, or administer LEMTRADA.

Enter ZIP Code

Please enter ZIP Code.

REMS Certified Prescriber
 REMS Certified Healthcare Facility

Please make a selection.

Find

LEMTRADA REMS Requirements

PRESCRIBERS

Prescribers must be enrolled in the LEMTRADA REMS to prescribe LEMTRADA for patients with multiple sclerosis. [Learn about Prescriber Enrollment >](#)

HEALTHCARE FACILITIES

Healthcare facilities must be enrolled in the LEMTRADA REMS to dispense/administer LEMTRADA for patients with multiple sclerosis. *One representative needs to enroll per healthcare setting.* [Learn about Healthcare Facility Enrollment >](#)

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Pharmacies must be enrolled in the LEMTRADA REMS to be able to dispense LEMTRADA for patients with multiple sclerosis. [Learn about Pharmacy Enrollment >](#)

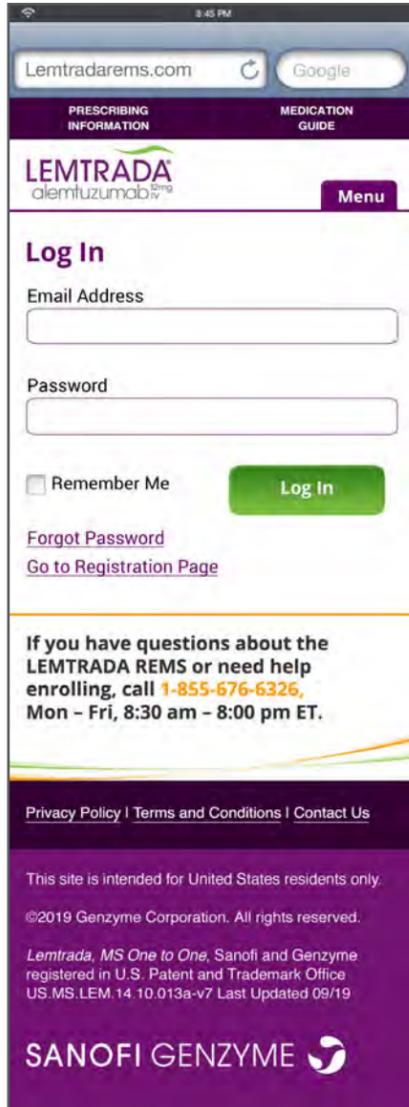
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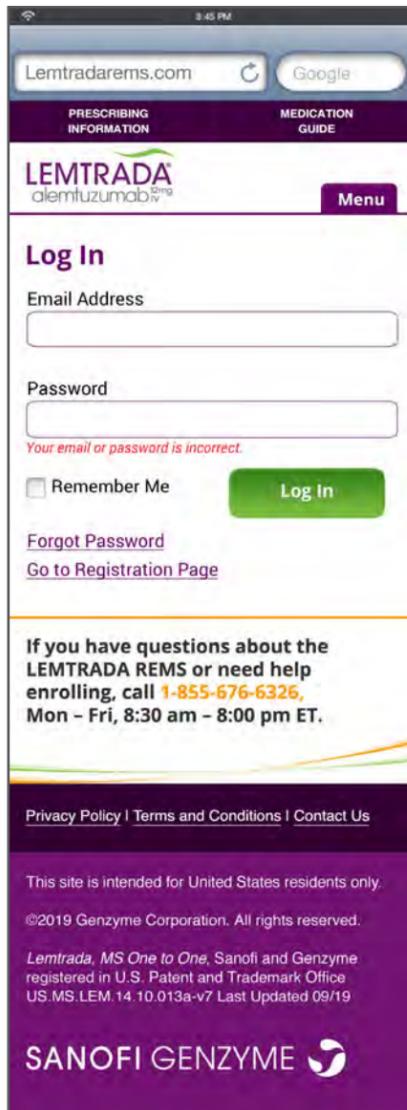
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Set Password

Passwords must be at least 8 characters in length and contain a minimum of 3 out of the following: A number, an upper-case letter, a lower-case letter, a special character (e.g. !, ", #, \$, etc.)

New Password

Confirm Password

Log In

If you have questions about the LEMTRADA REMS or need help enrolling, call **1-855-676-6326**, Mon - Fri, 8:30 am - 8:00 pm ET.

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Please confirm your password.

Log In

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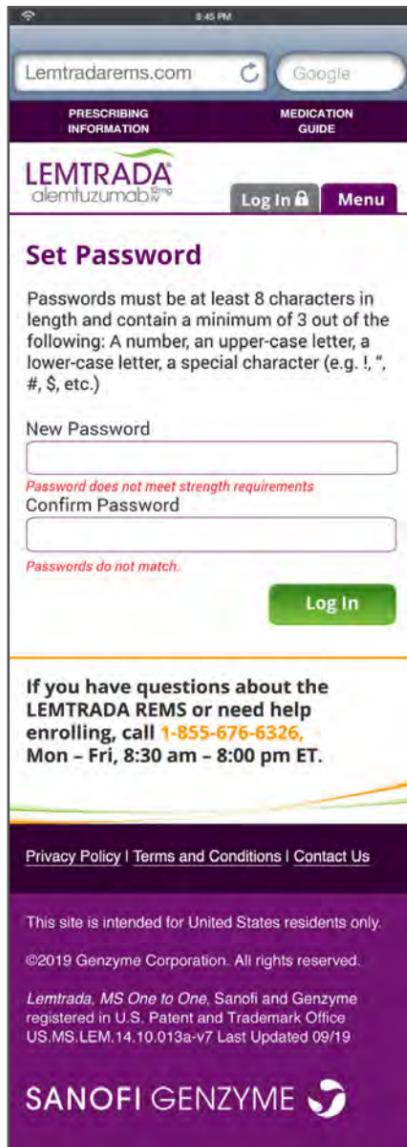
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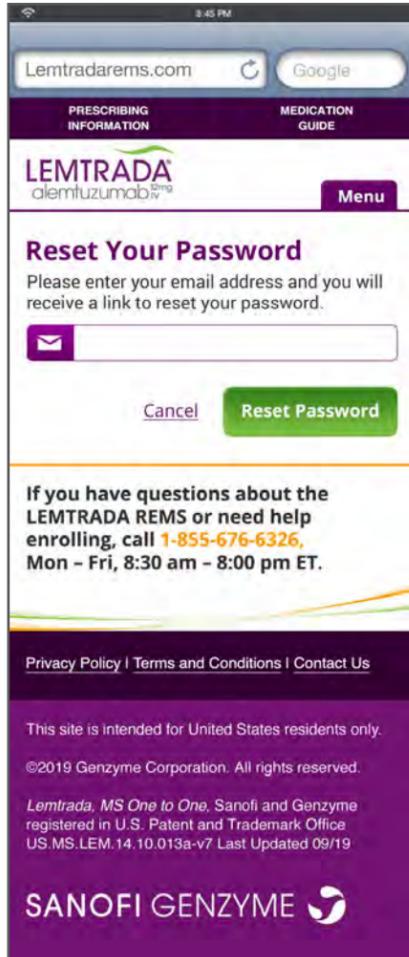
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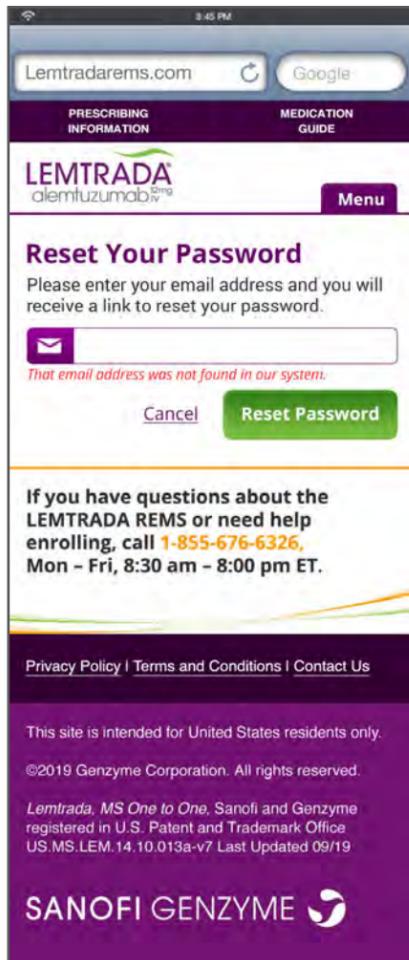
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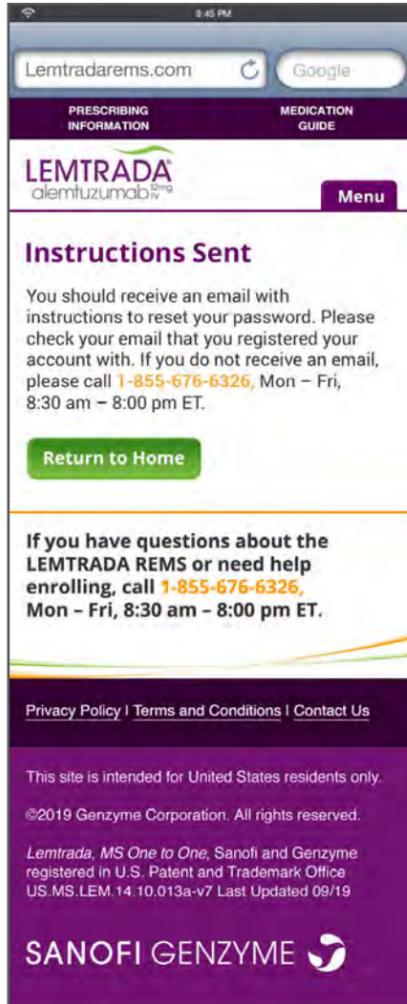
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The screenshot shows the mobile app interface for LEMTRADA REMS Prescriber Enrollment. At the top, there is a search bar with 'Lemtradarems.com' and a 'Google' button. Below the search bar are two tabs: 'PRESCRIBING INFORMATION' and 'MEDICATION GUIDE'. The LEMTRADA logo is displayed, along with 'Log In' and 'Menu' buttons. The main heading is 'LEMTRADA REMS Prescriber Enrollment'. Below this, there are two bullet points: 'Prescribers must be enrolled in the LEMTRADA REMS to be able to prescribe LEMTRADA for patients with relapsing forms of multiple sclerosis (MS). Because of its safety profile, the use of LEMTRADA should generally be reserved for patients who have had an inadequate response to two or more drugs indicated for the treatment of MS' and 'Note that your healthcare facility must be separately enrolled in the LEMTRADA REMS to dispense/administer LEMTRADA'. A section titled 'To enroll in the program, prescribers must complete the following steps:' follows, with a numbered list of four steps: 1. Register with the LEMTRADA REMS Online Training Center; 2. Review the LEMTRADA REMS Education Program for Prescribers, including the LEMTRADA REMS Program Overview and the LEMTRADA full Prescribing Information in the online module on this site; 3. Successfully complete the 8-question Knowledge Assessment at the end of the module; 4. After completing the assessment, complete and sign the LEMTRADA REMS Prescriber Enrollment Form. A green button labeled 'Register for Online Enrollment' is positioned below the steps. The 'PROGRAM MATERIALS' section is titled 'For Prescribers' and lists ten PDF documents: LEMTRADA REMS Program Overview, LEMTRADA REMS Education Program for Prescribers, LEMTRADA REMS Knowledge Assessment, Healthcare Provider Letter: Patient Status, LEMTRADA REMS Prescriber Enrollment Form, LEMTRADA REMS Patient Authorization and Baseline Lab Form, LEMTRADA REMS Patient Enrollment Form, LEMTRADA REMS Prescription Ordering Form, LEMTRADA REMS Patient Status Form, and What You Need to Know About LEMTRADA Treatment: A Patient Guide. A contact information box states: 'If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6326, Mon - Fri, 8:30 am - 8:00 pm ET.' The footer contains links for 'Privacy Policy | Terms and Conditions | Contact Us', a disclaimer 'This site is intended for United States residents only.', copyright information '©2019 Genzyme Corporation. All rights reserved.', and the Sanofi Genzyme logo.

The screenshot shows a mobile application interface for LEMTRADA REMS. At the top, there is a search bar with 'Lemtradarems.com' and a 'Google' search button. Below the search bar are two tabs: 'PRESCRIBING INFORMATION' and 'MEDICATION GUIDE'. The main header features the LEMTRADA logo with 'alemtuzumab' underneath, and 'Log In' and 'Menu' buttons. The main content area is titled 'LEMTRADA REMS Healthcare Facility Enrollment'. It includes a bullet point stating that healthcare facilities must be enrolled to dispense/administer LEMTRADA for patients with relapsing forms of multiple sclerosis (MS). Below this, it states that an authorized representative of the healthcare facility must complete five steps to enroll in the program. These steps are: 1. Designate an authorized representative; 2. Register the authorized representative with the LEMTRADA REMS Training Center; 3. Authorized representative must review the LEMTRADA REMS Education Program for Healthcare Facilities and the LEMTRADA REMS Program Overview through the online module on this site; 4. After completing the online module, complete and sign the LEMTRADA REMS Healthcare Facility Enrollment Form. This enrollment must be renewed every 2 years; 5. Implement the necessary staff training and processes to comply with the LEMTRADA REMS requirements. A green button labeled 'Register for Online Enrollment' is positioned below the steps. Underneath is a section titled 'PROGRAM MATERIALS For Healthcare Facilities' which lists five PDF documents: 'LEMTRADA REMS Program Overview', 'LEMTRADA REMS Education Program for Healthcare Facilities', 'LEMTRADA REMS Healthcare Facility Enrollment Form', 'LEMTRADA REMS Infusion Checklist', and 'What You Need to Know About LEMTRADA Treatment and Infusion Reactions: A Patient Guide'. At the bottom of this section, it provides contact information: 'If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6326, Mon - Fri, 8:30 am - 8:00 pm ET.' The footer contains links for 'Privacy Policy | Terms and Conditions | Contact Us', a disclaimer 'This site is intended for United States residents only.', copyright information '©2019 Genzyme Corporation. All rights reserved.', and registration information 'Lemtrada, MS One to One, Sanofi and Genzyme registered in U.S. Patent and Trademark Office US.MS.LEM.14.10.013a-v7 Last Updated 09/19'. The Sanofi Genzyme logo is at the very bottom.

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To enroll in the program, an authorized representative of the healthcare facility must complete the following steps:

- 1 Designate an authorized representative
- 2 Register the authorized representative with the LEMTRADA REMS Training Center
- 3 Authorized representative must review the LEMTRADA REMS Education Program for Healthcare Facilities and the LEMTRADA REMS Program Overview through the online module on this site
- 4 After completing the online module, complete and sign the LEMTRADA REMS Healthcare Facility Enrollment Form. This enrollment must be renewed every 2 years
- 5 Implement the necessary staff training and processes to comply with the LEMTRADA REMS requirements

[Register for Online Enrollment](#)

PROGRAM MATERIALS

For Healthcare Facilities

- LEMTRADA REMS Program Overview
- LEMTRADA REMS Education Program for Healthcare Facilities
- LEMTRADA REMS Healthcare Facility Enrollment Form
- LEMTRADA REMS Infusion Checklist
- What You Need to Know About LEMTRADA Treatment and Infusion Reactions: A Patient Guide

If you have questions about the LEMTRADA REMS or need help enrolling, call **1-855-676-6326**, Mon - Fri, 8:30 am - 8:00 pm ET.

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The screenshot shows a mobile application interface for LEMTRADA REMS Pharmacy Enrollment. At the top, there is a navigation bar with 'PRESCRIBING INFORMATION' and 'MEDICATION GUIDE'. Below this is the LEMTRADA logo and a search bar. The main content area features a title 'LEMTRADA REMS Pharmacy Enrollment' and a list of five steps for pharmacy enrollment. A green button labeled 'Register for Online Enrollment' is positioned below the steps. Underneath, there is a section for 'PROGRAM MATERIALS' with links to 'LEMTRADA REMS Program Overview' and 'LEMTRADA REMS Pharmacy Enrollment Form'. At the bottom, there is contact information for enrollment assistance and a footer with legal notices and the Sanofi Genzyme logo.

LEMTRADA REMS Pharmacy Enrollment

- Pharmacies must be enrolled in the LEMTRADA REMS to be able to dispense LEMTRADA for patients with multiple sclerosis

To enroll in the program, an authorized representative of the pharmacy must complete the following steps:

- 1 Designate an authorized representative
- 2 Register the authorized representative with the LEMTRADA REMS Training Center
- 3 Authorized representative must review the LEMTRADA REMS Program Overview through the online module on this site
- 4 After reviewing the material, complete and sign the LEMTRADA REMS Pharmacy Enrollment Form. This enrollment must be renewed every 2 years
- 5 Implement the necessary staff and training processes to comply with the LEMTRADA REMS requirements

[Register for Online Enrollment](#)

PROGRAM MATERIALS

For Pharmacies

- [LEMTRADA REMS Program Overview](#)
- [LEMTRADA REMS Pharmacy Enrollment Form](#)

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Please enter street address, city, state, or ZIP Code you would like to search for.

New Search:

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<p style="font-size: 10px; margin: 0;"> Certified Prescriber Name Address Address P. (888) - 888 - 8888 </p>	<p style="font-size: 10px; margin: 0;"> Certified Prescriber Name Address Address P. (888) - 888 - 8888 </p>
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This site is provided as a resource for prescribers and is not intended as medical advice. Information on the site is updated periodically (approximately every 12 hours).

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REMS Certified Prescriber & Healthcare Facility Locator

Search for prescribers or healthcare facilities that are enrolled and certified in the LEMTRADA REMS and able to prescribe or dispense/administer LEMTRADA.

Please enter street address, city, state, or ZIP Code you would like to search for.

New Search:

🔍



REMS Certified Prescriber
REMS Certified Healthcare Facilities

📍

Certified Center Name

Address

Address

P. (888) - 888 - 8888

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Certified Center Name

Address

Address

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Call Center Hours: Mon – Fri,
8:30 am – 8:00 pm ET

All fields are required.

First Name

Last Name

What can we help you with?

Select One

How would you like to be contacted?

Email Phone

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The screenshot shows a mobile web browser interface for the LEMTRADA REMS mobile site. At the top, there is a search bar with 'Lemtrada.rems.com' and a 'Google' search button. Below the search bar are two tabs: 'PRESCRIBING INFORMATION' and 'MEDICATION GUIDE'. The LEMTRADA logo is displayed, along with 'alemtuzumab' and 'Log In' and 'Menu' buttons. The main heading is 'Contact Us'. The text reads: 'For any questions about LEMTRADA, please contact LEMTRADA Support Services by phone or complete the form below.' The phone number is '1-855-676-6326' and call center hours are 'Mon - Fri, 8:30 am - 8:00 pm ET'. A note states 'All fields are required.' There are two text input fields for 'First Name' and 'Last Name'. Below these is a dropdown menu titled 'What can we help you with?' with options: 'Select', 'Patient Support' (checked), 'Product', 'Technical', and 'Other'. A green 'Submit' button is at the bottom of the form. The footer contains links for 'Privacy Policy | Terms and Conditions | Contact Us', a disclaimer 'This site is intended for United States residents only.', copyright information '©2019 Genzyme Corporation. All rights reserved.', and the Sanofi Genzyme logo.

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All fields are required.

First Name

Please enter your first name.

Last Name

Please enter your last name.

What can we help you with?

Please make a selection.

How would you like to be contacted?

Email Phone

Please enter a valid email address.

Submit

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All fields are required.

First Name

Please enter your first name.

Last Name

Please enter your last name.

What can we help you with?

Please make a selection.

How would you like to be contacted?

Email Phone

Please enter a 10-digit phone number.

Submit

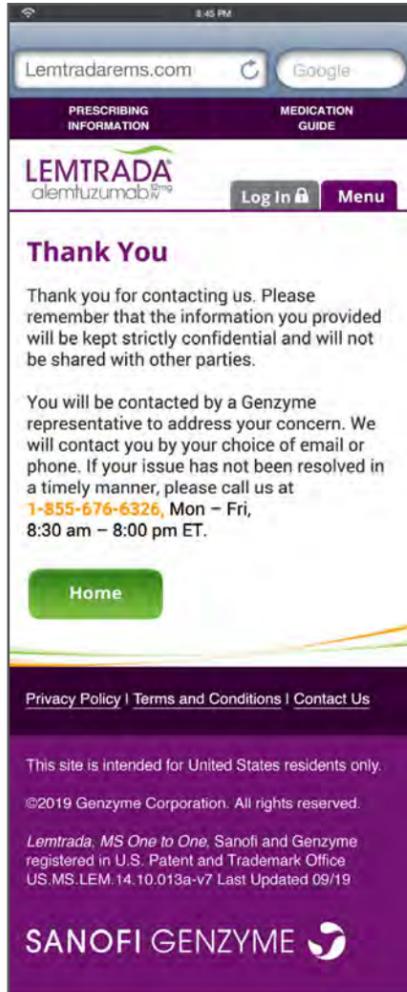
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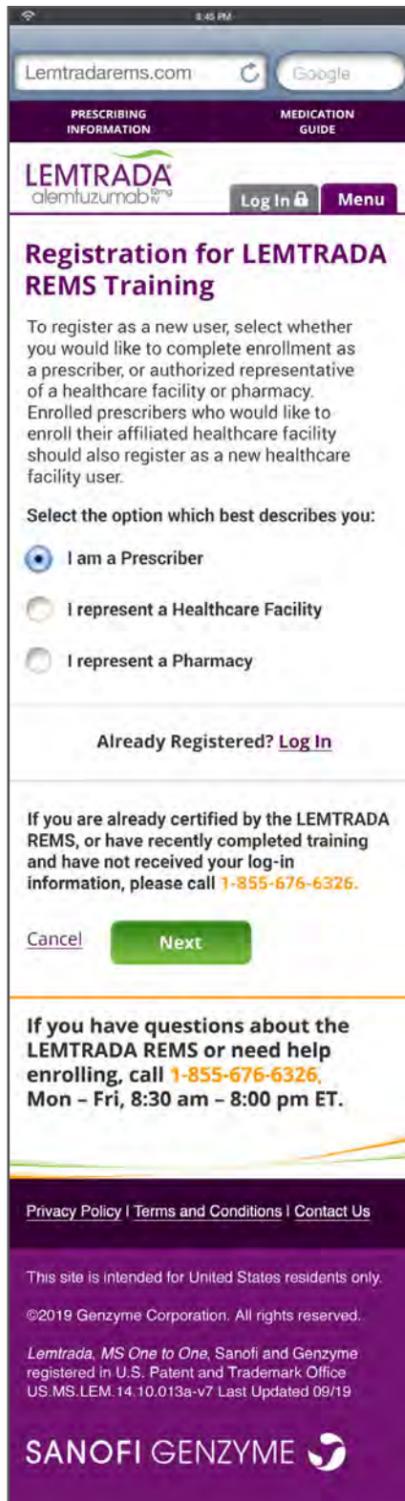
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PRESCRIBER TRAINING PAGES



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Prescriber Registration for LEMTRADA REMS Training

To complete your training for the LEMTRADA REMS, please set up an account.

*Required

Email Address*

Create a Password*

Passwords must be at least 8 characters in length and contain a minimum of 3 out of the following: A number, an upper-case letter, a lower-case letter, a special character (e.g. !, ", #, \$, etc.)

Confirm Password*

First Name*

Last Name*

Degree*

National Provider Identification (NPI) Number*

Name of Institution or Healthcare Facility*

Street Address*

City*

State* **ZIP Code***

Office Phone Number*

Office Fax Number*

Mobile Phone Number

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Confirm Password*

First Name*

Last Name*

Degree*

- Select
- Doctor of Osteopathy
- Doctor of Pharmacy
- Medical Doctor
- Nurse Practitioner
- Physician Assistant
- Registered Nurse
- Registered Pharmacist

State* **ZIP Code***

Office Phone Number*

Office Fax Number*

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Confirm Password*

First Name*

Last Name*

Degree*

National Provider Identification (NPI) Number*

Name of Institution or Healthcare Facility*

Street Address*

City*

State* **ZIP Code***

- ↕ Select
- Alabama
- Alaska
- American Samoa
- Arizona
- Arkansas
- California
- Colorado
- Connecticut
- Delaware
- District of Columbia
- Florida
- Georgia
- Guam
- Hawaii
- Idaho
- Illinois
- Indiana
- Iowa
- Kansas
- Kentucky
- Louisiana
- Maine
- Maryland
- Massachusetts
- Michigan

- Minnesota
- Mississippi
- Missouri
- Montana
- Nebraska
- Nevada
- New Hampshire
- New Jersey
- New Mexico
- New York
- North Carolina
- North Dakota
- Northern Mariana Islands
- Ohio
- Oklahoma
- Oregon
- Pennsylvania
- Puerto Rico
- Rhode Island
- South Carolina
- South Dakota
- Tennessee
- Texas
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Confirm Password*

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First Name*

Please enter your first name.

Last Name*

Please enter your last name.

Degree*

Select One

Please select degree.

National Provider Identification (NPI) Number*

Please enter a valid NPI number.

Name of Institution or Healthcare Facility*

Please enter name of institution or healthcare facility.

Street Address*

Please enter primary office address.

City*

Please enter city.

State* ZIP Code*

Select One

Please select a state. Please enter a 5-digit ZIP Code.

Office Phone Number*

Please enter a 10-digit phone number.

Office Fax Number*

Please enter a 10-digit fax number.

Mobile Phone Number

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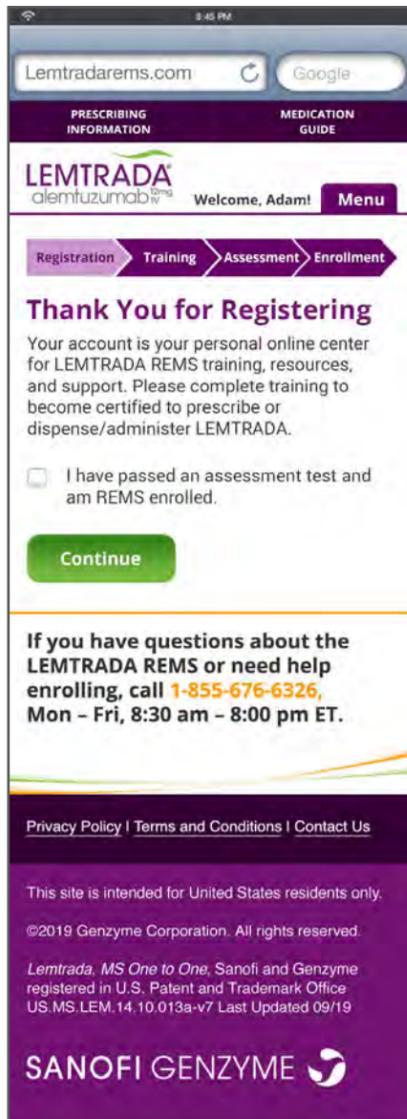
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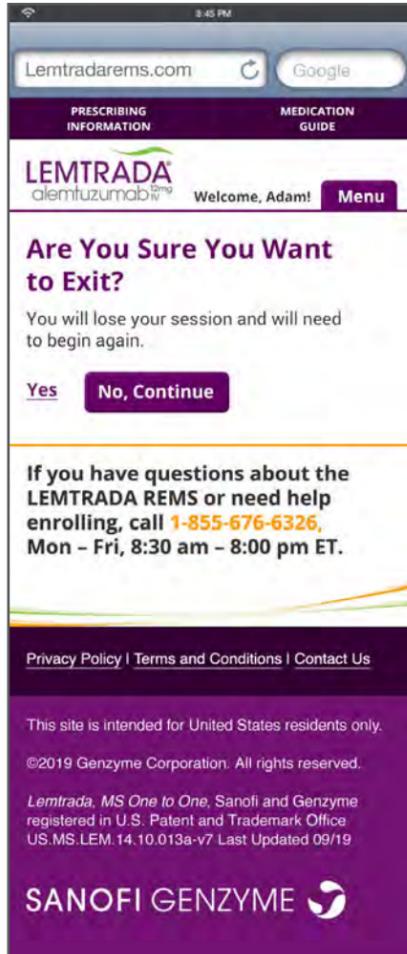
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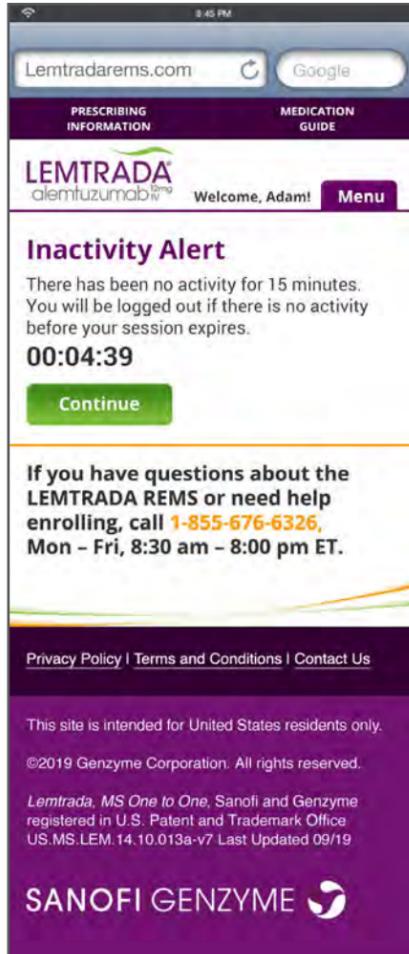
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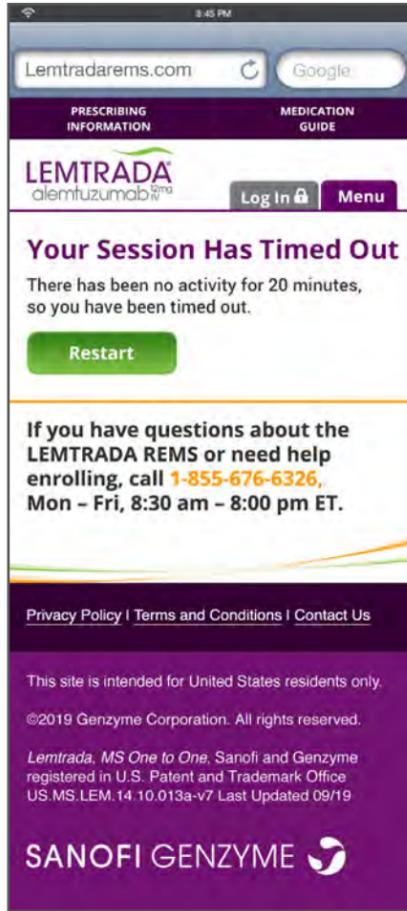
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The screenshot shows a mobile application interface for the LEMTRADA REMS Online Training Module. At the top, there is a browser address bar with 'Lemtradorems.com' and a Google search bar. Below this is a navigation bar with 'PRESCRIBING INFORMATION' and 'MEDICATION GUIDE'. The main header features the LEMTRADA logo, the text 'Welcome, Adam!', and a 'Menu' button. A progress indicator shows 'Registration', 'Training', 'Assessment', and 'Enrollment', with 'Training' being the active step. The main content area is titled 'LEMTRADA REMS Online Training Module' and contains a warning: 'If inactive on the training module for 20 minutes, you will be automatically logged off the LEMTRADA website and lose your training progress.' This is followed by three bullet points: 1) Review training materials (Prescribing Information, REMS Program Overview, and Education Program for Prescribers) at your own pace. 2) Answer 8 questions correctly at the end of the module; otherwise, review materials. 3) Ineligibility for enrollment after 6 failed assessment attempts. A note states that training takes approximately 20 minutes and progress may be lost if inactive. A green 'Continue' button is located below the text. At the bottom of the main content area, there is contact information: 'If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6326, Mon - Fri, 8:30 am - 8:00 pm ET.' The footer contains links for 'Privacy Policy | Terms and Conditions | Contact Us', a disclaimer for US residents, copyright information for Genzyme Corporation (©2019), and the Sanofi Genzyme logo.







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Registration Training Assessment Enrollment

LEMTRADA REMS Training

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3. WARNINGS AND PRECAUTIONS	4. ADVERSE REACTIONS
5. DRUG INTERACTIONS	6. USE IN SPECIFIC POPULATIONS
7. DOSAGE AND ADMINISTRATION	8. HOW SUPPLIED/AVAILABILITY
9. ACTION STATEMENT	10. CLINICAL STUDIES
11. REFERENCES	12. FULL PRESCRIBING INFORMATION (PI)
13. PATENT INFORMATION	14. OTHER INFORMATION
15. HOW TO OBTAIN INFORMATION	16. CONTACT INFORMATION
17. PRODUCT DESCRIPTION	18. PATENT INFORMATION
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91. PATENT INFORMATION	92. PATENT INFORMATION
93. PATENT INFORMATION	94. PATENT INFORMATION
95. PATENT INFORMATION	96. PATENT INFORMATION
97. PATENT INFORMATION	98. PATENT INFORMATION
99. PATENT INFORMATION	100. PATENT INFORMATION

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LEMTRADA REMS Training

Full Prescribing Information (3 of 27)

Total Training Screens: 3 of 41

FULL PRESCRIBING INFORMATION

WARNING: AUTOIMMUNITY, INFUSION REACTIONS, STROKE, AND MALNUTRICES

- LEMTRADA causes serious, sometimes fatal, autoimmune conditions such as immune thrombocytopenia and anti-glomerular basement membrane disease. Monitor complete blood counts with differential, serum creatinine levels, and urinalysis with urine cell counts at periodic intervals for 48 months after the last dose of LEMTRADA. *See Warnings and Precautions (5.1).*
- LEMTRADA causes serious and life-threatening infusion reactions. LEMTRADA must be administered in a setting with appropriate equipment and personnel to manage anaphylaxis or serious infusion reactions. Monitor patients for two hours after each infusion. Make patients aware that serious infusion reactions can also occur after the 3-hour monitoring period. *See Warnings and Precautions (5.2).*
- Seizures and life-threatening strokes (including ischemic and hemorrhagic strokes) has been reported within 2 days of LEMTRADA administration. Monitor patients and immediately medical attention if symptoms of stroke occur. *See Warnings and Precautions (5.3).*
- LEMTRADA may cause an increased risk of malignancies, including thyroid cancer, melanoma, and lymphoproliferative disorders. Perform baseline and yearly skin exams. *See Warnings and Precautions (5.4).*
- Because of the risk of autoimmunity, infusion reactions, and malignancies, LEMTRADA is available only through restricted distribution under a Risk Reduction Mitigation Strategy (REMS) Program. Call 1-855-676-6326 to enroll in the LEMTRADA REMS program. *See Warnings and Precautions (5.5).*

1 INDICATIONS AND USAGE

LEMTRADA is indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include relapsing-remitting disease and active secondary progressive disease, in adults. Because of its safety profile, the use of LEMTRADA should generally be reserved for patients who have had an inadequate response to two or more drugs indicated for the treatment of MS. *See Warnings and Precautions (5.2).*

Administration

LEMTRADA is not recommended for use in patients with clinically isolated syndrome (CIS) because of its safety profile. *See Warnings and Precautions (5.1).*

2 DOSAGE AND ADMINISTRATION

2.1 Testing and Procedures Prior to Treatment

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LEMTRADA REMS Training

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Baseline Laboratory Tests are required prior to treatment with LEMTRADA (see Dosage and Administration (2.6)). In addition, prior to starting treatment with LEMTRADA (see Dosage and Administration (2.6)):

- complete any necessary immunizations at least 6 weeks prior to treatment.
- determine whether patients have a history of varicella or have been vaccinated for varicella zoster virus (VZV). If not, test the patient for antibodies to VZV and consider vaccination for those who are antibody-negative. Postpone treatment with LEMTRADA until 6 weeks after VZV vaccination.
- perform tuberculin testing according to local guidelines.
- instruct patients to avoid potential sources of *Coccidioides immitis* exposure.

2.2 Recommended Pre-medication and Concomitant Medication

Concomitants

Prescribe all patients with high-dose corticosteroids (1,000 mg methylprednisolone or equivalent) immediately prior to LEMTRADA infusion and for the first 3 days of each treatment course (see Dosage and Administration (2.2)).

Herpes Prophylaxis

Administer anti-viral prophylaxis for herpes viral infections starting on the first day of each treatment course and continue for a minimum of two weeks following treatment with LEMTRADA or until the CD4+ lymphocyte count is at least 200 cells per milliliter, whichever occurs later (see Dosage and Administration (2.2)).

2.3 Recommended Dosage

- The recommended dosage of LEMTRADA is 12 mg/kg administered by intravenous infusion for 2 treatment courses. First Treatment Course: 12 mg/kg on 3 consecutive days (60 mg total dose).
- Second Treatment Course: 12 mg/kg on 3 consecutive days (36 mg total dose) administered 12 weeks after the first treatment course.

Following the second treatment course, subsequent treatment courses of 12 mg/kg on 3 consecutive days (36 mg total dose) may be administered, as needed, at least 12 weeks after the last dose of any prior treatment course.

2.4 Preparation Instructions

Follow the steps below to prepare the diluted solution of LEMTRADA for intravenous infusion:

- Inspect LEMTRADA visually for particulate matter and discoloration prior to administration. Do not use if particulate matter is present or the solution is discolored. Do not freeze or shake vial prior to use.
- Withdraw 1.2 mL of LEMTRADA from the vial into a syringe using aseptic technique and inject into a 100 mL bag of 0.9% Sodium Chloride, USP or 0.9% Electrolyte in Water, USP.

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2.5 Infusion Instructions

Infuse LEMTRADA over a 90-minute period starting within 8 hours after dilution. Examine the solution of the infusion if clinically indicated.

Administer LEMTRADA in a setting in which equipment and personnel are appropriately trained to manage anaphylaxis or serious infusion reactions as available (see Warnings and Precautions (2.2)).

Do not add or discontinue any other drug infusions through the same intravenous line; do not administer as an intravenous push or bolus.

Monitor vital signs before the infusion and periodically during the infusion. Provide appropriate symptomatic treatment for infusion reactions as needed. Consider immediate discontinuation of the intravenous infusion if severe infusion reactions occur.

Observe patients for infusion reactions during and for at least 2 hours after each LEMTRADA infusion. Consider longer periods of observation if clinically indicated. Inform patients that they should report symptoms that occur during and after each infusion because they may indicate a need for prompt medical intervention (see Warnings and Precautions (2.2)).

2.6 Laboratory Testing and Monitoring to Assess Safety

Monitor the white blood cell count prior to initiation of treatment. Conduct the following laboratory tests at baseline and at periodic intervals until 48 months after the last treatment course of LEMTRADA in order to monitor for early signs of potentially serious adverse effects:

- Complete blood count (CBC) with differential (prior to treatment initiation and at monthly intervals thereafter)
- Neutrophil count (prior to treatment initiation and at monthly intervals thereafter)
- Viralysis with active cell count (prior to treatment initiation and at monthly intervals thereafter)
- A test of renal function, such as the mid-stanceing Creatinine (mMol/L) test (prior to treatment initiation and every 3 months thereafter)

Screen for cytomegalovirus (CMV) seropositivity (S1.1) and hepatitis B surface antigen (HBsAg) and total hepatitis B core (prior to treatment initiation and periodically thereafter). Conduct baseline and yearly skin exams to monitor for melanoma (see Warnings and Precautions (2.6)).

3 DOSAGE FORMS AND STRENGTHS

Injection: 12 mg (2 mL, 10 mg/mL) in a single-dose vial. LEMTRADA is a clear and colorless to slightly yellow solution that requires dilution prior to intravenous infusion.

4 CONTRAINDICATIONS

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LEMTRADA is contraindicated in patients who are infected with Human Immunodeficiency Virus (HIV). Because LEMTRADA causes prolonged reduction of CD4+ lymphocyte counts.

8 WARNINGS AND PRECAUTIONS

8.1 Autoimmunity

Treatment with LEMTRADA can result in the formation of autoantibodies and increase the risk of serious autoimmune-related conditions.

In clinical studies (controlled and open-label extension), LEMTRADA-treated patients experienced thyroid disorders (36.8%), immune thrombocytopenia (ITP), and glomerular nephropathy (GN) (see Warnings and Precautions (7.1, 7.2, 7.3, 7.4). Yellow and brownish-brown/gray vesicles occurred in 8.3% of patients. Autoimmune pneumonitis (see Warnings and Precautions (7.5)), significant non-infectious pneumonitis, and type I diabetes mellitus occurred in 2.7% of patients. Documented arthritis, retinal pigment epitheliopathy, and acquired hemophilia A (anti-factor VIII antibodies) occurred in 0.9% of patients. Emerging pneumonia-like cases of varicella, infectious hepatitis (see Warnings and Precautions (7.10)), and Guillain-Barre syndrome have been reported (see Adverse Reactions (6.3)).

Chronic, inflammatory demyelinating polyradiculoneuropathy has been reported in the treatment of patients with B-cell chronic lymphocytic leukemia (CLL), as well as other autoimmune disorders, generally at higher and more frequent doses than recommended in MS. In multiple patient treated with alemtuzumab had fast brainstem-associated gait/ataxia (see Adverse Reactions (6.3)).

Immunosuppression may be manifested from the mother to the fetus during pregnancy. A case of congenital loss of anti-CD3 receptor antibodies resulting in neonatal HIV-1 disease occurred after alemtuzumab treatment in the mother (see Use in Specific Populations (8.5)).

LEMTRADA may increase the risk of other autoimmune conditions because of the broad range of autoantibody formation with LEMTRADA.

Monitor the same patients to maintain stable prior to initiation of treatment. Monitor complete blood counts with differential, serum creatinine levels, and activities with serum cell counts before starting treatment and then at monthly intervals until 48 months after the last dose of LEMTRADA to allow for early detection and treatment of autoimmune adverse reactions (see Warnings and Precautions (7.6)). After 48 months, testing should be performed based on clinical findings suggestive of autoimmunity.

LEMTRADA is available only through a restricted program under a REMS (see Warnings and Precautions (7.7)).

8.2 Infection Reactions

LEMTRADA causes cellular release cytokines resulting in infection reactions, some of which may be serious and life threatening. In clinical studies, 9% of LEMTRADA-treated patients experienced infection reactions. In other patients, infection reactions were reported more than 24 hours after LEMTRADA infusion. Infection reactions occurred in 3% of patients and included asplenia in 2 patients (including asplenic shock), angiodema, bronchopneumonia, hepatitis, chest pain, bacillary, tuberculosis (including aortic dissection), transient neurological symptoms, hypotension, headache, pyrexia, and rash. Other infection reactions included sinusitis, arthritis, pyelitis, sinusitis, otitis, flu-like, herpes, streptococcal pneumonia.

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...infections, dyspnea, depression, dizziness, and pain. In clinical trials, 54% of patients with relapsing-remitting multiple sclerosis or secondary progressive multiple sclerosis reported at least one adverse event. In clinical trials, 54% of patients with relapsing-remitting multiple sclerosis or secondary progressive multiple sclerosis reported at least one adverse event. In clinical trials, 54% of patients with relapsing-remitting multiple sclerosis or secondary progressive multiple sclerosis reported at least one adverse event.

3.2 Hematology

In the postmarketing setting, cases of pancytopenia (leukopenia, neutropenia, and thrombocytopenia) have been reported within 48 hours of LEMTRADA infusion. Cases of neutropenia (including febrile neutropenia) have been reported within 2 months of LEMTRADA infusion. Some cases resulted in severe granulocyte colony-stimulating factor treatment. Mild to moderate decreases in platelet counts, starting at the time of LEMTRADA infusion and often resolving without treatment, have been reported. Other serious and sometimes fatal infusion reactions (e.g., bronchitis, cystitis, acute respiratory distress syndrome, respiratory arrest, myocardial infarction, acute cardiac insufficiency, cardiac arrest) have been reported in the treatment of patients with MS, as well as other disorders, generally at higher and more frequent doses than recommended in MS.

In the postmarketing setting, serious and life-threatening events (including ischemic and hemorrhagic stroke) have been reported within 3 days of LEMTRADA administration, with most cases occurring within 1 day (see Warnings and Precautions (5.1)).

Pre-treat patients with corticosteroids immediately prior to LEMTRADA infusion for the first 3 days of each treatment course. In clinical studies, patients received 1000 mg of methylprednisolone for the first 3 days of each LEMTRADA treatment course. Consider pre-treatment with methylprednisolone and/or intravenous immunoglobulin prior to LEMTRADA administration. Infusion reactions may occur despite pre-treatment.

Consider additional monitoring in patients with medical conditions which predispose them to cardiovascular or pulmonary compromise. Physicians should alert patients that an infusion reaction could occur within 48 hours of infusion.

LEMTRADA can only be administered in certified healthcare settings that have on-site access to equipment and personnel trained to manage infusion reactions (including anaphylaxis and cardiac and respiratory emergencies).

LEMTRADA is available only through a restricted program under a REMS (see Warnings and Precautions (5.3)).

3.3 Stroke and Cervicoprophalic Arterial Dissection

Stroke

In the postmarketing setting, serious and life-threatening events (including ischemic and hemorrhagic stroke) have been reported within 3 days of LEMTRADA administration, with most cases occurring within 1 day.

Cervicoprophalic Arterial Dissection

In the postmarketing setting, cases of cervicoprophalic (e.g., vertebral, carotid) arterial dissection involving multiple arteries have been reported within 3 days of LEMTRADA administration. Ischemic stroke was reported in one of these cases.

Advise patients on the symptoms of stroke and cervicoprophalic (e.g., vertebral, carotid) arterial dissection. Instruct patients to seek immediate medical attention if symptoms of stroke or cervicoprophalic arterial dissection occur.

3.4 Malignancies

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Thyroid Cancer

LEMTRADA may increase the risk of thyroid cancer. In controlled clinical studies, 1 of 199 (0.5%) LEMTRADA-treated patients developed thyroid cancer compared to none in the placebo-treated group. However, screening for thyroid cancer is not performed routinely. Frequently in the LEMTRADA-treated group because of the higher incidence of autoimmune thyroid disorders in these patients. Two additional cases of thyroid cancer in LEMTRADA-treated patients occurred in uncontrolled studies.

Patients and healthcare providers should monitor for symptoms of thyroid cancer including a new lump or swelling in the neck, pain in the front of the neck, persistent hoarseness or other voice changes, trouble swallowing or breathing, or a constant cough not due to an upper respiratory tract infection.

