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:

<table>
<thead>
<tr>
<th>To become certified to prescribe</th>
<th>1. Review the drug’s Prescribing Information.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2. Review the following: Program Overview and Education Program for Prescribers.</td>
</tr>
<tr>
<td></td>
<td>3. Successfully complete the Knowledge Assessment and submit it to the REMS Program.</td>
</tr>
<tr>
<td></td>
<td>4. Enroll in the REMS by completing the Prescriber Enrollment Form and submitting it to the REMS Program.</td>
</tr>
</tbody>
</table>

Before treatment initiation (first dose)

| 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

| 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

| 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

| 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

| 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

13. Report any adverse events suggestive of autoimmune conditions, infusion reactions, stroke, and malignancies to Genzyme.

14. Report if an enrolled patient who has received LEMTRADA within the last 48 months is no longer under your care to Genzyme.

2. Patients who are prescribed LEMTRADA:

Before treatment initiation

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.

2. Enroll in the REMS Program by completing the Patient Enrollment Form with the prescriber. Enrollment information will be provided to the REMS Program.

3. Get a skin exam.

Before treatment initiation, within 30 days prior to the first infusion date of each treatment course

4. Be monitored for autoimmune conditions and/or malignancies.

During treatment; after each infusion for at least 2 hours

5. Be monitored for infusion reactions.

During treatment, at periodic intervals

6. Be monitored for autoimmune conditions and/or malignancies.

7. Inform the prescriber if you have had a stroke.

During treatment, yearly

8. Get a skin exam.

After last infusion, at periodic intervals for 48 months

9. Be monitored for autoimmune conditions and/or malignancies.

10. Inform the prescriber if you have had a stroke.

At all times

11. Inform the prescriber if any reactions or symptoms are experienced after receiving LEMTRADA.

12. Have the Patient Safety Information Card with you.

3. Pharmacies that dispense LEMTRADA must:
<table>
<thead>
<tr>
<th>To become certified to dispense</th>
<th>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.</th>
</tr>
</thead>
<tbody>
<tr>
<td>2. Have the authorized representative review the Program Overview.</td>
<td></td>
</tr>
<tr>
<td>3. Have the authorized representative enroll in the REMS Program by completing the Pharmacy Enrollment Form and submitting it to the REMS Program.</td>
<td></td>
</tr>
<tr>
<td>4. Train all relevant staff involved in dispensing LEMTRADA using the Program Overview.</td>
<td></td>
</tr>
<tr>
<td>5. Establish processes and procedures to verify that the Prescription Ordering Form is received for each prescription.</td>
<td></td>
</tr>
<tr>
<td>Before dispensing</td>
<td>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.</td>
</tr>
<tr>
<td>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.</td>
<td></td>
</tr>
<tr>
<td>To maintain certification to dispense, every 2 years</td>
<td>8. Have the authorized representative re-enroll in the REMS Program by completing the Pharmacy Enrollment Form.</td>
</tr>
<tr>
<td>At all times</td>
<td>9. Maintain records of training.</td>
</tr>
<tr>
<td>10. Maintain records of all processes and procedures including compliance with those processes and procedures.</td>
<td></td>
</tr>
<tr>
<td>11. Comply with audits carried out by Genzyme to ensure that all processes and procedures are in place and are being followed.</td>
<td></td>
</tr>
</tbody>
</table>

4. Healthcare facilities that dispense and administer LEMTRADA must:
| To become certified to dispense and administer | 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 | 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 | 10. Assess the patient for infusion reactions. |
| After the last infusion, within 5 business days | 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

1. 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 hard copy 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:

<table>
<thead>
<tr>
<th>Target Audience</th>
<th>Communication Materials and Dissemination Plans</th>
</tr>
</thead>
</table>
| Healthcare Providers and Healthcare Facilities enrolled in the LEMTRADA REMS Program. | REMS Letter: REMS Letter 2 for Healthcare Providers  
1. Email within 60 calendar days of approval of the REMS modification (04/2019).  
   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  
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).  
   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
22. Patient Letter: Monitoring Reminder
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® (alemtuzumab) 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.

Reference ID: 4512344
**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

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Lemtrada, Sanofi and Genzyme registered in U.S. Patent and Trademark Office.