Myeloma

LEMTRADA may increase the risk of fractures. In MS clinical studies (controlled and open-label extension), 1 of 1400 (0.07%) LEMTRADA-treated patients developed osteoporosis or osteopenia or one of these patients had evidence of locally advanced disease. Patients should have yearly dual energy x-ray absorptiometry (DEXA) scans to monitor for osteoporosis in patients receiving LEMTRADA.

Lymphoproliferative Disorders and Lymphoma

Cases of lymphoproliferative disorders and lymphoma have occurred in LEMTRADA-treated patients with MS, including a T-cell lymphoma, Castleman's Disease, and a follicle lymphoma following treatment of non-Hodgkin B-cell lymphoma. There are postmarketing reports of Epstein-Barr Virus-associated lymphoproliferative disorders in post-MS patients. Because LEMTRADA is an immunomodulatory therapy, caution should also be exercised in initiating LEMTRADA in patients with preexisting or ongoing malignancies.

LEMTRADA is available only through a restricted program under a REMS (see Warnings and Precautions 5.3).

5.5 LEMTRADA REMS Program

LEMTRADA is available only through a restricted program under a REMS called the LEMTRADA REMS Program because of the risks of autoimmunity, infection reactions, and malignancies (see Warnings and Precautions 5.1, 5.2, 5.4).

Noticeable requirements of the LEMTRADA REMS Program include the following:

- Practitioners must be certified with the program by enrolling and completing training.
- Patients must enroll in the program and comply with ongoing monitoring requirements (see Usage and Administration 2.6).
- Practitioners must be certified with the program and must only dispense to certified healthcare facilities that are authorized to receive LEMTRADA.
- Healthcare facilities must enroll in the program and verify that patients are authorized before initiating LEMTRADA. Healthcare facilities must have secure access to enrollment and personnel trained to manage infection reactions.

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Further information, including a list of qualified healthcare facilities, is available at 1-855-676-6326.

5.6 Immune Thrombocytopenia

Immune thrombocytopenia (ITP) occurred in 2% of LEMTRADA-treated patients in MS clinical studies (controlled and open-label extensions).

In a controlled clinical study in patients with MS, one LEMTRADA-treated patient developed ITP that was not reported prior to the implementation of monthly blood monitoring requirements, and had been misdiagnosed as hemiparesis. No other clinical cases (≥0.001 with the molecule or a month of ITP occurred in 2% of all LEMTRADA-treated patients in clinical studies in US. Available information did not provide ITP cases. ITP has been diagnosed more than 1 year after the last LEMTRADA dose.

Symptoms of ITP include easy bruising, petechiae, spontaneous mucocutaneous bleeding (e.g., epistaxis, hemoptysis), and hematuria that cannot be explained by another condition. Hemoptysis may also be indicative of anti-glomerular basement membrane (GBM) disease (see Warnings and Precautions (5.7)), and an appropriate differential diagnosis has to be undertaken. Inform the patient to contact right away for symptoms they may experience and to seek immediate medical help if they have any concerns.

Obtain complete blood count (CBC) with differential prior to initiation of treatment and at monthly intervals thereafter until 18 months after the last infusion. For Change and Information (2.6). After 18th period of dosing, testing should be performed based on clinical findings suggestive of ITP. If ITP is suspected, a complete blood count should be obtained immediately. If ITP was confirmed, promptly initiate appropriate medical intervention.

5.7 Glomerular Nephropathies Including Anti-Glomerular Basement Membrane Disease

Glomerular nephropathy occurred in 0.9% of LEMTRADA-treated patients in MS clinical studies. There were 3 cases of membranous glomerulonephritis and 2 cases of anti-glomerular basement membrane (anti-GBM) disease.

In postmarketing cases, some LEMTRADA-treated patients with anti-GBM disease developed anti-GBM antibody disease requiring dialysis or renal transplantation. Organ dysfunction and treatment is required, because early treatment can improve the preservation of renal function. Anti-GBM disease can be fatal if untreated. If renal insufficiency, manifested as hemoptysis, is a common component of anti-GBM disease and has been reported in postmarketing cases. Cases of anti-GBM disease have been diagnosed up to 40 months after the last dose of LEMTRADA.

Symptoms of nephropathy may include edema, hematuria, change in urine color, decreased urine output, fatigue, dizziness, and hemoptysis. Patients and caregivers should be instructed to seek medical advice if they have concerns.

Obtain serum creatinine levels, urea nitrogen with cell counts, and urine protein to creatinine ratio prior to initiation of treatment. Obtain serum creatinine levels and urea nitrogen with cell counts at monthly intervals thereafter until 18 months after the last infusion. After this period of time, testing should be performed based on clinical findings suggestive of nephropathy.

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For serum diphenylpicrylhydrazyl (DPPH) protein or greater, measure the serum protein concentration. For serum protein to stabilize (rate greater than 200 mg/L, decrease in serum protein greater than 50% or significant hypotension, perform further evaluation for nephropathy. Increased serum urea nitrogen with hematuria or signs of pulmonary involvement of anti-CD20 disease (e.g., hemoptysis, chest pain) require immediate evaluation. Early detection and treatment of nephropathy may decrease the risk of poor outcomes.

5.8 Thyroid Disorders

Thyroid endocrine disorders, including autoimmune thyroid disease, occurred in 50.0% of LEMTRADA-treated patients in 3/5 arms of studies (controlled and open-label extension). Newly diagnosed thyroid disease occurred throughout the uncontrolled clinical study. Events up to 7 years after the first LEMTRADA dose. Autoimmune thyroid disease included Graves' disease, hyperthyroidism, hypothyroidism, autoimmune thyroiditis, and other Graves' ophthalmopathy with decreased vision, eye pain, and exophthalmos, occurred in 2% of LEMTRADA-treated patients. Seven patients required surgical thyroid decompression. Further thyroid events occurred in about 3.2% of LEMTRADA-treated patients in clinical studies and included ophthalmic and psychiatric events associated with thyroid disease. Of all LEMTRADA-treated patients, 3.8% underwent thyroidectomy.

Thyroid disease poses special risks to women who are pregnant (see 1 in the Specific Population—PREG).

Obtain thyroid function tests, such as TSH levels, prior to initiation of treatment and every 3 months thereafter until 48 months after the last infusion. Continue to test thyroid function after 48 months if clinically indicated.

In patients with ongoing thyroid disease, LEMTRADA should be administered only if the potential benefit justifies the potential risks.

5.9 Other Autoimmune Cytopenias

Autoimmune cytopenias such as neutropenia (0.1%), hemolytic anemia (0.3%), and pancytopenia (0.2%) occurred in LEMTRADA-treated patients in 1/5 clinical studies (controlled and open-label extension). In case of autoimmune hemolytic anemia, perform initial positive for direct antiglobulin antibodies, and track hemoglobin levels through first 30 to 60 days. Symptoms of autoimmune cytopenias include weakness, shortness of breath, dark urine, and jaundice. One LEMTRADA-treated patient with autoimmune pancytopenia died from events.

During postmarketing use, additional autoimmune cytopenias, including fatal autoimmune hemolytic anemia and aplastic anemia, have been reported in the treatment of patients with B-CLL, as well as other diseases, generally at higher and more frequent doses of LEMTRADA than recommended in US.

Use CBC results to monitor for cytopenias. Prompt medical intervention is indicated if a cytopenia is confirmed.

5.10 Autoimmune Hepatitis

Autoimmune hepatitis (including chronic hepatitis liver injury, including acute liver failure requiring transplant, has been reported in patients treated with LEMTRADA in the postmarketing setting. If a patient develops clinical signs, including unexplained liver enzyme

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elevations or symptoms suggestive of hepatic dysfunction (e.g., serophthalmic icterus, vomiting, abdominal pain, fatigue, anorexia, or jaundice and/or dark urine), promptly monitor serum transaminase and total bilirubin, and discontinue treatment with LEMTRADA, as appropriate.

Prior to starting treatment with LEMTRADA, obtain serum transaminase (ALT and AST) and total bilirubin levels. Obtain transaminase levels and total bilirubin levels periodically until 48 months after the last dose.

5.11 Infections
 Infections occurred in 70% of LEMTRADA-treated patients compared to 57% of patients treated with interferon beta-1a in controlled clinical studies (N=212) in duration. Infections that occurred more often in LEMTRADA-treated patients than interferon beta-1a patients included nasopharyngitis, upper tract infections, upper respiratory tract infections, sinusitis, herpes infections, influenza, and Herpesvirus. Serious infections occurred in 1% of patients treated with LEMTRADA as compared to 3% of patients treated with interferon beta-1a. Serious infections in the LEMTRADA group included: opportunistic, gastroenteritis, pneumonia, herpes zoster, and tick infection.

Do not administer live viral vaccines following a course of LEMTRADA. Patients treated with LEMTRADA have altered immunity and may be at increased risk of infection following administration of live viral vaccines. Consider delaying LEMTRADA administration in patients with active infection until the infection is fully controlled. Concomitant use of LEMTRADA with immunosuppressive therapies could increase the risk of immunosuppression.

Opportunistic Infections
 In the postmarketing setting, serious, sometimes fatal, opportunistic infections have been reported in patients taking LEMTRADA, including aspergillosis, cryptococcosis, histoplasmosis, Pneumocystis carinii pneumonia, toxoplasmosis and cytomegalovirus infections.

Listeria monocytogenes Infections
 Listeria monocytogenes infection (e.g., meningitis, septicemia, sepsis, and gastroenteritis), including fatal cases of Listeria meningitis/septicemia, have occurred in LEMTRADA-treated patients. Listeria infections have occurred as early as 3 days after treatment and up to 8 months after the last LEMTRADA dose. The duration of increased risk for Listeria infection after LEMTRADA treatment is unknown.

Advise patients to avoid or adequately heat foods that are potential sources of Listeria monocytogenes (e.g., deli meat, dairy products made with unpasteurized milk, soft cheeses, or undercooked poultry, seafood, or produce). Inform these Listeria prevention practices prior to starting LEMTRADA treatment. The incubation period for Listeria meningitis/sepsis ranges from 3 to 70 days. In most cases, signs and symptoms of serious infections that occur 8 months of exposure to Listeria monocytogenes. Symptoms of Listeria infection include fever, chills, diarrhea, muscle aching, headache, pain in joints and muscles, neck stiffness, difficulty walking, mental status changes, coma, and other neurologic changes. As in the case with many infections, treatment cannot always prevent morbidity and mortality related to Listeria infections. Therefore, advise

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patients to watch for symptoms of *Listeria* infection and seek prompt medical help if symptoms occur.

Herpes Viral Infections

In controlled clinical studies, 10% of LEMTRADA-treated patients developed a herpes viral infection compared to 3% of untreated patients. These events included oral herpes (HSV-1), herpes zoster (VZV), herpes simplex (HSV-2), and genital herpes (HSV-2). Herpes simplex infection in LEMTRADA-treated patients included genital herpes (HSV-2), herpes zoster (VZV), and herpes encephalitis (HE). Administer antiviral agents for herpes prophylaxis at appropriate suppressive dosing regimens. Administer antiviral prophylaxis for herpes viral infections starting on the first day of each treatment course and continue for a minimum of two months following treatment with LEMTRADA or until the CD4+ lymphocyte count is ≥ 200 with appropriate, whichever occurs later (see [Contraindications](#) and [Adverse Reactions](#) (2.2)).

Herpes Pneumonia Virus

Cervical herpes pneumonia virus (HPV) infection, including cervical dysplasia, occurred in 2% of LEMTRADA-treated patients. Annual HPV screening is recommended for female patients.

Tuberculosis

Tuberculosis occurred in patients treated with LEMTRADA and interferon beta. In its controlled clinical studies, active and latent tuberculosis cases occurred in 12% of LEMTRADA-treated patients, most often in endemic regions. Perform tuberculin testing according to local guidelines prior to initiation of LEMTRADA. For patients testing positive for tuberculous screening, treat by standard medical practice prior to therapy with LEMTRADA.

Contraindications

Fungal infections, especially oral and vaginal candidiasis, occurred more commonly in LEMTRADA-treated patients (12%) than in patients treated with interferon beta-1a (IFN) in controlled clinical studies in MS.

Infections in Non-MS Patients

During premarketing use, serious and sometimes fatal viral, bacterial, protozoan, and fungal infections, including meningitis and encephalitis, have been reported in the treatment of patients with MS. LEMTRADA, as well as other interferons, generally at higher and more frequent doses than recommended in MS.

Toxicity

No data are available on the association of LEMTRADA with Hepatitis B virus (HBV) or Hepatitis C virus (HCV) reactivation because patients with evidence of active or chronic infections were excluded from the clinical studies. Consider screening patients at high risk of HBV and HCV infection before initiation of LEMTRADA and consider testing for preexisting LEMTRADA in patients identified as carriers of HBV and/or HCV as these patients may be at risk of developing liver disease related to a potential liver reactivation in a reversionary of their pre-existing status.

5.12 Progressive Multifocal Leukoencephalopathy (PML)

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Progressive multifocal leukoencephalopathy (PML) has occurred in a patient with MS treated with LEMTRADA. PML is an opportunistic viral infection of the brain caused by the JC virus (JCV). It typically only occurs in patients who are immunocompromised, and that usually leads to death or severe disability. PML was diagnosed two months after the second course of LEMTRADA. The patient had previously received multiple MS therapies, but had not received other drugs for treatment of MS for more than one year. The patient had no other identified systemic medical conditions resulting in compromised immune system function and had not previously been treated with antineoplastic, which has a known association with PML. The patient was not taking any immunosuppressive or immunomodulatory medications concomitantly. After the diagnosis of PML, the patient developed immune reconstitution inflammatory syndrome (IRIS). The patient's condition improved, but still required corticosteroid treatment at last follow-up.

In the first sign or symptom suggestive of PML, withhold LEMTRADA and perform an appropriate diagnostic evaluation. Typical symptoms associated with PML are discrete, progress over days or weeks, and include progressive weakness on one side of the body or absence of limb, disturbance of vision, and changes in thinking, memory, and orientation leading to confusion and personality change.

MR findings may be present before clinical signs or symptoms. Cases of PML diagnosed based on MRI findings and the detection of JCV DNA in the cerebrospinal fluid in the absence of clinical signs or symptoms specific to PML, have been reported in patients treated with other MS medications associated with PML. Many of these patients subsequently became symptomatic with PML. Therefore, monitoring with MRI for signs that may be consistent with PML may be useful, and any suspicious findings should lead to further investigation to allow for an early diagnosis of PML, if present. Following discontinuation of another MS medication associated with PML, local PML-related academic and non-academic have been reported in patients who were initially asymptomatic or diagnosed compared to patients who had characteristic clinical signs and symptoms of diagnosis. It is not known whether these differences are due to early detection and discontinuation of MS treatment or due to differences in disease in these patients.

5.13 Acute Acanthamoeba Chorioretinitis

LEMTRADA may increase the risk of acute acanthamoeba chorioretinitis. In controlled clinical studies, 0.7% of LEMTRADA-treated MS patients developed acute acanthamoeba chorioretinitis, compared to 0% of patients treated with interferon beta-1a. During postmarketing use, additional cases of acute acanthamoeba chorioretinitis have been reported in LEMTRADA-treated patients. Time to onset of symptoms ranged from less than 24 hours to 2 months after LEMTRADA initiation. Typical risk or predisposing factors such as recurrent contact lens use after not applying abnormal ultrasonic or computer tomography was used to support the diagnosis of acute acanthamoeba chorioretinitis. In some cases, these patients were initially misdiagnosed with uveitis and associated with surgical intervention, whereas others underwent chorioretinectomies.

Symptoms of acute acanthamoeba chorioretinitis include abdominal pain, abdominal tenderness, fever, nausea, and vomiting. Leukocytosis and abnormal liver enzymes are also commonly observed. Acute acanthamoeba chorioretinitis is a condition that is associated with high morbidity and mortality rates if not diagnosed early and treated. If acute acanthamoeba chorioretinitis is suspected, consult and treat promptly.

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5.14 Pneumonia

In clinical studies, 6 of 1217 (0.5%) LEMTRADA-treated patients had pneumonia of varying severity. Cases of bacterial pneumonia and pneumonia with fibrin exudate in clinical studies. Patients should be advised to report symptoms of pneumonia, which may include: discharge of breath, cough, wheezing, chest pain or tightness and hemoptysis.

5.15 Drug Products with Same Active Ingredient

LEMTRADA contains the same active ingredient (alemtuzumab) found in CASMF 0147. If LEMTRADA is considered for use in a patient who has previously received CASMF 0147, exercise increased vigilance for additive and heightening effects on the immune system.

6 ADVERSE REACTIONS

The following serious adverse reactions are described below and elsewhere in the labeling:

- Anemias (see Clinical History and Pathogenesis and Precautions (5.1))
- Infectious Events (see Clinical History and Pathogenesis and Precautions (5.2))
- Stroke and Cerebrovascular Medical Disorders (see Warnings and Precautions (5.1))
- Malnutrition (see Warnings and Precautions (5.4))
- Diabetes (see Adverse Reactions (5.6))
- Ocular Nephropathy Including Anti-Oxidant Basement Membrane Disint. (see Warnings and Precautions (5.7))
- Thyroid Disorders (see Warnings and Precautions (5.8))
- Other Autoimmune Complications (see Warnings and Precautions (5.9))
- Systemic Lupus (see Warnings and Precautions (5.10))
- Infections (see Warnings and Precautions (5.11))
- Progressive Multifocal Leukoencephalopathy (PML) (see Warnings and Precautions (5.12))
- Acute Nucleolar Cholesterolemia (see Warnings and Precautions (5.13))
- Pneumonia (see Warnings and Precautions (5.14))

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

In a controlled clinical study (Study 1) and Study 2, a total of 913 patients with relapsing forms of MS received LEMTRADA. The population was 18 to 73 years of age, 67% were female, and 97% were Caucasian. 1,044 of 913 patients received 1 course of therapy, and 799 patients received a second course of therapy at 12 months. The overall follow-up in the controlled trials was approximately 1023 patient-years.

In MS clinical studies (controlled and open-label extensions), overall, a total of 1217 patients received LEMTRADA. Approximately 60% of patients received a total of 2 treatment courses, and approximately 20% of patients received a total of 3 treatment courses; others received a total of 4 or more treatment courses, although data beyond 3 treatment courses are limited. The

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patients, at months 1, 3, and 12 (Course 1) as well as 6P, 8P, and 7P of LEMTRADA-treated patients at months 11, 15, and 24 (Course 2). Samples that tested positive for binding antibodies were further evaluated for evidence of in vivo inhibition across a time-course study. Neutralizing antibodies were detected in 8P, 6P, and 7P of positive binding antibody patients at months 1, 3, and 12 (Course 1) as well as 6P, 8P, and 8P of positive binding antibody patients at months 11, 15, and 24 (Course 2). Anti-dsDNA antibodies were measured with decreased dsDNA concentrations during Course 1, but not Course 2. Through 2 treatment courses, there was no evidence from clinical trials that the presence of binding or inhibitory anti-dsDNA antibodies had a significant effect on clinical outcomes and lymphocyte count, or adverse events. High titer anti-dsDNA antibodies, which were observed in 11 patients, were associated with incomplete lymphocyte depletion following a third or fourth treatment course, but there was no clear effect of anti-dsDNA antibodies on the clinical efficacy or safety profile of LEMTRADA.

8.5 Postmarketing Experience
The following adverse reactions have been identified during post approval use of Lemtrada. Because these reactions are reported infrequently from a population of patients, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Postmarketing Experience with LEMTRADA
Blood and Lymphatic System Disorders: Neutropenia, thrombocytopenia [see Warnings and Precautions (3.2)].
Cardiovascular Disorders: Stroke, including hemorrhagic, and ischemic stroke and cerebrovascular accident/dissection [see Warnings and Precautions (3.2)].
Gastrointestinal System Disorders: Cholecystitis, including acalculous cholecystitis and acute calculous cholecystitis [see Warnings and Precautions (3.2)].
Hematology Disorders: Autoimmune hemolytic [see Warnings and Precautions (3.1B)].
Infections and Infestations: Opportunistic infections [see Warnings and Precautions (3.1)].
Progressive multifocal leukoencephalopathy [see Warnings and Precautions (3.2)].
Immune System Disorders: Autoimmune hepatitis, vasculitis, Guillain-Barre syndrome [see Warnings and Precautions (3.2)], hemophagocytic lymphohistiocytosis.
Pulmonary System Disorders: Pulmonary arterial hypertension [see Warnings and Precautions (3.2)].

Postmarketing Experience with CAMPATH
CAMPATH is approved for the treatment of B-cell chronic lymphocytic leukemia (B-CLL) and is generally administered at higher and more frequent doses (e.g., 20 mg) than recommended in the treatment of MS.
Cancer Disorders: Complete heart failure, conduction system, and distal esophageal function in non-MS patients previously treated with purine/thymidine agents.

8 USE IN SPECIFIC POPULATIONS
8.1 Pregnancy

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Preconception Pregnancy Risk:

There is a pregnancy exposure register that monitors pregnancy outcomes in women exposed to LEMTRADA during pregnancy. Physicians are encouraged to register patients by calling 1-800-734-2296.

Risk Summary:

There are no adequate data on the developmental risk associated with the use of LEMTRADA in pregnant women. LEMTRADA was administered in pregnant hCD20 transgenic mice when administered during organogenesis (see Clinical Data). Administration may develop after administration of LEMTRADA. Placental transfer of anti-CD20 antibodies resulting in neonatal CD20+ disease has been reported.

In the U.S. general population, the estimated background risk of major birth defects and miscarriages in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively. The background risk of major birth defects and miscarriages for the indicated population is unknown.

Clinical Considerations:

LEMTRADA reduces persistent thyroid disorders (see Warnings and Precautions (4.6)). Caution is recommended in pregnant women because the risk for miscarriage and any other effects on the fetus including mental retardation and dwarfism. In women with CD20+ disease, neonatal thyroid abnormalities because receptor antibodies can be transferred to a developing fetus and can cause neonatal CD20+ disease. In a patient who develops CD20+ disease after treatment with abatacept, placental transfer of anti-CD20 receptor antibodies resulted in neonatal CD20+ disease with thyroid storm in her infant who was born 1 year after abatacept administration (see Warnings and Precautions (4.6)).

Data:

Animal data:

When LEMTRADA was administered to pregnant hCD20 transgenic mice during organogenesis (gestation days GD9.5-10 or GD 11-13) at doses of 3 or 10 mg/kg IV, no teratogenic effects were observed. However, there was an increase in embryonic mortality (increased post-implantation loss and the number of dams with all fetuses dead or resorbed) in pregnant animals dosed during GD 11-13. In a separate study, in pregnant hCD20 transgenic mice, administration of LEMTRADA during organogenesis (GD 9-10 or GD 11-13) at doses of 3 or 10 mg/kg IV, decreases in D- and F1 offspring's populations were observed in the offspring at both doses tested.

In pregnant hCD20 transgenic mice administered LEMTRADA at doses of 3 or 10 mg/kg IV throughout gestation and lactation, there was an increase in pup deaths during the lactation period at 20 mg/kg. Decreases in T- and B-lymphocyte populations and an antibody response were observed in offspring at both doses tested.

Human data:

There are no data on the prevention of abatacept in humans with the effects on the neonatal fetus or on the effects of the drug on milk production. Abatacept was detected in the milk of lactating hCD20 transgenic mice administered LEMTRADA (see Clinical Data).

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The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for LEMTRADA and any potential adverse effects on the breastfed child from LEMTRADA or from the underlying maternal condition.

Data

Animal data

Alemtuzumab was studied in the path of lactating lactating mice following intravenous administration of LEMTRADA at a dose of 10 mg/kg on postpartum days 1 to 12. Some levels of alemtuzumab were similar to lactating mice and offspring on postpartum day 13 and were associated with evidence of pharmacological activity (decrease in lymphocyte count) in the offspring.

8.3 Fertility and Male of Reproductive Potential

Contraception

Before initiation of LEMTRADA treatment, women of childbearing potential should be counseled on the potential for a serious risk to the fetus. To avoid an adverse exposure to LEMTRADA, women of childbearing potential should use effective contraceptive measures when receiving a course of treatment with LEMTRADA and for 4 months following the course of treatment (see Use in Specific Populations 8.1).

8.4 Pediatric Use

Safety and effectiveness in pediatric patients less than 17 years of age have not been established. Use of LEMTRADA is not recommended in pediatric patients due to the risk of immunosuppression, infection, and stroke, and because it may increase the risk of malignancies (lymphoid neoplasms, lymphoproliferative disorders, and lymphomas) (see Warnings and Precautions 5.1, 5.2, 5.3, 5.6).

8.5 Geriatric Use

Clinical studies of LEMTRADA did not include sufficient numbers of patients aged 65 and over to determine whether they respond differently than younger patients.

10 OVERDOSEAGE

The MS patients experienced various reactions (headache, rash, and other hypersensitivity or vasculitis) after a single accidental infusion up to 60 mg of LEMTRADA. Doses of LEMTRADA greater than those recommended may increase the intensity and/or duration of adverse reactions or to serious effects. There is no known antidote for alemtuzumab overdose.

11 DESCRIPTION

Alemtuzumab is a recombinant humanized IgG1 kappa monoclonal antibody directed against the cell surface glycoprotein, CD52. Alemtuzumab has an approximate molecular weight of 150 kDa.

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Alemtuzumab is produced in mammalian cells (Chinese hamster ovary) expression system in a nutrient medium containing streptomycin. Streptomycin is not detectable in the final product. LEMTRADA (alemtuzumab) requires a 1-month, clear and stable to slightly yellow, solution (pH 7.2-8.2) for intravenous infusion. Each 1 mL of solution contains 50 mg alemtuzumab, 0.01 mg sodium chloride (0.11 mg), 0.01 mg sodium citrate dihydrate (0.0187 mg), polyethylene glycol (0.1 mg), potassium chloride (0.2 mg), potassium dihydrogen phosphate (0.2 mg), sodium chloride (0.2 mg), and Water for Injection USP.

12. CLINICAL PHARMACOLOGY
12.1 Mechanism of Action
 The precise mechanism by which alemtuzumab exerts its therapeutic effects in multiple sclerosis is unknown but is presumed to involve binding to CD52, a cell surface antigen present on T and B lymphocytes, and on natural killer cells, monocytes, and macrophages. Following cell surface binding to T and B lymphocytes, alemtuzumab results in antibody-dependent cellular cytotoxicity and complement-mediated lysis.

12.2 Pharmacodynamics
Effects of LEMTRADA on the Lymphocyte Population
 LEMTRADA induces circulating T and B lymphocyte lysis after each treatment course. In clinical trials, the lowest cell counts occurred 1 month after a course of treatment at the time of the first post-treatment blood count. Lymphocyte counts then increased over time. T cell counts usually returned within 6 months. T cell counts increased more slowly and usually remained below baseline 12 months after treatment. Approximately 90% of patients had total lymphocyte counts below the lower limit of normal 6 months after each treatment course and 20% had counts below the lower limit of normal after 12 months. Reconstitution of the lymphocyte population varies for the different lymphocyte subsets. In Month 1 in clinical trials, the mean CD4+ lymphocyte count was 40 cells per microliter and, at Month 12, 7% cells per microliter. In 36 months, approximately half of patients had CD4+ lymphocyte counts that remained below the lower limit of normal.

Cardiac Electrophysiology
 In a study of 33 MS patients, alemtuzumab 12 mg per day for 5 days caused no changes in the QTc interval of greater than 20 ms. An average 22 to 26 beats-per-minute increase in heart rate was observed for at least 2 hours after the first and subsequent infusions.

12.3 Pharmacokinetics
 The pharmacokinetics of LEMTRADA were evaluated in a total of 148 patients with relapsing forms of MS who received 12 mg for up to 3 consecutive days, followed by 12 mg for up to 3 consecutive days 12 months following the first treatment course.

Steady State
 Steady state concentrations increased with each consecutive dose within a treatment course, with the highest observed concentrations occurring following the last infusion of a treatment course. The mean maximum concentration was 864 µg/mL on Day 1 of the first treatment course, and 22.6 µg/mL on Day 3 of the second treatment course.

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Distribution

LEMTRADA is largely confined to the blood and interstitial space with a central volume of distribution of 14.1 L.

Pharmacokinetics

The elimination half-life was approximately 2 weeks and was comparable between sexes. The serum concentrations were generally undetectable (<10 ng/mL) within approximately 30 days following each treatment course.

Specific Considerations

No toxic or genetic had no effect on the pharmacokinetics of LEMTRADA.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Studies to assess the carcinogenic or genotoxic potential of LEMTRADA have not been conducted.

When LEMTRADA (2 or 10 mg/kg IV) was administered to hCD2 transgenic mice once per 2 consecutive days prior to cohabitation with untreated wild-type females, no effect on fertility or reproductive performance was observed. However, adverse effects on postpartum parameters (including abnormal morphology [fetofetal or fetal] and reduced fetal count and viability) were observed at both doses tested.

When LEMTRADA (2 or 10 mg/kg IV) was administered to hCD2 transgenic female mice for 2 consecutive days prior to cohabitation with untreated wild-type males, there was a decrease in the average number of corpora lutea and implantation sites and an increase in postimplantation loss, resulting in lower viable offspring at the higher dose tested.

14 CLINICAL STUDIES

The efficacy of LEMTRADA was demonstrated in two studies (Study 1 and 2) that evaluated LEMTRADA (2 mg) in patients with relapsing-remitting multiple sclerosis (RRMS). LEMTRADA was administered by intravenous infusion once daily over a 5-day course, followed one year later by intravenous maintenance once daily over a 3-day course. Both studies included patients who had experienced at least 2 relapses during the 2 years prior to trial entry and at least 1 relapse during the year prior to trial entry. Neurological assessments were performed every 12 weeks and at the time of relapsed relapse. Magnetic resonance imaging (MRI) evaluations were performed annually.

Study 1

Study 1 was a 2-year randomized, open-label, non-blinded, active-comparator (interferon beta 1a) and intravenous administered subcutaneous three times a week controlled study in patients with RRMS. Patients assigned to Study 1 had Expanded Disability Status Scale (EDSS) scores of 1-6 and had to have experienced at least one relapse while on interferon beta or glatiramer acetate therapy.

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Patients were randomized to receive LEMTRADA (n=202) or interferon beta-1a (n=202). At baseline, the mean age was 35 years, the mean disease duration was 4.5 years, and the mean EDSS score was 2.7.

The clinical outcome measures were the annualized relapse rate (ARR) over 2 years and the time to confirmed disability progression. Confirmed disability progression was defined as at least a 1-point increase above baseline EDSS (1.5-point increase for patients with baseline EDSS of 3) sustained for 6 months. The MS outcome measure was the change in T2 lesion volume.

The annualized relapse rate was significantly lower in patients treated with LEMTRADA than in patients who received interferon beta-1a. Time to onset of 6-month confirmed disability progression was significantly delayed with LEMTRADA treatment compared to interferon beta-1a. There was no significant difference between the treatment groups for the change in T2 lesion volume. The results of Study 1 are shown in Table 2 and Figure 1.

Table 2: Clinical and MS Outcome Results of Study 1

	LEMTRADA (n=202)	interferon beta-1a (n=202)	p-value
Annualized Relapse Rate			
Annualized relapse rate	0.25	0.42	<0.0001
Relative reduction	40%		
Time to Onset of 6-Month Confirmed Disability Progression			
Time to onset of 6-month confirmed disability progression	18%	29%	<0.0004
Relative reduction	42%		
MS Outcome			
Percent of patients meeting criteria for EDSS 3 or 4	40%	40%	0.9243
Percent change in T2 lesion volume from baseline	-13	-12	0.14

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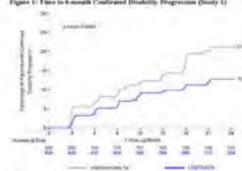

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Figure 1: Time to Event Confirmed Disability Progression (Study 1)



Study 1: Study 1 was a 2-year randomized, open-label, active-controlled, multicenter comparative (parallel-treat) study in patients with RRMS. Patients entering Study 1 had EDSS scores of 7 or less and no prior treatment for multiple sclerosis.

Patients: Patients were randomized to receive LEMTRADA (n=176) or interferon beta-1a (n=187). At baseline, the mean age was 37 years, the mean disease duration was 7 years, and the mean EDSS score was 7.

Primary endpoint: The primary endpoint was the time to confirmed disability progression (CDP) over 2 years and the time to confirmed disability progression, as defined in Study 1. The MSIS outcome measure was the change in T2 lesion volume.

Results: The time to confirmed disability progression was significantly longer in patients treated with LEMTRADA than in patients who received interferon beta-1a. There was no significant difference between the treatment groups for the time to confirmed disability progression and for the primary MSIS endpoint (change in T2 lesion volume). The results for Study 1 are shown in Table 1.

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Table 3: Clinical and MRI Results of Study 2

Clinical Outcome	LEMTRADA (n=20)	Interferon beta-1a (n=20)	p-value
Unassisted walking time (minutes) reduction	0.28 (94%)	0.05 (95%)	0.0004
Improvement of gait speed with disability progression at 1 Year 2 (minutes) reduction	8% (8%)	-10% (-10%)	0.02
Mean of lesion volume (ml) at 1 Year 2	16%	18%	0.0004
MRI Outcomes			
Mean change in T2 lesion volume (ml) at 1 Year 2	-18.2	-14.4	0.04

16 HOW SUPPLIED/STORAGE AND HANDLING

16.1 How Supplied
LEMTRADA (alemtuzumab) injection is a sterile, clear and colorless to slightly yellow solution for intravenous infusion, containing an antineoplastic preservative.
Each LEMTRADA vial (NDC 58448-0200-1) contains one single-dose vial that delivers 12 mg (1.2 mL, 10 mg/mL). The vial stopper is not made with natural rubber latex.

16.2 Storage and Handling
Store LEMTRADA vials at 2°C to 8°C (36°F to 46°F). Do not freeze or shake. Store in original carton to protect from light.

17 PATIENT COUNSELING INFORMATION
Advise the patient to read the FDA-approved patient labeling (Medication Guide).

Adverse Reactions

- Advise patients to contact their healthcare provider promptly if they experience any symptoms of potential autoimmune disease. Give examples of symptoms (rash, such as blanching, easy bruising, petechiae, purpura, hematuria, anemia, jaundice, or hemoptysis) (see Warnings and Precautions) (1.1).
- Advise patients of the importance of weekly blood and urine tests for 48 weeks following the last course of LEMTRADA to monitor for signs of autoimmunity, because early detection and prompt treatment can help prevent serious and potentially fatal outcomes associated with these events. Advise patients that monitoring may need to continue past 48 weeks if they have signs or symptoms of autoimmunity.

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- Advise patients that LEMTRADA may cause hypotension or hypotension disorders.
- Advise patients to contact their healthcare provider if they experience symptoms reflective of a potential allergic reaction such as unexplained weight loss or gain, fast heartbeat or palpitations, nervousness, worsening headache, eye swelling, congestion, or feeling cold.
- Advise women of childbearing potential of the risk of pregnancy with concomitant steroid therapy. Advise women of childbearing potential to discuss pregnancy planning with their doctor.
- Cases of autoimmune hepatitis have been reported in patients treated with LEMTRADA. Advise patients to contact their healthcare provider right away if they develop signs or symptoms suggestive of hepatic dysfunction such as unexplained nausea, vomiting, abdominal pain, fatigue, weakness, jaundice and/or dark urine, or bleeding or bruising more easily than normal.

Infection Precautions

- Advise patients that infection reactions can occur at the time of infusion or after they leave the infusion center (see Warnings and Precautions (2.2)). Educate patients that serious infection reactions can occur at the time of infusion or within 48 hours after the last infusion. Advise patients to contact their healthcare provider promptly if they experience symptoms of an infection reaction, including:
 - Swelling in the mouth or throat, difficulty breathing, weakness, abnormal heart rate (fast, slow, or irregular), rash, chest pain (or tightness or discomfort), or coughing up blood.
- Inform the patient to remain in the infusion center for 2 hours after each LEMTRADA infusion, or longer at the discretion of the physician.

Spinal and Cervicogenic Headache Precautions

- Educate patients on the symptoms and instruct patients to seek immediate medical attention if symptoms of neck or cervicogenic spinal discomfort occur (e.g., neck pain, weakness), or one side. Instruct them to breathe slowly through the nose, swallow several sips of water, and/or use heat.

Warnings

- Advise patients that LEMTRADA may increase their risk of malignancies including breast cancer and melanoma (see Warnings and Precautions (3.4)).
- Advise patients to report symptoms of breast cancer including a new lump or swelling in the breast, pain in the breast, changes in breast color or other color changes that do not go away, nipple swelling or bleeding, or a constant ache or pain in the breast.
- Advise patients that they should have baseline and periodic skin examinations.

LEMTRADA REMS Program

- LEMTRADA is available only through a restricted program called the LEMTRADA REMS Program (see Warnings and Precautions (3.5)). Inform the patient of the following enrollment requirements:
 - Patients and providers must be enrolled in the program.

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Patients must comply with the ongoing monitoring requirements.

- Patients must report any side effects or symptoms to their doctor.
- LEMTRADA is available only at certified infusion centers participating in the program. Therefore, provide patients with information on the LEMTRADA REMS Program as well as links to website content.
- Advise patients to read the LEMTRADA REMS material for patients, if the first visit to Area (see LEMTRADA Treatment, 1 Patient Guide and What You Need to Know About LEMTRADA Treatment and Infusion Treatment, 2 Patient Guide).
- Advise patients to carry the LEMTRADA REMS Patient Safety Information Card with them at all times if appropriate.

Indications

- Advise patients to contact their healthcare provider if they develop symptoms of serious infection risk or fever or swollen glands (see Warnings and Precautions 2.1.1).
- Advise patients to complete any necessary immunizations at least 6 weeks prior to treatment with LEMTRADA (see Dosage and Administration 2.2). Advise patients that they should talk to their healthcare provider before taking any vaccine or other treatment with LEMTRADA (see Warnings and Precautions 2.3.1).
- Advise patients to avoid or adequately treat both any potential sources of *Cytomegalovirus* reactivation prior to receiving LEMTRADA and if they have had a recent course of LEMTRADA. The absence of increased risk for *Cytomegalovirus* infection after LEMTRADA administration is not known. Advise patients that *Cytomegalovirus* can lead to significant complications or death (see Warnings and Precautions 2.3.1).
- Advise patients to take their prescribed medication for herpes prophylaxis as directed by their healthcare provider (see Warnings and Precautions 2.3.1).
- Advise patients that yearly HIV screening is recommended (see Warnings and Precautions 2.3.1).

Prevention Multicystic Leukocysticallitis

- Advise patients that progressive multifocal leukoencephalopathy (PML) has occurred in a patient who received LEMTRADA. Advise the patient that PML is characterized by a progression of deficits and usually leads to death or severe disability, over weeks or months. Emphasize the patient of the importance of contacting their doctor if they develop any symptoms suggestive of PML. Advise the patient that typical symptoms associated with PML are abnormal progress over time to weakness, and include progressive weakness on one side of the body, or abnormality of taste, disturbance of vision, and changes in thinking, memory, and actions leading to confusion and personality changes (see Warnings and Precautions 2.3.2).

Adult Atypical Chlamydia

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- Advise patients to report symptoms of acute weakness, dizziness. These include abdominal pain, abdominal tenderness, fever, nausea, and vomiting (see Warnings and Precautions (5.1)).
- Pharmacology**
- Advise patients that paresthesia has been reported in patients treated with LEMTRADA (see Warnings and Precautions (5.1)). Advise patients to report symptoms of tingling, numbness, such as numbness of hands, cough, wheezing, chest pain or tightness, and hoarseness.
- Concomitant Use of CASPATRI**
- Advise patients that administration of the same drug as CASPATRI for use in RELL. Patients should inform their healthcare provider if they have taken CASPATRI (see Warnings and Precautions (5.1)).
- Reproductive Considerations**
- Advise patients that there is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to LEMTRADA during pregnancy (see Use in Specific Populations (6.1)).
- Fetal Risk**
- Inform patients that LEMTRADA may cause fetal harm. Discuss with women of childbearing age whether they are pregnant, might be pregnant, or are trying to become pregnant. Advise women of childbearing age of the need for effective contraception during LEMTRADA treatment and for 4 months after a treatment course of LEMTRADA. Advise the patient that if she should not become pregnant, she should immediately inform her physician.

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LEMTRADA REMS Program Overview (1 of 2)

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LEMTRADA LEMTRADA REMS PROGRAM OVERVIEW

What is the LEMTRADA REMS (Risk Evaluation and Mitigation Strategy)?

A REMS is a strategy to manage known or potential risks associated with a drug. It is required by the FDA to ensure that the benefits of the drug outweigh its risks. Due to serious risks of autoimmune conditions, infusion reactions, liver and lung problems, LEMTRADA (alemtuzumab) is only available through a restricted program called the LEMTRADA REMS.

LEMTRADA REMS Requirements

- Prescribers must be enrolled in the LEMTRADA REMS to be able to prescribe LEMTRADA.
- Pharmacies must be enrolled in the LEMTRADA REMS to be able to dispense LEMTRADA.
- Healthcare Facilities must be enrolled in the LEMTRADA REMS to be able to dispense and administer LEMTRADA.
- Patients must be enrolled and authorized in the LEMTRADA REMS to order to receive LEMTRADA.

PRESCRIBER ENROLLMENT INSTRUCTIONS

- Complete the training program, which includes reviewing the following:
 - LEMTRADA prescribing information
 - LEMTRADA REMS Program Overview
 - LEMTRADA REMS education program for prescribers
- Successfully complete the 4-question LEMTRADA REMS knowledge assessment.
- Enroll in the program by completing a LEMTRADA REMS Prescriber Enrollment Form.
- Submit the completed and signed Form to the LEMTRADA REMS.

PHARMACY ENROLLMENT INSTRUCTIONS

- An authorized representative must enroll on behalf of the pharmacy by reviewing the LEMTRADA REMS Program Overview and completing the LEMTRADA REMS Pharmacy Enrollment Form, which certifies that the pharmacy agrees to follow the procedures outlined in the LEMTRADA REMS, including:
 - All requests for LEMTRADA from the pharmacy will be handled with the dispensing of LEMTRADA used for research and clinical.
 - The pharmacy will verify that a LEMTRADA REMS Prescription Ordering Form is received for each prescription.
 - The pharmacy will verify that prescribers and healthcare facilities are certified and patients are authorized to receive LEMTRADA prior to dispensing LEMTRADA.
 - Enrollment in the LEMTRADA REMS must be renewed every 2 years from initial enrollment.
- Submit the completed and signed LEMTRADA REMS Pharmacy Enrollment Form to the LEMTRADA REMS.

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HEALTHCARE FACILITY ENROLLMENT INSTRUCTIONS

1. An authorized representative must visit all sites of the healthcare facility to complete the LEMTRADA REMS Healthcare Facility Enrollment Form and complete the LEMTRADA REMS Healthcare Facility Enrollment Form, which acknowledges that the healthcare facility agrees to follow the procedures outlined in the LEMTRADA REMS, including:

- all staff at the facility who will be involved with the dispensing and administration of LEMTRADA must be trained, and a written record of all staff REMS training must be kept on file.
- The healthcare facility will supply that practitioners are certified and patients are authorized to receive LEMTRADA prior to dispensing or administering LEMTRADA.
- The healthcare facility will provide a copy of what you need to know about LEMTRADA Treatment and Subsequent Medication, a Patient Guide to the patient on the first day of each treatment cycle visit. LEMTRADA is required.
- The healthcare facility will designate a LEMTRADA REMS Infection Control for each patient at the conclusion of each treatment cycle and submit it to the LEMTRADA REMS within 5 business days.
- Enrollment in the LEMTRADA REMS must be renewed every 3 years from initial enrollment.

2. Submit the completed and signed LEMTRADA REMS Healthcare Facility Enrollment Form to the LEMTRADA REMS.

PATIENT ENROLLMENT INSTRUCTIONS

1. Complete the LEMTRADA REMS Patient Enrollment Form, which contains information to be completed by both the prescriber and the patient.

2. Provide a copy of what you need to know about LEMTRADA Treatment, a Patient Guide and a LEMTRADA Patient Safety Information Card to each patient who will receive LEMTRADA. You must use what you need to know about LEMTRADA Treatment, a Patient Guide to ensure your patients use the correct dose and REMS requirements with the use of LEMTRADA.

3. Submit the completed and signed LEMTRADA REMS Patient Enrollment Form to the LEMTRADA REMS.

4. Provide the patient with a copy of the LEMTRADA REMS Patient Enrollment Form and keep a copy in the patient's medical record.

Where to find REMS information and resources:
 1. Search on the LEMTRADA REMS, call 1-855-676-6326. For information related to enrollment in the LEMTRADA REMS, call 1-855-676-6326 or visit www.LemtradaREMS.com.

Indications and Usage:
 LEMTRADA is indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include relapsing remitting disease and in the secondary progressive course, in adults. Because of its safety profile, the use of LEMTRADA should generally be reserved for patients who have had an inadequate response to first or second step indicated for the treatment of MS.

Limitations of use:
 LEMTRADA is not recommended for use in patients with clinically isolated syndrome (CIS) because of its safety profile.

The Prescribing Information includes REMS information for LEMTRADA. Please see accompanying Prescribing Information for complete safety information, including REMS information.

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For Prescribers

LEMTRADA REMS Education Program for Prescribers

This education program includes information about:

- The LEMTRADA REMS requirements
- Serious risks of autoimmune conditions, infusion reactions, stroke and malignancies
- Counseling and management of your patient

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What is the LEMTRADA REMS?

A REMS (Risk Evaluation and Mitigation Strategy) is a strategy to minimize known or potential risks associated with a drug, and is required by the FDA to ensure that the benefits of the drug outweigh its risks. Due to unique risks of alemtuzumab (Lemtrada), including serious, life-threatening, and fatal risks, LEMTRADA is only available through a restricted program called the LEMTRADA REMS.

This system has been developed as part of the LEMTRADA REMS to help educate prescribers about the risks associated with LEMTRADA and how to help reduce these risks, through periodic monitoring for, and prompt identification of, signs and symptoms of these events.

- Prescribers must be enrolled in the LEMTRADA REMS to be able to prescribe LEMTRADA.
- Pharmacies must be enrolled in the LEMTRADA REMS to be able to dispense LEMTRADA.
- Healthcare Facilities must be enrolled in the LEMTRADA REMS to be able to dispense and administer LEMTRADA.
- Patients must be enrolled and authorized in the LEMTRADA REMS in order to receive LEMTRADA.

Steps for Prescriber Certification and Enrollment in the LEMTRADA REMS

1. Complete the training program, which includes reviewing the following materials:
 - LEMTRADA Prescribing Information
 - LEMTRADA REMS Program Overview
 - LEMTRADA REMS Education Program for Prescribers
2. Successfully complete the 8-question Knowledge Assessment
3. Enroll in the program by completing a LEMTRADA REMS Prescriber Enrollment Form
4. Submit the completed and signed forms to the LEMTRADA REMS

The LEMTRADA REMS Program Overview, Knowledge Assessment, LEMTRADA Prescribing Information, and other REMS materials are available online at www.lemtradarems.com or by contacting the LEMTRADA REMS at 1-855-676-6326.

To enroll in the LEMTRADA REMS Program, visit www.lemtradarems.com or go to www.lemtradarems.com. Companies will need authorization of a prescriber's enrollment in the LEMTRADA REMS, including the prescriber's assigned LEMTRADA REMS identification number.

You will not be able to prescribe LEMTRADA without completing your certification in the LEMTRADA REMS. You should understand that if you fail to comply with the LEMTRADA REMS requirements, you may no longer be able to participate in the LEMTRADA REMS.

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Overview of Important Safety Information

INDICATION AND USAGE

LEMTRADA is indicated for the treatment of relapsing forms of multiple sclerosis (MS), but is not indicated for the treatment of relapsing and remitting forms of MS. Because of its safety profile, the use of LEMTRADA should generally be reserved for patients who have had an inadequate response to two or more drugs indicated for the treatment of MS.

Limitations of the LEMTRADA

LEMTRADA is not recommended for use in patients with clinically isolated syndrome (CIS) because of its safety profile.

The Prescribing Information includes a **BOXED WARNING** for LEMTRADA. Please see the Prescribing Information for complete safety information, including **BOXED WARNINGS**.

SERIOUS RISKS ASSOCIATED WITH LEMTRADA

Autoimmune Conditions

LEMTRADA has been associated with risk of autoimmune conditions, including immune thrombocytopenia, other cytopenias (including neutropenia, hemolytic anemia, and pancytopenia), thyroid disorders and glomerular nephropathy, which may occur many years after treatment and may be serious or life-threatening. Early detection and treatment of these conditions may decrease the risk of poor outcomes. Please review the sections that follow to gain a better understanding of the risks of autoimmune conditions.

Immune Thrombocytopenia (ITP)

Immune thrombocytopenia (ITP) occurred in 2% of LEMTRADA-treated patients in clinical studies (controlled and open-label extensions) in MS. Immune thrombocytopenia is an autoimmune disorder usually associated with auto-antibodies. Platelet depletion reduces the ability of the blood to clot. Symptoms of ITP could include but are not limited to nose bleeding, bruising, spontaneous mucocutaneous bleeding (epistaxis, hemoptysis), and heavier than normal or singular menstrual bleeding. These clinical signs of ITP may be apparent before visible bleeding develops. ITP can be a serious condition leading to morbidity and mortality, and may recur several years after dosing. It is important to monitor all patients for ITP as follows:

- Complete blood counts with differential should be obtained 10 days prior to initiation of treatment and at monthly intervals thereafter until 48 months after the patient's last infusion of LEMTRADA. After this period of time, testing should be performed based on clinical findings suggestive of ITP.
- Check the patient for clinical symptoms of ITP.
- Counsel the patient on the importance of complying with monthly monitoring of their blood and the need to continue for 48 months after their last infusion.
- Educate the patient on how to recognize ITP related symptoms, and emphasize the need to consult a physician for ITP.
- If ITP is suspected, appropriate medical intervention should be promptly initiated, including immediate referral to a specialist. Severe or widespread bleeding is life-threatening and demands immediate care.

The potential risk associated with retreatment with LEMTRADA following the occurrence of ITP is unknown.

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Potential Clinical Presentations of ITT

Note: These pictures are only a guide in order to show examples of lesions or perforation. The patient may have a less severe type of lesion or perforation than these pictures and still have ITT.

 <p style="font-size: 0.7em; margin: 0;">This is an example of a leg with perforation.</p> <p style="font-size: 0.7em; margin: 0;">Perforation on small, superficial, "punched" area under the skin that are red, pink or purple.</p> <p style="font-size: 0.7em; margin: 0;">Perforation on large area/holes on the patient's body, not just the leg.</p>	 <p style="font-size: 0.7em; margin: 0;">This is an example of any or numerous lesions.</p> <p style="font-size: 0.7em; margin: 0;">This could occur anywhere on the patient's body.</p>	 <p style="font-size: 0.7em; margin: 0;">This is an example of perforation under the tongue.</p> <p style="font-size: 0.7em; margin: 0;">Perfora could occur on any mucous membranes, including anywhere in the mouth (under the tongue, roof of the mouth, inner cheeks, tongue, gums).</p>
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Other Autoimmune Cytopenias (including neutropenia, hemolytic anemia, and pancytopenia)

Autoimmune cytopenias such as neutropenia, hemolytic anemia, and pancytopenia have been reported in clinical studies sponsored and sponsored extensions in US. One (1) ITT/US clinical patient with autoimmune pancytopenia died from sepsis. Symptoms of autoimmune hemolytic anemia may include weakness, chest pain, jaundice, dark urine, and fatigue. Use the severity (S/C) needs to monitor for cytopenias. If a cytopenia is confirmed, appropriate medical intervention should be promptly initiated.

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Glomerular Nephropathies

Glomerular nephropathies, including anti-glomerular basement membrane (GBM) disease, have been reported after treatment with LEMTRADA in multiple sclerosis patients in clinical trials. Cases of anti-GBM disease have been reported up to 42 months after the last dose of LEMTRADA.

In postmarketing cases, some LEMTRADA-treated patients with anti-GBM disease developed end-stage renal disease requiring dialysis or renal transplantation. Urgent evaluation and treatment is required. Discontinuing early treatment can improve the preservation of renal function. Anti-GBM disease can be life-threatening if not treated.

Clinical manifestations of nephropathy may include hematuria in some cases, edema, hematuria, change in urine color, decreased urine output, fatigue, changes, and/or proteinuria. While not observed in clinical trials, glomerular hemorrhage manifested as hematuria is a common occurrence of anti-GBM disease. Since patients may be asymptomatic, it is important that the monthly tests are conducted.

- Serum creatinine levels, urinalysis with cell counts, and urine protein to creatinine ratio should be obtained 30 days prior to the first infusion of LEMTRADA. Serum creatinine and urinalysis with cell counts should be obtained at monthly intervals thereafter until 48 months after the patient's last infusion. After this period of time, testing should be performed based on clinical findings suggestive of nephropathy.
- In monitoring females, consider the timing of urinalysis to avoid false positives. The observation of clinically significant changes from baseline in creatinine, unexplained hematuria, and/or proteinuria, should prompt further evaluation for nephropathy, including referral to a specialist.
- Early detection and treatment of nephropathy may decrease the risk of poor outcomes.
- Immediate referral to a specialist for further assessment for patients with suspected nephropathy is strongly recommended.

Thyroid Disorders

During clinical trials, autoimmune thyroid diseases including Graves' disease, hypothyroidism, hyperthyroidism, subacute thyroiditis, and goiter were reported. Thyroid endocrine disorders, including autoimmune thyroid disease, occurred in 26.8% of LEMTRADA-treated patients in clinical studies (controlled and open label extensions).

Newly diagnosed thyroid disorders occurred throughout the randomized clinical study follow-up period, more than 3 years after the first LEMTRADA dose. Serious thyroid events occurred in 5.2% of patients. Of all LEMTRADA-treated patients, 3.8% underwent thyroidectomy.

It is important to monitor all patients for thyroid disorders as follows:

- Thyroid function tests such as thyroid stimulating hormone (TSH) levels should be obtained 30 days prior to the first infusion of LEMTRADA and then every 3 months thereafter continuing until 48 months following the last infusion. Continue to test thyroid function after 48 months if clinically indicated.
- Additionally watch out for signs and symptoms of thyroid disorders, which may include excessive sweating, unexplained weight loss, eye swelling, nervousness and fast heartbeat (hyperthyroidism), or unexplained weight gain, feeling cold, worsening hoarseness and easily occurring constipation (hypothyroidism).

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Thyroid disease poses special risks to women who become pregnant. Untreated thyroid disease can lead harm to the unborn and newborn baby. Special caution should be taken for pregnant women with Graves' disease, an autoimmune thyroid condition characterized by excessive production of thyroid hormone. It is important that you understand the risks and can cause transient neonatal Graves' disease. The HCP responsible for managing the patient's pregnancy must be made aware of the increased risk of thyroid disorders due to the patient's LEMTRADA treatment, and the need for these to be appropriately treated.

Autoimmune Hepatitis
Autoimmune hepatitis causing clinically significant liver injury, including acute liver failure requiring transplant, has been reported in patients treated with LEMTRADA in the premarketing setting. If a patient develops clinical signs, including unexplained liver enzyme elevations or symptoms suggestive of hepatic dysfunction (e.g., unexplained nausea, vomiting, abdominal pain, fatigue, weakness, or jaundice and/or dark urine), promptly measure serum transaminases and total bilirubin and interrupt or discontinue treatment with LEMTRADA, as appropriate.

Prior to starting treatment with LEMTRADA, obtain serum transaminases (ALT and AST) and total bilirubin levels. Obtain transaminase levels and total bilirubin levels periodically and at 48 weeks after the last dose.

Strategies to Mitigate the Risk of Autoimmune Conditions
In order to minimize possible risks and side effects of LEMTRADA, prescribers and patients must consent to all monitoring of laboratory and other test results of LEMTRADA. It is important that patients understand that they should continue with the monitoring, even if they are feeling well.
Creating a partnership between you and your patient, along with careful review of the patient education tool (provided below) to share about LEMTRADA Treatment: A Patient Guide with your patient, will help patients see:

- Complete all periodic tests
- Identify and report symptoms early
- Receive prompt and appropriate treatment, if needed

 To enhance your understanding of the duration of the effects of treatment and the length of required follow-up, please refer to the diagrams below titled Overview of LEMTRADA Treatment and Overview of LEMTRADA Monitoring.

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Overview of LEMTRADA Treatment

Monthly monthly laboratory testing is required until 4 years after the last course with LEMTRADA. If more than 2 courses are administered, laboratory testing is required until 1 year after the last treatment course. Monthly monthly testing is required until 4 years and 4 months after the last course.

Overview of LEMTRADA Monitoring

Condition	Activity	Timing	Timing
Initial Laboratory Testing (LFT)	Complete blood count with differential	Pre to initiating LEMTRADA treatment	Repeat until all results are test infusable
Other patients to consider risk		Pre to initiating LEMTRADA treatment	
Glomerular dysfunction, including GFR, BUN, and Creatinine	Repeat creatinine	Pre to initiating LEMTRADA treatment	Repeat until all results are test infusable
Steady state with albumin		Pre to initiating LEMTRADA treatment	Repeat until all results are test infusable
Thyroid disorders	Thyroid function tests (TSH, FT4, FT3)	Pre to initiating LEMTRADA treatment	Every 2 months until all results are test infusable
Adverse events	Serum lipoproteins (LDL and HDL) and total cholesterol levels	Pre to initiating LEMTRADA treatment	Periodically until all results are test infusable
Adverse events	Side effects	Pre to initiating LEMTRADA treatment	Yearly

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Infusion Reactions

Most patients treated with LEMTRADA in controlled clinical trials in MS experienced infusion reactions during or after LEMTRADA administration. Some of these reactions were serious and life-threatening. In some patients, infusion reactions were reported more than 24 hours after LEMTRADA infusion. Serious reactions occurred in 3% of patients, including cases of anaphylaxis in 2 patients (including anaphylactic shock), angioedema, bronchospasm, hypotension, chest pain, back pain, tachycardia, tachypnea, flushing, facial edema, transient neurologic symptoms, hypertension, headache, dizziness, and rash. Other infusion reactions included nausea, vomiting, diarrhea, headache, chills, malaise, fatigue, dizziness, pulmonary edema, dyspnea, dyspnea, distention and pain. In clinical studies, 6.6% of patients with infusion reactions received epinephrine or atropine.

Cases of pulmonary edema, hemorrhage and myocardial ischemia have been reported with onset within 48 hours of LEMTRADA infusion.

Premedicate with high-dose corticosteroids (1000 mg of methylprednisolone or equivalent) immediately prior to LEMTRADA infusion and for the first 3 days of each treatment course. Consider premedication with antihistamines and/or antipyretics prior to LEMTRADA administration. Infusion reactions may occur in patients despite premedication.

Consider additional monitoring in patients with medical conditions which predispose them to cardiovascular or pulmonary compromise. Physicians should alert patients that an infusion reaction could occur within 48 hours of infusion.

LEMTRADA can only be administered in certified healthcare settings that have on-site access to equipment and personnel trained to manage infusion reactions (including anaphylaxis and cardiac and respiratory emergencies).

Patients must be observed for infusion reactions during and for at least 2 hours after each LEMTRADA infusion. Consider longer periods of observation if clinically indicated. Vital signs should be monitored before the infusion and periodically during the infusion. If an infusion reaction occurs, appropriate symptomatic treatment should be provided as needed. The duration of the infusion may be extended if clinically indicated. If severe infusion reactions occur, immediate discontinuation of the infusion should be considered.

Stroke and Cervicocephalic Arterial Dissection

Stroke

In the postmarketing setting, stroke and life-threatening stroke (including ischemic and hemorrhagic strokes) has been reported within 3 days of LEMTRADA administration, with most cases occurring within 1 day.

Cervicocephalic Arterial Dissection

In the postmarketing setting, cases of cervicocephalic (i.e., vertebral, carotid) arterial dissection involving multiple arteries have been reported within 3 days of LEMTRADA administration, between stroke was reported in one of these cases.

Advise patients on the symptoms of stroke and cervicocephalic (i.e., carotid, vertebral) arterial dissection. Instruct patients to seek immediate medical attention if symptoms of stroke or cervicocephalic arterial dissection occur.

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Malignancies

LEMTRADA is an immunomodulatory therapy, and caution should be exercised in treating LEMTRADA in patients with pre-existing or ongoing malignancies.

Thyroid Cancer

LEMTRADA may increase the risk of thyroid cancer. In controlled clinical studies, 0.3% of LEMTRADA-treated patients developed thyroid cancer, compared to none in the intravenous beta-2-tolerant group. However, screening for thyroid cancer was performed more frequently in the LEMTRADA-treated group, because of the higher incidence of autoimmune thyroid disorders in these patients. Two additional cases of thyroid cancer in LEMTRADA-treated patients occurred in uncontrolled studies.

Aplasia

LEMTRADA may increase the risk of aplasia. In clinical studies, including extension data, 0.3% of LEMTRADA-treated patients developed aplasia or aplasia in situ. One of these patients had evidence of locally advanced disease.

Lymphoproliferative Disorders and Lymphoma

Cases of lymphoproliferative disorders and lymphoma have occurred in LEMTRADA-treated patients with MS, including a BALT lymphoma, Castleman's disease, and a fatality following treatment of non-Hodgkin B-cell lymphoma (Burkitt's lymphoma). There are preliminary reports of Epstein-Barr Virus-associated lymphoproliferative disorders in non-MS patients.

Monitoring for Malignancies

Patients and healthcare providers should monitor for symptoms of thyroid cancer, including a new lump or swelling in the neck, pain in the front of the neck, persistent hoarseness or other voice changes, trouble swallowing or breathing, or a constant cough not due to an upper respiratory tract infection.

Perform baseline and yearly skin examinations to monitor for melanoma in patients receiving LEMTRADA.

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Patient Enrollment, Counseling, and Management

To enroll your patient in the LEMTRADA REMS, you must:

- Complete the LEMTRADA REMS Patient Enrollment Form for each patient and provide a completed copy to the patient. The completed form should be submitted to the LEMTRADA REMS and a copy shared with the patient's record.
- Enrollment forms can be obtained online (www.LemtradaREMS.com) or by phone (1-855-676-6326).
- Completed forms should be faxed to 1-855-557-2476.
- Genzyme will provide confirmation of patient enrollment.

As part of patient management and counseling, you must:

- Inform your patient about the risks associated with LEMTRADA, including the risks of autoimmune conditions, adverse reactions, order and management, and the need for baseline and periodic monitoring. A patient-directed educational guide has been developed for you to use in counseling your patients on the risks associated with LEMTRADA (what you need to know about LEMTRADA Treatment: A Patient Guide). You should review this guide with your patient on an ongoing basis. You must provide each patient with a copy of this guide and a LEMTRADA Patient Safety Information Card.
- Perform the baseline and periodic monitoring described above and in the Prescribing Information for LEMTRADA.
- Complete the LEMTRADA REMS Patient Status Form 6 months after the patient's first infusion with LEMTRADA, and every 6 months thereafter, until 48 months after the completion of the patient's last infusion of LEMTRADA, and submit the completed form to the LEMTRADA REMS.
- Notify Genzyme if an enrolled patient who has received LEMTRADA within the last 48 months is no longer under your care.

Ordering LEMTRADA

To order LEMTRADA, you must submit a LEMTRADA REMS Prescription Ordering Form for each LEMTRADA prescription to the LEMTRADA REMS. The ordering form can be obtained online (www.LemtradaREMS.com) or by phone (1-855-676-6326).

Completed forms should be faxed to 1-855-557-2476.

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Administering LEMTRADA

As part of the LEMTRADA REMS, a healthcare facility must be enrolled in the LEMTRADA REMS to be able to dispense/administer LEMTRADA. It is important that you enter a healthcare facility that is enrolled and active in the LEMTRADA REMS for your patient's infusion. A database of certified healthcare facilities is available by phone at 1-855-676-6326.

Prior to your patient's infusion, you must submit a LEMTRADA REMS Patient Authorization and Baseline Lab Form to the LEMTRADA REMS indicating completion of each patient's baseline lab within 30 days of the infusion date.

PRIOR TO EACH TREATMENT COURSE OF LEMTRADA

- Administer clemtuzumab (100 mg, every 3 weeks or equivalent) immediately prior to LEMTRADA administration for the first 3 days of any treatment course.
- Administer anti-viral prophylaxis for herpesic viral infection starting on the first day of each treatment course and continuing for a minimum of 3 months following treatment with LEMTRADA or until the CD4 lymphocyte count is ≥200 cells per microliter, whichever occurs later.
- Consider pre-treating patients with anti-infectives and/or anti-infectives prior to LEMTRADA administration as needed.

Adverse Event Reporting

Report suspected adverse events to Genzyme Medical Information at 1-800-745-4447 (option 2) or to FDA at 1-800-FDA-1088 or www.FDA.gov/medwatch.

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LEMTRADA REMS Knowledge Assessment

To confirm that prescribers understand the LEMTRADA REMS requirements, you must successfully complete the Knowledge Assessment below. You must answer **ALL 8** questions correctly in order to become enrolled in the LEMTRADA REMS. Please note that you will have 3 attempts to successfully complete the Knowledge Assessment or you will have to view the training materials again.

QUESTION 1 (select one)

Which of the following laboratory tests are required prior to initiating LEMTRADA treatment and within 30 days of the first infusion?

- A. Complete blood count (CBC) with differential
- B. Serum creatinine and urinalysis with urine cell counts
- C. Urine protein to creatinine ratio
- D. Thyroid function test
- E. All of the above

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Which of the following laboratory tests are required prior to initiating LEMTRADA treatment and within 30 days of the first infusion?

- A. Complete blood count (CBC) with differential
- B. Serum creatinine and urinalysis with urine cell counts
- C. Urine protein to creatinine ratio
- D. Thyroid function test
- E. All of the above

Submit

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QUESTION 2 (select one)

My patient must have monthly blood and urine tests for:

- A. 12 months after their last infusion
- B. 24 months after their last infusion
- C. 36 months after their last infusion
- D. 48 months after their last infusion

Submit

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QUESTION 3

I should assess my patient's compliance with required lab testing on an ongoing basis and document their compliance on the LEMTRADA REMS Patient Status Form every 6 months.

True

False

Submit

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QUESTION 4 (select one)

Which of the following symptoms could be associated with immune thrombocytopenia (ITP)?

- A. Headache, rash, pyrexia, nausea
- B. Easy bruising, petechiae, purpura, spontaneous mucocutaneous bleeding
- C. Weight gain, fatigue, constipation
- D. Pyrexia, chills, swollen glands

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QUESTION 5 (select one)

Which of the following could be associated with glomerular nephropathy?

- A. Elevation in serum creatinine, hematuria, or proteinuria
- B. Easy bruising, petechiae, purpura, spontaneous mucocutaneous bleeding (e.g., epistaxis, hemoptysis), and heavier than normal or irregular menstrual bleeding
- C. Weight gain, fatigue, constipation
- D. Weight loss, tachycardia, nervousness

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The screenshot shows a mobile application interface for LEMTRADA REMS. At the top, there is a search bar with 'Lemtrada.rems.com' and a 'Google' button. Below this are links for 'PRESCRIBING INFORMATION' and 'MEDICATION GUIDE'. The LEMTRADA logo is displayed with the text 'alemfuzumab^{lpm}' and a user greeting 'Welcome, Adam!' next to a 'Menu' button. A progress bar indicates the current step is 'Assessment', with 'Registration', 'Training', and 'Enrollment' also visible. The main heading is 'LEMTRADA REMS Knowledge Assessment'. The text explains that prescribers must complete an 8-question assessment to enroll, with 3 attempts allowed. The current question is 'QUESTION 6 (select one)' and asks what should be done before enrolling a patient. The options are: A. Provide 'What You Need to Know About LEMTRADA Treatment: A Patient Guide' to the patient; B. Counsel the patient on the serious risks associated with LEMTRADA and how to mitigate these risks through periodic monitoring; C. Provide a LEMTRADA Patient Safety Information Card to the patient; D. All of the above. A green 'Submit' button is at the bottom of the question. Below the question, there is contact information for help enrolling: '1-855-676-6326, Mon - Fri, 8:30 am - 8:00 pm ET.' The footer contains links for 'Privacy Policy', 'Terms and Conditions', and 'Contact Us', along with a disclaimer that the site is for US residents only, copyright information for Genzyme Corporation, and the Sanofi Genzyme logo.

The screenshot shows a mobile application interface for LEMTRADA REMS. At the top, there is a search bar with 'Lemtradarems.com' and a 'Google' search button. Below this are links for 'PRESCRIBING INFORMATION' and 'MEDICATION GUIDE'. The LEMTRADA logo is displayed with the text 'alemfuzumab^{lpm}' and a user greeting 'Welcome, Adam!' next to a 'Menu' button. A progress bar indicates the current step is 'Assessment', with 'Registration', 'Training', and 'Enrollment' also visible. The main heading is 'LEMTRADA REMS Knowledge Assessment'. The text explains that prescribers must complete an 8-question assessment to enroll, with 3 attempts allowed. The current question, 'QUESTION 7', asks if serious and life-threatening stroke cases have been reported within 3 days of LEMTRADA administration. Two radio button options are provided: 'True' and 'False'. A green 'Submit' button is at the bottom of the question area. Below the question is a contact information box for enrollment help. The footer contains legal disclaimers, copyright information for Genzyme Corporation, and the Sanofi Genzyme logo.

2:45 PM

Lemtradarems.com Google

PRESCRIBING INFORMATION MEDICATION GUIDE

LEMTRADA[®]
alemfuzumab^{lpm} Welcome, Adam! Menu

Registration Training Assessment Enrollment

LEMTRADA REMS Knowledge Assessment

To confirm that prescribers understand the LEMTRADA REMS requirements, you must successfully complete the Knowledge Assessment below. You must answer **ALL 8** questions correctly in order to become enrolled in the LEMTRADA REMS. Please note that you will have 3 attempts to successfully complete the Knowledge Assessment or you will have to view the training materials again.

QUESTION 7

Cases of serious and life-threatening stroke (including ischemic and hemorrhagic stroke) have been reported within 3 days of LEMTRADA administration, with most cases occurring within 1 day.

True

False

Submit

If you have questions about the LEMTRADA REMS or need help enrolling, call **1-855-676-6326**, Mon - Fri, 8:30 am - 8:00 pm ET.

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SANOFI GENZYME

The screenshot shows a mobile application interface for LEMTRADA REMS. At the top, there is a search bar with 'Lemtrada.rems.com' and a 'Google' button. Below this are links for 'PRESCRIBING INFORMATION' and 'MEDICATION GUIDE'. The LEMTRADA logo is displayed, along with the text 'alemfuzumab^{lpm}' and a personalized greeting 'Welcome, Adam!'. A navigation bar contains 'Registration', 'Training', 'Assessment', and 'Enrollment', with 'Assessment' being the active tab. The main heading is 'LEMTRADA REMS Knowledge Assessment'. The text explains that prescribers must complete an 8-question assessment to become enrolled, with 3 attempts allowed. The current question, 'QUESTION 8', asks if a healthcare facility administering LEMTRADA infusions must be REMS certified and have specific emergency equipment. Two radio button options are provided: 'True' and 'False'. A green 'Submit' button is at the bottom of the question. A footer section provides contact information for enrollment help: '1-855-676-6326, Mon - Fri, 8:30 am - 8:00 pm ET.' The bottom of the screen features a purple bar with 'SANOFI GENZYME' and its logo, along with a disclaimer: 'This site is intended for United States residents only. ©2019 Genzyme Corporation. All rights reserved. Lemtrada, MS One to One, Sanofi and Genzyme registered in U.S. Patent and Trademark Office US.MS.LEM.14.10.013a-v7 Last Updated 09/19'.

The screenshot shows a mobile app interface for LEMTRADA REMS. At the top, there is a search bar with 'Lemtrada.rems.com' and a 'Google' search button. Below the search bar are two tabs: 'PRESCRIBING INFORMATION' and 'MEDICATION GUIDE'. The main header features the LEMTRADA logo (alemfuzumab^{lpm}) and a welcome message 'Welcome, Adam!' with a 'Menu' button. A progress bar indicates the user is in the 'Assessment' stage, with 'Registration', 'Training', and 'Enrollment' also visible. The main content area is titled 'LEMTRADA REMS Knowledge Assessment'. It contains a paragraph explaining that prescribers must answer all 8 questions correctly to become enrolled, with 3 attempts allowed. Below this, a red heading reads 'Please Review the Training Materials Again'. The score is displayed as 'Score: X / 8', followed by a paragraph stating that only X out of 8 questions were answered correctly and that the user must review the training materials. Two buttons are provided: 'View Training Materials' and 'Take Assessment Again'. At the bottom of the main content area, there is a call to action: 'If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6326, Mon - Fri, 8:30 am - 8:00 pm ET.' The footer contains links for 'Privacy Policy', 'Terms and Conditions', and 'Contact Us', along with a disclaimer: 'This site is intended for United States residents only.' and copyright information: '©2019 Genzyme Corporation. All rights reserved.' The Sanofi Genzyme logo is at the very bottom.

2:45 PM

Lemtrada.rems.com Google

PRESCRIBING INFORMATION MEDICATION GUIDE

LEMTRADA[®]
alemfuzumab^{lpm} Welcome, Adam! Menu

Registration Training Assessment Enrollment

LEMTRADA REMS Knowledge Assessment

To confirm that prescribers understand the LEMTRADA REMS requirements, you must successfully complete the Knowledge Assessment below. You must answer **ALL 8** questions correctly in order to become enrolled in the LEMTRADA REMS. Please note that you will have 3 attempts to successfully complete the Knowledge Assessment or you will have to view the training materials again.

Please Review the Training Materials Again

Score: X / 8

You only answered X out of 8 questions correctly. In order to become certified in the LEMTRADA REMS, you must answer ALL 8 questions correctly. Please review the training materials again.

[View Training Materials](#)

[Take Assessment Again](#)

If you have questions about the LEMTRADA REMS or need help enrolling, call **1-855-676-6326**, Mon - Fri, 8:30 am - 8:00 pm ET.

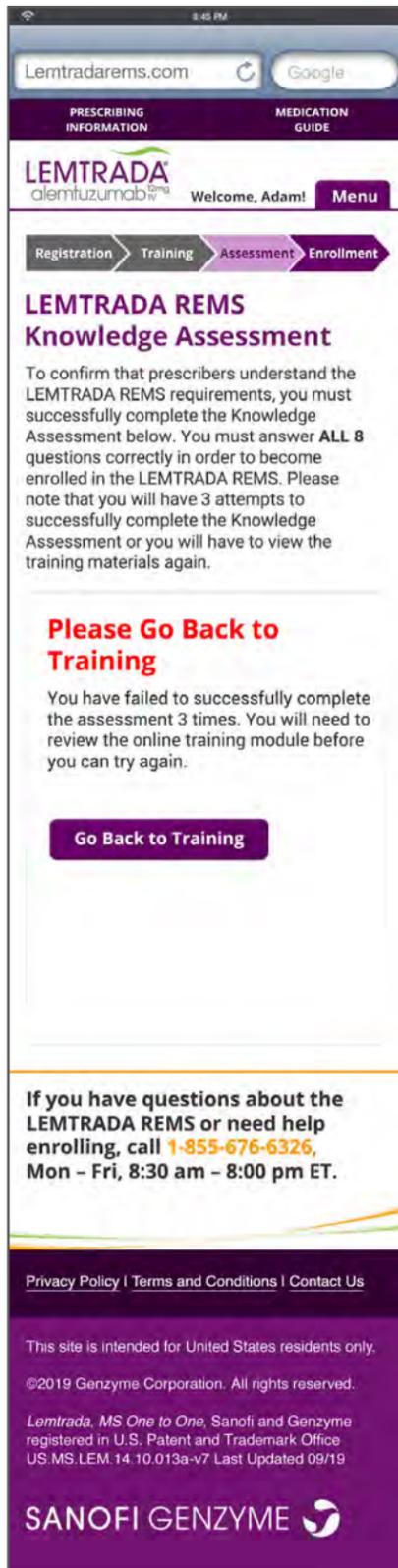
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LEMTRADA REMS Mobile - Prescriber Enrollment

PRESCRIBING INFORMATION
MEDICATION GUIDE



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Enrollment

LEMTRADA REMS PRESCRIBER ENROLLMENT FORM

LEMTRADA is available only through the LEMTRADA REMS, a restricted distribution program. Only prescribers, healthcare facilities, and patients enrolled in the program are able to prescribe, dispense, administer, and receive LEMTRADA. Please review the following information and submit to Genzyme using the button below. Complete any missing information and correct any errors prior to submission.

*Required

PRESCRIBER INFORMATION

First Name*

Last Name*

Degree*

Name of Institution or Healthcare Facility*

Street Address*

City*

State*

ZIP Code*

Office Phone Number*

Fax Number*

Mobile Phone Number

Email Address*

National Provider Identification (NPI) Number*

If you are dispensing LEMTRADA from your clinic, a LEMTRADA REMS Healthcare Facility Enrollment Form must also be completed and submitted.

PRESCRIBER AGREEMENT

By completing this form, I attest that:

- I understand that LEMTRADA is indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include relapsing-remitting disease and active secondary progressive disease, in adults. Because of its safety profile, the use of LEMTRADA should generally be reserved for patients who have had an inadequate response to two or more drugs indicated for the treatment of MS. LEMTRADA is not recommended for use in patients with clinically isolated syndrome (CIS) because of its safety profile.
- I understand that LEMTRADA is only available through the LEMTRADA REMS and that I must comply with the program requirements in order to prescribe LEMTRADA.

- I have completed the LEMTRADA REMS Education Program for Prescribers, including a review of the LEMTRADA Prescribing Information, and successfully completed the LEMTRADA REMS Knowledge Assessment.
- I understand that by completing the training program and signing this LEMTRADA REMS Prescriber Enrollment Form, I will be enrolled in the LEMTRADA REMS and can prescribe LEMTRADA.
- I understand that I am responsible for reviewing *What You Need to Know About LEMTRADA Treatment: A Patient Guide* with each patient, and counseling each patient on an ongoing basis about the serious risks associated with the use of LEMTRADA and how to mitigate these risks through periodic monitoring.
- I understand that I must enroll all patients being treated with LEMTRADA into the LEMTRADA REMS prior to initiating the patient on treatment with LEMTRADA. I am responsible for completing a LEMTRADA REMS Patient Enrollment Form with the patient (or patient's legal representative), obtaining the patient's (or patient's legal representative's) signature on the form, and submitting the signed form to the LEMTRADA REMS. A completed copy should be provided to the patient and another copy should be stored in the patient's records.
- I will provide enrolled patients with a LEMTRADA Patient Safety Information Card and instruct patients to carry this card with them at all times in case of an emergency.
- I understand that I must submit a LEMTRADA REMS Prescription Ordering Form for each LEMTRADA prescription.
- I understand that I am responsible for completing baseline lab monitoring within 30 days prior to infusion of LEMTRADA.
- I understand that I must submit a LEMTRADA REMS Patient Authorization and Baseline Lab Form indicating completion of each patient's baseline labs within 30 days prior to the patient's infusion date.
- I understand the risks of autoimmune conditions and malignancies associated with the use of LEMTRADA, and the need for periodic monitoring in order to identify and mitigate these risks:
 - Complete blood counts with differential obtained within 30 days prior to initiation of treatment and at monthly intervals thereafter until 48 months after the last infusion.
 - Serum creatinine levels obtained within 30 days prior to initiation of treatment and at monthly intervals thereafter until 48 months after the last infusion.
 - Urinalysis with urine cell counts obtained within 30 days prior to initiation of treatment and at monthly intervals thereafter until 48 months after the last infusion.
 - Measure the urine protein to creatinine ratio within 30 days prior to initiation of treatment
 - Thyroid function tests, such as thyroid stimulating hormone (TSH) level, obtained within 30 days prior to initiation of treatment and every 3 months thereafter until 48 months after the last infusion.
 - Baseline and yearly skin examinations.
- I understand the risk of stroke during and following the administration of LEMTRADA
- I will report any adverse events of autoimmune conditions, infusion reactions, or malignancies to Genzyme.
- I will complete the LEMTRADA REMS Patient Status Form 6 months after the patient's first infusion and every 6 months thereafter, until 48 months after the completion of the patient's last infusion.
- I understand that I will notify Genzyme if a patient is no longer under my care.
- I understand that if I fail to comply with the requirements of the LEMTRADA REMS, I may no longer be able to participate in the program.
- I understand Genzyme and its agents may contact me via phone, mail, fax, or email to support administration of the LEMTRADA REMS.

I understand that the LEMTRADA REMS will publish my name, business address and phone number ("Contact Information") on its website in a directory of physicians certified to prescribe and administer LEMTRADA and consent to the foregoing. I understand that I am waiving the right to inspect my Contact Information prior to its inclusion on the website, and I agree to hold harmless and release the LEMTRADA REMS and Genzyme and its affiliates from any and all actions, claims, or demands arising out of or in connection with the

use of my Contact Information on the website. I understand that I can request the removal of my Contact Information from the LEMTRADA REMS website at any time by contacting the LEMTRADA REMS at 1-855-676-6326.

Yes No

I have verified that all details are correct.

By providing my e-signature, I attest that I have completed the educational training about LEMTRADA for prescribers and that I understand the benefits and risks of LEMTRADA. I understand that my e-signature will be used to verify my enrollment in the LEMTRADA REMS.

By entering my name, NPI number, and password, I confirm that I have completed the LEMTRADA REMS training and that I will comply with the requirements of the program.

Full Name*

NPI Number*

Password*

[Cancel](#)

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LEMTRADA REMS Mobile - Prescriber Enrollment, Degree Selection

PRESCRIBING INFORMATION
MEDICATION GUIDE



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LEMTRADA REMS PRESCRIBER ENROLLMENT FORM

LEMTRADA is available only through the LEMTRADA REMS, a restricted distribution program. Only prescribers, healthcare facilities, and patients enrolled in the program are able to prescribe, dispense, administer, and receive LEMTRADA. Please review the following information and submit to Genzyme using the button below. Complete any missing information and correct any errors prior to submission.

*Required

PRESCRIBER INFORMATION

First Name*

Last Name*

Degree*

- Select
- Doctor of Osteopathy
- Doctor of Pharmacy
- Medical Doctor
- Nurse Practitioner
- Physician Assistant
- Registered Nurse
- Registered Pharmacist

State

ZIP Code*

Office Phone Number*

Fax Number*

Mobile Phone Number

Email Address*

National Provider Identification (NPI) Number*

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- I understand that LEMTRADA is only available through the LEMTRADA REMS and that I must comply with the program requirements in order to prescribe LEMTRADA.

- I have completed the LEMTRADA REMS Education Program for Prescribers, including a review of the LEMTRADA Prescribing Information, and successfully completed the LEMTRADA REMS Knowledge Assessment.
- I understand that by completing the training program and signing this LEMTRADA REMS Prescriber Enrollment Form, I will be enrolled in the LEMTRADA REMS and can prescribe LEMTRADA.
- I understand that I am responsible for reviewing *What You Need to Know About LEMTRADA Treatment: A Patient Guide* with each patient, and counseling each patient on an ongoing basis about the serious risks associated with the use of LEMTRADA and how to mitigate these risks through periodic monitoring.
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 - Measure the urine protein to creatinine ratio within 30 days prior to initiation of treatment
 - Thyroid function tests, such as thyroid stimulating hormone (TSH) level, obtained within 30 days prior to initiation of treatment and every 3 months thereafter until 48 months after the last infusion.
 - Baseline and yearly skin examinations.
- I understand the risk of stroke during and following the administration of LEMTRADA
- I will report any adverse events of autoimmune conditions, infusion reactions, or malignancies to Genzyme.
- I will complete the LEMTRADA REMS Patient Status Form 6 months after the patient's first infusion and every 6 months thereafter, until 48 months after the completion of the patient's last infusion.
- I understand that I will notify Genzyme if a patient is no longer under my care.
- I understand that if I fail to comply with the requirements of the LEMTRADA REMS, I may no longer be able to participate in the program.
- I understand Genzyme and its agents may contact me via phone, mail, fax, or email to support administration of the LEMTRADA REMS.

I understand that the LEMTRADA REMS will publish my name, business address and phone number ("Contact Information") on its website in a directory of physicians certified to prescribe and administer LEMTRADA and consent to the foregoing. I understand that I am waiving the right to inspect my Contact Information prior to its inclusion on the website, and I agree to hold harmless and release the LEMTRADA REMS and Genzyme and its affiliates from any and all actions, claims, or demands arising out of or in connection with the

use of my Contact Information on the website. I understand that I can request the removal of my Contact Information from the LEMTRADA REMS website at any time by contacting the LEMTRADA REMS at 1-855-676-6326.

Yes No

I have verified that all details are correct.

By providing my e-signature, I attest that I have completed the educational training about LEMTRADA for prescribers and that I understand the benefits and risks of LEMTRADA. I understand that my e-signature will be used to verify my enrollment in the LEMTRADA REMS.

By entering my name, NPI number, and password, I confirm that I have completed the LEMTRADA REMS training and that I will comply with the requirements of the program.

Full Name*

NPI Number*

Password*

[Cancel](#)

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LEMTRADA REMS Mobile - Prescriber Enrollment, State Selection

LEMTRADAREMS.COM

PRESCRIBING INFORMATION MEDICATION GUIDE

LEMTRADA alemtuzumab [®] Welcome, Adam! Menu

Registration Training Assessment Enrollment

LEMTRADA REMS PRESCRIBER ENROLLMENT FORM

LEMTRADA is available only through the LEMTRADA REMS, a restricted distribution program. Only prescribers, healthcare facilities, and patients enrolled in the program are able to prescribe, dispense, administer, and receive LEMTRADA. Please review the following information and submit to Genzyme using the button below. Complete any missing information and correct any errors prior to submission.

*Required

PRESCRIBER INFORMATION

First Name*
Adam

Last Name*
Smith

Degree*
Medical Doctor

Name of Institution or Healthcare Facility*
Massachusetts Institute

Street Address*
72-04 Maple Lane

City*
Boston

State*

- Select
- Alabama
- Alaska
- American Samoa
- Arizona
- Arkansas
- California
- Colorado
- Connecticut
- Delaware
- District of Columbia
- Florida
- Georgia
- Guam
- Hawaii
- Idaho
- Illinois
- Indiana
- Iowa
- Kansas
- Kentucky
- Louisiana
- Maine
- Maryland
- Massachusetts
- Michigan
- Minnesota
- Mississippi
- Missouri
- Montana
- Nebraska
- Nevada

- New Hampshire
- New Jersey
- New Mexico
- New York
- North Carolina
- North Dakota
- Northern Mariana Islands
- Ohio
- Oklahoma
- Oregon
- Pennsylvania
- Puerto Rico
- Rhode Island
- South Carolina
- South Dakota
- Tennessee
- Texas
- Utah
- Vermont
- Virginia
- Virgin Islands
- Washington
- West Virginia
- Wisconsin
- Wyoming

I understand that I must submit a LEMTRADA REMS Patient Authorization and Baseline Lab Form indicating completion of each patient's baseline labs within 30 days prior to the patient's infusion date.

I understand the risks of autoimmune conditions and malignancies associated with the use of LEMTRADA, and the need for periodic monitoring in order to identify and mitigate these risks:

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I understand the risk of stroke during and following the administration of LEMTRADA

I will report any adverse events of autoimmune conditions, infusion reactions, or malignancies to Genzyme.

I will complete the LEMTRADA REMS Patient Status Form 6 months after the patient's first infusion and every 6 months thereafter, until 48 months after the completion of the patient's last infusion.

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Full Name*

NPI Number*

Password*

[Cancel](#) [Submit](#)

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LEMTRADA REMS Mobile - Prescriber Enrollment, Error

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*Required

PRESCRIBER INFORMATION

First Name*

Please enter your first name.

Last Name*

Please enter your last name.

Degree*

Select One

Please select degree.

Name of Institution or Healthcare Facility*

Please enter name of institution or healthcare facility.

Street Address*

Please enter your street address.

City*

Please enter city.

State*

Select One

Please select a state.

ZIP Code*

Please enter a 5-digit ZIP Code.

Office Phone Number*

Please enter a 10-digit phone number.

Fax Number*

Please enter a 10-digit fax number.

Mobile Phone Number

Email Address*

Please enter a valid email address.

National Provider Identification (NPI) Number*

Please enter a valid NPI number.

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 - Thyroid function tests, such as thyroid stimulating hormone (TSH) level, obtained within 30 days prior to initiation of treatment and every 3 months thereafter until 48 months after the last infusion.
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- I understand that I will notify Genzyme if a patient is no longer under my care.
- I understand that if I fail to comply with the requirements of the LEMTRADA REMS, I may no longer be able to participate in the program.
- I understand Genzyme and its agents may contact me via phone, mail, fax, or email to support administration of the LEMTRADA REMS.

I understand that the LEMTRADA REMS will publish my name, business address and phone number ("Contact Information") on its website in a directory of physicians certified to prescribe and administer LEMTRADA and consent to the foregoing. I understand that I am waiving the right to inspect my Contact Information prior to its inclusion on the website, and I agree to hold harmless and release the LEMTRADA REMS and Genzyme and its affiliates from any and all actions, claims, or demands arising out of or in connection with the

use of my Contact Information on the website. I understand that I can request the removal of my Contact Information from the LEMTRADA REMS website at any time by contacting the LEMTRADA REMS at 1-855-676-6326.

Yes No Please make a selection.

I have verified that all details are correct. Please indicate information has been verified. By providing my e-signature, I attest that I have completed the educational training about LEMTRADA for prescribers and that I understand the benefits and risks of LEMTRADA. I understand that my e-signature will be used to verify my enrollment in the LEMTRADA REMS.

By entering my name, NPI number, and password, I confirm that I have completed the LEMTRADA REMS training and that I will comply with the requirements of the program.

Full Name*

Please enter your full name.

NPI Number*

Please enter a valid NPI number.

Password*

Please enter a valid password.

If you have questions about the LEMTRADA REMS or need help enrolling, call **1-855-676-6326**, Mon – Fri, 8:30 am – 8:00 pm ET.

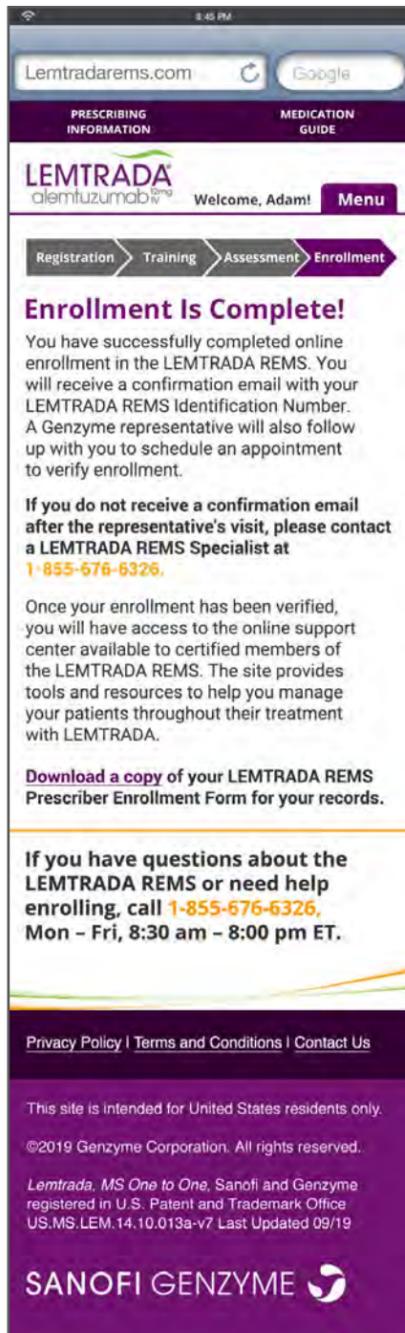
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PRESCRIBING INFORMATION
MEDICATION GUIDE


Welcome, Adam!
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LEMTRADA REMS (Risk Evaluation and Mitigation Strategy)

What is the LEMTRADA REMS?