US.MS.LEM.14.10.011-v5 Last Updated 07/19

Reference ID: 4512344
# 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® (alemtuzumab). 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)

<table>
<thead>
<tr>
<th>Name (Last, First)*</th>
<th>Date of Birth (MM/DD/YYYY)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Street Address*</td>
<td>City*</td>
</tr>
<tr>
<td>Phone Number*</td>
<td>Gender* □ Male □ Female</td>
</tr>
<tr>
<td>Secondary Contact (Last, First)</td>
<td>Phone Number</td>
</tr>
</tbody>
</table>

## PRESCRIBER INFORMATION (PLEASE PRINT)

| Prescriber Name (Last, First)* | NPI Number* | Phone Number* |

## 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 LEMTRA is associated with serious risks, including autoimmune conditions, infusion reactions, stroke, 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 every 3 months 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 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.

I prefer to be contacted:
- By mail □ By phone
- By email (please provide email address)

## PATIENT SIGNATURE

Patient/Legal Representative

| Print Name* | Relationship to | Date* |

## PRESCRIBER SIGNATURE

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

| Prescriber Signature* | Date* |
**LEMTTRA® 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*

LEMTTRA® (alemtuzumab) 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 PRINT**

<table>
<thead>
<tr>
<th>PHARMACY INFORMATION (PLEASE PRINT)</th>
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<tbody>
<tr>
<td>Name of Pharmacy*</td>
</tr>
<tr>
<td>Pharmacy Address*</td>
</tr>
<tr>
<td>City*</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>Name of Authorized Pharmacy Rep.</td>
</tr>
<tr>
<td>Phone Number*</td>
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</tr>
</tbody>
</table>

**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**

<table>
<thead>
<tr>
<th>Authorized Pharmacy Representative Signature*</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Print Name*</td>
<td>Title</td>
</tr>
</tbody>
</table>

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

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US.MS.LEM.14.11.006-v3 Last Updated 03/19

Reference ID: 4512344
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® (alemtuzumab) 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)

<table>
<thead>
<tr>
<th>Name of Institution or Healthcare Facility*</th>
<th>NPI Number*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infusion Facility Address*</td>
<td></td>
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<tr>
<td>City*</td>
<td>State*</td>
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<tr>
<td>Ship-to Street Address (if different)*</td>
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<td>City*</td>
<td>State*</td>
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<tr>
<td>Phone Number*</td>
<td>Fax Number*</td>
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<tr>
<td>Name of Authorized Healthcare Facility Representative*</td>
<td>Title*</td>
</tr>
</tbody>
</table>

Site Affiliation
☐ Academic ☐ Government ☐ Ambulatory/Freestanding ☐ Hospital Based ☐ 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:

- 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.

Reference ID: 4512344
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.

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

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Lemtrada, Sanofi and Genzyme registered in U.S. Patent and Trademark Office
US.MS.LEM.14.11.004-v4 Last Updated 3/19

Reference ID: 4512344
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.

LEMTARDA 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
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](http://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](http://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

<table>
<thead>
<tr>
<th>Condition</th>
<th>Activity</th>
<th>Timing</th>
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</thead>
<tbody>
<tr>
<td>Immune Thrombocytopenia (ITP)</td>
<td>Complete blood count with differential</td>
<td>Prior to initiating LEMTRADA treatment</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Monthly until 48 months after last infusion</td>
</tr>
<tr>
<td>Glomerular Nephropathies, including anti-GBM disease</td>
<td>Urine protein to creatinine ratio</td>
<td>Prior to initiating LEMTRADA treatment</td>
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<td></td>
<td>Serum creatinine</td>
<td>Prior to initiating LEMTRADA treatment</td>
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<td></td>
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<td></td>
<td>Urinalysis with microscopy</td>
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<td>Thyroid Disorders</td>
<td>Thyroid function tests (such as TSH)</td>
<td>Prior to initiating LEMTRADA treatment</td>
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<tr>
<td></td>
<td></td>
<td>Every 3 months until 48 months after last infusion</td>
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<tr>
<td>Autoimmune Hepatitis</td>
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<td></td>
<td>Periodically until 48 months after last infusion</td>
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<tr>
<td>Melanoma</td>
<td>Skin examinations</td>
<td>Prior to initiating LEMTRADA treatment</td>
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<td>Yearly</td>
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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.

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# Overview of LEMTRADA Monitoring

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Reference ID: 4512344
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.
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: ____________________________
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)
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 LEMTRADA REMS Education Program for Healthcare Facilities, 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
- Nurse
- Director of infusion center
- Prescriber
- 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.
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
LEMTURADA 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.