A REMS is a strategy to manage known or potential serious risks associated with a drug product and is required by the FDA to ensure the benefits of a drug outweigh its risks. The purpose of the LEMTRADA REMS is to inform prescribers, pharmacies, healthcare facilities, and patients about the risks of:

AUTOIMMUNE CONDITIONS
LEMTRADA causes serious, sometimes fatal, autoimmune conditions such as immune thrombocytopenia and anti-glomerular basement membrane disease. Monitor complete blood counts with differential, serum creatinine levels, and urinalysis with urine cell counts at periodic intervals for 48 months after the last dose of LEMTRADA.

INFUSION REACTIONS
LEMTRADA causes serious and life-threatening infusion reactions. LEMTRADA must be administered in a setting with appropriate equipment and personnel to manage anaphylaxis or serious infusion reactions.

STROKE
Serious and life-threatening stroke (including ischemic and hemorrhagic stroke) has been reported within 3 days of LEMTRADA administration. Instruct patients to seek immediate medical attention if symptoms of stroke occur.

MALIGNANCIES
LEMTRADA may cause an increased risk of malignancy including thyroid cancer, melanoma, and lymphoproliferative disorders. Perform baseline and yearly skin exams.

Complete Enrollment in the LEMTRADA REMS



You have not completed your review of the training materials. You must review the training materials in order to complete your enrollment in the LEMTRADA REMS.

Review Training Materials

Find a REMS Certified Prescriber or Healthcare Facility



Search for prescribers or healthcare facilities that are certified by the LEMTRADA REMS to prescribe, dispense, or administer LEMTRADA.

Enter ZIP Code

REMS Certified Prescriber
 REMS Certified Healthcare Facility

Find

LEMTRADA REMS Requirements

PRESCRIBERS

Prescribers must be enrolled in the LEMTRADA REMS to prescribe LEMTRADA for patients with multiple sclerosis.

[Learn about Prescriber Enrollment](#)

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Complete Enrollment in the LEMTRADA REMS



You have not completed answering the LEMTRADA REMS Knowledge Assessment questions.

[Continue Assessment](#)

Find a REMS Certified Prescriber or Healthcare Facility



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Enter ZIP Code

REMS Certified Prescriber
 REMS Certified Healthcare Facility

[Find](#)

LEMTRADA REMS Requirements

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[Learn about Prescriber Enrollment](#) ▶

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Complete Enrollment in the LEMTRADA REMS



You must review the training materials in order to complete your enrollment in the LEMTRADA REMS.

Please call *MS One to One*® at 1-855-676-6326 to speak with a Genzyme representative.

Find a REMS Certified Prescriber or Healthcare Facility



Search for prescribers or healthcare facilities that are certified by the LEMTRADA REMS to prescribe, dispense, or administer LEMTRADA.

Enter ZIP Code

REMS Certified Prescriber
 REMS Certified Healthcare Facility

Find

LEMTRADA REMS Requirements

PRESCRIBERS

Prescribers must be enrolled in the LEMTRADA REMS to prescribe LEMTRADA for patients with multiple sclerosis.

[Learn about Prescriber Enrollment ▶](#)

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Complete Enrollment in the LEMTRADA REMS



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Review Enrollment Form

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Enter ZIP Code

REMS Certified Prescriber
 REMS Certified Healthcare Facility

Find

LEMTRADA REMS Requirements

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LEMTRADA
alemtuzumab^{gms}

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Review Training Materials Again

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REMS Certified Prescriber
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Find

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[Learn about Prescriber Enrollment](#) ▶

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[Review Training Materials Again](#)

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REMS Certified Prescriber
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LEMTRADA[®]
alemtuzumab ¹²⁵I

Welcome, Adam! Menu

LEMTRADA REMS Training

Full Prescribing Information (1 of 27)
Total Training Screens: 1 of 41



Next (1 of 41)

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alemtuzumab injection Welcome, Adam! Menu

LEMTRADA REMS Support Tools

View individual profiles of your LEMTRADA patients and the healthcare facilities they visit. These resources can help you learn more about patients' authorization status, infusion records, and monitoring program activity.

LEMTRADA REMS Support Tools

You have 10 LEMTRADA patients ?

Patient (REMS ID)	REMS Status
John Doe (123456789)	Authorized

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The screenshot displays the LEMTRADA REMS mobile application interface. At the top, there is a search bar with 'Lemtrada.com' and a 'Google' button. Below this are navigation links for 'PRESCRIBING INFORMATION' and 'MEDICATION GUIDE'. The main header features the LEMTRADA logo, the text 'Welcome, Adam!', and a 'Menu' button. A red alert banner at the top states 'You have 4 patient alerts!'. The main content area is titled 'LEMTRADA REMS Support Tools' and includes a description of the tools and a green button labeled 'LEMTRADA REMS Support Tools'. Below this, a section indicates 'You have 10 LEMTRADA patients' with a search icon. A table lists 10 patients with columns for 'Patient (REMS ID)' and 'REMS Status'. The table contains the following data:

Patient (REMS ID)	REMS Status
John Doe (123456789)	Authorized
John Doe (123456789)	Authorized
John Doe (123456789)	Authorized
John Doe (123456789)	Baseline Lab Form
John Doe (123456789)	Authorized
John Doe (123456789)	Patient Status Form Baseline Lab Form
John Doe (123456789)	Authorized

Below the table, there is a disclaimer: 'This site is provided as a resource for prescribers and is not intended as medical advice. Information on the site is updated periodically (approximately every 12 hours).' A contact information section follows: 'If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6326, Mon - Fri, 8:30 am - 8:00 pm ET.' The footer contains links for 'Privacy Policy | Terms and Conditions | Contact Us', a disclaimer 'This site is intended for United States residents only.', copyright information '©2019 Genzyme Corporation. All rights reserved.', and the Sanofi Genzyme logo.

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PRESCRIBING INFORMATION
MEDICATION GUIDE

Welcome, Adam!
Menu

! You have 4 patient alerts!

You have **4 patients** who have authorization requirements.

- **1 patient** is overdue for authorization by the LEMTRADA REMS Patient Status Form.
- **3 patients** need to be authorized by the LEMTRADA Patient Status Form in 1 month.

[Manage my patient alert email preferences](#)

LEMTRADA REMS Support Tools

View individual profiles of your LEMTRADA patients and the healthcare facilities they visit. These resources can help you learn more about patients' authorization status, infusion records, and monitoring program activity.

LEMTRADA REMS Support Tools

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	John Doe (123456789)	Authorized
	John Doe (123456789)	Authorized
!	John Doe (123456789)	Baseline Lab Form
	John Doe (123456789)	Authorized
!	John Doe (123456789)	Patient Status Form Baseline Lab Form
	John Doe (123456789)	Authorized

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PRESCRIBING INFORMATION
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LEMTRADA REMS Support Tools

You have 10 LEMTRADA patients ?

Search, sort, and navigate information about your patients below. Click on a form to complete authorization requirements.

Doe (123456789)	Authorized
John Doe (123456789)	Authorized
John Doe (123456789)	Authorized
! John Doe (123456789)	Baseline Lab Form
John Doe (123456789)	Authorized
! John Doe (123456789)	Patient Status Form Baseline Lab Form
John Doe (123456789)	Authorized

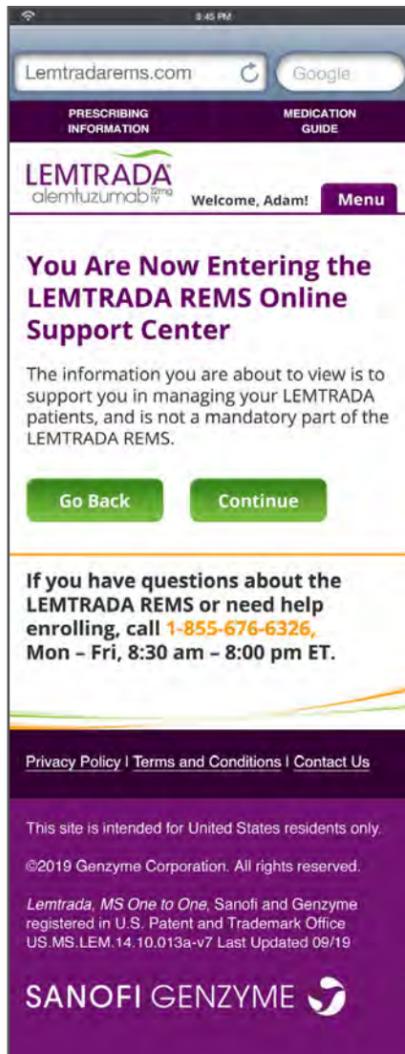
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PRESCRIBING INFORMATION
MEDICATION GUIDE

Welcome, Adam!
Menu

My Profile

Adam Smith

(REMS ID 123456)
 7776 Golden Blossom Run
 Zook, IL 62056-3630
 Office Phone: xxx-xxx-xxxx
 Mobile Phone: xxx-xxx-xxxx
 Fax: xxx-xxx-xxxx

If any of your information is incorrect or has recently changed, please call **1-855-676-6326**, Mon – Fri, 8:30 am – 8:00 pm ET, so we can make the appropriate updates.

Manage My Alert Preferences

Customize how often you would like to receive emails about the status of your LEMTRADA patients. Please note that you will continue to receive important communications from Genzyme, if warranted.

Patient Alert Emails

As part of the LEMTRADA REMS, you will automatically receive emails to update you on the status of your LEMTRADA patients. How often would you like to receive emails regarding patient alert summaries?

- Please provide a monthly summary of alerts
- Please provide a weekly summary of alerts
- Please do not provide a summary of alerts

Update Alert Preferences

Change Your Password

Passwords must be at least 8 characters in length and contain a minimum of 3 out of the following: A number, an upper-case letter, a lower-case letter, a special character (e.g. !, ", #, \$, etc.)

Current Password

New Password

Confirm Password

Change Password

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The screenshot shows a mobile web browser interface for the LEMTRADA REMS mobile application. At the top, there is a navigation bar with 'PRESCRIBING INFORMATION' and 'MEDICATION GUIDE' options. Below this is the LEMTRADA logo and a welcome message 'Welcome, Adam!' with a 'Menu' button. The main content area is titled 'My Profile' and features a dark header with the name 'Adam Smith'. Below the name, the user's REMS ID (123456) and contact information (address, office phone, mobile phone, and fax) are listed. A notice states that if any information is incorrect or recently changed, the user should call 1-855-676-6326. The 'Manage My Alert Preferences' section allows the user to customize email alerts, with three radio button options: 'Please provide a monthly summary of alerts', 'Please provide a weekly summary of alerts' (which is selected), and 'Please do not provide a summary of alerts'. A green 'Update Alert Preferences' button is located below these options. The 'Change Your Password' section includes a warning about password requirements (at least 8 characters, including a number, uppercase letter, lowercase letter, and special character) and three input fields for 'Current Password', 'New Password', and 'Confirm Password', each with a red error message below it. A green 'Change Password' button is at the bottom of this section. A disclaimer states that the site is not intended as medical advice. A call to action for help enrolling is provided, along with contact information. The footer contains links for 'Privacy Policy', 'Terms and Conditions', and 'Contact Us', followed by a copyright notice for Genzyme Corporation and the Sanofi Genzyme logo.

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PRESCRIBING INFORMATION MEDICATION GUIDE

LEMTRADA
alemtuzumab

Welcome, Adam! Menu

My Profile

Adam Smith

(REMS ID 123456)
7776 Golden Blossom Run
Zook, IL 62056-3630
Office Phone: xxx-xxx-xxxx
Mobile Phone: xxx-xxx-xxxx
Fax: xxx-xxx-xxxx

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Customize how often you would like to receive emails about the status of your LEMTRADA patients. Please note that you will continue to receive important communications from Genzyme, if warranted.

Patient Alert Emails

As part of the LEMTRADA REMS, you will automatically receive emails to update you on the status of your LEMTRADA patients. How often would you like to receive emails regarding patient alert summaries?

- Please provide a monthly summary of alerts
- Please provide a weekly summary of alerts
- Please do not provide a summary of alerts

[Update Alert Preferences](#)

Change Your Password

Passwords must be at least 8 characters in length and contain a minimum of 3 out of the following: A number, an upper-case letter, a lower-case letter, a special character (e.g. !, ", #, \$, etc.)

Current Password

Please enter password.

New Password

Please enter valid password.

Confirm Password

Please confirm new password.

[Change Password](#)

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If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6326, Mon - Fri, 8:30 am - 8:00 pm ET.

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The screenshot shows a mobile application interface for LEMTRADA REMS. At the top, there is a navigation bar with 'PRESCRIBING INFORMATION' and 'MEDICATION GUIDE'. Below this is the LEMTRADA logo and a welcome message 'Welcome, Adam!' with a 'Menu' button. The main content area is titled 'My Profile' and features a header for 'Adam Smith' with a '(REMS ID 123456)'. The profile information includes an address in Zook, IL, and placeholder phone and fax numbers. A notice states that if information is incorrect, users should call 1-855-676-6326. Below this is a 'Manage My Alert Preferences' section with three radio button options for alert frequency: monthly, weekly (selected), or no summary. A green 'Update Alert Preferences' button is at the bottom of this section. The next section is 'Change Your Password', which contains three input fields. The first field is labeled 'Current Password' and has a red error message 'Password is incorrect.' below it. The second field is 'New Password' with a red error message 'Password does not meet strength requirements.' The third field is 'Confirm Password' with a red error message 'Passwords do not match.' A green 'Change Password' button is at the bottom of this section. Below the password section is a disclaimer: 'This site is provided as a resource for prescribers and is not intended as medical advice. Information on the site is updated periodically (approximately every 12 hours).' This is followed by contact information: 'If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6326, Mon - Fri, 8:30 am - 8:00 pm ET.' The footer contains links for 'Privacy Policy | Terms and Conditions | Contact Us', a disclaimer 'This site is intended for United States residents only.', copyright information '©2019 Genzyme Corporation. All rights reserved.', and the Sanofi Genzyme logo.

The screenshot displays the mobile app interface for LEMTRADA REMS. At the top, there is a navigation bar with 'PRESCRIBING INFORMATION' and 'MEDICATION GUIDE'. Below this is the LEMTRADA logo and a welcome message 'Welcome, Adam!' with a 'Menu' button. The main content area is titled 'Forms' and 'FAQs'. Under 'Forms', there is a section for 'Required LEMTRADA REMS Forms & Materials' with a sub-header 'Refer to these materials for information about the safe use of LEMTRADA through the LEMTRADA REMS.' A list of links follows, including 'LEMTRADA REMS Program Overview', 'LEMTRADA REMS Education Program for Prescribers', 'LEMTRADA REMS Prescriber Enrollment Form', 'LEMTRADA REMS Patient Authorization and Baseline Lab Form', 'LEMTRADA REMS Patient Enrollment Form', 'LEMTRADA REMS Prescription Ordering Form', 'LEMTRADA REMS Patient Status Form', and 'What You Need to Know About LEMTRADA Treatment and Infusion Reactions: A Patient Guide'. A call to action box at the bottom of the list states: 'If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6326, Mon - Fri, 8:30 am - 8:00 pm ET.' The footer contains links for 'Privacy Policy | Terms and Conditions | Contact Us', a disclaimer 'This site is intended for United States residents only.', copyright information '©2019 Genzyme Corporation. All rights reserved.', and the Sanofi Genzyme logo.

2:45 PM

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PRESCRIBING INFORMATION

MEDICATION GUIDE

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alemtuzumab[®]

Welcome, Adam! Menu

Forms

FAQs

Required LEMTRADA REMS Forms & Materials

Refer to these materials for information about the safe use of LEMTRADA through the LEMTRADA REMS.

[Online](#) | [PDF](#) LEMTRADA REMS Program Overview

[Online](#) | [PDF](#) LEMTRADA REMS Education Program for Prescribers

[PDF](#) LEMTRADA REMS Prescriber Enrollment Form

[Online](#) | [PDF](#) LEMTRADA REMS Patient Authorization and Baseline Lab Form

[PDF](#) LEMTRADA REMS Patient Enrollment Form

[PDF](#) LEMTRADA REMS Prescription Ordering Form

[Online](#) | [PDF](#) LEMTRADA REMS Patient Status Form

[PDF](#) What You Need to Know About LEMTRADA Treatment and Infusion Reactions: A Patient Guide

If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6326, Mon - Fri, 8:30 am - 8:00 pm ET.

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LEMTRADA REMS PATIENT STATUS FORM

This form must be completed every 6 months for each LEMTRADA patient under your care. Please complete this form 6 months after your patient's first infusion with LEMTRADA, and every 6 months thereafter, until 48 months after the patient's last infusion. Please complete the form and submit to Genzyme using the button below.

All fields are required.

PRESCRIBER INFORMATION

First Name

Last Name

Office Phone Number

Address Line 1

Address Line 2

City

State **ZIP Code**

PATIENT INFORMATION

First Name

Last Name

Patient LEMTRADA REMS Identification Number

Date of Birth (MM/DD/YYYY)

Date of Last LEMTRADA Infusion (MM/DD/YYYY)

Is the above-named patient still under your care?
 Yes No

IF YES, please complete the following information

The patient has completed the periodic monitoring within the last 6 months:
 Yes No

Since submitting the last LEMTRADA REMS Patient Status Form, has the patient been diagnosed with any of the following?

Autoimmune conditions
 Yes No

Infusion reactions
 Yes No

Stroke
 Yes No

Malignancies
 Yes No

This adverse event has already been reported to Genzyme (specify date of report):

Report all adverse events to Genzyme Medical Information at 1-800-745-4447 (option 2) or the FDA at 1-800-FDA-1088 (1-800-332-1088) or www.FDA.gov/medwatch

In signing this form, I acknowledge that I have reviewed *What You Need to Know About LEMTRADA Treatment: A Patient Guide* with this patient and counseled the patient about the serious risks associated with the use of LEMTRADA, and how to mitigate these risks through periodic monitoring.

By providing my e-signature, I attest that I have filled out the Patient Status Form to the best of my knowledge. I understand that my e-signature will be used to verify my enrollment in the LEMTRADA REMS.

By entering my name, NPI number, and password, I confirm that I have completed the LEMTRADA REMS training and that I will comply with the requirements of the program.

Full Name

National Provider Identification (NPI) Number

Password

[Cancel](#)

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All fields are required.

PRESCRIBER INFORMATION

First Name

Please enter first name.

Last Name

Please enter last name.

Office Phone Number

Please enter a 10-digit phone number.

Address Line 1

Address Line 2

Please enter address.

City

Please enter city.

State **ZIP Code**
Please select state. Please enter a 5-digit ZIP Code.

PATIENT INFORMATION

First Name

Please enter first name.

Last Name

Please enter last name.

Patient LEMTRADA REMS Identification Number

Please enter LEMTRADA REMS identification number.

Date of Birth (MM/DD/YYYY)

Please enter a valid date of birth.

Date of Last LEMTRADA Infusion (MM/DD/YYYY)

Please enter a valid date.

Is the above-named patient still under your care?

Yes No *Please make a selection.*

IF YES, please complete the following information

The patient has completed the periodic monitoring within the last 6 months:

Yes No *Please make a selection.*

Since submitting the last LEMTRADA REMS Patient Status Form, has the patient been diagnosed with any of the following?

Autoimmune conditions

Yes No *Please make a selection.*

Infusion reactions

Yes No *Please make a selection.*

Stroke

Yes No *Please make a selection.*

Malignancies

Yes No *Please enter valid date.*

This adverse event has already been reported to Genzyme (specify date of report):

Report all adverse events to Genzyme Medical Information at 1-800-745-4447 (option 2) or the FDA at 1-800-FDA-1088 (1-800-332-1088) or www.FDA.gov/medwatch

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By providing my e-signature, I attest that I have filled out the Patient Status Form to the best of my knowledge. I understand that my e-signature will be used to verify my enrollment in the LEMTRADA REMS.

By entering my name, NPI number, and password, I confirm that I have completed the LEMTRADA REMS training and that I will comply with the requirements of the program.

Full Name

Please enter your name.

National Provider Identification (NPI) Number

Please enter a valid NPI number.

Password

Please enter your password.

[Cancel](#)

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All fields are required.

PRESCRIBER INFORMATION

First Name

Last Name

Office Phone Number

Address Line 1

Address Line 2

City

State **ZIP Code**

PATIENT INFORMATION

First Name

Last Name

Patient LEMTRADA REMS Identification Number

Date of Birth (MM/DD/YYYY)

Date of Last LEMTRADA Infusion (MM/DD/YYYY)

Is the above-named patient still under your care?

Yes No

IF NO, please indicate the name of the healthcare provider now responsible for this patient's care.

Healthcare Provider's Name

Healthcare Provider's Phone Number

- OR -

Patient's Current Healthcare Provider Is Unknown

In signing this form, I acknowledge that I have reviewed *What You Need to Know About LEMTRADA Treatment: A Patient Guide* with this patient and counseled the patient about the serious risks associated with the use of LEMTRADA, and how to mitigate these risks through periodic monitoring.

By providing my e-signature, I attest that I have filled out the Patient Status Form to the best of my knowledge. I understand that my e-signature will be used to verify my enrollment in the LEMTRADA REMS.

By entering my name, NPI number, and password, I confirm that I have completed the LEMTRADA REMS training and that I will comply with the requirements of the program.

Full Name

National Provider Identification (NPI) Number

Password

[Cancel](#)

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This form must be completed every 6 months for each LEMTRADA patient under your care. Please complete this form 6 months after your patient's first infusion with LEMTRADA, and every 6 months thereafter, until 48 months after the patient's last infusion. Please complete the form and submit to Genzyme using the button below.

All fields are required.

PRESCRIBER INFORMATION

First Name

Please enter first name.

Last Name

Please enter last name.

Office Phone Number

Please enter a 10-digit phone number.

Address Line 1

Address Line 2

Please enter address.

City

Please enter city.

State **ZIP Code**
Please select state. *Please enter a 5-digit ZIP Code.*

PATIENT INFORMATION

First Name

Please enter first name.

Last Name

Please enter last name.

Patient LEMTRADA REMS Identification Number

Please enter LEMTRADA REMS identification number.

Date of Birth (MM/DD/YYYY)

Please enter a valid date of birth.

Date of Last LEMTRADA Infusion (MM/DD/YYYY)

Please enter a valid date.

Is the above-named patient still under your care?

Yes
 No
 Please make a selection.

IF NO, please indicate the name of the healthcare provider now responsible for this patient's care.

Healthcare Provider's Name

Please enter healthcare provider's name.

Healthcare Provider's Phone Number

Please enter healthcare provider's 10-digit phone number.

- OR -

Patient's Current Healthcare Provider Is Unknown

In signing this form, I acknowledge that I have reviewed *What You Need to Know About LEMTRADA Treatment: A Patient Guide* with this patient and counseled the patient about the serious risks associated with the use of LEMTRADA, and how to mitigate these risks through periodic monitoring.

By providing my e-signature, I attest that I have filled out the Patient Status Form to the best of my knowledge. I understand that my e-signature will be used to verify my enrollment in the LEMTRADA REMS.

By entering my name, NPI number, and password, I confirm that I have completed the LEMTRADA REMS training and that I will comply with the requirements of the program.

Full Name

Please enter your name.

National Provider Identification (NPI) Number

Please enter a valid NPI number.

Password

Please enter your password.

[Cancel](#)
Submit

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LEMTRADA REMS Mobile - Patient Status Form, Confirmation

The screenshot shows a mobile web browser interface for Lemtrada REMS. At the top, there is a search bar with 'Lemtradorems.com' and a 'Google' button. Below the search bar are two tabs: 'PRESCRIBING INFORMATION' and 'MEDICATION GUIDE'. The main content area features the LEMTRADA logo (clemtuzumab) and a personalized greeting 'Welcome, Adam!' with a 'Menu' button. The primary message is 'LEMTRADA REMS Patient Status Form Complete.' followed by instructions to allow 1-2 business days for processing and contact information for questions. A green 'Back' button is provided. Below this is a section for further assistance: 'If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6326, Mon - Fri, 8:30 am - 8:00 pm ET.' The footer contains links for 'Privacy Policy | Terms and Conditions | Contact Us', a disclaimer 'This site is intended for United States residents only.', copyright information '©2019 Genzyme Corporation. All rights reserved.', and the Sanofi Genzyme logo.

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LEMTRADA
clemtuzumab

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LEMTRADA REMS Patient Status Form Complete.

Please allow 1-2 business days for the form to be processed. If you have questions about your form submission, please contact the LEMTRADA REMS at 1-855-676-6326, Mon - Fri, 8:30 am - 8:00 pm ET.

Download a copy of your LEMTRADA REMS Patient Status Form for your records.

Back

If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6326, Mon - Fri, 8:30 am - 8:00 pm ET.

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LEMTRADA REMS PATIENT AUTHORIZATION AND BASELINE LAB FORM

This form must be completed within 30 days prior to the first infusion date of each LEMTRADA patient's treatment course. Please complete the form and submit to Genzyme using the button below.

All fields are required.

PRESCRIBER INFORMATION

First Name

Last Name

Office Phone Number

Address Line 1

Address Line 2

City

State **ZIP Code**

Prescriber LEMTRADA REMS Identification Number

PATIENT INFORMATION

First Name

Last Name

Patient LEMTRADA REMS Identification Number

Date of Birth (MM/DD/YYYY)

AUTHORIZATION AND BASELINE LABS

Do you authorize LEMTRADA treatment for the above-referenced patient?
 Yes No

Do you attest that required baseline laboratory testing has been completed prior to LEMTRADA treatment and within 30 days of the patient's first infusion?
 Yes No

PRESCRIPTION INFORMATION

Select one

Initial course (1 vial [12 mg/day]) X 5 consecutive days
 Total number of vials ordered

Subsequent course (1 vial [12 mg/day]) X 3 consecutive days
 Total number of vials ordered

By providing my e-signature, I attest that I have filled out the Patient Authorization and Baseline Lab Form to the best of my knowledge. I understand that my e-signature will be used to verify my enrollment in the LEMTRADA REMS.

By entering my name, NPI number, and password, I confirm that I have completed the LEMTRADA REMS training and that I will comply with the requirements of the program.

Full Name

National Provider Identification (NPI) Number

Password

[Cancel](#)
Submit

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LEMTRADA REMS PATIENT AUTHORIZATION AND BASELINE LAB FORM

This form must be completed within 30 days prior to the first infusion date of each LEMTRADA patient's treatment course. Please complete the form and submit to Genzyme using the button below.

All fields are required.

PRESCRIBER INFORMATION

First Name

Please enter first name.

Last Name

Please enter last name.

Office Phone Number

Please enter a 10-digit phone number.

Address Line 1

Address Line 2

Please enter address.

City

Please enter city.

State **ZIP Code**
Please select a state. *Please enter a 5-digit ZIP Code.*

Prescriber LEMTRADA REMS Identification Number

Please enter LEMTRADA REMS Identification Number.

PATIENT INFORMATION

First Name

Please enter first name.

Last Name

Please enter last name.

Patient LEMTRADA REMS Identification Number

Please enter LEMTRADA REMS identification number.

Date of Birth (MM/DD/YYYY)

Please enter valid date of birth.

AUTHORIZATION AND BASELINE LABS

Do you authorize LEMTRADA treatment for the above-referenced patient?
 Yes No *Please make a selection.*

Do you attest that required baseline laboratory testing has been completed prior to LEMTRADA treatment and within 30 days of the patient's first infusion?
 Yes No *Please make a selection.*

PRESCRIPTION INFORMATION

Select one
Please make a selection.

Initial course (1 vial [12 mg/day]) X 5 consecutive days
 Total number of vials ordered
Please enter number of vials.

Subsequent course (1 vial [12 mg/day]) X 3 consecutive days
 Total number of vials ordered
Please enter number of vials.

By providing my e-signature, I attest that I have filled out the Patient Authorization and Baseline Lab Form to the best of my knowledge. I understand that my e-signature will be used to verify my enrollment in the LEMTRADA REMS.

By entering my name, NPI number, and password, I confirm that I have completed the LEMTRADA REMS training and that I will comply with the requirements of the program.

Full Name

Please enter your name.

National Provider Identification (NPI) Number

Please enter a valid NPI number.

Password

Please enter a valid password.

Cancel
Submit

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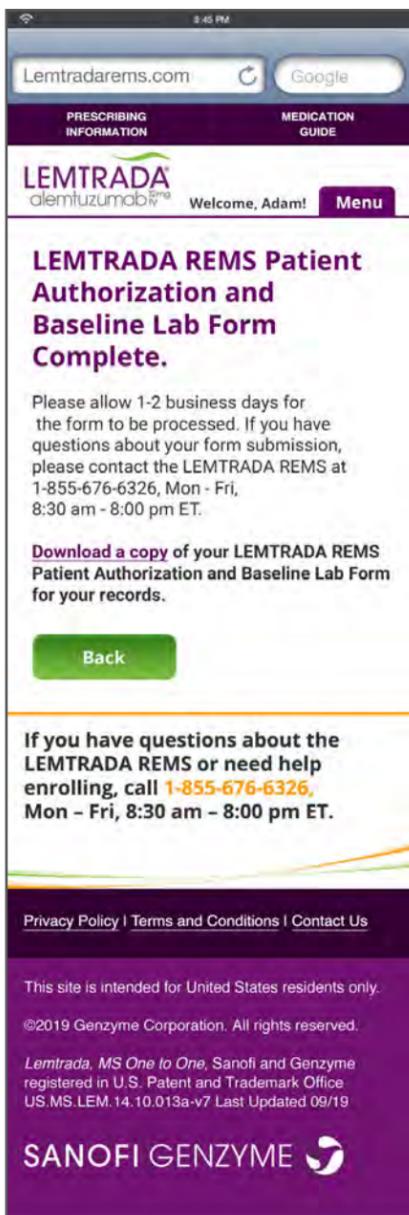
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The screenshot shows the mobile app interface for LEMTRADA REMS. At the top, there is a navigation bar with 'PRESCRIBING INFORMATION' and 'MEDICATION GUIDE'. Below this is the LEMTRADA logo and a welcome message 'Welcome, Adam!' with a 'Menu' button. The main content area has two tabs: 'Forms' and 'FAQs'. The 'FAQs' tab is active, displaying a 'Frequently Asked Questions' section. The text in this section reads: 'Use the following FAQs to answer your questions about the LEMTRADA REMS. If you cannot find an answer to your question, or if you have additional questions, contact a LEMTRADA REMS Specialist at 1-855-676-6326, Mon - Fri, 8:30 am - 8:00 pm.' There is an 'Expand' link below this text. A list of 11 questions follows, with the first question expanded to show its answer. The questions are: 1. How do I add a patient to this website? 2. How can a healthcare facility be added to this portal? 3. How can I find an infusion center for my patients? 4. What is the LEMTRADA REMS Patient Authorization and Baseline Lab Form? 5. What is the LEMTRADA REMS Patient Status Form? 6. Why do I have an alert that my patient is "Not REMS Authorized"? 7. What are Patient Alerts and how do I view them? 8. How can I change the frequency of Patient Alert emails? 9. How can I access my profile? 10. How can I update contact information on this site? 11. How do I reset my password? Below the list is a call to action: 'If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6326, Mon - Fri, 8:30 am - 8:00 pm ET.' At the bottom, there are links for 'Privacy Policy | Terms and Conditions | Contact Us', a disclaimer 'This site is intended for United States residents only.', copyright information '©2019 Genzyme Corporation. All rights reserved.', and the Sanofi Genzyme logo.

LEMTRADA
alemtuzumab

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Forms FAQs

Frequently Asked Questions

Use the following FAQs to answer your questions about the LEMTRADA REMS. If you cannot find an answer to your question, or if you have additional questions, contact a LEMTRADA REMS Specialist at 1-855-676-6326, Mon - Fri, 8:30 am - 8:00 pm.

[Expand](#)

1. How do I add a patient to this website?

This site displays information about patients enrolled in the LEMTRADA REMS. REMS certified prescribers can enroll new patients in the LEMTRADA REMS by submitting a completed LEMTRADA Patient Enrollment Form to Genzyme. A PDF of the LEMTRADA Patient Enrollment Form is available in the [Forms & FAQs](#) section. Once patients are enrolled in the program, their information will be available.

Please contact the LEMTRADA REMS at 1-855-676-6326 if you have questions about the enrollment process or if an enrolled patient's information is missing or incorrect.

2. How can a healthcare facility be added to this portal?

3. How can I find an infusion center for my patients?

4. What is the LEMTRADA REMS Patient Authorization and Baseline Lab Form?

5. What is the LEMTRADA REMS Patient Status Form?

6. Why do I have an alert that my patient is "Not REMS Authorized"?

7. What are Patient Alerts and how do I view them?

8. How can I change the frequency of Patient Alert emails?

9. How can I access my profile?

10. How can I update contact information on this site?

11. How do I reset my password?

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Forms FAQs

Frequently Asked Questions

Use the following FAQs to answer your questions about the LEMTRADA REMS. If you cannot find an answer to your question, or if you have additional questions, contact a LEMTRADA REMS Specialist at 1-855-676-6326, Mon – Fri, 8:30 am – 8:00 pm.

[Collapse](#)

1. How do I add a patient to this website?

This site displays information about patients enrolled in the LEMTRADA REMS. REMS certified prescribers can enroll new patients in the LEMTRADA REMS by submitting a completed LEMTRADA Patient Enrollment Form to Genzyme. A PDF of the LEMTRADA Patient Enrollment Form is available in the **Forms & FAQs** section. Once patients are enrolled in the program, their information will be available.

Please contact the LEMTRADA REMS at 1-855-676-6326 if you have questions about the enrollment process or if an enrolled patient's information is missing or incorrect.

2. How can a healthcare facility be added to this portal?

An authorized representative of the healthcare facility must register with the LEMTRADA REMS Training Center. After registration, the representative must review the *LEMTRADA REMS Education Program for Healthcare Facilities*, complete the online module, complete and sign the LEMTRADA REMS Healthcare Facility Enrollment Form, and implement the necessary staff training and processes.

For further information, contact a LEMTRADA REMS Specialist at 1-855-676-6326.

3. How can I find an infusion center for my patients?

Use the **REMS Certified Prescriber & Healthcare Facility Locator** to find infusion centers and healthcare facilities for your patients. You can search by state, address, or ZIP Code to find a center that is certified by the LEMTRADA REMS to dispense/administer LEMTRADA. You can also contact the LEMTRADA REMS at 1-855-676-6326 to speak with a LEMTRADA REMS Specialist.

4. What is the LEMTRADA REMS Patient Authorization and Baseline Lab Form?

The LEMTRADA REMS Patient Authorization and Baseline Lab Form is a **mandatory form** that must be filled out within 30 days prior to the first infusion date of each LEMTRADA patient's treatment course. The form can be found in the **Forms** section.

5. What is the LEMTRADA REMS Patient Status Form?

The LEMTRADA REMS Patient Status Form is a **mandatory form** that must be filled out every 6 months after a patient's first infusion with LEMTRADA, and until 48 months after a patient's final infusion. The form can be found in the **Forms** section.

6. Why do I have an alert that my patient is "Not REMS Authorized"?

Alerts are generated when patients are overdue for authorization by the LEMTRADA REMS Patient Authorization Form and/or the LEMTRADA REMS Patient Status Form. Authorization forms that have not been received by the LEMTRADA REMS are available for submission next to the patient's name.

For more information about why your patient is "Not REMS Authorized," click the link to the **LEMTRADA REMS Support** tools to view the individual Patient Profile page.

7. What are Patient Alerts and how do I view them?

Patient Alerts notify prescribers when a patient is behind on their authorization requirements. You can view a summarized version of all of your Patient Alerts from any page by clicking the **My Patients** tab. To see alerts for a specific patient, click the link to the LEMTRADA REMS Support Tools to view the individual's Patient Profile page.

8. How can I change the frequency of Patient Alert emails?

To change the frequency of Patient Alert emails, first click **My Profile** in the navigation bar. Under the "Manage My Alert Preferences" section, you may choose the new frequency you would like. To complete the change, click the "Update Alert Preferences" button.

9. How can I access my profile?

You can access your profile from any page by clicking on **My Profile** in the top right corner of the site.

10. How can I update contact information on this site?

To update your contact information, contact the LEMTRADA REMS at 1-855-676-6326.

11. How do I reset my password?

To change your password, visit the **My Profile** page and find the "Change Password" section. Enter and confirm a new password. To complete the change, click the "Change Password" button.

If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6326, Mon – Fri, 8:30 am – 8:00 pm ET.

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2:45 PM

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PRESCRIBING INFORMATION
MEDICATION GUIDE

LEMTRADA
alemtuzumab injection
Welcome, Adam!
Menu

REMS Certified Prescriber & Healthcare Facility Locator

Search for prescribers or healthcare facilities that are enrolled and certified in the LEMTRADA REMS and able to prescribe or dispense/administer LEMTRADA.

Please enter street address, city, state, or ZIP Code you would like to search for.

New Search:

Street address, city, state, or ZIP Code 🔍

REMS Certified Prescriber

REMS Certified Healthcare Facilities

📍 Certified Prescriber Name
 Address
 Address
 P. (888) - 888 - 8888

📍 Certified Prescriber Name
 Address
 Address
 P. (888) - 888 - 8888

📍 Certified Prescriber Name
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 Address
 P. (888) - 888 - 8888

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 P. (888) - 888 - 8888

📍 Certified Prescriber Name
 Address
 Address
 P. (888) - 888 - 8888



Genzyme is providing this search feature to help patients find prescribers and healthcare facilities that have been certified by the LEMTRADA REMS. Genzyme does not receive payment for providing this feature, and does not endorse, recommend, have jurisdiction over, or accept responsibility for the actions of any of the prescribers or healthcare facilities listed herein.

If you are a prescriber that would like to request the removal of your contact information from this website, please call the LEMTRADA REMS at 1-855-676-6326.

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MEDICATION GUIDE

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Please enter street address, city, state, or ZIP Code you would like to search for.

New Search:

🔍

REMS Certified Prescriber
REMS Certified Healthcare Facilities

	<p>Certified Center Name Address Address P. (888) - 888 - 8888</p>
	<p>Certified Center Name Address Address P. (888) - 888 - 8888</p>
	<p>Certified Center Name Address Address P. (888) - 888 - 8888</p>
	<p>Certified Center Name Address Address P. (888) - 888 - 8888</p>
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PRESCRIBING INFORMATION MEDICATION GUIDE

LEMTRADA
clemtuzumab^{injection} Welcome, Adam! Menu

REMS Activity Prescriber Enrollment Patient Guides

LEMTRADA REMS Requirements

Welcome to the LEMTRADA REMS. Here you can:

- Retrain and enroll in the LEMTRADA REMS when indicated by a Genzyme representative
- Manage and/or track your progress through the LEMTRADA REMS training and enrollment
- Download materials to help inform your patients about treatment with LEMTRADA

LEMTRADA REMS Activity

Steps	Activity	Progress
1.	Account Registration	Completed
2.	Training	Completed
3.	Assesment Test	Completed
4.	Enrollment Form Submission	Completed
5.	Enrollment Processed	Completed
6.	REMS ID Assigned	Completed

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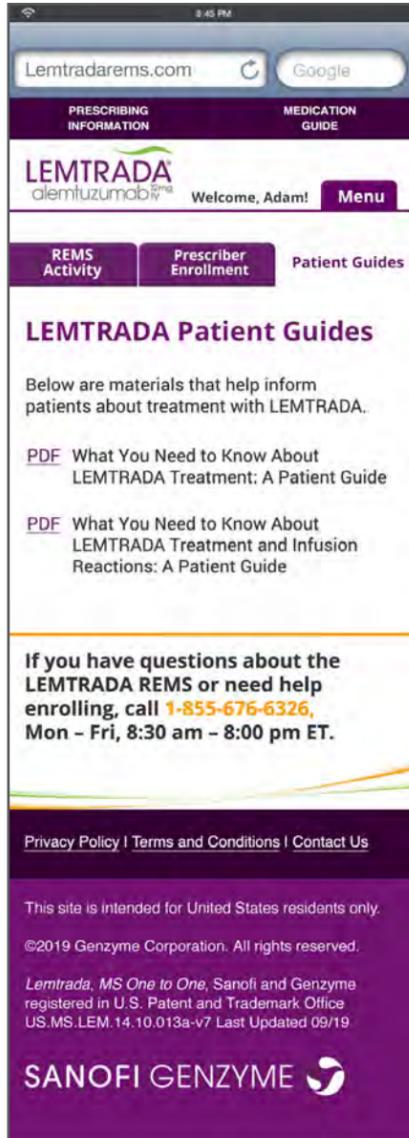
The screenshot shows the mobile app interface for LEMTRADA REMS. At the top, there is a search bar with 'Lemtrada.rems.com' and a Google search button. Below this are navigation tabs for 'PRESCRIBING INFORMATION' and 'MEDICATION GUIDE'. The main header features the LEMTRADA logo, the text 'Welcome, Adam!', and a 'Menu' button. A secondary navigation bar includes 'REMS Activity', 'Prescriber Enrollment' (which is selected), and 'Patient Guides'. The main content area is titled 'LEMTRADA REMS Prescriber Enrollment' and contains the following text:

- Prescribers must be enrolled in the LEMTRADA REMS to be able to prescribe LEMTRADA for patients with relapsing forms of multiple sclerosis (MS). Because of its safety profile, the use of LEMTRADA should generally be reserved for patients who have had an inadequate response to two or more drugs indicated for the treatment of MS.
- Note that your healthcare facility must be separately enrolled in the LEMTRADA REMS to dispense/administer LEMTRADA.

To enroll in the program, prescribers must complete the following steps:

- 1 Register with the LEMTRADA REMS Online Training Center
- 2 Review the LEMTRADA REMS Education Program for Prescribers, including the LEMTRADA REMS Program Overview and the LEMTRADA full Prescribing Information in the online module on this site
- 3 Successfully complete the 8-question Knowledge Assessment at the end of the module
- 4 After completing the assessment, complete and sign the LEMTRADA REMS Prescriber Enrollment Form

Below the list is a green button labeled 'Review Online Training'. At the bottom of the main content area, there is a call to action: 'If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6326, Mon - Fri, 8:30 am - 8:00 pm ET.' The footer contains links for 'Privacy Policy | Terms and Conditions | Contact Us', a disclaimer 'This site is intended for United States residents only.', copyright information '©2019 Genzyme Corporation. All rights reserved.', and the Sanofi Genzyme logo.



BOTH A PRESCRIBER AND HEALTHCARE FACILITY USER

The screenshot shows a mobile application interface for the LEMTRADA REMS program. At the top, there is a navigation bar with 'PRESCRIBING INFORMATION' and 'MEDICATION GUIDE' options. Below this is a header section with the LEMTRADA logo, a 'Prescriber' role indicator, and a 'Welcome, Adam!' message. A 'Menu' button is also present.

The main content area features a section titled 'LEMTRADA REMS Support Tools' with a brief description: 'View individual profiles of your LEMTRADA patients and the healthcare facilities they visit. These resources can help you learn more about patients' authorization status, infusion records, and monitoring program activity.' A green button labeled 'LEMTRADA REMS Support Tools' is positioned below the text.

Below the support tools section, a notification states 'You have 10 LEMTRADA patients' with a question mark icon. This is followed by a table listing patient details and their REMS status.

Patient (REMS ID)	REMS Status
John Doe (123456789)	Authorized

Below the table, a disclaimer states: 'This site is provided as a resource for prescribers and is not intended as medical advice. Information on the site is updated periodically (approximately every 12 hours).' A call to action follows: 'If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6326, Mon - Fri, 8:30 am - 8:00 pm ET.'

The footer contains links for 'Privacy Policy | Terms and Conditions | Contact Us', a note that the site is for United States residents only, copyright information for Genzyme Corporation (©2019), and the Sanofi Genzyme logo.

LEMTRADA REMS MOBILE

REMS Certified Healthcare Facility Pages Only

HEALTHCARE FACILITY TRAINING PAGES

The screenshot shows a mobile browser interface for the LEMTRADA REMS website. At the top, there is a search bar with 'lemtradarems.com' and a 'Google' search button. Below the search bar are two navigation tabs: 'PRESCRIBING INFORMATION' and 'MEDICATION GUIDE'. The LEMTRADA logo is prominently displayed, along with a 'Log In' button and a 'Menu' button. The main heading is 'Registration for LEMTRADA REMS Training'. The text explains that users can register as a prescriber, healthcare facility, or pharmacy. The 'I represent a Healthcare Facility' option is selected. Below this, there is a 'Log In' link for already registered users. A note mentions that certified users should call 1-855-676-6326. At the bottom of the registration section, there are 'Cancel' and 'Next' buttons. A footer section contains links for 'Privacy Policy', 'Terms and Conditions', and 'Contact Us', along with copyright information for Genzyme Corporation and Sanofi Genzyme.

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PRESCRIBING INFORMATION MEDICATION GUIDE

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Log In Menu

Registration for LEMTRADA REMS Training

To register as a new user, select whether you would like to complete enrollment as a prescriber, or authorized representative of a healthcare facility or pharmacy. Enrolled prescribers who would like to enroll their affiliated healthcare facility should also register as a new healthcare facility user.

Select the option which best describes you:

I am a Prescriber

I represent a Healthcare Facility

I represent a Pharmacy

Already Registered? [Log In](#)

If you are already certified by the LEMTRADA REMS, or have recently completed training and have not received your log-in information, please call **1-855-676-6326**.

[Cancel](#) [Next](#)

If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6326, Mon – Fri, 8:30 am – 8:00 pm ET.

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PREScribing INFORMATION MEDICATION GUIDE

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alemtuzumab  [Log In](#) [Menu](#)

Registration Training Enrollment

Healthcare Facility Registration for LEMTRADA REMS Training

To complete your training for the LEMTRADA REMS, please set up an account.

*Required

Email Address*

Create a Password*

Passwords must be at least 8 characters in length and contain a minimum of 3 out of the following: A number, an upper-case letter, a lower-case letter, a special character (e.g. !, ", #, \$, etc.)

Confirm Password*

Name of Institution or Healthcare Facility*

National Provider Identification (NPI) Number*

Infusion Facility Address*

City*

State* **ZIP Code***

Phone Number*

Fax Number*

Site Affiliation*

Ship-to is the same as facility address

Ship-to Address*

City*

State* **ZIP Code***

Name of Authorized Healthcare Facility Representative

First Name*

Last Name*

Title*

*By checking this box, you indicate you will comply with our [terms and conditions](#).

[Cancel](#)

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National Provider Identification (NPI) Number*

Infusion Facility Address*

City*

State* ZIP Code*

- ✓ Select
- Alabama
- Alaska
- American Samoa
- Arizona
- Arkansas
- California
- Colorado
- Connecticut
- Delaware
- District of Columbia
- Florida
- Georgia
- Guam
- Hawaii
- Idaho
- Illinois
- Indiana
- Iowa
- Kansas
- Kentucky
- Louisiana
- Maine
- Maryland
- Massachusetts
- Michigan
- Minnesota
- Mississippi
- Missouri
- Montana
- Nebraska
- Nevada

- Nevada
- New Hampshire
- New Jersey
- New Mexico
- New York
- North Carolina
- North Dakota
- Northern Mariana Islands
- Ohio
- Oklahoma
- Oregon
- Pennsylvania
- Puerto Rico
- Rhode Island
- South Carolina
- South Dakota
- Tennessee
- Texas
- Utah
- Vermont
- Virginia
- Virgin Islands
- Washington
- West Virginia
- Wisconsin
- Wyoming

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PREScribing INFORMATION MEDICATION GUIDE

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Confirm Password*

Name of Institution or Healthcare Facility*

National Provider Identification (NPI) Number*

Infusion Facility Address*

City*

State* **ZIP Code***

Phone Number*

Fax Number*

Site Affiliation*

- Select
- Academic
- Government
- Ambulatory/Free Standing
- Hospital Based
- Private Practice (in office)

State* **ZIP Code***

Name of Authorized Healthcare Facility Representative

First Name*

Last Name*

Title*

*By checking this box, you indicate you will comply with our [terms and conditions](#).

[Cancel](#) [Register](#)

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Log In Menu

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Confirm Password*

Name of Institution or Healthcare Facility*

National Provider Identification (NPI) Number*

Infusion Facility Address*

City*

State* **ZIP Code***

Phone Number*

Fax Number*

Site Affiliation*

Ship-to is the same as facility address

Ship-to Address*

City*

State* **ZIP Code***

- ✓ Select
- Alabama
- Alaska
- American Samoa
- Arizona
- Arkansas
- California
- Colorado
- Connecticut
- Delaware
- District of Columbia
- Florida
- Georgia
- Guam
- Hawaii
- Idaho

- Illinois
- Indiana
- Iowa
- Kansas
- Kentucky
- Louisiana
- Maine
- Maryland
- Massachusetts
- Michigan
- Minnesota
- Mississippi
- Missouri
- Montana
- Nebraska
- Nevada
- New Hampshire
- New Jersey
- New Mexico
- New York
- North Carolina
- North Dakota
- Northern Mariana Islands
- Ohio
- Oklahoma
- Oregon
- Pennsylvania
- Puerto Rico
- Rhode Island
- South Carolina
- South Dakota
- Tennessee
- Texas
- Utah
- Vermont
- Virginia
- Virgin Islands
- Washington
- West Virginia
- Wisconsin
- Wyoming

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alemtuzumab^{lym}

Log In Menu

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Please confirm password.

Name of Institution or Healthcare Facility*

Please enter name of institution or healthcare facility.

National Provider Identification (NPI) Number*

Please enter a valid NPI number.

Infusion Facility Address*

Please enter infusion facility address.

City*

Please enter city.

State* **ZIP Code***

Select One

Please select a state. *Please enter a 5-digit ZIP Code.*

Phone Number*

Please enter a 10-digit phone number.

Fax Number*

Please enter a 10-digit fax number.

Site Affiliation*

Select One

Please select a site affiliation.

Ship-to is the same as facility address

Ship-to Address*

Please enter ship-to address.

City*

Please enter city.

State* **ZIP Code***

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Name of Authorized Healthcare Facility Representative

First Name*

Please enter first name.

Last Name*

Please enter last name.

Title*

Please enter title.

*By checking this box, you indicate you will comply with our [terms and conditions](#).
Terms and conditions not selected.

[Cancel](#) [Register](#)

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Please enter city.

State* **ZIP Code***
Please select a state. Please enter a 5-digit ZIP Code.

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Please enter a 10-digit phone number.

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Please enter a 10-digit fax number.

Site Affiliation*
Please select a site affiliation.

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Terms and conditions not selected.

[Cancel](#) [Register](#)

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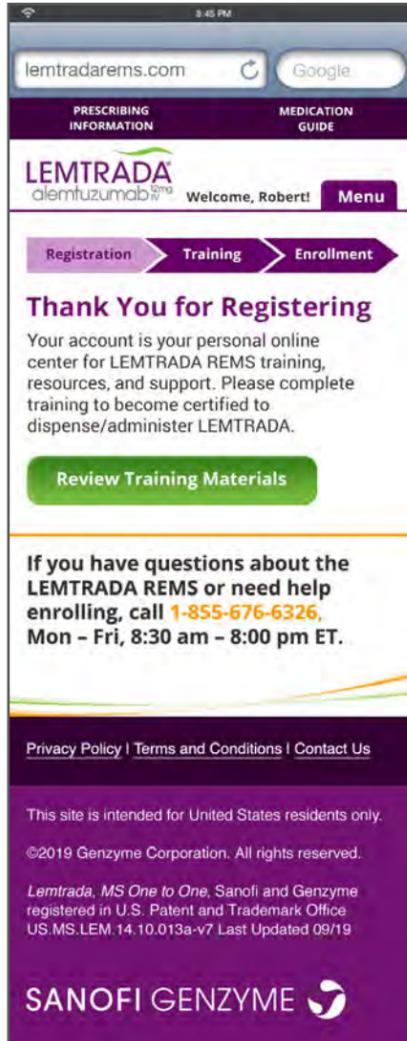
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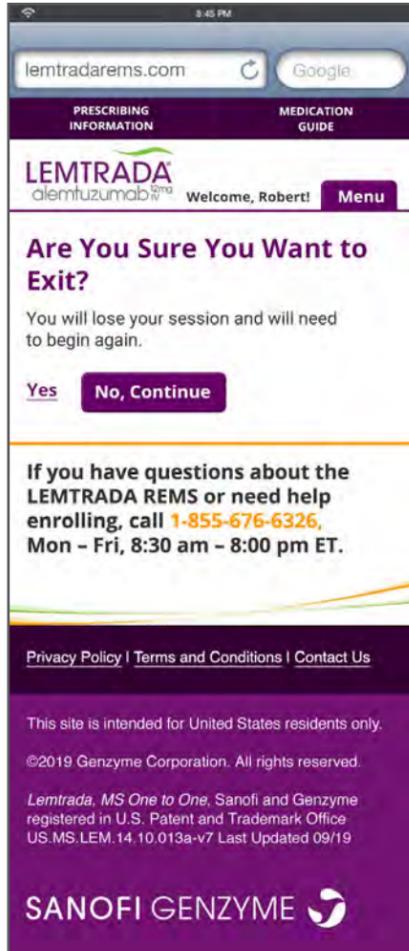
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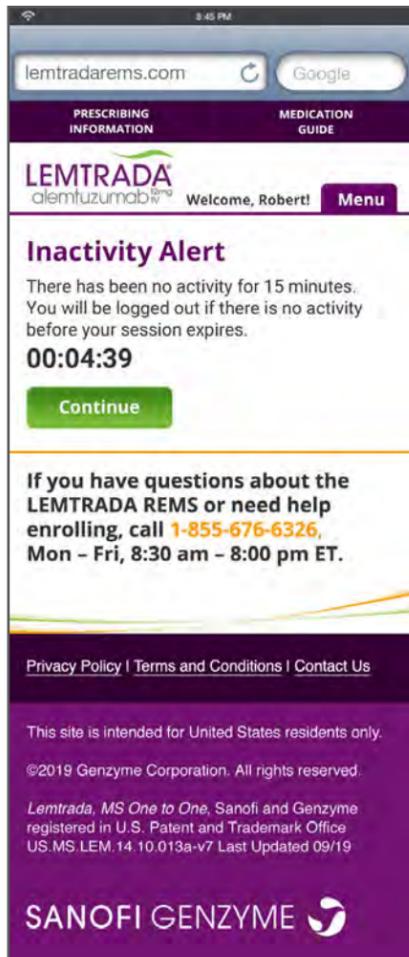
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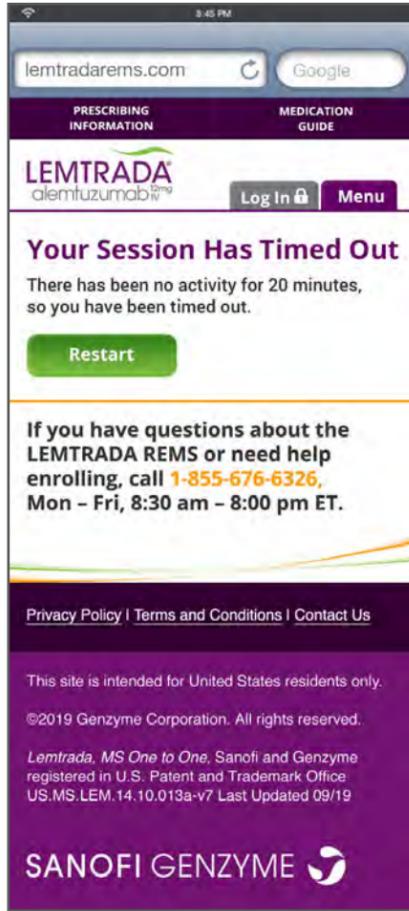
LEMTRADA REMS Mobile - HCF Registration, Confirmation



The screenshot shows a mobile web browser interface for the LEMTRADA REMS Online Training Module. At the top, there is a search bar with 'lemtradarems.com' and a Google logo. Below the search bar are two tabs: 'PRESCRIBING INFORMATION' and 'MEDICATION GUIDE'. The main header features the LEMTRADA logo (with 'alemtuzumab' below it), a 'Welcome, Robert!' message, and a 'Menu' button. A navigation bar below the header has three buttons: 'Registration', 'Training' (which is highlighted), and 'Enrollment'. The main content area is titled 'LEMTRADA REMS Online Training Module' and contains a warning: 'If inactive on the training module for 20 minutes, you will be automatically logged off the LEMTRADA website and lose your training progress.' This is followed by three bullet points: 1) 'Please review the LEMTRADA REMS Training Materials, including the LEMTRADA REMS Program Overview, and the LEMTRADA REMS Education Program for Healthcare Facilities. You may review the material at your own pace and go back to any point of the presentation at your discretion.' 2) 'After reviewing the material in the module, you will be asked to review and sign the LEMTRADA REMS Healthcare Facility Enrollment Form to complete your enrollment.' 3) 'All staff at your site who will be involved with the dispensing/administration of LEMTRADA must be trained on the information in the module and adhere to the requirements of the LEMTRADA REMS.' Below the bullet points is a paragraph: 'Online training will take approximately 20 minutes. Please allow enough time to view the entire module. You will be automatically logged out after 20 minutes of inactivity and your training progress may be lost.' A green 'Continue' button is positioned below this text. At the bottom of the main content area, there is a call to action: 'If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6326, Mon - Fri, 8:30 am - 8:00 pm ET.' The footer contains links for 'Privacy Policy | Terms and Conditions | Contact Us', a disclaimer 'This site is intended for United States residents only.', copyright information '©2019 Genzyme Corporation. All rights reserved.', and a note 'Lemtrada, MS One to One, Sanofi and Genzyme registered in U.S. Patent and Trademark Office US.MS.LEM.14.10.013a-v7 Last Updated 09/19'. The Sanofi Genzyme logo is at the very bottom.







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LEMTRADA REMS Training

LEMTRADA REMS Program Overview (1 of 2)
Total Training Screens: 1 of 10

LEMTRADA LEMTRADA REMS PROGRAM OVERVIEW

What is the LEMTRADA REMS (Risk Evaluation and Mitigation Strategy)?
A REMS is a strategy to manage known or potential risks associated with a drug. It is required by the FDA to ensure that the benefits of the drug outweigh its risks. Due to serious risks of autoimmune conditions, including multiple sclerosis and myasthenia, LEMTRADA (alemtuzumab) is only available through a restricted program called the LEMTRADA REMS.

LEMTRADA REMS Requirements

- Prescribers must be enrolled in the LEMTRADA REMS to be able to prescribe LEMTRADA.
- Pharmacies must be enrolled in the LEMTRADA REMS to be able to dispense LEMTRADA.
- Healthcare Facilities must be enrolled in the LEMTRADA REMS to be able to dispense and administer LEMTRADA.
- Patients must be enrolled and authorized in the LEMTRADA REMS to receive LEMTRADA.

PRESCRIBER ENROLLMENT INSTRUCTIONS

- Complete the training program, which includes reviewing the following:
 - LEMTRADA prescribing information
 - LEMTRADA REMS Program Overview
 - LEMTRADA REMS Enrollment Form for Prescribers
- Successfully complete the 4-question LEMTRADA REMS knowledge assessment.
- Enroll in the program by completing a LEMTRADA REMS Prescriber Enrollment Form.
- Submit the completed and signed forms to the LEMTRADA REMS.

PHARMACY ENROLLMENT INSTRUCTIONS

- An authorized representative must enroll on behalf of the pharmacy by reviewing the LEMTRADA REMS Program Overview and completing the LEMTRADA REMS Pharmacy Enrollment Form, which acknowledges that the pharmacy agrees to follow the procedures outlined in the LEMTRADA REMS, including:
 - All outreach staff at the pharmacy who will be involved with the dispensing of LEMTRADA must be enrolled and trained.
 - The pharmacy will verify that all LEMTRADA REMS Prescription Ordering Forms is received for each prescription.
 - The pharmacy will verify that prescribers and healthcare facilities are certified and patients are authorized to receive LEMTRADA prior to dispensing LEMTRADA.
 - Enrollment in the LEMTRADA REMS must be renewed every 3 years from annual enrollment.
- Submit the completed and signed LEMTRADA REMS Pharmacy Enrollment Form to the LEMTRADA REMS.

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If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6326, Mon – Fri, 8:30 am – 8:00 pm ET.

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LEMTRADA REMS Training

LEMTRADA REMS Program Overview (2 of 2)

Total Training Screens: 2 of 10

HEALTHCARE FACILITY ENROLLMENT INSTRUCTIONS

1. An authorized representative must enroll on behalf of the healthcare facility by receiving the LEMTRADA REMS Enrollment Form for Prescription Facilities and completing the LEMTRADA REMS Enrollment Form, which contains information that the healthcare facility agrees to follow the procedures outlined in the LEMTRADA REMS, including:
 - All staff of the facility who will be involved with the dispensing and administration of LEMTRADA must be trained, and a written record of all staff REMS training must be kept on file.
 - The healthcare facility will verify that prescribers are certified and patients are authorized to receive LEMTRADA prior to dispensing or administering LEMTRADA.
 - The healthcare facility will provide a copy of what you listed to show about LEMTRADA Treatment and adverse reactions, a Patient Guide to the patient on the first day of each treatment course when LEMTRADA is dispensed.
 - The healthcare facility will complete a LEMTRADA REMS Incident Checklist for each patient at the conclusion of each treatment course and submit it to the LEMTRADA REMS within 1 business day.
 - Enrollment in the LEMTRADA REMS must be renewed every 2 years from initial enrollment.
2. Submit the completed and signed LEMTRADA REMS Healthcare Facility Enrollment Form to the LEMTRADA REMS.

PATIENT ENROLLMENT INSTRUCTIONS

1. Complete the LEMTRADA REMS Patient Enrollment Form, which contains information to be completed by both the provider and the patient.
2. Provide a copy of what you listed to show about LEMTRADA Treatment, a Patient Guide and a LEMTRADA REMS Safety Information Card to each patient who will receive LEMTRADA. You must also make the patient read about LEMTRADA Treatment, a Patient Guide to ensure your patients fully understand the risks and REMS requirements with the use of LEMTRADA.
3. Submit the completed and signed LEMTRADA REMS Patient Enrollment Form to the LEMTRADA REMS.
4. Provide the patient with a copy of the LEMTRADA REMS Patient Enrollment Form and keep a copy in the patient's medical record.

Where to Find REMS Information and Resources
Go to [www.lemtradarems.com](#) or call 1-855-676-6326. For information related to enrollment in the LEMTRADA REMS, call 1-855-676-6326 or visit [www.lemtradarems.com](#).

Indications and Usage
LEMTRADA is indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include relapsing remitting disease and all the secondary progressive disease, in adults. Because of its safety profile, the use of LEMTRADA should generally be reserved for patients who have had an inadequate response to one or more drugs indicated for the treatment of MS.

Limitations of Use
LEMTRADA is not recommended for use in patients with clinically relevant syndrome (SJS) because of its safety profile. The Prescribing Information includes a **BOXED WARNING** for LEMTRADA.
Please see accompanying Prescribing Information for complete safety information, including BOXED WARNING.

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VV-REG-0833078 0.1

Reference ID: 4512344

The screenshot displays the mobile interface of the LEMTRADA REMS application. At the top, there is a browser address bar showing 'lemtradorems.com' and a search bar with 'Google'. Below this is a navigation bar with 'PRESCRIBING INFORMATION' and 'MEDICATION GUIDE'. The main header features the LEMTRADA logo (alemfuzumab^{120mg}), a personalized greeting 'Welcome, Robert!', and a 'Menu' button. A progress indicator shows three steps: 'Registration', 'Training' (the current step), and 'Enrollment'. The main content area is titled 'LEMTRADA REMS Training' and includes the text 'LEMTRADA REMS Education Program for Healthcare Facilities (1 of 8)' and 'Total Training Screens: 3 of 10'. A large image shows the cover of the educational piece, which includes the title 'LEMTRADA REMS Education Program for Healthcare Facilities' and a list of topics: 'The LEMTRADA REMS requirements to implement in your healthcare facility', 'Serious risks of adverse reactions, infusion reactions, under and malignancy', and 'Proper administration of LEMTRADA[®] alemfuzumab'. Below the image are 'Previous' and 'Next' buttons, and a '(3 of 10)' indicator. A call-to-action box states: 'If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6326, Mon - Fri, 8:30 am - 8:00 pm ET.' The footer contains links for 'Privacy Policy | Terms and Conditions | Contact Us', a disclaimer 'This site is intended for United States residents only.', copyright information '©2019 Genzyme Corporation. All rights reserved.', and the Sanofi Genzyme logo.

The screenshot displays the LEMTRADA REMS mobile application interface. At the top, there is a navigation bar with 'PRESCRIBING INFORMATION' and 'MEDICATION GUIDE'. Below this is the LEMTRADA logo and a personalized greeting 'Welcome, Robert!' with a 'Menu' button. A progress indicator shows 'Registration' (completed), 'Training' (current), and 'Enrollment' (upcoming). The main heading is 'LEMTRADA REMS Training' with a subtitle 'LEMTRADA REMS Education Program for Healthcare Facilities (2 of 8)' and 'Total Training Screens: 4 of 10'. The content area features a section titled 'What is the LEMTRADA REMS (Risk Evaluation and Mitigation Strategy)?' with a detailed paragraph and a bulleted list of requirements for prescribers, pharmacists, healthcare facilities, and patients. Below this is a 'STEPS FOR HEALTHCARE FACILITY CERTIFICATION' section with a numbered list of four steps. At the bottom of the content area, there are 'Previous' and 'Next' buttons and a '(4 of 10)' indicator. A call-to-action box below the content area reads: 'If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6326, Mon - Fri, 8:30 am - 8:00 pm ET.' The footer contains links for 'Privacy Policy | Terms and Conditions | Contact Us', a disclaimer 'This site is intended for United States residents only.', copyright information '©2019 Genzyme Corporation. All rights reserved.', and the Sanofi Genzyme logo.

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LEMTRADA REMS Training

LEMTRADA REMS Education Program for Healthcare Facilities (3 of 8)

Total Training Screens: 5 of 10

Who Can Be An Authorized Representative?

An authorized representative of the healthcare facility can be:

- Pharmacist
- Director of infusion center
- Pharmacist
- Nurse
- On-site responsible individual in the healthcare facility

Please check with your manager to ensure the appropriate person represents the healthcare facility. All persons in the enrollment requirements as stated on the LEMTRADA REMS Healthcare Facility Enrollment Form.

- One representative needs to enroll per healthcare facility (an "authorized representative"). One authorized representative can enroll more than one healthcare facility.
- Please note, there are no LEMTRADA REMS requirements for staff at a healthcare facility who will not be involved with dispensing or administering LEMTRADA.

Overview of Important Safety Information

INDICATION AND USAGE

LEMTRADA is indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include relapsing-remitting disease and active secondary progressive disease, in adults. Because of its safety profile, the use of LEMTRADA should generally be reserved for patients who have had an inadequate response to one or more drugs indicated for the treatment of MS.

Limitations of Use

LEMTRADA is not recommended for use in patients with clinically isolated syndrome (CIS) because of its safety profile.

The Prescribing Information includes a **BOXED WARNING** for LEMTRADA.

Please see the Prescribing Information for complete safety information, including **BOXED WARNING**.

SERIOUS RISKS ASSOCIATED WITH LEMTRADA

Infusion Reactions

Most patients treated with LEMTRADA in controlled clinical trials in MS experienced infusion reactions during or after LEMTRADA administration. Some of these reactions were serious and life-threatening. In some patients, infusion reactions were reported more than 24 hours after LEMTRADA infusion. Serious reactions occurred in 3% of patients, including cases of angioedema in 7 patients (including angioedema throat, angioedema, bronchospasm, hypotension, chest pain, bradycardia, tachycardia including atrial fibrillation, transient myocardial infarction, hypertension, headache, syncope, and rash). Other infusion reactions included nausea, vertigo, anaphylaxis, insomnia, chills, flushing, fatigue, dizziness, pulmonary infiltration, dyspnea, dysphagia, edema, and pain. In clinical studies, 34% of patients with infusion reactions received epinephrine or atropine. Cases of pulmonary alveolar hemorrhage and myocardial infarction have been reported with chest pain at hours of LEMTRADA infusion.

Premedicate patients with high-dose corticosteroids (1000 mg of methylprednisolone or equivalent) immediately prior to LEMTRADA infusion for the first 3 days of each 6-month course. Consider premedication with antihistamines and/or antipyretics prior to LEMTRADA administration. Infusion reactions may occur in patients despite premedication.

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LEMTRADA REMS Education Program for Healthcare Facilities (4 of 8)

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Consider additional monitoring to patients with medical conditions which predispose them to cardiovascular or pulmonary complications. Physicians should alert patients that an infusion reaction could occur within 48 hours of infusion.

LEMTRADA can only be administered to certified healthcare settings that have on-site access to emergency and personnel trained to manage infusion reactions (including anaphylaxis and cardiac and respiratory arrest/monitoring).

Patients must be observed for infusion reactions during and for at least 2 hours after each LEMTRADA infusion. Consider longer periods of observation if clinically indicated. Vital signs should be monitored before and periodically during the infusion. If an infusion reaction occurs, appropriate symptomatic treatment should be provided as needed. If the infusion is not well tolerated, the duration of the infusion may be restricted. If severe infusion reactions occur, immediate discontinuation of the infusion should be considered.

Stroke and Cervicocranial Arterial Dissection

Stroke
 In the postmarketing setting, ischemic and hemorrhagic stroke (including ischemic and hemorrhagic stroke) has been reported within 3 days of LEMTRADA administration, with most cases occurring within 1 day.

Cervicocranial Arterial Dissection
 In the postmarketing setting, cases of cervicocranial (i.e., vertebral, carotid) arterial dissection leading to major strokes have been reported within 3 days of LEMTRADA administration. Arterial stroke was reported in one of these cases.

Educate patients on the symptoms of stroke and cervicocranial (i.e., carotid, vertebral) arterial dissection. Instruct patients to seek immediate medical attention if symptoms of stroke or cervicocranial arterial dissection occur.

Autoimmune Conditions
 LEMTRADA has been associated with risk of autoimmune conditions, including immune thrombocytopenia, other cytopenias (including neutropenia, hemolytic anemia, and pancytopenia), thyroid disorders, and glomerular nephropathy, which may occur many years after treatment and may be serious or life threatening. Early detection and prompt treatment can help prevent serious and potentially fatal outcomes associated with these events.

Please review the sections that follow to gain a better understanding of the risks of autoimmune conditions.

Immune Thrombocytopenia (ITP)
 Immune thrombocytopenia (ITP) is an autoimmune disorder usually associated with anti-platelet antibodies.

Partial condition reflects the ability of the blood to clot.

ITP was reported in 2% of patients in clinical trials in which ITP was not a serious condition leading to mortality and morbidity, and may occur many years after therapy. Physicians are required to monitor all patients for ITP by obtaining complete blood counts with differential 130 days prior to initiation of treatment and at weekly intervals thereafter until 60 months after the patient's last infusion of LEMTRADA. After this period of time, testing should be performed based on clinical findings suggestive of ITP. Patients should also be monitored for clinical symptoms of ITP. Symptoms of ITP could include bruising and/or bleeding from easy bruising, petechiae, spontaneous mucous membrane bleeding (epistaxis, hemoptysis), and heavy menstrual or

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LEMTRADA REMS Education Program for Healthcare Facilities (6 of 8)
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Initiation of treatment. Obtain serum creatinine levels and urinalysis with cell counts at monthly intervals. Repeat serum creatinine and urinalysis after the period of time, testing should be performed based on clinical finding suggestive of nephropathy.

Thyroid Disorders
Thyroid endocrine disorders, including autoimmune thyroid disorders occurred in 3.8% of LEMTRADA-treated patients in clinical studies (controlled and open-label extensions). Newly diagnosed thyroid disorders occurred throughout the uncontrolled clinical study follow-up period, more than 7 years after the first LEMTRADA dose. Serious thyroid disorders occurred in 5.2% of patients. Prescribers are required to monitor all patients for thyroid disorders by obtaining thyroid function tests, such as thyroid-stimulating hormone (TSH) levels 120 days prior to the first infusion of LEMTRADA, and then 12 months thereafter (containing well 48 months) following the first infusion. Continue to test thyroid function after 48 months if clinically indicated. Prescribers should also monitor for signs and symptoms of thyroid disorders, which may include excessive sweating, unexplained weight loss, night sweating, nervousness and fast heartbeat (tachycardia), or unexplained weight gain, feeling cold, worsening constipation, and newly occurring constipation (hypothyroidism).

Adverse Hepatitis
Adverse hepatitis causing clinically significant liver injury, including acute liver failure requiring transplant, has been reported in patients treated with LEMTRADA in the postmarketing period. If a patient develops clinical signs, including unexplained liver enzyme elevations or symptoms suggestive of hepatic dysfunction (e.g., unexplained fatigue, weakness, abdominal pain, fever, anorexia, or jaundice) and/or dark urine, prescribers should promptly measure serum transaminases and total bilirubin and interrupt or discontinue treatment with LEMTRADA, as appropriate.

Prior to starting treatment with LEMTRADA, prescribers are to obtain serum transaminases (ALT and AST) and total bilirubin levels. Prescribers should obtain transaminase levels and total bilirubin levels periodically until 48 months after the last dose.

Malignancies
LEMTRADA may increase the risk of thyroid cancer. Patients and prescribers should monitor for symptoms of thyroid cancer, including a swelling or lump in the neck, pain in the front of the neck, persistent hoarseness or other voice changes, trouble swallowing or breathing, or a constant cough not due to an upper respiratory tract infection.
LEMTRADA may increase the risk of melanoma. Prescribers should perform baseline and yearly skin examinations to monitor for melanoma in patients receiving LEMTRADA. Cases of lymphoproliferative disorder and pneumonia have occurred in LEMTRADA-treated patients with risk.

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LEMTRADA REMS Training

LEMTRADA REMS Education Program for Healthcare Facilities (7 of 8)
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Strategies to Implement in Your Healthcare Facility to Mitigate Risk of Infusion Reactions

- Ensure the infusion site is equipped with the necessary equipment and personnel to manage infusion reactions (including anaphylaxis and cardiac and respiratory emergencies).
- Pre-medicate patients with high-dose corticosteroids (100 mg of methylprednisolone or equivalent) immediately prior to LEMTRADA infusion for the first 3 days of each LEMTRADA treatment course. Consider pre-medication with antihistamines and/or antipyretics prior to LEMTRADA administration. Infusion reactions may occur despite pre-medication.
- Observe patients for infusion reactions during and for at least 2 hours after each LEMTRADA infusion.
- Consider longer periods of observation if clinically indicated. Monitor vital signs before and periodically during the infusion.
- Provide appropriate symptomatic treatment as needed if an infusion reaction occurs.
- Consider extending the duration of the infusion if the infusion is not well tolerated.
- Consider immediate discontinuation of the infusion if severe infusion reactions occur.
- Do not administer LEMTRADA outside of the authorized representative's certified healthcare facility.

Proper Storage and Administration

STORAGE OF LEMTRADA

- LEMTRADA is packaged in 10 mg/1.2 mL (10 mg/mL) single-use vials.
- LEMTRADA vials should be stored at 2° to 8° C (36° to 46° F). Do not freeze or shake. Protect from light.

PRIOR TO EACH TREATMENT COURSE OF LEMTRADA

- Confirm pre-medication is completed and patients are enrolling and authorized to receive LEMTRADA.
- Check each patient **ABOUT** the risk for infusion reactions.
- Provide the patient with what you need to know about LEMTRADA treatment and infusion reactions: a Patient Guide prior to receiving LEMTRADA.
- Administer corticosteroids immediately prior to LEMTRADA administration for the first 3 days of each treatment course.
- Ensure vital prophylaxis for herpes infection is available or has been prescribed to start on the first day of each treatment course. Consider pre-treating patients with antihistamines and/or antipyretics prior to LEMTRADA administration as needed.
- Monitor vital signs before and periodically during the infusion.

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LEMTRADA REMS Training

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ADMINISTRATION OF LEMTRADA

1. Inspect vial for particulate matter (microscopic or visible).
2. Withdraw 1.2 mL of LEMTRADA from the vial into a syringe using aseptic technique.
3. Inject into 100 mL, sterile 0.9% Sodium Chloride, USP or 5% Dextrose in Water, USP. Gently invert the bag to mix the solution.
4. Cover IV solution bag to protect from light.
5. Administer 12 mg/day over approximately 4 hours.
6. Do not administer as IV push or bolus.
7. If infusion is not well tolerated, infusion duration may be extended.
8. Use the LEMTRADA diluted product within 8 hours after dilution. LEMTRADA diluted product may be stored at room temperature (15° to 25° C) or refrigerated conditions (2° to 8° C). Protect from light. Do not administer as IV push or bolus.
9. Monitor patient vital signs before and periodically during the infusion, and provide appropriate symptomatic treatments for adverse reactions as needed.
10. Monitor patients for at least 2 hours after each LEMTRADA infusion or longer if clinically indicated.

FOLLOWING THE CONCLUSION OF EACH LEMTRADA TREATMENT COURSE

1. Complete a LEMTRADA REMS Infection Checklist for each patient at the conclusion of each treatment course and fax (1-855-676-6326) to the LEMTRADA REMS or submit online at www.lemtradarems.com within 3 Business Days of the last infusion.
2. Return unused vials of LEMTRADA to Genzyme within 30 days of receipt of the LEMTRADA REMS Patient Authorization and Reuseable Lab Form.

Adverse Event Reporting
Report suspected adverse events to Genzyme Medical Information at 1-800-745-4447 (option 2) or to FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

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If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6326, Mon – Fri, 8:30 am – 8:00 pm ET.

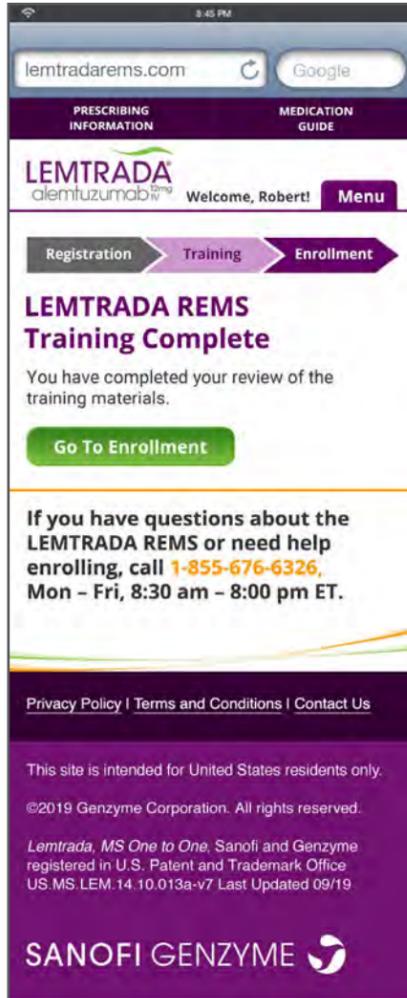
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Registration Training Enrollment

LEMTRADA REMS HEALTHCARE FACILITY ENROLLMENT FORM

LEMTRADA is only available through the LEMTRADA REMS, a restricted distribution program. Only prescribers, pharmacies, healthcare facilities, and patients enrolled in the program are able to prescribe, dispense, administer, and receive LEMTRADA. An authorized representative of the healthcare facility must enroll the facility in the LEMTRADA REMS.

Please review the following information and submit to Genzyme by clicking the button below. Complete any missing information and correct any errors prior to submission. All fields are required.

HEALTHCARE FACILITY INFORMATION

Name of Institution or Healthcare Facility

National Provider Identification (NPI) Number

Infusion Facility Address

City

State

ZIP Code

Phone Number

Fax Number

Site Affiliation

Ship-to is the same as facility address

Ship-to Address

City

State

ZIP Code

Name of Authorized Healthcare Facility Representative

First Name

Last Name

Email Address

Title

HEALTHCARE FACILITY AGREEMENT

I am the authorized representative designated by my healthcare facility to coordinate the activities of the LEMTRADA REMS. By signing this form, I agree to comply with the following requirements:

- I understand that my healthcare facility must be certified with the LEMTRADA REMS to receive or administer LEMTRADA.
- I have completed the review of the *LEMTRADA REMS Education Program for Healthcare Facilities* and the LEMTRADA REMS Program Overview.
- I understand that my healthcare facility must confirm that the patient is authorized to receive LEMTRADA by contacting the LEMTRADA REMS or verifying online at www.LemtradaREMS.com prior to initiation of each treatment course.
- I understand the risk of serious infusion reactions during and following the administration of LEMTRADA.
- I understand the risk of stroke during and following the administration of LEMTRADA.
- I understand the need to monitor patients for infusion reactions during and for at least 2 hours after each LEMTRADA infusion.
 - To include the monitoring of patient vital signs before the infusion and periodically during the infusion.
- I understand that my healthcare facility must be equipped with the necessary on-site equipment and personnel to manage anaphylaxis or serious infusion reactions.
- I understand that my healthcare facility must renew enrollment in the LEMTRADA REMS every 2 years from initial enrollment.
- This healthcare facility will establish procedures and protocols that are subject to audit, to help ensure compliance with the safe use conditions required in the LEMTRADA REMS, including the following:
 - Ensure that a LEMTRADA REMS Prescription Ordering Form is received for each prescription.
 - Ensure that the prescriber is certified and the patient is enrolled and authorized by either calling the LEMTRADA REMS or verifying this information via the LEMTRADA REMS website prior to dispensing and administering LEMTRADA.
 - Ensure that the infusion site is equipped to manage infusion reactions.
 - Ensure that LEMTRADA is not dispensed outside of the authorized representative's certified healthcare facility.
 - Prior to the first day of each treatment course, counsel and provide a copy of *What You Need to Know About LEMTRADA Treatment and Infusion Reactions: A Patient Guide* to each patient to inform them about the risk of serious infusion reactions.
 - Observe each patient administered LEMTRADA at my healthcare facility during and for at least 2 hours after each LEMTRADA infusion, in order to provide appropriate medical treatment in the event of serious infusion reactions following LEMTRADA infusion.
 - For each patient, complete and return the LEMTRADA REMS Infusion Checklist to the LEMTRADA REMS within 5 business days from the patient's last infusion of LEMTRADA within a specific treatment course.
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 - To make available to Genzyme documentation to verify understanding of, and adherence to, the requirements of the LEMTRADA REMS.
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 - To ensure that all non-prescribing HCPs who administer LEMTRADA in my healthcare setting are trained using the LEMTRADA REMS Program Overview and the *LEMTRADA REMS Education Program for Healthcare Facilities*, and a record regarding such training must be maintained.

I have verified that all details are correct.

By providing my e-signature, I acknowledge that I have completed the

educational training required for LEMTRADA for healthcare facilities and I understand the benefits and risks of LEMTRADA. I acknowledge that all staff members from my site must be trained on the information in the module and adhere to the requirements of the LEMTRADA REMS.

I understand that I must complete this LEMTRADA REMS Healthcare Facility Enrollment Form in order to complete this enrollment process.

By entering my name, NPI number, and password, I confirm that I have completed the LEMTRADA REMS training and that I will comply with the requirements of the program.

Full Name

NPI Number

Password

[Cancel](#) Submit

If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6326, Mon - Fri, 8:30 am - 8:00 pm ET.

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Registration Training Enrollment

LEMTRADA REMS HEALTHCARE FACILITY ENROLLMENT FORM

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HEALTHCARE FACILITY INFORMATION

Name of Institution or Healthcare Facility
Extrophy Institute

National Provider Identification (NPI) Number
0123456789

Infusion Facility Address
43 Eleanor St

City
Los Angeles

State

- Select
- Alabama
- Alaska
- American Samoa
- Arizona
- Arkansas
- California
- Colorado
- Connecticut
- Delaware
- District of Columbia
- Florida
- Georgia
- Guam
- Hawaii
- Idaho
- Illinois
- Indiana
- Iowa
- Kansas
- Kentucky
- Louisiana
- Maine
- Maryland
- Massachusetts
- Michigan
- Minnesota
- Mississippi
- Missouri
- Montana
- Nebraska
- Nevada
- New Hampshire
- New Jersey

- New Mexico
- New York
- North Carolina
- North Dakota
- Northern Mariana Islands
- Ohio
- Oklahoma
- Oregon
- Pennsylvania
- Puerto Rico
- Rhode Island
- South Carolina
- South Dakota
- Tennessee
- Texas
- Utah
- Vermont
- Virginia
- Virgin Islands
- Washington
- West Virginia
- Wisconsin
- Wyoming

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[Cancel](#)

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0123456789

Infusion Facility Address
43 Eleanor St

City
Los Angeles

State
California

ZIP Code
90212

Phone Number
555-555-5555

Fax Number
555-555-5555

Site Affiliation

- Select
- Academic
- Government
- Ambulatory/Free Standing
- Hospital Based
- Private Practice (in office)

City
Los Angeles

State
California

ZIP Code
90212

Name of Authorized Healthcare Facility Representative

First Name
John

Last Name
Doe

Email Address
jdoe@abc123.com

Title
MD

HEALTHCARE FACILITY AGREEMENT

I am the authorized representative designated by my healthcare facility to coordinate the activities of the LEMTRADA REMS. By signing this form, I agree to comply with the following requirements:

- I understand that my healthcare facility must be certified with the LEMTRADA REMS to receive or administer LEMTRADA.
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Full Name

NPI Number

Password

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0123456789

Infusion Facility Address
43 Eleanor St

City
Los Angeles

State
California

ZIP Code
90212

Phone Number
555-555-5555

Fax Number
555-555-5555

Site Affiliation
Academic

Ship-to is the same as facility address

Ship-to Address
43 Eleanor St

City

- Select
- Alabama
- Alaska
- American Samoa
- Arizona
- Arkansas
- California
- Colorado
- Connecticut
- Delaware
- District of Columbia
- Florida
- Georgia
- Guam
- Hawaii
- Idaho
- Illinois

- Indiana
- Iowa
- Kansas
- Kentucky
- Louisiana
- Maine
- Maryland
- Massachusetts
- Michigan
- Minnesota
- Mississippi
- Missouri
- Montana
- Nebraska
- Nevada
- New Hampshire
- New Jersey
- New Mexico
- New York
- North Carolina
- North Dakota
- Northern Mariana Islands
- Ohio
- Oklahoma
- Oregon
- Pennsylvania
- Puerto Rico
- Rhode Island
- South Carolina
- South Dakota
- Tennessee
- Texas
- Utah
- Vermont
- Virginia
- Virgin Islands
- Washington
- West Virginia
- Wisconsin
- Wyoming

Treatment and Infusion Reactions: A Patient Guide to each patient to inform them about the risk of serious infusion reactions.

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[Cancel](#) [Submit](#)

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HEALTHCARE FACILITY INFORMATION

Name of Institution or Healthcare Facility

Please enter name of institution or healthcare facility.

National Provider Identification (NPI) Number

Please enter valid NPI number.

Infusion Facility Address

Please enter infusion facility address.

City

State
Select One
Please select state.

ZIP Code

Please enter a 5-digit ZIP Code.

Phone Number

Please enter a 10-digit phone number.

Fax Number

Please enter a 10-digit fax number.

Site Affiliation
Select One
Please select a site affiliation.

Ship-to is the same as facility address

Ship-to Address

Please enter ship-to address.

City

State
Select One
Please select state.

ZIP Code

Please enter a 5-digit ZIP Code.

Name of Authorized Healthcare Facility Representative

First Name

Please enter first name.

Last Name

Please enter last name.

Email Address

Please enter a valid email address.

Title

Please enter title.

HEALTHCARE FACILITY AGREEMENT

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Full Name

Please enter your full name.

NPI Number

Please enter a valid NPI number.

Password

Please enter a password.

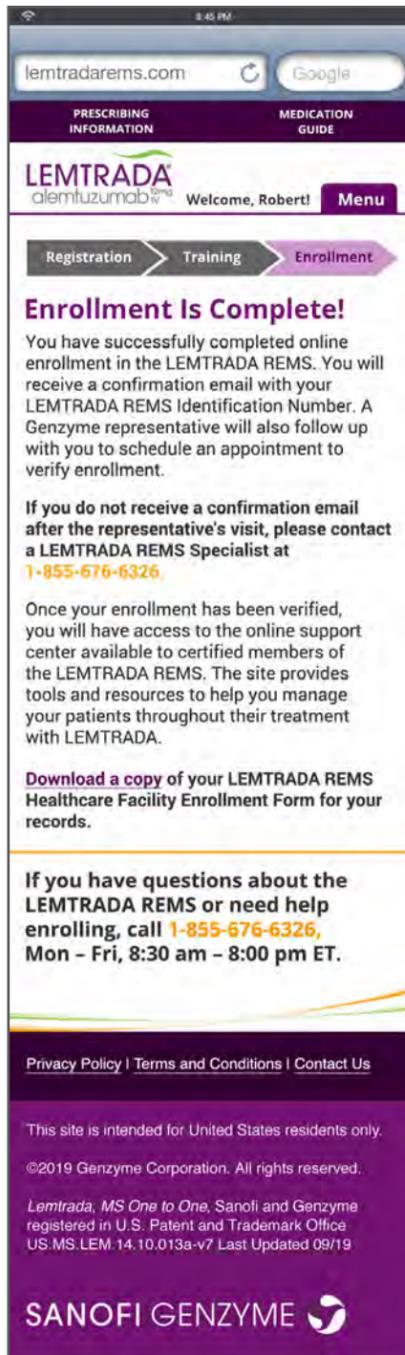
[Cancel](#)

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LEMTRADA REMS (Risk Evaluation and Mitigation Strategy)

What is the LEMTRADA REMS?

A REMS is a strategy to manage known or potential serious risks associated with a drug product and is required by the FDA to ensure the benefits of a drug outweigh its risks. The purpose of the LEMTRADA REMS is to inform prescribers, pharmacies, healthcare facilities, and patients about the risks of:

AUTOIMMUNE CONDITIONS
LEMTRADA causes serious, sometimes fatal, autoimmune conditions such as immune thrombocytopenia and anti-glomerular basement membrane disease. Monitor complete blood counts with differential, serum creatinine levels, and urinalysis with urine cell counts at periodic intervals for 48 months after the last dose of LEMTRADA.

INFUSION REACTIONS
LEMTRADA causes serious and life threatening infusion reactions. LEMTRADA must be administered in a setting with appropriate equipment and personnel to manage anaphylaxis or serious infusion reactions.

STROKE
Serious and life-threatening stroke (including ischemic and hemorrhagic stroke) has been reported within 3 days of LEMTRADA administration. Instruct patients to seek immediate medical attention if symptoms of stroke occur.

MALIGNANCIES
LEMTRADA may cause an increased risk of malignancy including thyroid cancer, melanoma, and lymphoproliferative disorders. Perform baseline and yearly skin exams.

Complete Enrollment in the LEMTRADA REMS

You have not completed your review of the training materials. You must review the training materials in order to complete your enrollment in the LEMTRADA REMS.

[Review Training Materials](#)

Find a REMS Certified Prescriber or Healthcare Facility

Search for prescribers or healthcare facilities that are certified by the LEMTRADA REMS to prescribe, dispense, or administer LEMTRADA.

Enter ZIP Code

REMS Certified Prescriber
 REMS Certified Healthcare Facility

[Find](#)

LEMTRADA REMS Requirements

HEALTHCARE FACILITIES

Healthcare facilities must be enrolled in the

LEMTRADA REMS to dispense/administer LEMTRADA for patients with multiple sclerosis. *One representative needs to enroll per healthcare setting.*

[Learn about Healthcare Facility Enrollment](#)

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Enter ZIP Code

REMS Certified Prescriber
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Find

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PRESCRIBING INFORMATION MEDICATION GUIDE

LEMTRADA
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LEMTRADA REMS (Risk Evaluation and Mitigation Strategy)

What is the LEMTRADA REMS?

A REMS is a strategy to manage known or potential serious risks associated with a drug product and is required by the FDA to ensure the benefits of a drug outweigh its risks. The purpose of the LEMTRADA REMS is to inform prescribers, pharmacies, healthcare facilities, and patients about the risks of:

AUTOIMMUNE CONDITIONS
LEMTRADA causes serious, sometimes fatal, autoimmune conditions such as immune thrombocytopenia and anti-glomerular basement membrane disease. Monitor complete blood counts with differential, serum creatinine levels, and urinalysis with urine cell counts at periodic intervals for 48 months after the last dose of LEMTRADA.