LEMTURADA 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/discholoration 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.
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.
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.

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

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

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

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

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.

Images © 2015 Genzyme Corporation.

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.

Delivering 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)

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

LEMTTRA 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?

<table>
<thead>
<tr>
<th>Overactive thyroid, or hypothyroidism</th>
<th>Underactive thyroid, or hypothyroidism</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Excessive sweating</td>
<td>- Unexplained weight gain</td>
</tr>
<tr>
<td>- Unexplained weight loss</td>
<td>- Feeling cold</td>
</tr>
<tr>
<td>- Eye swelling</td>
<td>- Worsening tiredness</td>
</tr>
<tr>
<td>- Nervousness</td>
<td>- Newly occurring constipation</td>
</tr>
<tr>
<td>- Fast heartbeat</td>
<td></td>
</tr>
</tbody>
</table>

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.

<table>
<thead>
<tr>
<th>Test</th>
<th>When</th>
<th>For how long</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood tests</td>
<td>Before treatment starts and every month after treatment</td>
<td>until 4 years after your last LEMTRADA infusion</td>
</tr>
<tr>
<td>Urine tests</td>
<td>Before treatment starts and every month after treatment</td>
<td>until 4 years after your last LEMTRADA infusion</td>
</tr>
</tbody>
</table>

**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](http://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.

<table>
<thead>
<tr>
<th>Doctor/Healthcare Team</th>
<th>Telephone Number</th>
<th>Address</th>
</tr>
</thead>
</table>
Important information to know about LEMTRADA

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.

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.

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LEMTTRA 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)

Infusion reactions (may occur more than 24 hours after the infusions), such as:
- hypersensitivity reactions (including anaphylaxis)
- fever
- hives
- irregular heartbeat

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
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.
• 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
**LEMTTRA® 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)

<table>
<thead>
<tr>
<th>Name (Last, First)*</th>
<th>Office Phone Number*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Address*</td>
<td></td>
</tr>
<tr>
<td>City*</td>
<td>State*</td>
</tr>
<tr>
<td>ZIP Code*</td>
<td></td>
</tr>
<tr>
<td>Prescriber LEMTRADA REMS Program Identification Number*</td>
<td></td>
</tr>
</tbody>
</table>

### PATIENT INFORMATION (PLEASE PRINT)

<table>
<thead>
<tr>
<th>Name (Last, First)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient LEMTRADA REMS Identification Number*</td>
</tr>
<tr>
<td>Date of Birth (MM/DD/YYYY)*</td>
</tr>
</tbody>
</table>

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

Total number of vials: _______

### SIGNATURE

Prescriber Signature*  
Date*

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US.MS.LEM.14.11.002-v3 Last Updated 03/19

Reference ID: 4512344
*Indicates a mandatory field.

I: PATIENT INFORMATION (PLEASE PRINT)

Name (Last, First)*
Date of Birth (MM/DD/YYYY)*
Street Address 1*
Street Address 2*
City* State* ZIP Code*
Phone Number*

THIS SECTION SHOULD BE FILLED OUT BY THE PRESCRIBER

II: INSURANCE INFORMATION

Primary Insurance Company
Secondary Insurance Company

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

Check one* 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*

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.

V: INFUSION CENTER INFORMATION†

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

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US.MS.LEM.14.10.012-v4 Last Updated 03/19

Reference ID: 4512344
**LEMTTRADA REMS PATIENT STATUS 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 every 6 months for each LEMTRADA® (alemtuzumab) patient under your care. Please submit 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.

### PRESCRIBER INFORMATION (PLEASE PRINT)

<table>
<thead>
<tr>
<th>Name (Last, First)*</th>
<th>Office Phone Number*</th>
</tr>
</thead>
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</tbody>
</table>

### PATIENT INFORMATION (PLEASE PRINT)

<table>
<thead>
<tr>
<th>Name (Last, First)*</th>
<th>Patient LEMTRADA REMS Identification Number*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date of Birth (MM/DD/YYYY)*</td>
<td>Date of Last LEMTRADA Infusion (MM/DD/YYYY)*</td>
</tr>
</tbody>
</table>

### IS THE ABOVE-NAMED PATIENT STILL UNDER YOUR CARE?*

<table>
<thead>
<tr>
<th>(Check one)</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

### IF NO, PLEASE INDICATE THE NAME OF THE HEALTHCARE PROVIDER NOW RESPONSIBLE FOR THIS PATIENT’S CARE

Healthcare Provider Name

Healthcare Provider Phone Number

Patient’s Current Healthcare Provider Is Unknown

### 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
- Malignancies [ ] Yes [ ] No
- Stroke [ ] 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

### PRESCRIBER’S SIGNATURE

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.