INFUSION REACTIONS
LEMTRADA causes serious and life threatening infusion reactions. LEMTRADA must be administered in a setting with appropriate equipment and personnel to manage anaphylaxis or serious infusion reactions.

STROKE
Serious and life-threatening stroke (including ischemic and hemorrhagic stroke) has been reported within 3 days of LEMTRADA administration. Instruct patients to seek immediate medical attention if symptoms of stroke occur.

MALIGNANCIES
LEMTRADA may cause an increased risk of malignancy including thyroid cancer, melanoma, and lymphoproliferative disorders. Perform baseline and yearly skin exams.

Complete Enrollment in the LEMTRADA REMS



You have not completed your review and submission of the LEMTRADA REMS Healthcare Facility Enrollment Form.

[Review Enrollment Form](#)

Find a REMS Certified Prescriber or Healthcare Facility



Search for prescribers or healthcare facilities that are certified by the LEMTRADA REMS to prescribe, dispense, or administer LEMTRADA.

Enter ZIP Code

REMS Certified Prescriber
 REMS Certified Healthcare Facility

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LEMTRADA REMS Requirements

HEALTHCARE FACILITIES

Healthcare facilities must be enrolled in the

LEMTRADA REMS to dispense/administer LEMTRADA for patients with multiple sclerosis. *One representative needs to enroll per healthcare setting.*

[Learn about Healthcare Facility Enrollment](#)

This site is provided as a resource for prescribers and is not intended as medical advice. Information on the site is updated periodically (approximately every 12 hours).

If you have questions about the LEMTRADA REMS or need help enrolling, call **1-855-676-6326**, Mon – Fri, 8:30 am – 8:00 pm ET.

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[Review Training Materials Again](#)

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REMS Certified Prescriber & Healthcare Facility Locator

Search by ZIP Code, city, or street address

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REMS CERTIFIED HEALTHCARE FACILITY DASHBOARD PAGES

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🔍

Patient (REMS ID)	Prescriber (REMS ID)	REMS Status
John Doe (123456789)	Adam Smith (123456789)	Authorized
John Doe (123456789)	Adam Smith (123456789)	Authorized
🔔 John Doe (123456789)	Adam Smith (123456789)	Not Authorized
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John Doe (123456789)	Adam Smith (123456789)	Authorized
John Doe (123456789)	Adam Smith (123456789)	Authorized
John Doe (123456789)	Adam Smith (123456789)	Infusion Verification
John Doe (123456789)	Adam Smith (123456789)	Authorized

Re-enroll in the LEMTRADA REMS

Healthcare Facilities must renew their enrollment every 2 years and authorized representatives must renew their enrollment every year.

Re-enroll Now

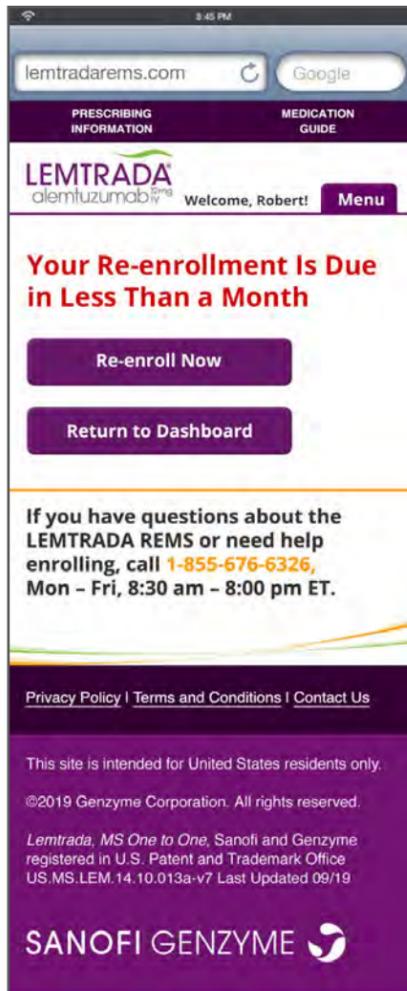
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Re-enroll Now

Find a REMS Certified Prescriber or Healthcare Facility

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Enter ZIP Code

REMS Certified Prescriber
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LEMTRADA REMS Requirements

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You have 10 LEMTRADA patients ?

Search, sort, and navigate information about your patients below. Click on a name to view their individual profile.

John Doe (123456789)	Adam Smith (123456789)	Authorized
John Doe (123456789)	Adam Smith (123456789)	Authorized
🚨 John Doe (123456789)	Adam Smith (123456789)	Not Authorized
🚨 John Doe (123456789)	Adam Smith (123456789)	Not Authorized
John Doe (123456789)	Adam Smith (123456789)	Authorized
🚨 John Doe (123456789)	Adam Smith (123456789)	Not Authorized
John Doe (123456789)	Adam Smith (123456789)	Authorized
John Doe (123456789)	Adam Smith (123456789)	Authorized
John Doe (123456789)	Adam Smith (123456789)	<div style="border: 1px solid black; padding: 2px 5px; display: inline-block;"> Infusion Verification </div>
John Doe (123456789)	Adam Smith (123456789)	Authorized

Re-enroll in the LEMTRADA REMS

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🚨 You have 5 patient alerts!

You have **5 patients** who have authorization requirements.

- **2 patients** are overdue for the LEMTRADA REMS Patient Status Form.
- **2 patients** need to be authorized by the LEMTRADA REMS Patient Status Form in 1 month.
- **1 patient** needs to be verified before their infusion.

[Manage my patient alert email preferences](#)

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John Doe (123456789)	Adam Smith (123456789)	Authorized
John Doe (123456789)	Adam Smith (123456789)	Infusion Verification
John Doe (123456789)	Adam Smith (123456789)	Authorized

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LEMTRADA REMS INFUSION VERIFICATION

Patients cannot be infused until the patient, their prescriber, and the healthcare facility are verified under the LEMTRADA REMS . **John Doe** is scheduled to be infused on **XX/XX/XXXX**. If this date is incorrect or the date changes, please contact the LEMTRADA REMS at 1-855-676-6326.

Check marks indicate that verification has been completed.

Patient	✓
Certified Prescriber	✓
Certified Healthcare Facility	✓

✓ - Verified

Yes, I have verified my patient is ready for infusion.

Confirm

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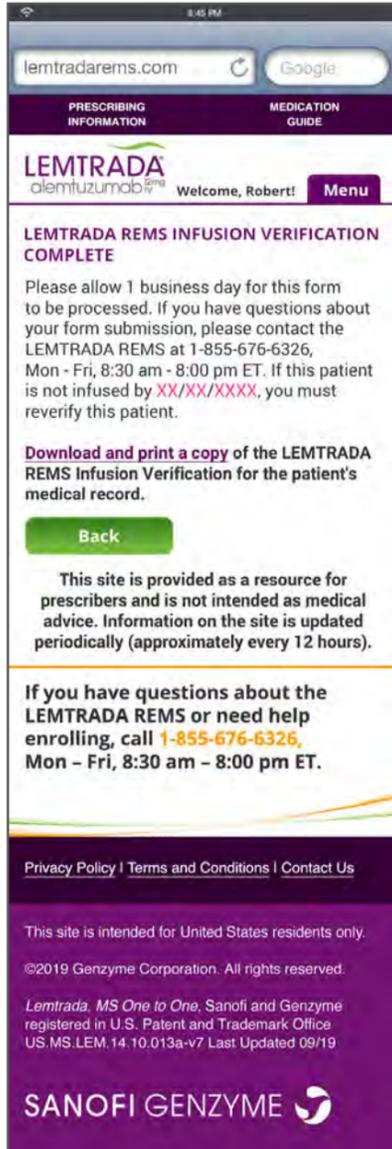
Below the text are three verification status boxes, each with a green checkmark:
- Patient
- Certified Prescriber
- Certified Healthcare Facility

A legend shows a green checkmark followed by '- Verified'. Below this is a checkbox labeled 'Yes, I have verified my patient is ready for infusion.' which is currently unchecked. A red italicized note says 'Please indicate verification.' Below that is a green 'Confirm' button.

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John Doe
(REMS ID 129684352)

REMS Authorized

Year of Birth: 1982
7776 Golden Blossom Run
Zook, IL 62056-3630
Home Phone: xxx-xxx-xxxx
Mobile Phone: xxx-xxx-xxxx

 [LEMTRADA REMS Infusion Checklist](#)

Insurance

Provider: BlueCross BlueShield of Kansas City

Coverage: Completed ([View](#))

Infusion Information

Next Infusion Date: 6/10/12

Infusion Facility: Facility 01

Prescriber Information

Physician: [Adam Smith, MD](#)

REMS ID: 0123456789

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LEMTRADA REMS INFUSION CHECKLIST

As a condition of your healthcare facility's authorization to infuse LEMTRADA® (alemtuzumab), this Infusion Checklist **must** be completed for each patient by the last day of each patient's treatment course and submitted within **5 business days**. This **Infusion Checklist must also be completed and returned even if LEMTRADA is not infused**. Keep a copy of this checklist in the patient's medical record.

Please complete the form and submit to Genzyme by clicking the button below.

All fields are required.

PATIENT INFORMATION

Patient First Name

Patient Last Name

Patient LEMTRADA REMS Identification Number

DOB (MM/DD/YYYY)
 [Full Patient Record](#)

PRESCRIBER INFORMATION

Prescriber First Name

Prescriber Last Name

Prescriber LEMTRADA REMS Identification Number

HEALTHCARE FACILITY INFORMATION

Healthcare Facility Name

Healthcare Facility LEMTRADA REMS Identification Number

Step 1: CONFIRM that the patient is authorized to receive LEMTRADA

You must complete the LEMTRADA REMS infusion verification online or contact the LEMTRADA REMS by phone (1-855-676-6326) prior to initiation of each treatment course.

Is the patient authorized to receive LEMTRADA?

Yes No

Step 2: CONFIRM that the patient has been counseled and has received *What You Need to Know About LEMTRADA Treatment and Infusion Reactions: A Patient Guide*

The patient must be counseled about the risk for infusion reactions and provided with *What You Need to Know About LEMTRADA Treatment and Infusion Reactions: A Patient Guide* prior to the first infusion of each treatment course.

Has the patient been counseled and received the guide?

Yes No

Step 3: CONFIRM appropriate medical measures available for infusion

Appropriate medical support measures are available:

1. In case of serious infusion reactions.
2. To monitor patient's vital signs before, during, and post-infusion.

Are the appropriate medical measures listed above available?

Yes No

Step 4: RECORD infusion information

Was patient infused with LEMTRADA?

Yes No

Step 5: RETURN of unused vials of LEMTRADA

Unused vials of LEMTRADA must be returned within 50 days of submission of the LEMTRADA REMS Patient Authorization and Lab Form. Contact the LEMTRADA REMS at 1-855-676-6326 for additional information.

Step 6: SIGNATURE

By providing my e-signature, I attest that I have filled out the Infusion Checklist to the best of my knowledge. I understand that my e-signature will be used to verify my enrollment in the LEMTRADA REMS. By entering my name, NPI number, and password, I confirm my e-signature of this form.

Name of staff member completing checklist

Password

NPI Number

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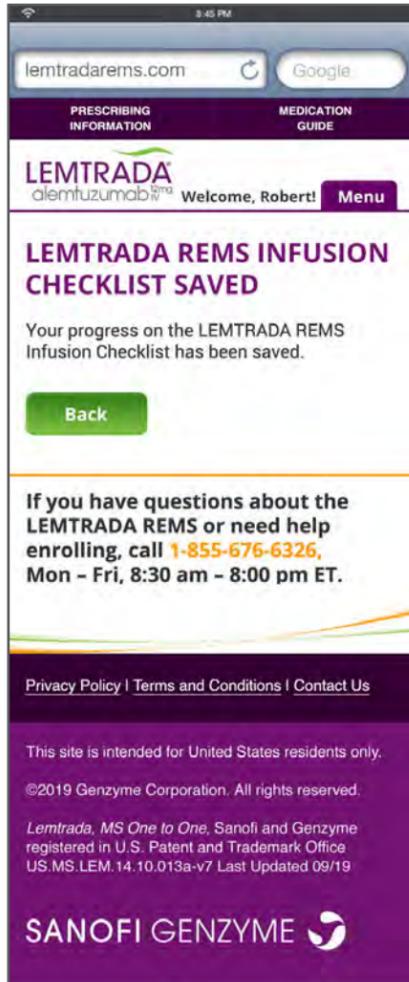
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LEMTRADA REMS INFUSION CHECKLIST

As a condition of your healthcare facility's authorization to infuse LEMTRADA® (alemtuzumab), this Infusion Checklist **must** be completed for each patient by the last day of each patient's treatment course and submitted within **5 business days**. **This Infusion Checklist must also be completed and returned even if LEMTRADA is not infused.** Keep a copy of this checklist in the patient's medical record.

Please complete the form and submit to Genzyme by clicking the button below.

All fields are required.

PATIENT INFORMATION

Patient First Name

Patient Last Name

Patient LEMTRADA REMS Identification Number

DOB (MM/DD/YYYY)
 [Full Patient Record](#)

PRESCRIBER INFORMATION

Prescriber First Name

Prescriber Last Name

Prescriber LEMTRADA REMS Identification Number

HEALTHCARE FACILITY INFORMATION

Healthcare Facility Name

Healthcare Facility LEMTRADA REMS Identification Number

Step 1: CONFIRM that the patient is authorized to receive LEMTRADA

You must complete the LEMTRADA REMS infusion verification online or contact the LEMTRADA REMS by phone (1-855-676-6326) prior to initiation of each treatment course.

Is the patient authorized to receive LEMTRADA?
 Yes No

Alert!

STOP – DO NOT INFUSE.
Refer patient back to the LEMTRADA prescriber.

Step 2: CONFIRM that the patient has been counseled and has received *What You Need to Know About LEMTRADA Treatment and Infusion Reactions: A Patient Guide*

The patient must be counseled about the risk for infusion reactions and provided with *What You Need to Know About LEMTRADA Treatment and Infusion Reactions: A Patient Guide* prior to the first infusion of each treatment course.

Has the patient been counseled and received the guide?
 Yes No

Step 3: CONFIRM appropriate medical measures available for infusion

Appropriate medical support measures are available:
1. In case of serious infusion reactions.
2. To monitor patient's vital signs before, during, and post-infusion.

Are the appropriate medical measures listed above available?
 Yes No

Step 4: RECORD infusion information

Was patient infused with LEMTRADA?
 Yes No

Step 5: RETURN of unused vials of LEMTRADA

Unused vials of LEMTRADA must be returned within 50 days of submission of the LEMTRADA REMS Patient Authorization and Lab Form. Contact the LEMTRADA REMS at 1-855-676-6326 for additional information.

Step 6: SIGNATURE

By providing my e-signature, I attest that I have filled out the Infusion Checklist to the best of my knowledge. I understand that my e-signature will be used to verify my enrollment in the LEMTRADA REMS. By entering my name, NPI number, and password, I confirm my e-signature of this form.

Name of staff member completing checklist

Password

NPI Number

[Cancel](#)

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If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6326, Mon – Fri, 8:30 am – 8:00 pm ET.

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LEMTRADA REMS INFUSION CHECKLIST

As a condition of your healthcare facility's authorization to infuse LEMTRADA® (alemtuzumab), this Infusion Checklist **must** be completed for each patient by the last day of each patient's treatment course and submitted within **5 business days**. This **Infusion Checklist must also be completed and returned even if LEMTRADA is not infused**. Keep a copy of this checklist in the patient's medical record.

Please complete the form and submit to Genzyme by clicking the button below.

All fields are required.

PATIENT INFORMATION

Patient First Name

Please enter patient's first name.

Patient Last Name

Please enter patient's last name.

Patient LEMTRADA REMS Identification Number

Please enter patient's LEMTRADA REMS Identification Number.

DOB (MM/DD/YYYY)
 [Full Patient Record](#)
Please enter patient's valid date of birth.

PRESCRIBER INFORMATION

Prescriber First Name

Please enter prescriber's first name.

Prescriber Last Name

Please enter prescriber's last name.

Prescriber LEMTRADA REMS Identification Number

Please enter prescriber's LEMTRADA REMS Identification Number.

HEALTHCARE FACILITY INFORMATION

Healthcare Facility Name

Please enter healthcare facility name.

Healthcare Facility LEMTRADA REMS Identification Number

Please enter Healthcare Facility LEMTRADA REMS Identification Number.

Step 1: CONFIRM that the patient is authorized to receive LEMTRADA

You must complete the LEMTRADA REMS infusion verification online or contact the LEMTRADA REMS by phone (1-855-676-6326) prior to initiation of each treatment course.

Is the patient authorized to receive LEMTRADA?
 Yes No

Alert!
STOP – DO NOT INFUSE.
Refer patient back to the LEMTRADA prescriber.

Step 2: CONFIRM that the patient has been counseled and has received *What You Need to Know About LEMTRADA Treatment and Infusion Reactions: A Patient Guide*

The patient must be counseled about the risk for infusion reactions and provided with *What You Need to Know About LEMTRADA Treatment and Infusion Reactions: A Patient Guide* prior to the first infusion of each treatment course.

Has the patient been counseled and received the guide?
 Yes No

Alert!
STOP – Provide the patient guide.
Proceed to the next question after the patient has received the guide and has been counseled.

Step 3: CONFIRM appropriate medical measures available for infusion

Appropriate medical support measures are available:
1. In case of serious infusion reactions.
2. To monitor patient's vital signs before, during, and post-infusion.

Are the appropriate medical measures listed above available?
 Yes No

Alert!
STOP – DO NOT INFUSE
until appropriate medical support measures are available. Please contact the LEMTRADA REMS for additional information.

Step 4: RECORD infusion information

Was patient infused with LEMTRADA?
 Yes No

Alert!
Proceed to Step 5.

Step 5: RETURN of unused vials of LEMTRADA

Unused vials of LEMTRADA must be returned within 50 days of submission of the LEMTRADA REMS Patient Authorization and Lab Form. Contact the LEMTRADA REMS at 1-855-676-6326 for additional information.

Step 6: SIGNATURE

By providing my e-signature, I attest that I have filled out the Infusion Checklist to the best of my knowledge. I understand that my e-signature will be used to verify my enrollment in the LEMTRADA REMS. By entering my name, NPI number, and password, I confirm my e-signature of this form.

Name of staff member completing checklist

Password

NPI Number

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LEMTRADA REMS INFUSION CHECKLIST

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Please complete the form and submit to Genzyme by clicking the button below.

All fields are required.

PATIENT INFORMATION

Patient First Name

Patient Last Name

Patient LEMTRADA REMS Identification Number

DOB (MM/DD/YYYY)
 [Full Patient Record](#)

PRESCRIBER INFORMATION

Prescriber First Name

Prescriber Last Name

Prescriber LEMTRADA REMS Identification Number

HEALTHCARE FACILITY INFORMATION

Healthcare Facility Name

Healthcare Facility LEMTRADA REMS Identification Number

Step 1: CONFIRM that the patient is authorized to receive LEMTRADA

You must complete the LEMTRADA REMS infusion verification online or contact the LEMTRADA REMS by phone (1-855-676-6326) prior to initiation of each treatment course.

Is the patient authorized to receive LEMTRADA?
 Yes No

Step 2: CONFIRM that the patient has been counseled and has received *What You Need to Know About LEMTRADA Treatment and Infusion Reactions: A Patient Guide*

The patient must be counseled about the risk for infusion reactions and provided with *What You Need to Know About LEMTRADA Treatment and Infusion Reactions: A Patient Guide* prior to the first infusion of each treatment course.

Has the patient been counseled and received the guide?
 Yes No

Step 3: CONFIRM appropriate medical measures available for infusion

Appropriate medical support measures are available:
 1. In case of serious infusion reactions.
 2. To monitor patient's vital signs before, during, and post-infusion.

Are the appropriate medical measures listed above available?
 Yes No

Step 4: RECORD infusion information

Was patient infused with LEMTRADA?
 Yes No

Fill in Dates of Infusion below and then proceed to Step 5.

LEMTRADA Infusions

Dates of Infusion:

Date: 

Date: 

Date: 

Date: 

Date: 

Step 5: RETURN of unused vials of LEMTRADA

Unused vials of LEMTRADA must be returned within 50 days of submission of the LEMTRADA REMS Patient Authorization and Lab Form. Contact the LEMTRADA REMS at 1-855-676-6326 for additional information.

Step 6: SIGNATURE

By providing my e-signature, I attest that I have filled out the Infusion Checklist to the best of my knowledge. I understand that my e-signature will be used to verify my enrollment in the LEMTRADA REMS. By entering my name, NPI number, and password, I confirm my e-signature of this form.

Name of staff member completing checklist

Password

NPI Number

[Cancel](#) [Save](#) [Submit](#)

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LEMTRADA REMS INFUSION CHECKLIST

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Please complete the form and submit to Genzyme by clicking the button below.

All fields are required.

PATIENT INFORMATION

Patient First Name
John

Patient Last Name
Doe

Patient LEMTRADA REMS Identification Number
125698909

DOB (MM/DD/YYYY)
06/10/1965 [Full Patient Record](#)

PRESCRIBER INFORMATION

Prescriber First Name
Adam

Prescriber Last Name
Smith

Prescriber LEMTRADA REMS Identification Number
125698909

HEALTHCARE FACILITY INFORMATION

Healthcare Facility Name
Facility 01

Healthcare Facility LEMTRADA REMS Identification Number
098789678

Step 1: CONFIRM that the patient is authorized to receive LEMTRADA

You must complete the LEMTRADA REMS infusion verification online or contact the LEMTRADA REMS by phone (1-855-676-6326) prior to initiation of each treatment course.

Is the patient authorized to receive LEMTRADA?
 Yes No

Step 2: CONFIRM that the patient has been counseled and has received *What You Need to Know About LEMTRADA Treatment and Infusion Reactions: A Patient Guide*

The patient must be counseled about the risk for infusion reactions and provided with *What You Need to Know About LEMTRADA Treatment and Infusion Reactions: A Patient Guide* prior to the first infusion of each treatment course.

Has the patient been counseled and received the guide?
 Yes No

Step 3: CONFIRM appropriate medical measures available for infusion

Appropriate medical support measures are available:
1. In case of serious infusion reactions.
2. To monitor patient's vital signs before, during, and post-infusion.

Are the appropriate medical measures listed above available?
 Yes No

Step 4: RECORD infusion information

Was patient infused with LEMTRADA?
 Yes No

Fill in Dates of Infusion below and then proceed to Step 5.

LEMTRADA Infusions

Dates of Infusion:

Date: 10 / 1 / 2007

Date: 10 / 2 / 2007

Date: 10 / 3 / 2007

Date: 10 / 4 / 2007

Date: 10 / 5 / 2007

Step 5: RETURN of unused vials of LEMTRADA

Unused vials of LEMTRADA must be returned within 50 days of submission of the LEMTRADA REMS Patient Authorization and Lab Form. Contact the LEMTRADA REMS at 1-855-676-6326 for additional information.

Step 6: SIGNATURE

By providing my e-signature, I attest that I have filled out the Infusion Checklist to the best of my knowledge. I understand that my e-signature will be used to verify my enrollment in the LEMTRADA REMS. By entering my name, NPI number, and password, I confirm my e-signature of this form.

Name of staff member completing checklist
Robert Clark

Password

NPI Number
1234567890

[Cancel](#) [Save](#) [Submit](#)

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LEMTRADA REMS INFUSION CHECKLIST

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Please complete the form and submit to Genzyme by clicking the button below.

All fields are required.

PATIENT INFORMATION

Patient First Name:

Patient Last Name:

Patient LEMTRADA REMS Identification Number:

DOB (MM/DD/YYYY): [Full Patient Record](#)

PRESCRIBER INFORMATION

Prescriber First Name:

Prescriber Last Name:

Prescriber LEMTRADA REMS Identification Number:

HEALTHCARE FACILITY INFORMATION

Healthcare Facility Name:

Healthcare Facility LEMTRADA REMS Identification Number:

Step 1: CONFIRM that the patient is authorized to receive LEMTRADA

You must complete the LEMTRADA REMS infusion verification online or contact the LEMTRADA REMS by phone (1-855-676-6326) prior to initiation of each treatment course.

Is the patient authorized to receive LEMTRADA?
 Yes No

Step 2: CONFIRM that the patient has been counseled and has received *What You Need to Know About LEMTRADA Treatment and Infusion Reactions: A Patient Guide*

The patient must be counseled about the risk for infusion reactions and provided with *What You Need to Know About LEMTRADA Treatment and Infusion Reactions: A Patient Guide* prior to the first infusion of each treatment course.

Has the patient been counseled and received the guide?
 Yes No

Step 3: CONFIRM appropriate medical measures available for infusion

Appropriate medical support measures are available:
 1. In case of serious infusion reactions.
 2. To monitor patient's vital signs before, during, and post-infusion.

Are the appropriate medical measures listed above available?
 Yes No

Step 4: RECORD infusion information

Was patient infused with LEMTRADA?
 Yes No

Fill in Dates of Infusion below and then proceed to Step 5.

LEMTRADA Infusions

Dates of Infusion:
Please enter valid date (MM/DD/YYYY).

Date:

Date:

Date:

Date:

Date:

Step 5: RETURN of unused vials of LEMTRADA

Unused vials of LEMTRADA must be returned within 50 days of submission of the LEMTRADA REMS Patient Authorization and Lab Form. Contact the LEMTRADA REMS at 1-855-676-6326 for additional information.

Step 6: SIGNATURE

By providing my e-signature, I attest that I have filled out the Infusion Checklist to the best of my knowledge. I understand that my e-signature will be used to verify my enrollment in the LEMTRADA REMS. By entering my name, NPI number, and password, I confirm my e-signature of this form.

Name of staff member completing checklist:

Password:

NPI Number:

[Cancel](#) [Save](#) [Submit](#)

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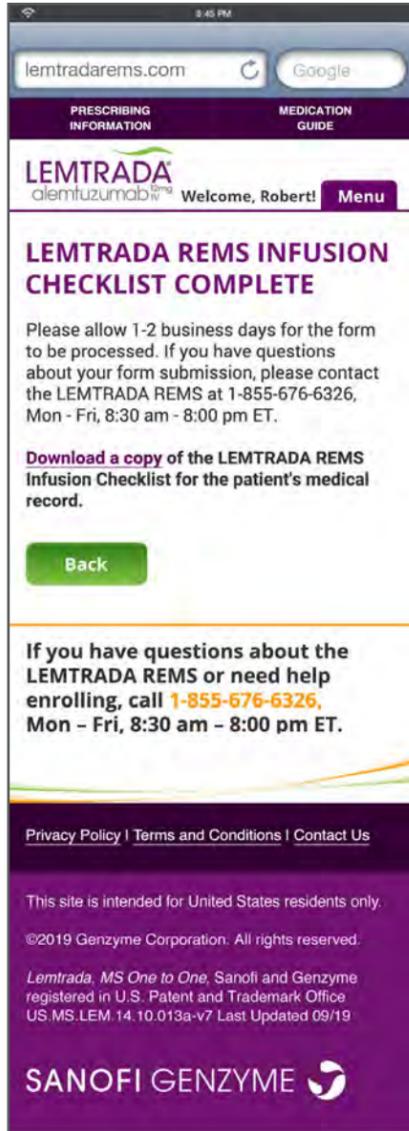
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The screenshot shows a mobile web application interface for LEMTRADA REMS. At the top, there is a browser address bar with 'lemtradarems.com' and a search bar with 'Google'. Below this is a navigation bar with 'PRESCRIBING INFORMATION' and 'MEDICATION GUIDE'. The main header features the LEMTRADA logo, the text 'alemfuzumab', a welcome message 'Welcome, Robert!', and a 'Menu' button. A 'Previous Page' link is visible. The patient's name 'John Doe' and 'REMS ID 129684352' are displayed, along with a green 'REMS Authorized' badge. Patient details include 'Year of Birth: 1982', address '7776 Golden Blossom Run, Zook, IL 62056-3630', and phone numbers. A link to the 'LEMTRADA REMS Infusion Checklist' is provided. The checklist section shows a message: 'Your progress on the LEMTRADA REMS Infusion Checklist has been saved. The checklist must be completed by the last day of the patient's treatment course.' with a 'View Checklist' link. Below this are sections for 'Insurance' (Provider: BlueCross BlueShield of Kansas City, Coverage: Completed), 'Infusion Information' (First Course: 6/10/12 - 6/14/12, Infusion Facility: Facility 01), and 'Prescriber Information' (Physician: Adam Smith, MD, REMS ID: 0123456789). A disclaimer states: 'This site is provided as a resource for prescribers and is not intended as medical advice. Information on the site is updated periodically (approximately every 12 hours).' A contact information box says: 'If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6326, Mon - Fri, 8:30 am - 8:00 pm ET.' The footer contains links for 'Privacy Policy | Terms and Conditions | Contact Us', a note 'This site is intended for United States residents only.', copyright information '©2019 Genzyme Corporation. All rights reserved.', and the Sanofi Genzyme logo.

The screenshot displays the LEMTRADA REMS mobile application interface. At the top, there is a browser address bar with 'lemtradarems.com' and a search bar with 'Google'. Below this is a navigation bar with 'PRESCRIBING INFORMATION' and 'MEDICATION GUIDE'. The main header features the LEMTRADA logo, the text 'Welcome, Robert!', and a 'Menu' button. The patient's name 'John Doe' and 'REMS ID 129684352' are prominently displayed. A green badge indicates 'REMS Authorized'. Patient details include 'Year of Birth: 1982', address '7776 Golden Blossom Run, Zook, IL 62056-3630', and phone numbers. A link for 'LEMTRADA REMS Infusion Checklist' is provided. The 'Insurance' section shows 'Provider: BlueCross BlueShield of Kansas City' and 'Coverage: Completed (View)'. 'Infusion Information' includes 'First Course: 6/10/12 - 6/14/12 (View)' and 'Infusion Facility: Facility 01'. 'Prescriber Information' lists 'Physician: Adam Smith, MD' and 'REMS ID: 0123456789'. A disclaimer states: 'This site is provided as a resource for prescribers and is not intended as medical advice. Information on the site is updated periodically (approximately every 12 hours)'. A contact notice says: 'If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6326, Mon - Fri, 8:30 am - 8:00 pm ET.' The footer contains 'Privacy Policy | Terms and Conditions | Contact Us', a disclaimer 'This site is intended for United States residents only.', copyright '©2019 Genzyme Corporation. All rights reserved.', and the Sanofi Genzyme logo.

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John Doe
(REMS ID 129684352)

Not REMS Authorized

Year of Birth: 1982
7776 Golden Blossom Run
Zook, IL 62056-3630
Home Phone: xxx-xxx-xxxx
Mobile Phone: xxx-xxx-xxxx

Alert

This patient is overdue for authorization by the LEMTRADA REMS Patient Status Form. Please contact the prescriber, who must complete the necessary form.

 [LEMTRADA REMS Infusion Checklist](#)

Insurance

Provider: BlueCross BlueShield of Kansas City

Coverage: Completed ([View](#))

Infusion Information

First Course: 6/10/12 - 6/14/12 ([View](#))

Infusion Facility: Facility 01

Next Infusion Date: 6/10/13

Infusion Facility: Facility 01

Prescriber Information

Physician: [Adam Smith, MD](#)

REMS ID: 0123456789

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John Doe
(REMS ID 129684352)

REMS Authorized

Year of Birth: 1982
7776 Golden Blossom Run
Zook, IL 62056-3630
Home Phone: xxx-xxx-xxxx
Mobile Phone: xxx-xxx-xxxx

Insurance

Provider: BlueCross BlueShield of Kansas City

Coverage: Completed ([View](#))

Infusion Information

First Course: 6/10/12 - 6/14/12 ([View](#))

Infusion Facility: Facility 01

Second Course: 6/10/13 - 6/12/13 ([View](#))

Infusion Facility: Facility 02

Prescriber Information

Physician: [Adam Smith, MD](#)

REMS ID: 0123456789

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⚠ You have 5 patient alerts!

Our Patients Prescribers Manage Users

You have 13 LEMTRADA prescribers associated with your patients ?

Search

Prescriber (REMS ID)	REMS Status	Patient Alerts
Adam Smith (123456789)	Certified	
Adam Smith (123456789)	Certified	
Adam Smith (123456789)	Certified	
Adam Smith (123456789)	Not Certified	⚠
Adam Smith (123456789)	Certified	
Adam Smith (123456789)	Not Certified	
Adam Smith (123456789)	Certified	
Adam Smith (123456789)	Certified	
Adam Smith (123456789)	Not Certified	⚠
Adam Smith (123456789)	Certified	

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🔔 You have 5 patient alerts!

Our Patients Prescribers Manage Users

You have 13 LEMTRADA prescribers associated with your patients ?

Search, sort, and navigate information about your prescribers below. Click on a name to view their individual profile.

Adam Smith (123456789)	Certified
Adam Smith (123456789)	Certified
Adam Smith (123456789)	Certified
Adam Smith (123456789)	Not Certified
Adam Smith (123456789)	Certified
Adam Smith (123456789)	Certified
Adam Smith (123456789)	Certified
Adam Smith (123456789)	Certified
Adam Smith (123456789)	Not Certified
Adam Smith (123456789)	Certified
Adam Smith (123456789)	Certified
Adam Smith (123456789)	Not Certified
Adam Smith (123456789)	Certified

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SANOI GENZYME

9:45 PM

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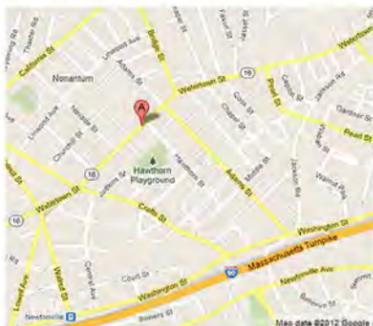
Welcome, Robert!
Menu

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Adam Smith, MD
(REMS ID 129684352)

REMS Certified

7776 Golden Blossom Run
Zook, IL 62056-3630
Office Phone: xxx-xxx-xxxx
Mobile Phone: xxx-xxx-xxxx
Fax: xxx-xxx-xxxx



[View Map](#)

Patients Seeing This Prescriber

! You have 1 patient alerts!

You have 10 LEMTRADA patients associated with this prescriber ?

Patient Name (REMS ID)	REMS Status
John Doe (123456789)	Authorized
John Doe (123456789)	Authorized
John Doe (123456789)	Not Authorized
John Doe (123456789)	Not Authorized
John Doe (123456789)	Authorized
John Doe (123456789)	Not Authorized
John Doe (123456789)	Authorized
John Doe (123456789)	Authorized
John Doe (123456789)	Authorized
John Doe (123456789)	Authorized
John Doe (123456789)	Authorized

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Adam Smith, MD
(REMS ID 129684352)

REMS Certified

7776 Golden Blossom Run
Zook, IL 62056-3630
Office Phone: xxx-xxx-xxxx
Mobile Phone: xxx-xxx-xxxx
Fax: xxx-xxx-xxxx

View Map

Patients Seeing This Prescriber

! You have 1 patient alerts!

You have 10 LEMTRADA patients associated with this prescriber ?

Search, sort, and navigate information about your patients below. Click on a name to view their individual profile.

John Doe (123456789)	Authorized
John Doe (123456789)	Authorized
John Doe (123456789)	Not Authorized
John Doe (123456789)	Not Authorized
John Doe (123456789)	Authorized
John Doe (123456789)	Not Authorized
John Doe (123456789)	Authorized
John Doe (123456789)	Authorized
John Doe (123456789)	Authorized
John Doe (123456789)	Authorized

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Patients Seeing This Prescriber

! You have 1 patient alerts!

You have **1 patient** who have authorization requirements.

- **1 patient** is due for the LEMTRADA REMS Patient Status Form in 1 month.

[Manage my patient alert email preferences](#)

You have 10 LEMTRADA patients associated with this prescriber ?

Patient Name (REMS ID)	REMS Status
John Doe (123456789)	Authorized
John Doe (123456789)	Authorized
John Doe (123456789)	Not Authorized
John Doe (123456789)	Not Authorized
John Doe (123456789)	Authorized
John Doe (123456789)	Not Authorized
John Doe (123456789)	Authorized
John Doe (123456789)	Authorized
John Doe (123456789)	Authorized
John Doe (123456789)	Authorized

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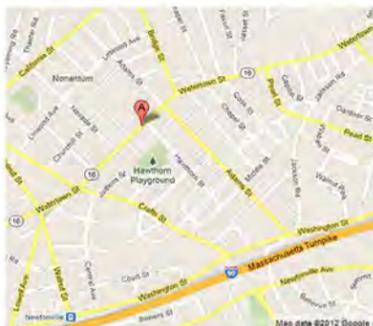

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(REMS ID 129684352)

Not REMS Certified

7776 Golden Blossom Run
Zook, IL 62056-3630
Office Phone: xxx-xxx-xxxx
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[View Map](#)

Patients Seeing This Prescriber

! You have 1 patient alerts!

You have 10 LEMTRADA patients associated with this prescriber ?

Patient Name (REMS ID)	REMS Status
John Doe (123456789)	Authorized
John Doe (123456789)	Authorized
John Doe (123456789)	Not Authorized
John Doe (123456789)	Not Authorized
John Doe (123456789)	Authorized
John Doe (123456789)	Not Authorized
John Doe (123456789)	Authorized
John Doe (123456789)	Authorized
John Doe (123456789)	Authorized
John Doe (123456789)	Authorized

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You have 5 patient alerts!

Our Patients Our Prescribers **Manage Users**

As a Facility Manager, you have access to LEMTRADA REMS certified facility staff profiles. This portal will help you navigate patient information and add users to your facility's LEMTRADA REMS portal. Use the list below to search and sort staff members enrolled in the LEMTRADA REMS at your healthcare facility. Click on a name to update a user's information, or delete a user.

Add New User

You have 6 certified users ?

Search

Certified Users	Last Logged In		
Robert Clark	10/14/2014	Edit	Delete
Robert Clark	10/14/2014	Edit	Delete
Robert Clark	10/14/2014	Edit	Delete
Robert Clark	10/14/2014	Edit	Delete
Robert Clark	10/14/2014	Edit	Delete
Robert Clark	10/14/2014	Edit	Delete

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Add New User

You have 6 certified users ?

All users below must have completed LEMTRADA REMS training. Click on a name to update user information or remove users who have access to your facility's account.

Robert Clark	10/14/2014	Edit	Delete
Robert Clark	10/14/2014	Edit	Delete
Robert Clark	10/14/2014	Edit	Delete
Robert Clark	10/14/2014	Edit	Delete
Robert Clark	10/14/2014	Edit	Delete
Robert Clark	10/14/2014	Edit	Delete

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The screenshot shows a mobile web browser interface for the LEMTRADA REMS Mobile HCF Dashboard. At the top, there is a navigation bar with 'PRESCRIBING INFORMATION' and 'MEDICATION GUIDE' links. Below this is the LEMTRADA logo and a welcome message 'Welcome, Robert!' with a 'Menu' button. The main content area is titled 'Add New User' and contains the following text: 'Only healthcare facilities enrolled in the LEMTRADA REMS can dispense and administer LEMTRADA. All new users must be appropriately trained to administer LEMTRADA before being added to this system.' Below this is a note 'All fields are required.' and a form with the following fields: 'First Name', 'Last Name', 'Email', and 'Confirm Email'. There is also a checkbox labeled 'User has received the required LEMTRADA REMS training.' At the bottom of the form are 'Cancel' and 'Save' buttons. Below the form is a section with the text: 'If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6326, Mon - Fri, 8:30 am - 8:00 pm ET.' At the very bottom, there is a footer with links for 'Privacy Policy | Terms and Conditions | Contact Us', a disclaimer 'This site is intended for United States residents only.', copyright information '©2019 Genzyme Corporation. All rights reserved.', and the Sanofi Genzyme logo.

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Add New User

Only healthcare facilities enrolled in the LEMTRADA REMS can dispense and administer LEMTRADA. All new users must be appropriately trained to administer LEMTRADA before being added to this system.

All fields are required.

First Name

Last Name

Email

Confirm Email

User has received the required LEMTRADA REMS training.

Cancel Save

If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6326, Mon - Fri, 8:30 am - 8:00 pm ET.

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Add New User

Only healthcare facilities enrolled in the LEMTRADA REMS can dispense and administer LEMTRADA. All new users must be appropriately trained to administer LEMTRADA before being added to this system.

All fields are required.

First Name

Please enter first name.

Last Name

Please enter last name.

Email

Please enter email.

Confirm Email

Please confirm email.

User has received the required LEMTRADA REMS training.
Please confirm that user has been trained.

[Cancel](#) [Save](#)

If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6326, Mon - Fri, 8:30 am - 8:00 pm ET.

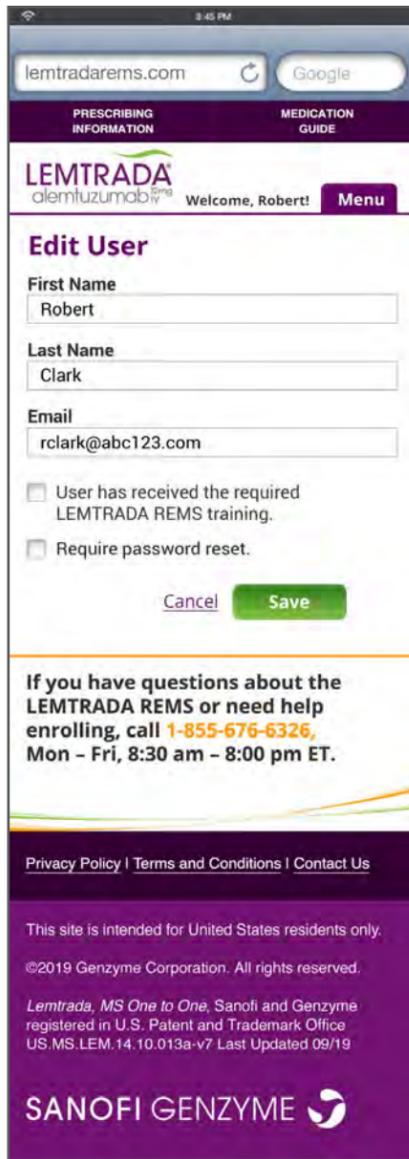
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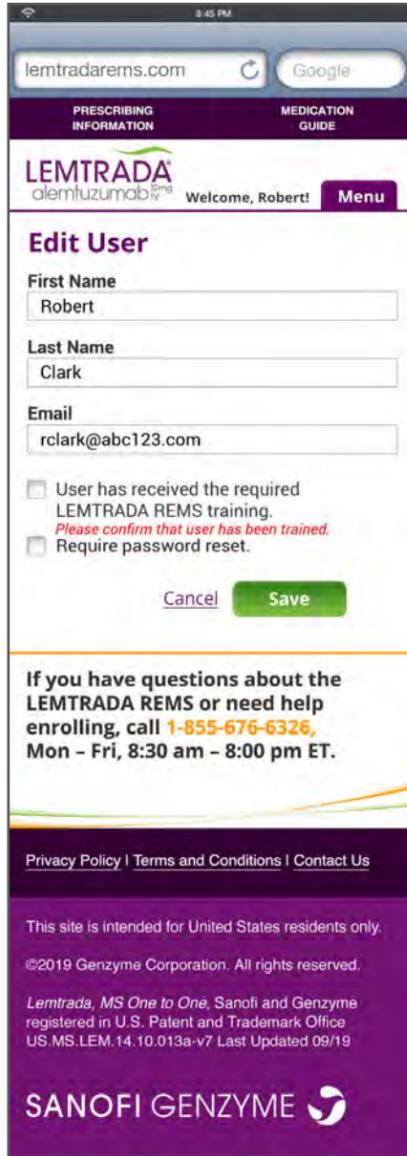
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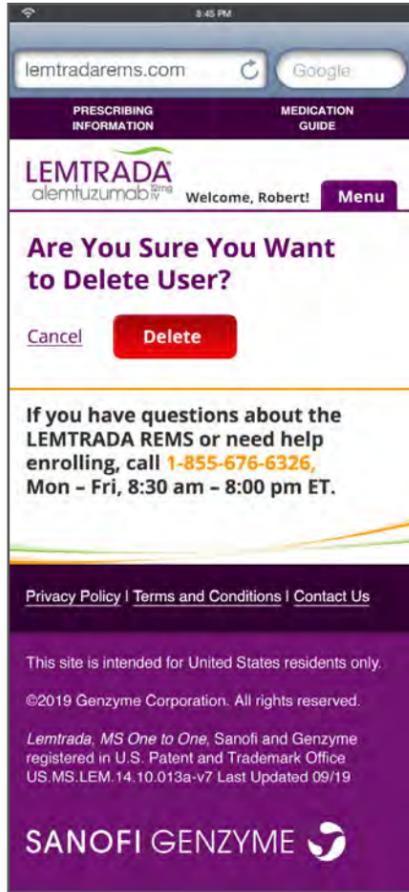
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My Profile

Robert Clark

(REMS ID 123456)
7776 Golden Blossom Run
Zook, IL 62056-3630
Office Phone: xxx-xxx-xxxx
Fax: xxx-xxx-xxxx

If any of your information is incorrect or has recently changed, please call **1-855-676-6326**, Mon – Fri, 8:30 am – 8:00 pm ET, so we can make appropriate updates.

Manage My Alert Preferences

Customize how often you would like to receive emails about the status of your LEMTRADA patients. Please note that you will continue to receive important communications from Genzyme, if warranted.

Patient Alert Emails

As a part of the LEMTRADA REMS you will automatically receive emails to update you on the status of your LEMTRADA patients. How often would you like to receive emails regarding patient alert summaries?

Please provide a monthly summary of alerts

Please provide a weekly summary of alerts

Please do not provide a summary of alerts

Update Alert

Change Your Password

Passwords must be at least 8 characters in length and contain a minimum of 3 out of the following: A number, an upper-case letter, a lower-case letter, a special character (e.g. !, ", #, \$, etc.)

Current Password

New Password

Confirm Password

Change Password

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- Please do not provide a summary of alerts

Update Alert

Change Your Password

Passwords must be at least 8 characters in length and contain a minimum of 3 out of the following: A number, an upper-case letter, a lower-case letter, a special character (e.g. !, ", #, \$, etc.)

Current Password

Please enter password.

New Password

Please enter valid password.

Confirm Password

Please confirm new password.

Change Password

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Current Password

Password is incorrect.

New Password

Password does not meet strength requirements.

Confirm Password

Passwords do not match.

Change Password

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Forms **FAQs**

Required LEMTRADA REMS Materials

Refer to these materials for information about the safe use of LEMTRADA through the LEMTRADA REMS.

- [ONLINE](#) | [PDF](#) LEMTRADA REMS Program Overview
- [ONLINE](#) | [PDF](#) LEMTRADA REMS Education Program for Healthcare Facilities
- [PDF](#) LEMTRADA REMS Healthcare Facility Enrollment Form
- [ONLINE](#) | [PDF](#) LEMTRADA REMS Infusion Checklist
- [PDF](#) What You Need to Know About LEMTRADA Treatment and Infusion Reactions: A Patient Guide

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LEMTRADA REMS INFUSION CHECKLIST

As a condition of your healthcare facility's authorization to infuse LEMTRADA® (alemtuzumab), this Infusion Checklist **must** be completed for each patient by the last day of each patient's treatment course and submitted within **5 business days**. **This Infusion Checklist must also be completed and returned even if LEMTRADA is not infused.** Keep a copy of this checklist in the patient's medical record.

Please complete the form and submit to Genzyme by clicking the button below.

All fields are required.

PATIENT INFORMATION

Patient First Name

Patient Last Name

Patient LEMTRADA REMS Identification Number

DOB (MM/DD/YYYY) [Full Patient Record](#)

PRESCRIBER INFORMATION

Prescriber First Name

Prescriber Last Name

Prescriber LEMTRADA REMS Identification Number

HEALTHCARE FACILITY INFORMATION

Healthcare Facility Name

Healthcare Facility LEMTRADA REMS Identification Number

Step 1: CONFIRM that the patient is authorized to receive LEMTRADA

You must complete the LEMTRADA REMS infusion verification online or contact the LEMTRADA REMS by phone (1-855-676-6326) prior to initiation of each treatment course.

Is the patient authorized to receive LEMTRADA?

Yes No

Step 2: CONFIRM that the patient has been counseled and has received *What You Need to Know About LEMTRADA Treatment and Infusion Reactions: A Patient Guide*

The patient must be counseled about the risk for infusion reactions and provided with *What You Need to Know About LEMTRADA Treatment and Infusion Reactions: A Patient Guide* prior to the first infusion of each treatment course.

Has the patient been counseled and received the guide?

Yes No

Step 3: CONFIRM appropriate medical measures available for infusion

Appropriate medical support measures are available:

1. In case of serious infusion reactions.
2. To monitor patient's vital signs before, during, and post-infusion.

Are the appropriate medical measures listed above available?

Yes No

Step 4: RECORD infusion information

Was patient infused with LEMTRADA?

Yes No

Step 5: RETURN of unused vials of LEMTRADA

Unused vials of LEMTRADA must be returned within 50 days of submission of the LEMTRADA REMS Patient Authorization and Lab Form. Contact the LEMTRADA REMS at 1-855-676-6326 for additional information.

Step 6: SIGNATURE

By providing my e-signature, I attest that I have filled out the infusion Checklist to the best of my knowledge. I understand that my e-signature will be used to verify my enrollment in the LEMTRADA REMS. By entering my name, NPI number, and password, I confirm my e-signature of this form.

Name of staff member completing checklist

Password

NPI Number

[Cancel](#) [Submit](#)

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All fields are required.

PATIENT INFORMATION

Patient First Name

Patient Last Name

Patient LEMTRADA REMS Identification Number

DOB (MM/DD/YYYY)

PRESCRIBER INFORMATION

Prescriber First Name

Prescriber Last Name

Prescriber LEMTRADA REMS Identification Number

HEALTHCARE FACILITY INFORMATION

Healthcare Facility Name

Healthcare Facility LEMTRADA REMS Identification Number

Step 1: CONFIRM that the patient is authorized to receive LEMTRADA

You must complete the LEMTRADA REMS infusion verification online or contact the LEMTRADA REMS by phone (1-855-676-6326) prior to initiation of each treatment course.

Is the patient authorized to receive LEMTRADA?

Yes No

Alert!

STOP – DO NOT INFUSE.
Refer patient back to the LEMTRADA prescriber.

Step 2: CONFIRM that the patient has been counseled and has received *What You Need to Know About LEMTRADA Treatment and Infusion Reactions: A Patient Guide*

The patient must be counseled about the risk for infusion reactions and provided with *What You Need to Know About LEMTRADA Treatment and Infusion Reactions: A Patient Guide* prior to the first infusion of each treatment course.

Has the patient been counseled and received the guide?

Yes No

Step 3: CONFIRM appropriate medical measures available for infusion

Appropriate medical support measures are available:

1. In case of serious infusion reactions.
2. To monitor patient's vital signs before, during, and post-infusion.

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Was patient infused with LEMTRADA?

Yes No

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By providing my e-signature, I attest that I have filled out the Infusion Checklist to the best of my knowledge. I understand that my e-signature will be used to verify my enrollment in the LEMTRADA REMS. By entering my name, NPI number, and password, I confirm my e-signature of this form.

Name of staff member completing checklist

Password

NPI Number

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Please complete the form and submit to Genzyme by clicking the button below.

All fields are required.

PATIENT INFORMATION

Patient First Name

Please enter patient's first name.

Patient Last Name

Please enter patient's last name.

Patient LEMTRADA REMS Identification Number

Please enter patient's LEMTRADA REMS Identification Number.

DOB (MM/DD/YYYY)
 [Full Patient Record](#)
Please enter patient's valid date of birth.

PRESCRIBER INFORMATION

Prescriber First Name

Please enter prescriber's first name.

Prescriber Last Name

Please enter prescriber's last name.

Prescriber LEMTRADA REMS Identification Number

Please enter prescriber's LEMTRADA REMS Identification Number.

HEALTHCARE FACILITY INFORMATION

Healthcare Facility Name

Please enter healthcare facility name.

Healthcare Facility LEMTRADA REMS Identification Number

Please enter Healthcare Facility LEMTRADA REMS Identification Number.

Step 1: CONFIRM that the patient is authorized to receive LEMTRADA

You must complete the LEMTRADA REMS infusion verification online or contact the LEMTRADA REMS by phone (1-855-676-6326) prior to initiation of each treatment course.

Is the patient authorized to receive LEMTRADA?
 Yes No

Alert!
STOP – DO NOT INFUSE.
Refer patient back to the LEMTRADA prescriber.

Step 2: CONFIRM that the patient has been counseled and has received *What You Need to Know About LEMTRADA Treatment and Infusion Reactions: A Patient Guide*

The patient must be counseled about the risk for infusion reactions and provided with *What You Need to Know About LEMTRADA Treatment and Infusion Reactions: A Patient Guide* prior to the first infusion of each treatment course.

Has the patient been counseled and received the guide?
 Yes No

Alert!
STOP – Provide the patient guide.
Proceed to the next question after the patient has received the guide and has been counseled.

Step 3: CONFIRM appropriate medical measures available for infusion

Appropriate medical support measures are available:
1. In case of serious infusion reactions.
2. To monitor patient's vital signs before, during, and post-infusion.

Are the appropriate medical measures listed above available?
 Yes No

Alert!
STOP – DO NOT INFUSE
until appropriate medical support measures are available. Please contact the LEMTRADA REMS for additional information.

Step 4: RECORD infusion information

Was patient infused with LEMTRADA?
 Yes No

Alert!
Proceed to Step 5.

Step 5: RETURN of unused vials of LEMTRADA

Unused vials of LEMTRADA must be returned within 50 days of submission of the LEMTRADA REMS Patient Authorization and Lab Form. Contact the LEMTRADA REMS at 1-855-676-6326 for additional information.

Step 6: SIGNATURE

By providing my e-signature, I attest that I have filled out the Infusion Checklist to the best of my knowledge. I understand that my e-signature will be used to verify my enrollment in the LEMTRADA REMS. By entering my name, NPI number, and password, I confirm my e-signature of this form.

Name of staff member completing checklist

Please enter name of staff member completing checklist.

Password

Please enter password.

NPI Number

Please enter a valid NPI number.

Cancel

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LEMTRADA REMS INFUSION CHECKLIST

As a condition of your healthcare facility's authorization to infuse LEMTRADA® (alemtuzumab), this Infusion Checklist must be completed for each patient by the last day of each patient's treatment course and submitted within 5 business days. This Infusion Checklist must also be completed and returned even if LEMTRADA is not infused. Keep a copy of this checklist in the patient's medical record.

Please complete the form and submit to Genzyme by clicking the button below.

All fields are required.

PATIENT INFORMATION

Patient First Name

Patient Last Name

Patient LEMTRADA REMS Identification Number

DOB (MM/DD/YYYY)
 [Full Patient Record](#)

PRESCRIBER INFORMATION

Prescriber First Name

Prescriber Last Name

Prescriber LEMTRADA REMS Identification Number

HEALTHCARE FACILITY INFORMATION

Healthcare Facility Name

Healthcare Facility LEMTRADA REMS Identification Number

Step 1: CONFIRM that the patient is authorized to receive LEMTRADA

You must complete the LEMTRADA REMS infusion verification online or contact the LEMTRADA REMS by phone (1-855-676-6326) prior to initiation of each treatment course.

Is the patient authorized to receive LEMTRADA?
 Yes No

Step 2: CONFIRM that the patient has been counseled and has received *What You Need to Know About LEMTRADA Treatment and Infusion Reactions: A Patient Guide*

The patient must be counseled about the risk for infusion reactions and provided with *What You Need to Know About LEMTRADA Treatment and Infusion Reactions: A Patient Guide* prior to the first infusion of each treatment course.

Has the patient been counseled and received the guide?
 Yes No

Step 3: CONFIRM appropriate medical measures available for infusion

Appropriate medical support measures are available:
1. In case of serious infusion reactions.
2. To monitor patient's vital signs before, during, and post-infusion.

Are the appropriate medical measures listed above available?
 Yes No

Step 4: RECORD infusion information

Was patient infused with LEMTRADA?
 Yes No

Fill in Dates of Infusion below and then proceed to Step 5.

LEMTRADA Infusions

Dates of Infusion:

Date:

Date:

Date:

Date:

Date:

Step 5: RETURN of unused vials of LEMTRADA

Unused vials of LEMTRADA must be returned within 50 days of submission of the LEMTRADA REMS Patient Authorization and Lab Form. Contact the LEMTRADA REMS at 1-855-676-6326 for additional information.

Step 6: SIGNATURE

By providing my e-signature, I attest that I have filled out the Infusion Checklist to the best of my knowledge. I understand that my e-signature will be used to verify my enrollment in the LEMTRADA REMS. By entering my name, NPI number, and password, I confirm my e-signature of this form.

Name of staff member completing checklist

Password

NPI Number

[Cancel](#)

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LEMTRADA REMS INFUSION CHECKLIST

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Please complete the form and submit to Genzyme by clicking the button below.

All fields are required.

PATIENT INFORMATION

Patient First Name
John

Patient Last Name
Doe

Patient LEMTRADA REMS Identification Number
125698909

DOB (MM/DD/YYYY)
06/10/1965 [Full Patient Record](#)

PRESCRIBER INFORMATION

Prescriber First Name
Adam

Prescriber Last Name
Smith

Prescriber LEMTRADA REMS Identification Number
125698909

HEALTHCARE FACILITY INFORMATION

Healthcare Facility Name
Facility 01

Healthcare Facility LEMTRADA REMS Identification Number
098789678

Step 1: CONFIRM that the patient is authorized to receive LEMTRADA

You must complete the LEMTRADA REMS infusion verification online or contact the LEMTRADA REMS by phone (1-855-676-6326) prior to initiation of each treatment course.

Is the patient authorized to receive LEMTRADA?
 Yes No

Step 2: CONFIRM that the patient has been counseled and has received *What You Need to Know About LEMTRADA Treatment and Infusion Reactions: A Patient Guide*

The patient must be counseled about the risk for infusion reactions and provided with *What You Need to Know About LEMTRADA Treatment and Infusion Reactions: A Patient Guide* prior to the first infusion of each treatment course.

Has the patient been counseled and received the guide?
 Yes No

Step 3: CONFIRM appropriate medical measures available for infusion

Appropriate medical support measures are available:
1. In case of serious infusion reactions.
2. To monitor patient's vital signs before, during, and post-infusion.

Are the appropriate medical measures listed above available?
 Yes No

Step 4: RECORD infusion information

Was patient infused with LEMTRADA?
 Yes No

Fill in Dates of Infusion below and then proceed to Step 5.

LEMTRADA Infusions

Dates of Infusion:

Date: 10 / 1 / 2007

Date: 10 / 2 / 2007

Date: 10 / 3 / 2007

Date: 10 / 4 / 2007

Date: 10 / 5 / 2007

Step 5: RETURN of unused vials of LEMTRADA

Unused vials of LEMTRADA must be returned within 50 days of submission of the LEMTRADA REMS Patient Authorization and Lab Form. Contact the LEMTRADA REMS at 1-855-676-6326 for additional information.

Step 6: SIGNATURE

By providing my e-signature, I attest that I have filled out the Infusion Checklist to the best of my knowledge. I understand that my e-signature will be used to verify my enrollment in the LEMTRADA REMS. By entering my name, NPI number, and password, I confirm my e-signature of this form.

Name of staff member completing checklist
Robert Clark

Password

NPI Number
1234567890

[Cancel](#) [Submit](#)

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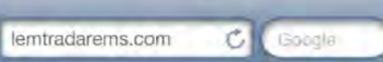
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LEMTRADA REMS INFUSION CHECKLIST

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Please complete the form and submit to Genzyme by clicking the button below.

All fields are required.

PATIENT INFORMATION

Patient First Name
John

Patient Last Name
Doe

Patient LEMTRADA REMS Identification Number
125698909

DOB (MM/DD/YYYY)
06/10/1965 [Full Patient Record](#)

PRESCRIBER INFORMATION

Prescriber First Name
Adam

Prescriber Last Name
Smith

Prescriber LEMTRADA REMS Identification Number
125698909

HEALTHCARE FACILITY INFORMATION

Healthcare Facility Name
Facility 01

Healthcare Facility LEMTRADA REMS Identification Number
098789678

Step 1: CONFIRM that the patient is authorized to receive LEMTRADA

You must complete the LEMTRADA REMS infusion verification online or contact the LEMTRADA REMS by phone (1-855-676-6326) prior to initiation of each treatment course.

Is the patient authorized to receive LEMTRADA?

Yes No

Step 2: CONFIRM that the patient has been counseled and has received *What You Need to Know About LEMTRADA Treatment and Infusion Reactions: A Patient Guide*

The patient must be counseled about the risk for infusion reactions and provided with *What You Need to Know About LEMTRADA Treatment and Infusion Reactions: A Patient Guide* prior to the first infusion of each treatment course.

Has the patient been counseled and received the guide?

Yes No

Step 3: CONFIRM appropriate medical measures available for infusion

Appropriate medical support measures are available:

- In case of serious infusion reactions.
- To monitor patient's vital signs before, during, and post-infusion.

Are the appropriate medical measures listed above available?

Yes No

Step 4: RECORD infusion information

Was patient infused with LEMTRADA?

Yes No

Fill in Dates of Infusion below and then proceed to Step 5.

LEMTRADA Infusions

Dates of Infusion:

Please enter valid date (MM/DD/YYYY).

Date: 

Date: 

Date: 

Date: 

Date: 

Step 5: RETURN of unused vials of LEMTRADA

Unused vials of LEMTRADA must be returned within 50 days of submission of the LEMTRADA REMS Patient Authorization and Lab Form. Contact the LEMTRADA REMS at 1-855-676-6326 for additional information.

Step 6: SIGNATURE

By providing my e-signature, I attest that I have filled out the Infusion Checklist to the best of my knowledge. I understand that my e-signature will be used to verify my enrollment in the LEMTRADA REMS. By entering my name, NPI number, and password, I confirm my e-signature of this form.

Name of staff member completing checklist
Robert Clark

Password

NPI Number
1234567890

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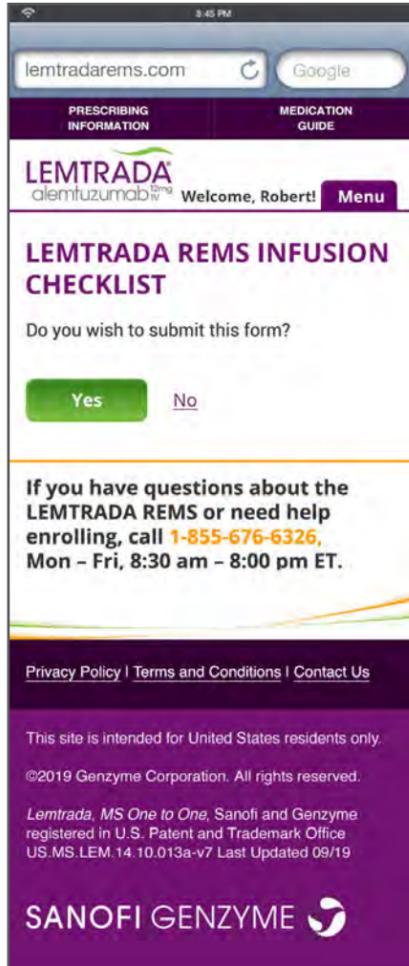
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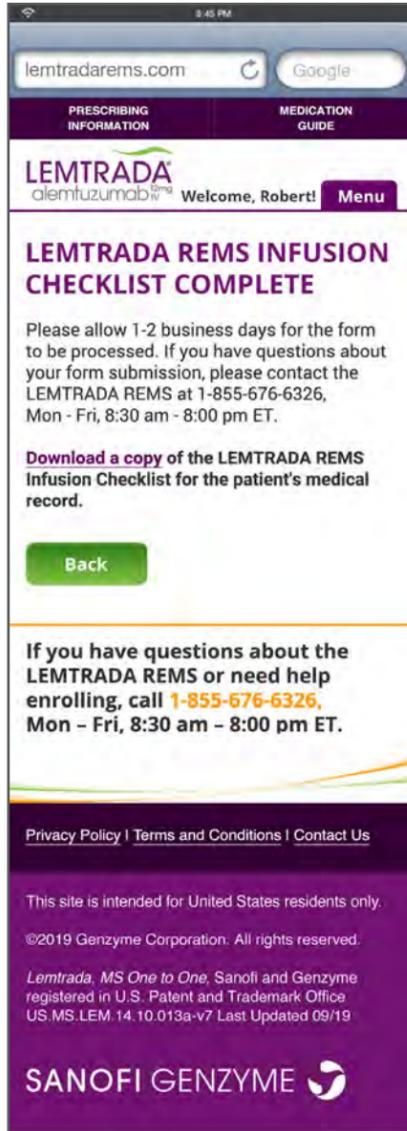
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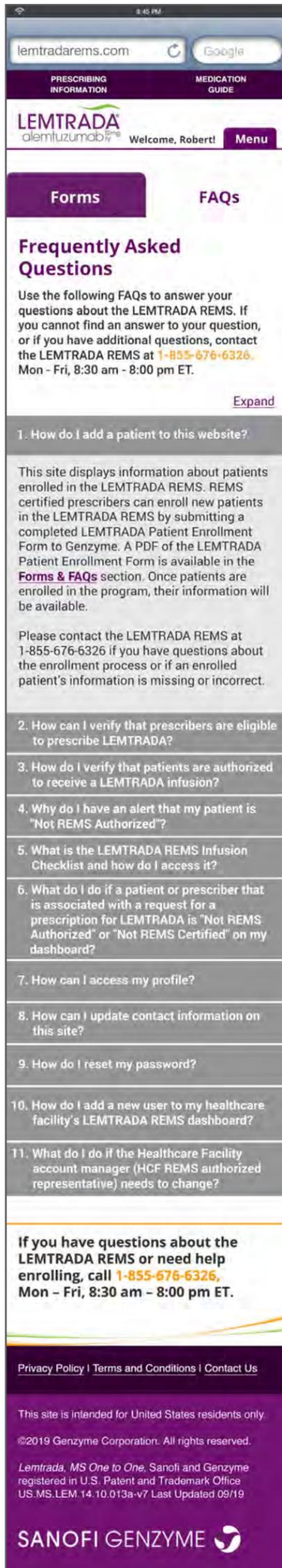
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Forms FAQs

Frequently Asked Questions

Use the following FAQs to answer your questions about the LEMTRADA REMS. If you cannot find an answer to your question, or if you have additional questions, contact the LEMTRADA REMS at **1-855-676-6326**, Mon - Fri, 8:30 am - 8:00 pm ET.

[Collapse](#)

1. How do I add a patient to this website?

This site displays information about patients enrolled in the LEMTRADA REMS. REMS certified prescribers can enroll new patients in the LEMTRADA REMS by submitting a completed LEMTRADA Patient Enrollment Form to Genzyme. A PDF of the LEMTRADA Patient Enrollment Form is available in the [Forms & FAQs](#) section. Once patients are enrolled in the program, their information will be available.

Please contact the LEMTRADA REMS at 1-855-676-6326 if you have questions about the enrollment process or if an enrolled patient's information is missing or incorrect.

2. How can I verify that prescribers are eligible to prescribe LEMTRADA?

"REMS Certified" prescribers are enrolled in the LEMTRADA REMS and eligible to prescribe LEMTRADA. You can view whether a prescriber is "REMS Certified" or "Not REMS Certified" by viewing the "Prescribers" tab on your dashboard.

3. How do I verify that patients are authorized to receive a LEMTRADA infusion?

Prior to your patient's treatment course, you will receive a notification on your dashboard with instructions to verify that your patient is authorized to receive LEMTRADA. Patients cannot be infused until the patient, their prescriber, and the healthcare facility are verified under the LEMTRADA REMS.

When you receive a verification alert, click the "Infusion Verification" button on your patient dashboard and follow the infusion verification instructions.

4. Why do I have an alert that my patient is "Not REMS Authorized"?

If your patient is "Not REMS Authorized," please check the individual's Patient Profile for more details about their status. Alerts are generated when patients are overdue for authorization by the LEMTRADA REMS Patient Authorization Form and/or the LEMTRADA REMS Patient Status Form. Prescribers must complete both forms in order to authorize patients for an infusion.

Contact the LEMTRADA REMS at 1-855-676-6326 to speak with a LEMTRADA REMS Specialist if you have questions about a patient's eligibility.

5. What is the LEMTRADA REMS Infusion Checklist and how do I access it?

After a patient completes a treatment course with LEMTRADA, healthcare facilities are required to complete a **LEMTRADA REMS Infusion Checklist**. The LEMTRADA REMS Infusion Checklist is intended to capture a patient's infusion history. You can view a PDF of a patient's completed post-infusion checklist by clicking "View Checklist" on the patient's profile page.

6. What do I do if a patient or prescriber that is associated with a request for a prescription for LEMTRADA is "Not REMS Authorized" or "Not REMS Certified" on my dashboard?

If a patient or the patient's prescriber is identified as "Not REMS Authorized" or "Not REMS Certified," **DO NOT** administer LEMTRADA vials to that patient or dispense LEMTRADA prescriptions from that prescriber. Contact a LEMTRADA REMS Specialist at 1-855-676-6326 if you have questions about the LEMTRADA REMS eligibility.

7. How can I access my profile?

You can access your profile from any page by clicking on [My Profile](#) in the top right corner of the site.

8. How can I update contact information on this site?

To update your contact information, contact the LEMTRADA REMS at 1-855-676-6326.

9. How do I reset my password?

Facilities Managers can change the password of the account by visiting the "Change Password" section on the [My Profile](#) page. To change the password, enter and confirm a new password and click the "Change Password" button.

10. How do I add a new user to my healthcare facility's LEMTRADA REMS dashboard?

Facilities Managers can add new users to the account by visiting the [Manage User](#) tab on your dashboard, and clicking the "Add New User" button to allow a staff member access to the account. Ensure that all users have been appropriately trained on the [LEMTRADA REMS requirements](#).

11. What do I do if the Healthcare Facility account manager (HCF REMS authorized representative) needs to change?

Please contact the LEMTRADA REMS at 1-855-676-6326.

If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6326, Mon - Fri, 8:30 am - 8:00 pm ET.

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REMS Certified Prescriber & Healthcare Facility Locator

Search for prescribers or healthcare facilities that are enrolled and certified in the LEMTRADA REMS and able to prescribe or dispense/administer LEMTRADA.

Please enter street address, city, state, or ZIP Code you would like to search for.

New Search:

Street address, city, state, or ZIP Code



REMS Certified Prescriber **REMS Certified Healthcare Facilities**

-  Certified Prescriber Name
Address
Address
P. (888) - 888 - 8888
-  Certified Prescriber Name
Address
Address
P. (888) - 888 - 8888
-  Certified Prescriber Name
Address
Address
P. (888) - 888 - 8888
-  Certified Prescriber Name
Address
Address
P. (888) - 888 - 8888
-  Certified Prescriber Name
Address
Address
P. (888) - 888 - 8888
-  Certified Prescriber Name
Address
Address
P. (888) - 888 - 8888

Genzyme is providing this search feature to help patients find prescribers and healthcare facilities that have been certified by the LEMTRADA REMS. Genzyme does not receive payment for providing this feature, and does not endorse, recommend, have jurisdiction over, or accept responsibility for the actions of any of the prescribers or healthcare facilities listed herein.

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REMS Certified Prescriber & Healthcare Facility Locator

Search for prescribers or healthcare facilities that are enrolled and certified in the LEMTRADA REMS and able to prescribe or dispense/administer LEMTRADA.

Please enter street address, city, state, or ZIP Code you would like to search for.

New Search:

Street address, city, state, or ZIP Code



REMS Certified Prescriber **REMS Certified Healthcare Facilities**

-  **Certified Center Name**
Address
Address
P. (888) - 888 - 8888
-  **Certified Center Name**
Address
Address
P. (888) - 888 - 8888
-  **Certified Center Name**
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The screenshot shows the mobile app interface for LEMTRADA REMS. At the top, there's a search bar with 'lemtrada.rems.com' and a 'Google' button. Below that are links for 'PRESCRIBING INFORMATION' and 'MEDICATION GUIDE'. The main header features the LEMTRADA logo, 'Welcome, Robert!', and a 'Menu' button. A navigation bar includes 'REMS Activity', 'Healthcare Facility Enrollment', and 'Patient Guides'. The main content area is titled 'LEMTRADA REMS Requirements' and lists key actions: retrain/enroll every 2 years, track progress, and download materials. Below this is a 'LEMTRADA REMS Activity' table showing five completed steps: Account Registration, Training, Enrollment Form Submission, Enrollment Processed, and REMS ID Assigned. A disclaimer states the site is for prescribers and updates every 12 hours. Contact information is provided: 1-855-676-6326, Mon-Fri, 8:30 am - 8:00 pm ET. The footer contains legal links, a disclaimer for US residents, copyright information for Genzyme (2019), and the Sanofi Genzyme logo.

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REMS Activity Healthcare Facility Enrollment Patient Guides

LEMTRADA REMS Requirements

Welcome to the LEMTRADA REMS. Here you can:

- Retrain and enroll in the LEMTRADA REMS every 2 years
- Manage and/or track your progress through the LEMTRADA REMS training and enrollment
- Download materials to help support implementation of the LEMTRADA REMS

LEMTRADA REMS Activity

Steps	Activity	Progress
1.	Account Registration	Completed
2.	Training	Completed
3.	Enrollment Form Submission	Completed
4.	Enrollment Processed	Completed
5.	REMS ID Assigned	Completed

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The screenshot shows a mobile web browser interface for lemtradarems.com. At the top, there are navigation links for 'PRESCRIBING INFORMATION' and 'MEDICATION GUIDE'. The main header features the LEMTRADA logo, the text 'Welcome, Robert!', and a 'Menu' button. Below this is a secondary navigation bar with 'REMS Activity', 'Healthcare Facility Enrollment', and 'Patient Guides'. The main content area is titled 'LEMTRADA REMS Requirements' and includes a bullet point stating that healthcare facilities must be enrolled to dispense/administer LEMTRADA. Below this is a section for 'LEMTRADA REMS Healthcare Facility Enrollment' with a list of five steps: 1. Designate an authorized representative; 2. Register the authorized representative; 3. Review the LEMTRADA REMS Education Program; 4. Complete and sign the enrollment form; 5. Implement staff training. A green button labeled 'Review Online Training' is positioned below the list. At the bottom, there is contact information for questions and a footer with legal notices and the Sanofi Genzyme logo.

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REMS Activity Healthcare Facility Enrollment Patient Guides

LEMTRADA REMS Requirements

- Healthcare facilities must be enrolled in the LEMTRADA REMS to be able to dispense/administer LEMTRADA for patients with relapsing forms of multiple sclerosis (MS). Because of its safety profile, the use of LEMTRADA should generally be reserved for patients who have had an inadequate response to two or more drugs indicated for the treatment of MS

LEMTRADA REMS Healthcare Facility Enrollment

To enroll in the program, an authorized representative of the pharmacy must complete the following steps:

- 1 Designate an authorized representative
- 2 Register the authorized representative with the LEMTRADA REMS Training Center
- 3 Authorized representative must review the LEMTRADA REMS Education Program for Healthcare Facilities and LEMTRADA REMS Program Overview through the online module on this site
- 4 After completing the online module, complete and sign the LEMTRADA REMS Healthcare Facility Enrollment Form. This enrollment must be renewed every 2 years
- 5 Implement the necessary staff training and processes to comply with the LEMTRADA REMS requirements

[Review Online Training](#)

If you have questions about the LEMTRADA REMS or need help enrolling, call **1-855-676-6326**, Mon - Fri, 8:30 am - 8:00 pm ET.

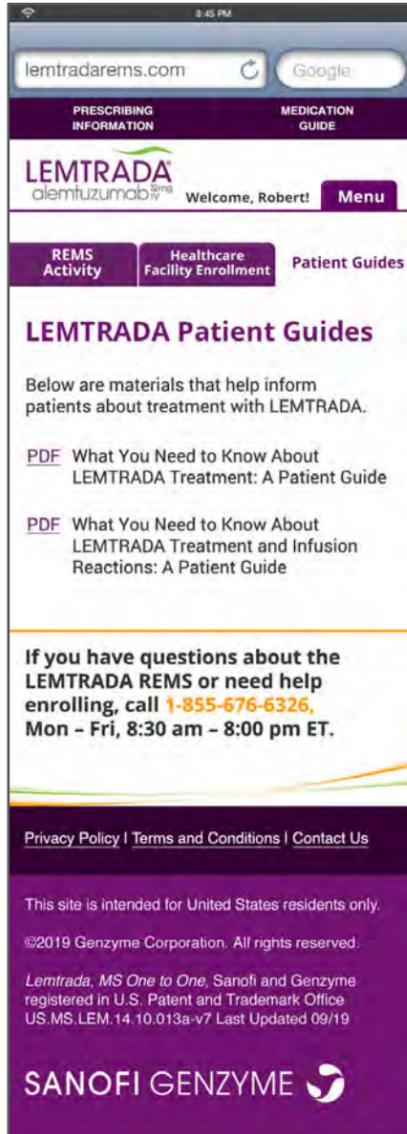
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DASHBOARD PAGES FOR HCF USERS WHO ARE NON-MANAGERS

The screenshot shows the LEMTRADA REMS Mobile dashboard. At the top, there is a search bar with 'lemtradarems.com' and a 'Google' button. Below the search bar are links for 'PRESCRIBING INFORMATION' and 'MEDICATION GUIDE'. The LEMTRADA logo is displayed with the text 'Welcome, Robert!' and a 'Menu' button. A red alert banner states 'You have 5 patient alerts!'. Below this, there are tabs for 'Our Patients' and 'Prescribers'. A text block explains that the list is for searching and sorting patient information. A tooltip is expanded over the patient list, containing the text: 'Search, sort, and navigate information about your patients below. Click on a name to view their individual profile.' The patient list consists of 10 rows, each with columns for Name, ID, and Authorization Status. The rows are: 1. John Doe (123456789) - Authorized; 2. John Doe (123456789) - Authorized; 3. John Doe (123456789) - Not Authorized; 4. John Doe (123456789) - Not Authorized; 5. John Doe (123456789) - Authorized; 6. John Doe (123456789) - Not Authorized; 7. John Doe (123456789) - Authorized; 8. John Doe (123456789) - Authorized; 9. John Doe (123456789) - Authorized; 10. John Doe (123456789) - Authorized. The tooltip is positioned over the 9th row. At the bottom of the list, there is an 'Infusion Verification' button. Below the list is a disclaimer: 'This site is provided as a resource for prescribers and is not intended as medical advice. Information on the site is updated periodically (approximately every 12 hours).' A contact information block follows: 'If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6326, Mon - Fri, 8:30 am - 8:00 pm ET.' The footer contains links for 'Privacy Policy | Terms and Conditions | Contact Us', a disclaimer 'This site is intended for United States residents only.', copyright information '©2019 Genzyme Corporation. All rights reserved.', and the Sanofi Genzyme logo.

9:45 PM

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[PRESCRIBING INFORMATION](#) [MEDICATION GUIDE](#)


Welcome, Robert! [Menu](#)

🔔 You have 5 patient alerts!

You have **5 patients** who have authorization requirements.

- **2 patients** are overdue for the LEMTRADA REMS Patient Status Form.
- **2 patients** need to be authorized by the LEMTRADA REMS Patient Status Form in 1 month.
- **1 patient** needs to be verified before their infusion.

[Manage my patient alert email preferences](#)

Our Patients Prescribers

Use the list below to search and sort information about patients using your healthcare facility to receive LEMTRADA. Only patients enrolled in the LEMTRADA REMS are eligible to receive infusions. Click on a patient's name to view their full profile.

You have 10 LEMTRADA patients ?

Search 🔍

Patient (REMS ID)	Prescriber (REMS ID)	REMS Status
John Doe (123456789)	Adam Smith (123456789)	Authorized
John Doe (123456789)	Adam Smith (123456789)	Authorized
🔔 John Doe (123456789)	Adam Smith (123456789)	Not Authorized
🔔 John Doe (123456789)	Adam Smith (123456789)	Not Authorized
John Doe (123456789)	Adam Smith (123456789)	Authorized
🔔 John Doe (123456789)	Adam Smith (123456789)	Not Authorized
John Doe (123456789)	Adam Smith (123456789)	Authorized
John Doe (123456789)	Adam Smith (123456789)	Authorized
John Doe (123456789)	Adam Smith (123456789)	Infusion Verification
John Doe (123456789)	Adam Smith (123456789)	Authorized

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PRESCRIBING INFORMATION
MEDICATION GUIDE

Welcome, Robert! [Menu](#)

LEMTRADA REMS (Risk Evaluation and Mitigation Strategy)

What is the LEMTRADA REMS?

A REMS is a strategy to manage known or potential serious risks associated with a drug product and is required by the FDA to ensure the benefits of a drug outweigh its risks. The purpose of the LEMTRADA REMS is to inform prescribers, pharmacies, healthcare facilities, and patients about the risks of:

AUTOIMMUNE CONDITIONS
LEMTRADA causes serious, sometimes fatal, autoimmune conditions such as immune thrombocytopenia and anti-glomerular basement membrane disease. Monitor complete blood counts with differential, serum creatinine levels, and urinalysis with urine cell counts at periodic intervals for 48 months after the last dose of LEMTRADA.

INFUSION REACTIONS
LEMTRADA causes serious and life threatening infusion reactions. LEMTRADA must be administered in a setting with appropriate equipment and personnel to manage anaphylaxis or serious infusion reactions.

STROKE
Serious and life-threatening stroke (including ischemic and hemorrhagic stroke) has been reported within 3 days of LEMTRADA administration. Instruct patients to seek immediate medical attention if symptoms of stroke occur.

MALIGNANCIES
LEMTRADA may cause an increased risk of malignancy including thyroid cancer, melanoma, and lymphoproliferative disorders. Perform baseline and yearly skin exams.

Re-enroll in the LEMTRADA REMS

You have been locked out due to incomplete re-enrollment. Please have the Healthcare Facility manager re-enroll in the LEMTRADA REMS in order for you to gain access to your profile information.

Find a REMS Certified Prescriber or Healthcare Facility

Search for prescribers or healthcare facilities that are certified by the LEMTRADA REMS to prescribe, dispense, or administer LEMTRADA.

Enter ZIP Code

REMS Certified Prescriber
 REMS Certified Healthcare Facility

Find

LEMTRADA REMS Requirements

HEALTHCARE FACILITIES

Healthcare facilities must be enrolled in the

LEMTRADA REMS to dispense/administer LEMTRADA for patients with multiple sclerosis. *One representative needs to enroll per healthcare setting.*

[Learn about Healthcare Facility Enrollment](#) ▶

This site is provided as a resource for prescribers and is not intended as medical advice. Information on the site is updated periodically (approximately every 12 hours).

If you have questions about the LEMTRADA REMS or need help enrolling, call **1-855-676-6326**,
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PRESCRIBING INFORMATION MEDICATION GUIDE

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alemtuzumab[®] Welcome, Robert! Menu

You have 5 patient alerts!

Our Patients Prescribers

You have 13 LEMTRADA prescribers associated with your patients ?

Search

Prescriber (REMS ID)	REMS Status	Patient Alerts
Adam Smith (123456789)	Certified	
Adam Smith (123456789)	Certified	
Adam Smith (123456789)	Certified	
Adam Smith (123456789)	Not Certified	!
Adam Smith (123456789)	Certified	
Adam Smith (123456789)	Not Certified	
Adam Smith (123456789)	Certified	
Adam Smith (123456789)	Certified	
Adam Smith (123456789)	Not Certified	!
Adam Smith (123456789)	Certified	

This site is provided as a resource for prescribers and is not intended as medical advice. Information on the site is updated periodically (approximately every 12 hours).

If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6326, Mon - Fri, 8:30 am - 8:00 pm ET.

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The screenshot shows the mobile app interface for LEMTRADA REMS. At the top, there's a navigation bar with 'PRESCRIBING INFORMATION' and 'MEDICATION GUIDE'. Below that is the LEMTRADA logo and a welcome message 'Welcome, Robert!' with a 'Menu' button. A red alert banner states 'You have 5 patient alerts!'. The main section is titled 'Our Patients' and 'Prescribers', with a sub-header 'You have 13 LEMTRADA prescribers associated with your patients'. A tooltip explains: 'Search, sort, and navigate information about your prescribers below. Click on a name to view their individual profile.' The list of prescribers includes names like 'Adam Smith' with phone numbers and certification status. Two entries are highlighted in red as 'Not Certified' with warning icons. A disclaimer at the bottom states: 'This site is provided as a resource for prescribers and is not intended as medical advice. Information on the site is updated periodically (approximately every 12 hours).' Contact information for help is provided: 'If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6326, Mon - Fri, 8:30 am - 8:00 pm ET.' The footer contains 'Privacy Policy | Terms and Conditions | Contact Us', a copyright notice for Genzyme Corporation, and the Sanofi Genzyme logo.

BOTH A PRESCRIBER AND HEALTHCARE FACILITY USER



FROM:
The LEMTRADA REMS
1-855-557-2478

TO:

«healthcare facility_site_name»
«healthcare facility_site_address»
«healthcare facility_site_city», «site_state» «site_zip»

RE: LEMTRADA® (alemtuzumab) Enrollment Confirmation and Authorization Verification for <<Patient_First_Name>> <<Patient_Last_Name>> REMS ID <<Patient_REMS_ID>> under care of Dr. <<Treating_Prescriber_Last_Name>>

This letter is to confirm that I, <<Representative_Name>> <<Representative_Last_Initial>> spoke to <<Insert contact name>> on <<Date>> and <<Time>> and confirmed that <<Patient_First_Name>> <<Patient_Last_Name>> REMS ID <<Patient_REMS_ID>> is enrolled and authorized to receive LEMTRADA at this time.

Attached you will find copies of the patient's LEMTRADA REMS Prescription Ordering Form and LEMTRADA REMS Authorization and Baseline Lab Form for your records.

If you have any questions regarding this information, or if there is a change in the patient's LEMTRADA treatment date, please contact the LEMTRADA REMS at 1-855-676-6326.

Please note that receipt of this document is not a guarantee of payment for medication.

Please see accompanying full Prescribing Information, including boxed WARNING, for Important Safety Information.

Sincerely,

The LEMTRADA REMS



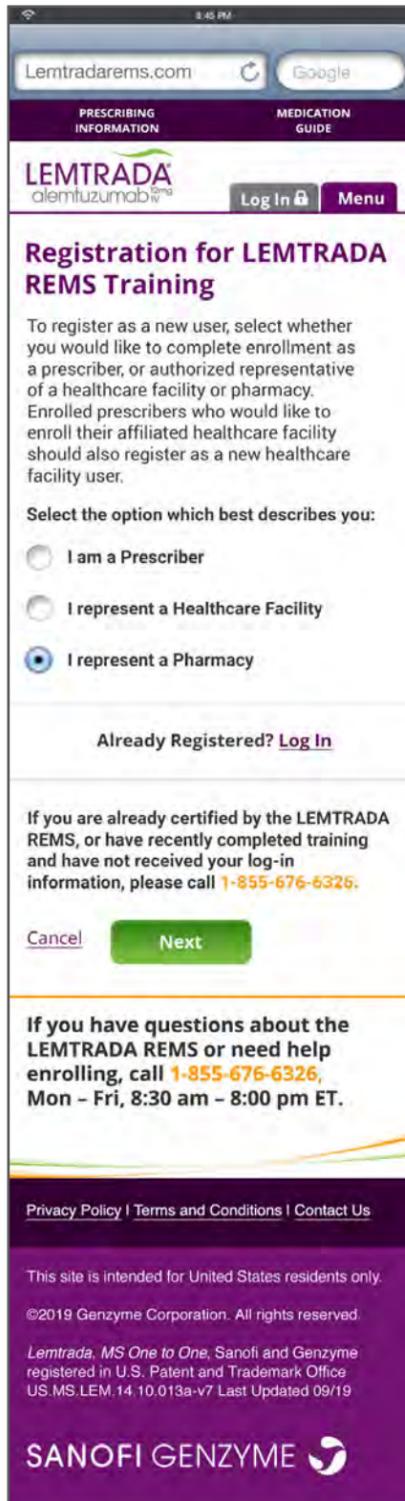
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LEMTRADA REMS MOBILE

Pharmacy Pages Only

PHARMACY TRAINING PAGES



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PRESCRIBING INFORMATION | MEDICATION GUIDE

LEMTRADA[®]
alemtuzumab[™]

Log In | Menu

Registration > Training > Enrollment

Pharmacy Registration for LEMTRADA REMS Training

To complete your training for the LEMTRADA REMS, please set up an account.

*Required

Email Address*

Create a Password*

Passwords must be at least 8 characters in length and contain a minimum of 3 out of the following: A number, an upper-case letter, a lower-case letter, a special character (e.g. !, *, #, \$, etc.)

Confirm Password*

Name of Pharmacy*

National Provider Identification (NPI) Number*

Pharmacy Address*

City*

State* **ZIP Code***

Select One |

Name of Authorized Pharmacy Representative*

Title*

Phone Number*

Fax Number*

*By checking this box, you indicate you will comply with our [terms and conditions](#).

[Cancel](#) [Register](#)

If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6326, Mon - Fri, 8:30 am - 8:00 pm ET.

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PRESCRIBING INFORMATION MEDICATION GUIDE

LEMTRADA[®]
alemtuzumab[®]

Log In Menu

Registration Training Enrollment

Pharmacy Registration for LEMTRADA REMS Training

To complete your training for the LEMTRADA REMS, please set up an account.

*Required

Email Address*

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Passwords must be at least 8 characters in length and contain a minimum of 3 out of the following: A number, an upper-case letter, a lower-case letter, a special character (e.g. !, *, #, \$, etc.)

Confirm Password*

Name of Pharmacy*

National Provider Identification (NPI) Number*

Pharmacy Address*

City*

State* **ZIP Code***

- ✓ Select
- Alabama
- Alaska
- American Samoa
- Arizona
- Arkansas
- California
- Colorado
- Connecticut
- Delaware
- District of Columbia
- Florida
- Georgia
- Guam
- Hawaii
- Idaho
- Illinois
- Indiana
- Iowa
- Kansas
- Kentucky
- Louisiana
- Maine
- Maryland
- Massachusetts
- Michigan
- Minnesota
- Mississippi
- Missouri
- Montana
- Nebraska
- Nevada
- New Hampshire

- New Jersey
- New Mexico
- New York
- North Carolina
- North Dakota
- Northern Mariana Islands
- Ohio
- Oklahoma
- Oregon
- Pennsylvania
- Puerto Rico
- Rhode Island
- South Carolina
- South Dakota
- Tennessee
- Texas
- Utah
- Vermont
- Virginia
- Virgin Islands
- Washington
- West Virginia
- Wisconsin
- Wyoming

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PRESCRIBING INFORMATION MEDICATION GUIDE

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Registration Training Enrollment

Pharmacy Registration for LEMTRADA REMS Training

To complete your training for the LEMTRADA REMS, please set up an account.

*Required

Email Address*

Please enter a valid email address.

Create a Password*

Please enter a password.
Passwords must be at least 8 characters in length and contain a minimum of 3 out of the following: A number, an upper-case letter, a lower-case letter, a special character (e.g. !, *, #, \$, etc.)

Confirm Password*

Please confirm password.

Name of Pharmacy*

Please enter name of pharmacy.

National Provider Identification (NPI) Number*

Please enter a valid NPI number.

Pharmacy Address*

Please enter pharmacy address.

City*

Please enter city.

State* **ZIP Code***

Select One

Please select a state. Please enter a 5-digit ZIP Code.

Name of Authorized Pharmacy Representative*

Please enter name of authorized pharmacy representative.

Title*

Please enter title.

Phone Number*

Please enter a 10-digit phone number.

Fax Number*

Please enter a 10-digit fax number.

*By checking this box, you indicate you will comply with our [terms and conditions](#).

Terms and conditions not selected.

Cancel Register

If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6326, Mon - Fri, 8:30 am - 8:00 pm ET.