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

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VV-REG-0833078 0.1
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® (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.

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.

VV-REG-0833078 0.1

Reference ID: 4512344
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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US.MS.LEM.14.10.005-v3 Last Updated 03/19

VV-REG-0833078 0.1

Reference ID: 4512344
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.

LEMTTRA 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
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

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Reference ID: 4512344
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.

MALIGNEANTIES
LEMTRADA may cause an increased risk of malignancy including thyroid cancer, melanomas, and lymphoproiferative 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 disperse, 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.

Find a REMS Certified Prescriber or Healthcare Facility
Search for prescribers or healthcare facilities that are certified by the LEMTRADA REMS to disperse, dispense, or administer LEMTRADA.

Find

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.
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.
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. L, *, & etc.)

New Password

Password does not meet strength requirements.

Confirm Password

Passwords do not match.

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.
Reset Your Password

Please enter your email address and you will receive a link to reset your password.

Email address was not found in our system.

Reset Password
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 1-855-676-9326, Mon – Fri, 8:30 am – 8:00 pm ET.

Return to Home
LEMTTRADE REMS Prescriber Enrollment

Prescribers must be enrolled in the LEMTRADE REMS to be able to prescribe LEMTRADE for patients with relapsing forms of multiple sclerosis (MS). Because of its safety profile, the use of LEMTRADE 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 LEMTRADE REMS to dispense/administer LEMTRADE.

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

1. Register with the LEMTRADE REMS Online Training Center
2. Review the LEMTRADE REMS Education Program for Prescribers, including the LEMTRADE REMS Program Overview and the LEMTRADE 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 LEMTRADE REMS Prescriber Enrollment Form.

If you have questions about the LEMTRADE REMS or need help enrolling, call 1-855-676-6326, Mon – Fri, 8:30 am – 8:00 pm ET.
LEMTTRAĐA REMS Pharmacy 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 LEMTRAĐA REMS Training Center
3. Authorized representative must review the LEMTRAĐA REMS Program Overview through the online module on this site
4. After reviewing the material, complete and sign the LEMTRAĐA REMS Pharmacy Enrollment Form. This enrollment must be renewed every 2 years
5. Implement the necessary staff and training processes to comply with the LEMTRAĐA REMS requirements

Register for Online Enrollment

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

Below are materials that help inform patients about treatment with LEMTRADA.

- What You Need to Know About LEMTRADA Treatment: A Patient Guide
- 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 – 5:00 pm ET.
LEMTTRADE 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.

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.
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.
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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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.
You Are Submitting Information to Genzyme

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Go Back  Continue
Contact Us

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

Phone: 1-855-676-6376
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

Submit

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Lemtrada, MS-Doc by Ong, Sanofi and Genzyme registered in U.S. Patent and Trademark Office
US 851,591.14, 15, 013.07. Last Updated 06/19
LEMTTRADE REMS Desktop - Public Home, Contact Us - Email Selected

Contact Us

For any questions about LEMTRADE, please contact LEMTRADE 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:
Contact Us

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

Phone: 1-855-676-6376
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

Submit

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lemtrada, MS Day by Day, Sanofi and Genzyme registered in U.S. Patent and Trademark Office
US 959,344 A 8.10.03 V 7 Last Updated 06/19
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?
- Option 1
- Option 2
How would you like to be contacted?
- Email
- Phone
- Please enter a valid email address:

Submit
Thank You

Thank you for contacting us. Please remember that the information you provided will be kept strictly confidential and will not be shared with other parties.

You will be contacted by a Genzyme representative to address your concern. We will contact you by your choice of email or phone. If your issue has not been resolved in a timely manner, please call us at 1-855-676-6376, Mon – Fri, 8:30 am – 8:00 pm ET.
PREScriber training pages
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

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.
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

Confirm Password

First Name

Last Name

Degree

Select

National Provider Identification (NPI) Number

Name of Institution or Healthcare Facility

Street Address

City

State

ZIP Code

Phone Number

Fax Number

Mobile Phone 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.
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*

Confirm Password*

First Name*

Last Name*

Degree*

Select

- 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 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.
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*

Confirm Password*

First Name*

Last Name*

Degree*

National Provider Identification (NPI) Number*

Name of Institution or Healthcare Facility*

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

This box, you indicate you will comply with terms and conditions.