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alemtuzumab[®]

Log In | Menu

Registration | Training | Enrollment

Pharmacy Registration for LEMTRADA REMS Training

To complete your training for the LEMTRADA REMS, please set up an account.

*Required

Email Address*

Please enter a valid email address.

Create a Password*

Password does not meet strength requirements.
Passwords must be at least 8 characters in length and contain a minimum of 3 out of the following: A number, an upper-case letter, a lower-case letter, a special character (e.g. !, *, #, \$, etc.)

Confirm Password*

Please confirm password.

Name of Pharmacy*

Please enter name of pharmacy.

National Provider Identification (NPI) Number*

Please enter a valid NPI number.

Pharmacy Address*

Please enter pharmacy address.

City*

Please enter city.

State* **ZIP Code***

Select One

Please select a state. Please enter a 5-digit ZIP Code.

Name of Authorized Pharmacy Representative*

Please enter name of authorized pharmacy representative.

Title*

Please enter title.

Phone Number*

Please enter a 10-digit phone number.

Fax Number*

Please enter a 10-digit fax number.

*By checking this box, you indicate you will comply with our [terms and conditions](#).

Terms and conditions not selected.

Cancel Register

If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6326, Mon - Fri, 8:30 am - 8:00 pm ET.

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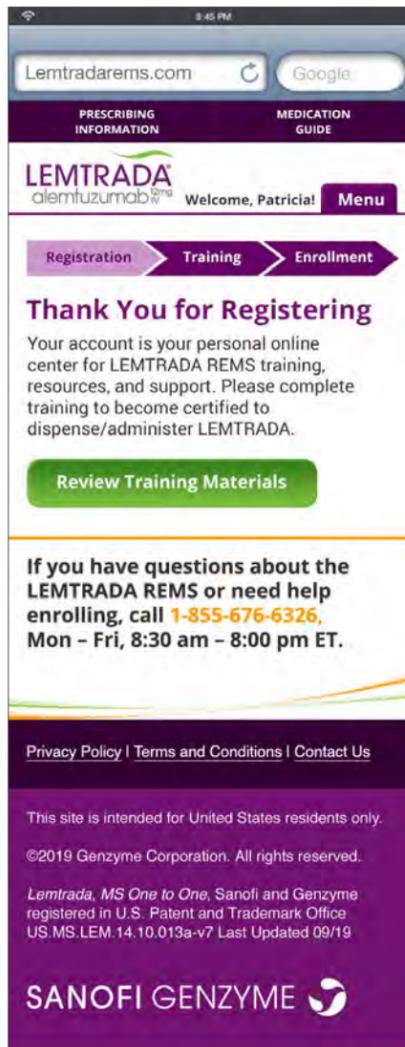
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LEMTRADA REMS Mobile - Pharmacy Registration Confirmation



The screenshot shows a mobile web browser interface for the LEMTRADA REMS Online Training Module. At the top, there is a search bar with 'LemtradaREMS.com' and a 'Google' search button. Below the search bar are two navigation links: 'PRESCRIBING INFORMATION' and 'MEDICATION GUIDE'. The main header features the LEMTRADA logo (alemfuzumabⁱⁿ), a welcome message 'Welcome, Patricia!', and a 'Menu' button. A progress indicator shows three steps: 'Registration', 'Training' (which is highlighted), and 'Enrollment'. The main content area is titled 'LEMTRADA REMS Online Training Module' and contains a warning: 'If inactive on the training module for 20 minutes, you will be automatically logged off the LEMTRADA website and lose your training progress.' This is followed by three bullet points: 1) Review LEMTRADA REMS Training Materials, including the Program Overview. 2) After reviewing, you will be asked to review and sign the LEMTRADA REMS Pharmacy Enrollment Form. 3) All staff at your site involved with dispensing/administrating LEMTRADA must be trained on the information in the module and adhere to the requirements of the LEMTRADA REMS. Below the bullet points, it states: 'Online training will take approximately 20 minutes. Please allow enough time to view the entire module. You will be automatically logged out after 20 minutes of inactivity and your training progress may be lost.' A green 'Continue' button is positioned below this text. At the bottom of the main content area, there is a call to action: 'If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6326, Mon - Fri, 8:30 am - 8:00 pm ET.' The footer contains links for 'Privacy Policy | Terms and Conditions | Contact Us', a disclaimer 'This site is intended for United States residents only.', copyright information '©2019 Genzyme Corporation. All rights reserved.', and the Sanofi Genzyme logo.

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alemfuzumabⁱⁿ

Welcome, Patricia! [Menu](#)

Registration Training Enrollment

LEMTRADA REMS Online Training Module

If inactive on the training module for 20 minutes, you will be automatically logged off the LEMTRADA website and lose your training progress.

- Please review the LEMTRADA REMS Training Materials, including the LEMTRADA REMS Program Overview in the module. You may review the material at your own pace and go back to any point of the presentation at your discretion
- After reviewing the material in the module, you will be asked to review and sign the LEMTRADA REMS Pharmacy Enrollment Form to complete your enrollment
- All staff at your site who will be involved with the dispensing/administrating of LEMTRADA must be trained on the information in the module and adhere to the requirements of the LEMTRADA REMS

Online training will take approximately 20 minutes. Please allow enough time to view the entire module. You will be automatically logged out after 20 minutes of inactivity and your training progress may be lost.

[Continue](#)

If you have questions about the LEMTRADA REMS or need help enrolling, call **1-855-676-6326**, Mon - Fri, 8:30 am - 8:00 pm ET.

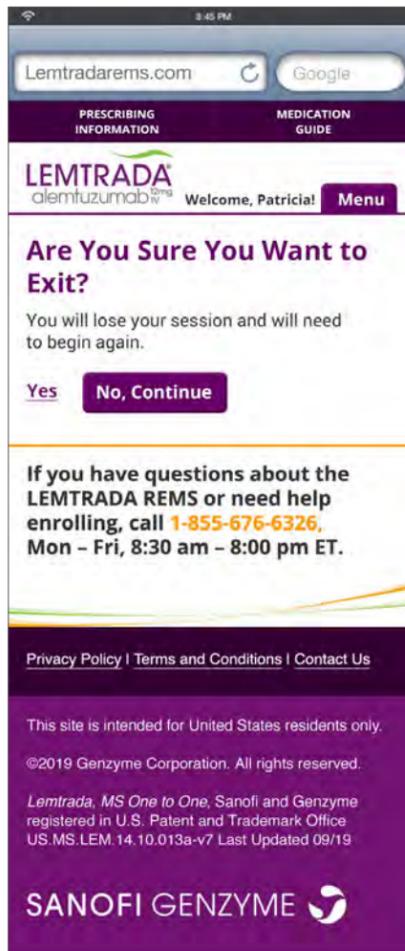
[Privacy Policy](#) | [Terms and Conditions](#) | [Contact Us](#)

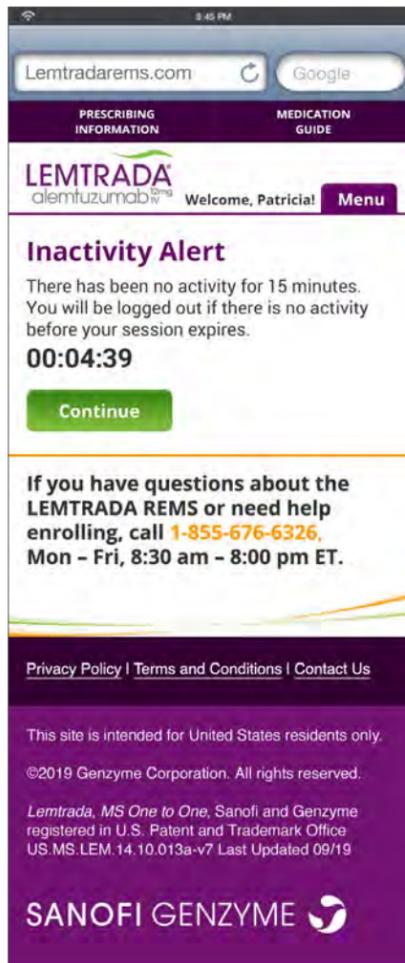
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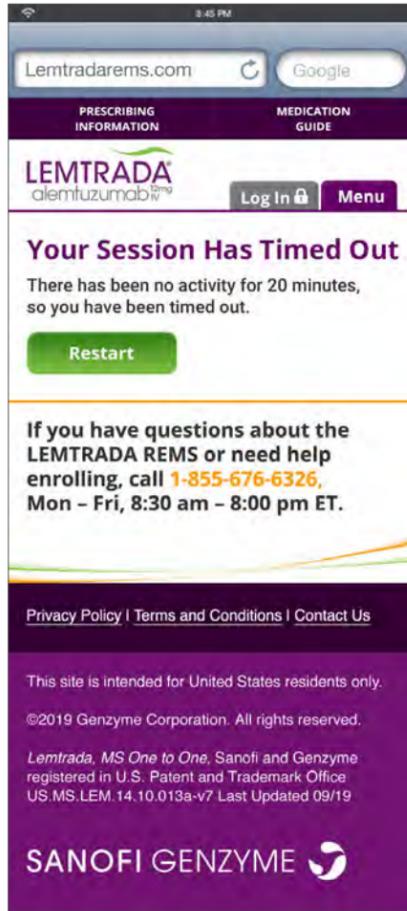
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LEMTRADA REMS Mobile - Pharmacy, Training Module Timed Out



9:45 PM

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PRESCRIBING INFORMATION
MEDICATION GUIDE

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Registration
Training
Enrollment

LEMTRADA REMS Training

LEMTRADA REMS Program Overview (1 of 2)

Total Training Screens: 1 of 2

LEMTRADA LEMTRADA REMS PROGRAM OVERVIEW

What is the LEMTRADA REMS (Risk Evaluation and Mitigation Strategy)?
 A REMS is a strategy to manage known or potential risks associated with a drug. It is required by the FDA to ensure that the benefits of the drug outweigh its risks. Due to serious risks of anti-tumor conditions, infection, neutropenia, and other complications, LEMTRADA (alemtuzumab) is only available through a restricted program called the LEMTRADA REMS.

LEMTRADA REMS Requirements

- Prescribers must be enrolled in the LEMTRADA REMS to be able to prescribe LEMTRADA.
- Pharmacies must be enrolled in the LEMTRADA REMS to be able to dispense LEMTRADA.
- Healthcare Facilities must be enrolled in the LEMTRADA REMS to be able to dispense and administer LEMTRADA.
- Patients must be notified and authorized to the LEMTRADA REMS in order to receive LEMTRADA.

PRESCRIBER ENROLLMENT INSTRUCTIONS

1. Complete the training program, which includes reviewing the following:
 - LEMTRADA Prescribing Information
 - LEMTRADA REMS Program Overview
 - LEMTRADA REMS Education Program for Prescribers
2. Successfully complete the 8-question LEMTRADA REMS knowledge assessment.
3. Enroll in the program by completing a LEMTRADA REMS Prescriber Enrollment Form.
4. Submit the completed and signed forms to the LEMTRADA REMS.

PHARMACY ENROLLMENT INSTRUCTIONS

1. An authorized representative must enroll on behalf of the pharmacy by reviewing the LEMTRADA REMS Program Overview and completing the LEMTRADA REMS Pharmacy Enrollment Form, which acknowledges that the pharmacy agrees to follow the provisions outlined in the LEMTRADA REMS, including:
 - All request staff at the pharmacy who will be involved with the dispensing of LEMTRADA must be authorized and trained.
 - The pharmacy will verify that a LEMTRADA REMS Prescription-Dispensing Form is received for each prescription.
 - The pharmacy will verify that prescriber and healthcare facilities are notified and patients are authorized to receive LEMTRADA prior to dispensing LEMTRADA.
 - Enrollment in the LEMTRADA REMS must be renewed every 3 years from initial enrollment.
2. Submit the completed and signed LEMTRADA REMS Pharmacy Enrollment Form to the LEMTRADA REMS.

Next
(1 of 2)

If you have questions about the LEMTRADA REMS or need help enrolling, call **1-855-676-6326**, Mon – Fri, 8:30 am – 8:00 pm ET.

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PRESCRIBING INFORMATION
MEDICATION GUIDE

alemfuzumabtm
Welcome, Patricia! [Menu](#)

Registration
▶
Training
▶
Enrollment

LEMTRADA REMS Training

LEMTRADA REMS Program Overview (2 of 2)

Total Training Screens: 2 of 2

HEALTHCARE FACILITY ENROLLMENT INSTRUCTIONS:

1. An authorized representative must enroll on behalf of the healthcare facility for receiving the LEMTRADA REMS training program for prescribers and completing the LEMTRADA REMS Healthcare Facility Enrollment Form, which authorizes the healthcare facility to enroll in the program outlined in the LEMTRADA REMS, including:
 - All staff of the facility who will be involved with the dispensing and administration of LEMTRADA must be trained, and a written record of all REMS training must be kept on file.
 - The healthcare facility will verify that prescribers are certified and patients are authorized to receive LEMTRADA prior to dispensing or administering LEMTRADA.
 - The healthcare facility will provide a copy of What You Need to Know About LEMTRADA Treatment and Safety Medicines, a Patient Guide to the patient on the first day of each treatment course when LEMTRADA is dispensed.
 - The healthcare facility will complete a LEMTRADA REMS Patient Enrollment Form for each patient at the conclusion of each treatment course and submit it to the LEMTRADA REMS within 1 business day.
 - Enrollment on the LEMTRADA REMS must be renewed every 3 years from initial enrollment.
2. Submit the completed and signed LEMTRADA REMS Healthcare Facility Enrollment Form to the LEMTRADA REMS.

PATIENT ENROLLMENT INSTRUCTIONS:

1. Complete the LEMTRADA REMS Patient Enrollment Form, which contains information to be completed by both the prescriber and the patient.
2. Provide a copy of What You Need to Know About LEMTRADA Treatment, a Patient Guide and a LEMTRADA REMS Safety Medicines Card to each patient who will receive LEMTRADA. You must also read the What You Need to Know About LEMTRADA Treatment, a Patient Guide to ensure you understand the risks, side effects and REMS requirements with the use of LEMTRADA.
3. Submit the completed and signed LEMTRADA REMS Patient Enrollment Form to the LEMTRADA REMS.
4. Provide the patient with a copy of the LEMTRADA REMS Patient Enrollment Form and keep a copy in the patient's medical record.

Where to Find REMS Information and Resources
Go to the LEMTRADA REMS web page at www.lemtradarems.com. For information related to enrollment in the LEMTRADA REMS, call 1-855-676-6326 or visit www.lemtradarems.com.

Indication and Usage
LEMTRADA is indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include relapsing remitting disease and active secondary progressive disease, in adults. Because of its safety profile, the use of LEMTRADA should generally be reserved for patients who have had no therapeutic response to first or second-line drugs indicated for the treatment of MS.

Contraindications of Use
LEMTRADA is not recommended for use in patients with clinically isolated syndrome (CIS) because of its safety profile. The Prescribing Information includes a **BOXED WARNING** for LEMTRADA. Please see accompanying Prescribing Information for complete safety information, including **BOXED WARNING**.

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Next
(2 of 2)

If you have questions about the LEMTRADA REMS or need help enrolling, call **1-855-676-6326**, Mon – Fri, 8:30 am – 8:00 pm ET.

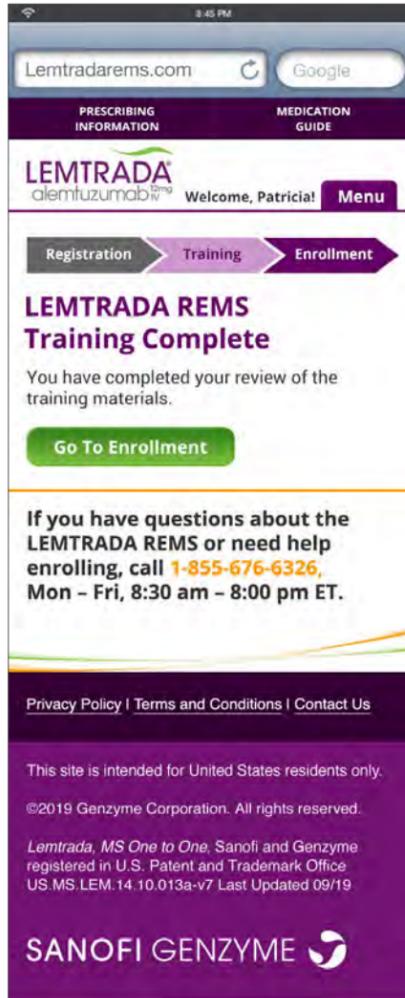
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Registration Training Enrollment

LEMTRADA REMS Pharmacy Enrollment Form

LEMTRADA is only available through the LEMTRADA REMS, a restricted distribution program. Only prescribers, pharmacies, healthcare facilities, and patients enrolled in the program are able to prescribe, dispense, administer, and receive LEMTRADA. An authorized representative of the pharmacy must enroll the pharmacy in the LEMTRADA REMS.

Please review the following information and submit to Genzyme by clicking the button below. Complete any missing information and correct any errors prior to submission.

All fields are required.

PHARMACY INFORMATION

Name of Pharmacy

National Provider Identification (NPI) Number

Pharmacy Address

City

State

ZIP Code

Name of Authorized Pharmacy Representative

Title

Phone Number

Fax Number

Email Address

PHARMACY AGREEMENT

I am the authorized representative designated by my pharmacy to coordinate the activities of the LEMTRADA REMS. By signing this form, I agree to comply with the following program requirements:

- I understand that my pharmacy must be certified with the LEMTRADA REMS to dispense LEMTRADA.
- I will oversee implementation and compliance with the LEMTRADA REMS requirements.
- I have reviewed the LEMTRADA REMS Program Overview.
- I will ensure that all relevant staff involved in the dispensing of LEMTRADA are educated and trained using the LEMTRADA REMS.
- I will put processes and procedures in place, and follow such processes and procedures, to ensure the following verifications are met prior to dispensing LEMTRADA:
 - The LEMTRADA REMS Prescription Ordering Form is received for each prescription.
 - The prescriber is certified, the infusion site is certified, and the patient is enrolled and authorized to receive LEMTRADA by contacting the LEMTRADA REMS prior to dispensing LEMTRADA.
 - Ensuring LEMTRADA is only dispensed to a certified infusion center.
- This pharmacy will establish procedures and protocols that are subject to audit, to help ensure compliance with the requirements of the LEMTRADA REMS.
- I understand that my pharmacy must renew enrollment in the LEMTRADA REMS every 2 years from initial enrollment.
- To make available to Genzyme, documentation to verify understanding of, and adherence to, the requirements of the LEMTRADA REMS.

I have verified that all details are correct.

By providing my e-signature, I attest that I have completed the educational training about LEMTRADA for pharmacies and I understand the benefits and risks of LEMTRADA. I understand that all staff members from my site must be trained on the information in the module and adhere to the requirements of the LEMTRADA REMS. I understand that I must complete this LEMTRADA REMS Pharmacy Enrollment Form in order to complete the enrollment process.

By entering my name, NPI number, and password, I confirm that I have completed the LEMTRADA REMS training and that I will comply with the requirements of the program.

[Cancel](#)

If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6326, Mon - Fri, 8:30 am - 8:00 pm ET.

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Please review the following information and submit to Genzyme by clicking the button below. Complete any missing information and correct any errors prior to submission.

All fields are required.

PHARMACY INFORMATION

Name of Pharmacy
Zebra Pharmacy

National Provider Identification (NPI) Number
0123456789

Pharmacy Address
70 Oak Street
Apartment 7C

City
Santa Monica

State

- ✓ Select
- Alabama
- Alaska
- American Samoa
- Arizona
- Arkansas
- California
- Colorado
- Connecticut
- Delaware
- District of Columbia
- Florida
- Georgia
- Guam
- Hawaii
- Idaho
- Illinois
- Indiana
- Iowa
- Kansas
- Kentucky
- Louisiana
- Maine
- Maryland
- Massachusetts
- Michigan
- Minnesota
- Mississippi
- Missouri
- Montana
- Nebraska

- Nevada
- New Hampshire
- New Jersey
- New Mexico
- New York
- North Carolina
- North Dakota
- Northern Mariana Islands
- Ohio
- Oklahoma
- Oregon
- Pennsylvania
- Puerto Rico
- Rhode Island
- South Carolina
- South Dakota
- Tennessee
- Texas
- Utah
- Vermont
- Virginia
- Virgin Islands
- Washington
- West Virginia
- Wisconsin
- Wyoming

Pharmacy Enrollment Form in order to complete the enrollment process.

By entering my name, NPI number, and password, I confirm that I have completed the LEMTRADA REMS training and that I will comply with the requirements of the program.

Full Name

NPI Number

Password

[Cancel](#)

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All fields are required.

PHARMACY INFORMATION

Name of Pharmacy

Please enter name of pharmacy.

National Provider Identification (NPI) Number

Please enter a valid NPI number.

Pharmacy Address

Please enter pharmacy address.

City

Please enter city.

State

Please select a state.

ZIP Code

Please enter a 5-digit ZIP Code.

Name of Authorized Pharmacy Representative

Please enter name of Authorized Pharmacy Representative.

Title

Please enter title.

Phone Number

Please enter a 10-digit phone number.

Fax Number

Please enter a 10-digit fax number.

Email Address

Please enter email address.

PHARMACY AGREEMENT

I am the authorized representative designated by my pharmacy to coordinate the activities of the LEMTRADA REMS. By signing this form, I agree to comply with the following program requirements:

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- To make available to Genzyme, documentation to verify understanding of, and adherence to, the requirements of the LEMTRADA REMS.

I have verified that all details are correct.
Please indicate information has been verified.
 By providing my e-signature, I attest that I have completed the educational training about LEMTRADA for pharmacies and I understand the benefits and risks of LEMTRADA. I understand that all staff members from my site must be trained on the information in the module and adhere to the requirements of the LEMTRADA REMS. I understand that I must complete this LEMTRADA REMS Pharmacy Enrollment Form in order to complete the enrollment process.

By entering my name, NPI number, and password, I confirm that I have completed the LEMTRADA REMS training and that I will comply with the requirements of the program.

Full Name

Please enter your full name.

NPI Number

Please enter your NPI number.

Password

Please enter a password.

[Cancel](#) [Submit](#)

If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6326, Mon - Fri, 8:30 am - 8:00 pm ET.

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The screenshot shows a mobile app interface for LEMTRADA REMS. At the top, there is a search bar with 'LemtradaREMS.com' and a 'Google' button. Below the search bar are two tabs: 'PRESCRIBING INFORMATION' and 'MEDICATION GUIDE'. The main header features the LEMTRADA logo (alemfuzumab^{inj}) and a personalized greeting 'Welcome, Patricia!' with a 'Menu' button. A progress bar indicates the user's status: 'Registration' (completed), 'Training' (in progress), and 'Enrollment' (current step). The main content area has a heading 'Enrollment Is Complete!' followed by a paragraph: 'You have successfully completed online enrollment in the LEMTRADA REMS. You will receive a confirmation email with your LEMTRADA REMS Identification Number. A Genzyme representative will also follow up with you to schedule an appointment to verify enrollment.' Below this is a bolded instruction: 'If you do not receive a confirmation email after the representative's visit, please contact a LEMTRADA REMS Specialist at 1-855-676-6326.' Another paragraph states: 'Once your enrollment has been verified, you will have access to the online support center available to certified members of the LEMTRADA REMS. The site provides tools and resources to help you manage your patients throughout their treatment with LEMTRADA.' A final instruction says: 'Download a copy of your LEMTRADA REMS Pharmacy Enrollment Form for your records.' A separate box contains: 'If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6326, Mon - Fri, 8:30 am - 8:00 pm ET.' The footer includes links for 'Privacy Policy | Terms and Conditions | Contact Us', a disclaimer 'This site is intended for United States residents only.', copyright information '©2019 Genzyme Corporation. All rights reserved.', and the Sanofi Genzyme logo.

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LEMTRADA REMS Training

LEMTRADA REMS Program Overview (1 of 2)
Total Training Screens: 1 of 2

LEMTRADA **LEMTRADA REMS PROGRAM OVERVIEW**

What is the LEMTRADA REMS (Risk Evaluation and Mitigation Strategy)?
A REMS is a strategy to manage known or potential risks associated with a drug. It is required by the FDA to ensure that the benefits of the drug outweigh its risks. Due to serious risks of autoimmune reactions, infusion reactions, stroke and malignancy, LEMTRADA (alemtuzumab) is only available through a restricted program called the LEMTRADA REMS.

LEMTRADA REMS Requirements

- Prescribers must be enrolled in the LEMTRADA REMS to be able to prescribe LEMTRADA.
- Pharmacists must be enrolled in the LEMTRADA REMS to be able to dispense LEMTRADA.
- Healthcare Facilities must be enrolled in the LEMTRADA REMS to be able to dispense and administer LEMTRADA.
- Patients must be enrolled and authorized in the LEMTRADA REMS in order to receive LEMTRADA.

PRESCRIBER ENROLLMENT INSTRUCTIONS

- Complete the training program, which includes reviewing the following:
 - LEMTRADA Prescribing Information
 - LEMTRADA REMS Program Overview
 - LEMTRADA REMS Enrollment Program for Prescribers
- Successfully complete the 8-question LEMTRADA REMS Knowledge Assessment.
- Email the program by completing a LEMTRADA REMS Prescriber Enrollment Form.
- Submit the completed and signed Form to the LEMTRADA REMS.

PHARMACY ENROLLMENT INSTRUCTIONS

- An authorized representative must enroll on behalf of the pharmacy by reviewing the LEMTRADA REMS Program Overview and completing the LEMTRADA REMS Pharmacy Enrollment Form, which acknowledges that the pharmacy agrees to follow the provisions outlined in the LEMTRADA REMS, including:
 - all relevant staff at the pharmacy who will be involved with the dispensing of LEMTRADA must be educated and trained.
 - The pharmacy will verify that a LEMTRADA REMS Prescription Ordering Form is received for each prescription.
 - The pharmacy will verify that prescribers and healthcare facilities are certified and patients are authorized to receive LEMTRADA prior to dispensing LEMTRADA.
 - Enrollment in the LEMTRADA REMS must be renewed every 2 years from initial enrollment.
- Submit the completed and signed LEMTRADA REMS Pharmacy Enrollment Form to the LEMTRADA REMS.

Next (1 of 2)

If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6326, Mon – Fri, 8:30 am – 8:00 pm ET.

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LEMTRADA REMS (Risk Evaluation and Mitigation Strategy)

What is the LEMTRADA REMS?

A REMS is a strategy to manage known or potential serious risks associated with a drug product and is required by the FDA to ensure the benefits of a drug outweigh its risks. The purpose of the LEMTRADA REMS is to inform prescribers, pharmacies, healthcare facilities, and patients about the risks of:

AUTOIMMUNE CONDITIONS
LEMTRADA causes serious, sometimes fatal, autoimmune conditions such as immune thrombocytopenia and anti-glomerular basement membrane disease. Monitor complete blood counts with differential, serum creatinine levels, and urinalysis with urine cell counts at periodic intervals for 48 months after the last dose of LEMTRADA.

INFUSION REACTIONS
LEMTRADA causes serious and life threatening infusion reactions. LEMTRADA must be administered in a setting with appropriate equipment and personnel to manage anaphylaxis or serious infusion reactions.

STROKE
Serious and life-threatening stroke (including ischemic and hemorrhagic stroke) has been reported within 3 days of LEMTRADA administration. Instruct patients to seek immediate medical attention if symptoms of stroke occur.

MALIGNANCIES
LEMTRADA may cause an increased risk of malignancy including thyroid cancer, melanoma, and lymphoproliferative disorders. Perform baseline and yearly skin exams.

Complete Enrollment in the LEMTRADA REMS

You have not completed your review of the training materials. You must review the training materials in order to complete your enrollment in the LEMTRADA REMS.

Review Training Materials

Find a REMS Certified Prescriber or Healthcare Facility

Search for prescribers or healthcare facilities that are certified by the LEMTRADA REMS to prescribe, dispense, or administer LEMTRADA.

Enter ZIP Code

REMS Certified Prescriber
 REMS Certified Healthcare Facility

Find

LEMTRADA REMS Requirements

PHARMACIES

Pharmacies must be enrolled in the

LEMTRADA REMS to be able to dispense LEMTRADA for patients with multiple sclerosis.

[Learn about Pharmacy Enrollment](#)

If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6326, Mon - Fri, 8:30 am - 8:00 pm ET.

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Complete Enrollment in the LEMTRADA REMS

You must review the training materials in order to complete your enrollment in the LEMTRADA REMS.
Please call *MS One to One*® at 1-855-676-6326 to speak with a Genzyme representative.

Find a REMS Certified Prescriber or Healthcare Facility

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Enter ZIP Code

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[Learn about Pharmacy Enrollment ▶](#)

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Review Training Materials Again

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Enter ZIP Code

REMS Certified Prescriber
 REMS Certified Healthcare Facility

[Find](#)

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PHARMACY DASHBOARD PAGES

The screenshot shows a mobile web browser interface for the LEMTRADA REMS Pharmacy Dashboard. At the top, there is a search bar with 'LemtradaREMS.com' and a 'Google' button. Below the search bar are two navigation links: 'PRESCRIBING INFORMATION' and 'MEDICATION GUIDE'. The main header features the LEMTRADA logo (alemtezumab[®]) and a personalized welcome message 'Welcome, Patricia!' with a 'Menu' button. The main content area is titled 'LEMTRADA REMS Pharmacy Dashboard' and includes a brief introduction: 'Authorized representatives of pharmacies can use this site to coordinate fulfilling the LEMTRADA REMS requirements.' A key section asks 'Have you verified all prescription requests?' and provides a phone number '1-855-676-6326' with hours 'Mon - Fri, 8:30 am - 8:00 pm ET'. A list of three verification steps is provided: 1) the prescriber is REMS certified to prescribe LEMTRADA, 2) the healthcare facility is REMS certified to administer LEMTRADA, and 3) the patient is enrolled and authorized by the LEMTRADA REMS. Below this, a note states '> Re-enroll in the LEMTRADA REMS' and explains that pharmacies must renew enrollment every 2 years while authorized representatives renew annually. A prominent green button labeled 'Re-enroll Now' is positioned below the text. A final section offers assistance: 'If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6326, Mon - Fri, 8:30 am - 8:00 pm ET.' The footer contains links for 'Privacy Policy | Terms and Conditions | Contact Us', a disclaimer 'This site is intended for United States residents only.', copyright information '©2019 Genzyme Corporation. All rights reserved.', and the Sanofi Genzyme logo.



8:45 PM

PRESCRIBING INFORMATION
MEDICATION GUIDE

Welcome, Patricia! [Menu](#)

LEMTRADA REMS (Risk Evaluation and Mitigation Strategy)

What is the LEMTRADA REMS?

A REMS is a strategy to manage known or potential serious risks associated with a drug product and is required by the FDA to ensure the benefits of a drug outweigh its risks. The purpose of the LEMTRADA REMS is to inform prescribers, pharmacies, healthcare facilities, and patients about the risks of:

AUTOIMMUNE CONDITIONS
LEMTRADA causes serious, sometimes fatal, autoimmune conditions such as immune thrombocytopenia and anti-glomerular basement membrane disease. Monitor complete blood counts with differential, serum creatinine levels, and urinalysis with urine cell counts at periodic intervals for 48 months after the last dose of LEMTRADA.

INFUSION REACTIONS
LEMTRADA causes serious and life threatening infusion reactions. LEMTRADA must be administered in a setting with appropriate equipment and personnel to manage anaphylaxis or serious infusion reactions.

STROKE
Serious and life-threatening stroke (including ischemic and hemorrhagic stroke) has been reported within 3 days of LEMTRADA administration. Instruct patients to seek immediate medical attention if symptoms of stroke occur.

MALIGNANCIES
LEMTRADA may cause an increased risk of malignancy including thyroid cancer, melanoma, and lymphoproliferative disorders. Perform baseline and yearly skin exams.

Re-enroll in the LEMTRADA REMS

You have been locked out due to incomplete re-enrollment. Please click the link below to re-enroll in the LEMTRADA REMS.

Re-enroll Now

Find a REMS Certified Prescriber or Healthcare Facility

Search for prescribers or healthcare facilities that are certified by the LEMTRADA REMS to prescribe, dispense, or administer LEMTRADA.

Enter ZIP Code

REMS Certified Prescriber
 REMS Certified Healthcare Facility

Find

LEMTRADA REMS Requirements

PHARMACIES

Pharmacies must be enrolled in the

LEMTRADA REMS to be able to dispense LEMTRADA for patients with multiple sclerosis.

[Learn about Pharmacy Enrollment](#) ▶

If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6326, Mon – Fri, 8:30 am – 8:00 pm ET.

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LEMTRADAREMS.COM | Google

PRESCRIBING INFORMATION | MEDICATION GUIDE

LEMTRADA
alemtuzumab [®] Welcome, Patricia! Menu

My Profile

Patricia Washington

(REMS ID 123456)
7776 Golden Blossom Run
Zook, IL 62056-3630
Office Phone: xxx-xxx-xxxx
Fax: xxx-xxx-xxxx

If any of your information is incorrect or has recently changed, please call **1-855-676-6326**, Mon - Fri, 8:30 am - 8:00 pm ET so we can make appropriate updates.

Change Your Password

Passwords must be at least 8 characters in length and contain a minimum of 3 out of the following: A number, an upper-case letter, a lower-case letter, a special character (e.g. !, ", #, \$, etc.)

Current Password

New Password

Confirm Password

Change Password

This site is provided as a resource for prescribers and is not intended as medical advice. Information on the site is updated periodically (approximately every 12 hours).

If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6326, Mon - Fri, 8:30 am - 8:00 pm ET.

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LEMTRADA REMS Mobile - Pharmacy, My Profile, Error

LEMTRADA
alemtuzumab

PRESCRIBING INFORMATION | MEDICATION GUIDE

Welcome, Patricia! Menu

My Profile

Patricia Washington

(REMS ID 123456)
7776 Golden Blossom Run
Zook, IL 62056-3630
Office Phone: xxx-xxx-xxxx
Fax: xxx-xxx-xxxx

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Current Password

Please enter password.

New Password

Please enter valid password.

Confirm Password

Please confirm new password.

Change Password

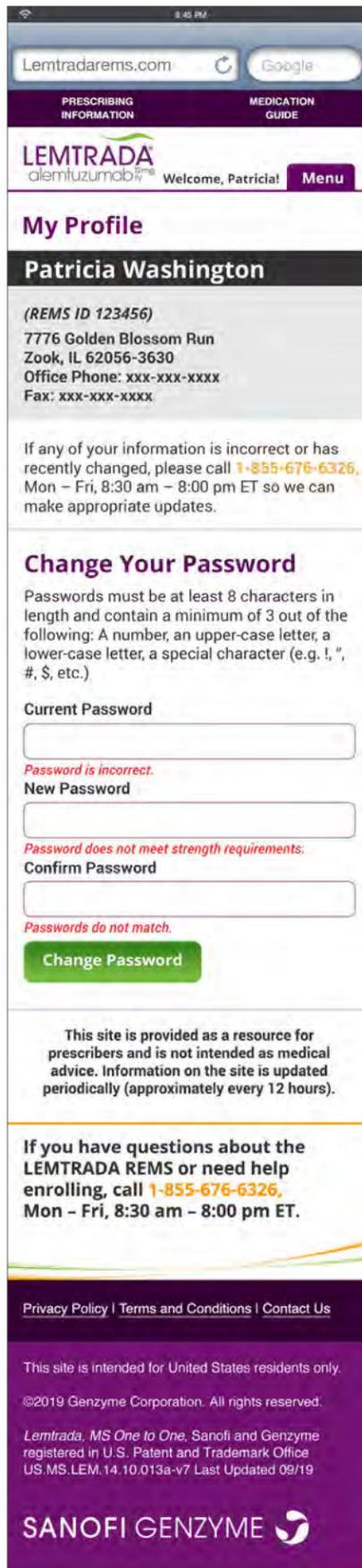
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The screenshot shows the mobile app interface for LEMTRADA REMS. At the top, there is a search bar with 'Lemtradarems.com' and a 'Google' button. Below this are navigation links for 'PRESCRIBING INFORMATION' and 'MEDICATION GUIDE'. The main header features the LEMTRADA logo, the text 'alemfuzumab', a personalized greeting 'Welcome, Patricia!', and a 'Menu' button. Two tabs, 'Forms' and 'FAQs', are visible, with 'FAQs' being the active tab. The 'Frequently Asked Questions' section includes an introductory paragraph and a list of eight questions. The first question is expanded, showing its answer. At the bottom, there is a call to action for help with enrollment, a footer with legal links, a disclaimer, copyright information, and the Sanofi Genzyme logo.

LEMTRADA
alemfuzumab

Welcome, Patricia! Menu

Forms FAQs

Frequently Asked Questions

Use the following FAQs to answer your questions about the LEMTRADA REMS. If you cannot find an answer to your question, or if you have additional questions, contact the LEMTRADA REMS at 1-855-676-6326, Mon – Fri, 8:30 am – 8:00 pm ET.

[Expand](#)

1. How can I verify that prescribers are eligible to prescribe LEMTRADA?
Please call the LEMTRADA REMS at 1-855-676-6326 to verify if a prescriber is REMS certified to prescribe LEMTRADA.
2. How can I verify that a healthcare facility is eligible to dispense/administer?
3. How do I verify that patients are authorized to receive a LEMTRADA infusion?
4. What do I do if a patient, prescriber, or healthcare facility that is associated with a request for a prescription for LEMTRADA is "Not REMS Authorized" or "Not REMS Certified"?
5. How can I access my profile?
6. How can I update contact information on this site?
7. How do I reset my password?
8. What do I do if the Pharmacy account manager (Pharmacy authorized representative) needs to change?

If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6326, Mon – Fri, 8:30 am – 8:00 pm ET.

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PRESCRIBING INFORMATION MEDICATION GUIDE

LEMTRADA clemtuzumab **LEMTRADA** Welcome, Patricia! Menu

REMS Certified Prescriber & Healthcare Facility Locator

Search for prescribers or healthcare facilities that are enrolled and certified in the LEMTRADA REMS and able to prescribe or dispense/administer LEMTRADA.

Please enter street address, city, state, or ZIP Code you would like to search for.

New Search:

Street address, city, state, or ZIP Code



REMS Certified Prescribers **REMS Certified Healthcare Facilities**

- Certified Prescriber Name**
Address
Address
P. (888) - 888 - 8888
- Certified Prescriber Name**
Address
Address
P. (888) - 888 - 8888
- Certified Prescriber Name**
Address
Address
P. (888) - 888 - 8888
- Certified Prescriber Name**
Address
Address
P. (888) - 888 - 8888
- Certified Prescriber Name**
Address
Address
P. (888) - 888 - 8888
- Certified Prescriber Name**
Address
Address
P. (888) - 888 - 8888

Genzyme is providing this search feature to help patients find prescribers and healthcare facilities that have been certified by the LEMTRADA REMS. Genzyme does not receive payment for providing this feature, and does not endorse, recommend, have jurisdiction over, or accept responsibility for the actions of any of the prescribers or healthcare facilities listed herein.

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[PRESCRIBING INFORMATION](#) [MEDICATION GUIDE](#)


Welcome, Patricia! [Menu](#)

REMS Certified Prescriber & Healthcare Facility Locator

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Please enter street address, city, state, or ZIP Code you would like to search for.

New Search:

Street address, city, state, or ZIP Code



REMS Certified Prescribers

REMS Certified Healthcare Facilities

Certified Center Name

Address

P. (888) - 888 - 8888

Certified Center Name

Address

P. (888) - 888 - 8888

Certified Center Name

Address

P. (888) - 888 - 8888

Certified Center Name

Address

P. (888) - 888 - 8888

Certified Center Name

Address

P. (888) - 888 - 8888

Certified Center Name

Address

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VV-REG-0833078 0.1

Reference ID: 4512344

The screenshot displays the mobile application interface for LEMTRADA REMS. At the top, there is a search bar with 'LemtradaREMS.com' and a 'Google' search button. Below this are links for 'PRESCRIBING INFORMATION' and 'MEDICATION GUIDE'. The main header features the LEMTRADA logo, the text 'Welcome, Patricia!', and a 'Menu' button. A navigation bar includes 'REMS Activity', 'Pharmacy Enrollment', and 'Patient Guides'. The main content area is titled 'LEMTRADA REMS Requirements' and includes a welcome message and a list of actions: 'Retrain and enroll in the LEMTRADA REMS every 2 years', 'Manage and/or track your progress through the LEMTRADA REMS training and enrollment', and 'Download materials to help support implementation of the LEMTRADA REMS'. Below this is a 'LEMTRADA REMS Activity' section with a progress table.

Steps	Activity	Progress
1.	Account Registration	Completed
2.	Training	Completed
3.	Enrollment Form Submission	Completed
4.	Enrollment Processed	Completed
5.	REMS ID Assigned	Completed

Below the table, there is a disclaimer: 'This site is provided as a resource for prescribers and is not intended as medical advice. Information on the site is updated periodically (approximately every 12 hours).' A call to action follows: 'If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6326, Mon - Fri, 8:30 am - 8:00 pm ET.' The footer contains links for 'Privacy Policy | Terms and Conditions | Contact Us', a notice that the site is for U.S. residents only, copyright information for Genzyme Corporation (©2019), and the Sanofi Genzyme logo.

LEMTRADA REMS Pharmacy Enrollment

- Pharmacies must be enrolled in the LEMTRADA REMS to be able to dispense LEMTRADA for patients with multiple sclerosis

To enroll in the program, an authorized representative of the pharmacy must complete the following steps:

- 1 Designate an authorized representative
- 2 Register the authorized representative with the LEMTRADA REMS Training Center
- 3 Authorized representative must review the LEMTRADA REMS Program Overview
- 4 After reviewing the material, complete and sign the LEMTRADA REMS Pharmacy Enrollment Form. This enrollment must be renewed every 2 years
- 5 Implement the necessary staff and training processes to comply with the LEMTRADA REMS

[Review Online Training](#)

If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6326, Mon - Fri, 8:30 am - 8:00 pm ET.

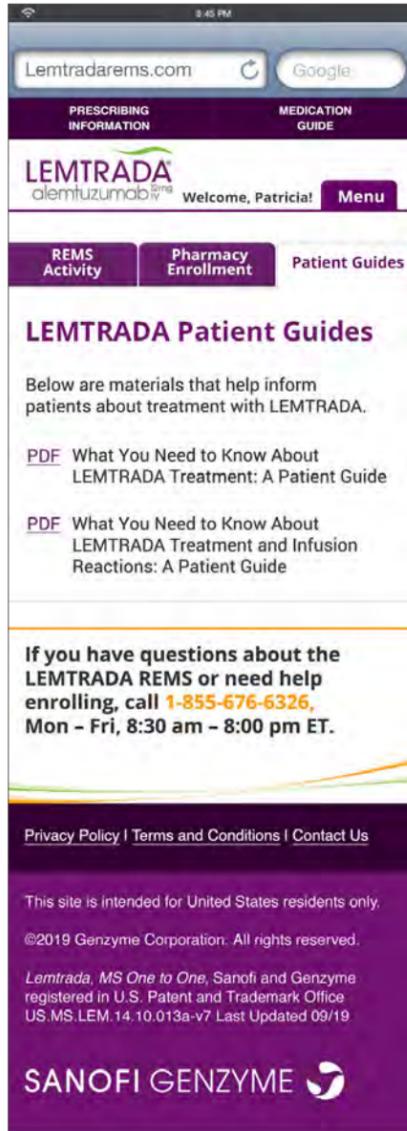
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[Date]

[Treating Provider First Name] [Treating Provider Last Name], [Treating Provider Title]
[Treating Correspondence Primary Contact First Name] [Treating Correspondence
Primary Contact Last Name]
[Treating Site Name]
[Treating Site Address 2]
[Treating Site Address 1]
[Treating Site City, State ZIP]

RE: Prescriber LEMTRADA® (alemtuzumab) REMS Responsibilities Reminder

Dear Dr. [Provider Last Name],

This letter is to remind you of your responsibilities as a prescriber enrolled in the LEMTRADA REMS . Please remember that you must:

1. **Keep Track of Needed Lab Monitoring:** Prescribers are required to keep track of the laboratory monitoring status of all patients who have been infused with LEMTRADA from first infusion until 48 months after the last infusion.
2. **Complete LEMTRADA REMS Status Forms:** For every patient who is infused with LEMTRADA, prescribers are required to complete a LEMTRADA REMS Patient Status Form 6 months after the first infusion, and then every subsequent 6 months until 48 months after the patient's last infusion.

If you have any questions about requirements, please call the LEMTRADA REMS program at 1-855-676-6326, Monday through Friday, 8:30 am to 8:00 pm Eastern Time.

Sincerely,

LEMTRADA REMS



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[Date]

[Patient_First_Name] [Patient_Last_Name]
[Patient_Primary_Address_2]
[Patient_Primary_Address_1]
[Patient_Primary_City], «Patient_State» «Patient_ZIP»

Dear [Patient_First_Name] [Patient_Last_Name]:

When enrolling in the LEMTRADA REMS, you and your doctor agreed that you will participate in monthly laboratory monitoring until 4 years after your last infusion to monitor for possible side effects.

The lab tests, which are required every 30 days, are important to identify side effects like autoimmune conditions. Please make sure to continue to schedule and go to your monthly lab appointments.

It is also important that you look for symptoms of these side effects by doing your own symptom self-checks, as described in *What You Need to Know About LEMTRADA Treatment: A Patient Guide* that your doctor gave you before you started your LEMTRADA treatment.

As part of the program, you are receiving these monthly reminders for your lab tests. For your convenience, the program offers options on how you can receive your monthly reminders:

- By mail
- By phone
- By email

If you wish to change the way you receive these reminders, please call the LEMTRADA REMS at 1-855-676-6326.

If you have questions about LEMTRADA or your monthly lab monitoring, please call the LEMTRADA REMS at 1-855-676-6326, Monday through Friday, 8:30 am to 8:00 pm ET. In addition, please contact the LEMTRADA REMS if your contact information has changed.

Sincerely,

LEMTRADA REMS



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/s/

NICHOLAS A KOZAUER
10/29/2019 09:02:32 AM