Register

About the LEMTRADA REMS Program

Call 1-855-676-6326, Mon – Fri, 8:30 am – 8:00 pm ET.

Contact Us

Terms of Use

SANOFI GENZYME

Reference ID: 4512344
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

Please enter a valid email address.
Password must be at least 8 characters in length and contain a minimum of 1 (out of the following: & number, an upper-case letter, a lower-case letter, a special character: e.g., !, #, %, etc.)

First Name

Last Name

Identify your first name.

Company Name

Degree

School

National Provider Identification (NPI) Number

Please enter a valid NPI number.

Name of Institution or Healthcare Facility

City

State

ZIP Code

Office Phone Number

Office Fax Number

Mobile Phone Number

if you have questions about the LEMTRADA REMS
or need help enrolling, call 1-855-476-6326, Mon – Fri, 8:30 am – 8:00 pm ET.
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*

Confirm Password*

Please enter your first name.
First Name*

Please enter your last name.
Last Name*

Educational degree.
Degree*

National Provider Identification (NPI) Number*

Name of Institution or Healthcare Facility*

Street Address*

Primary office address.
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.

Terms and conditions are required.

Cancel Register

if you have questions about the LEMTRADA REMS
or need help enrolling, call 1-855-476-6526, Mon – Fri, 8:30 am – 8:00 pm ET.
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

If you have questions about the LEMTRADA REMS or need help enrolling, call 1-833-676-6320, Mon – Fri, 8:30 am – 8:00 pm ET.
LEMTTRADE REMS Online Training Module

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

- Please review the LEMTRADE REMS Training Materials, including the full Prescribing Information, the LEMTRADE REMS Program Overview, and the LEMTRADE 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 3 attempts, you will be ineligible for online enrollment in the LEMTRADE REMS and will not be certified to prescribe/dispense LEMTRADE.

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.

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

If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6226, Mon – Fri, 8:30 am – 8:00 pm ET.

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Last Updated: 06/19
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.
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.
LEMTRADA REMS Training

Full Prescribing Information (3 of 27)  Total Training Screens: 3 of 41

FULL PRESCRIBING INFORMATION

WARNING: AUTODISEMBS, INJISION REACIONS, STROKE, AND MAJOR ADVERSE EVENTS

- LEMTRADA causes serious, sometimes fatal, autoimmune conditions such as demyelinating disease and uveitis. Patients may develop symptoms such as fatigue, fever, rash, or headaches. If these symptoms persist, discontinue treatment and refer the patient to a qualified healthcare provider.

- LEMTRADA increases the risk of infections, including urinary tract infections and pneumonia. Patients should be monitored for signs of infection, and appropriate antibiotics may be necessary.

- LEMTRADA increases the risk of stroke and major adverse events. Patients should be advised to report any symptoms of stroke, such as sudden numbness, weakness, or confusion.

- LEMTRADA increases the risk of thrombosis and arterial and venous thrombosis. Patients should be advised to report any symptoms of thrombosis, such as swelling, pain, or discoloration.

1 INDICATIONS AND USAGE

LEMTRADA is indicated for the treatment of relapsing forms of multiple sclerosis (RRMS) to decrease the frequency of exacerbations and to delay the occurrence of disability in adults. Because of its safety profile, the use of LEMTRADA should generally be reserved for patients who have had an inadequate response to other drugs indicated for the treatment of MS (see Warnings and Precautions (4.7)).

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 (4.7)).

2 DOSAGE AND ADMINISTRATION

2.1 Therapy and Procedures Prior to Treatment

If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6356, Mon – Fri, 8:30 am – 8:00 pm ET.
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 (5.1)): • complete any necessary vaccinations at least 4 weeks prior to treatment. • determine whether patients have a history of varicella and herpes zoster vaccine ≥ 2 years before treatment. For patients who are varicella-zoster seronegative, prevent treatment with LEMTRADA until ≥ 4 weeks after varicella vaccination. • instruct patients to avoid potential sources of Loa loa microfilariae. 2.2 Recommended Premedication and Concomitant Medication Concomitant Use Premedicate patients with high dose acetaminophen (1,000 mg orally/prednisolone or equivalent) immediately prior to LEMTRADA infusion and for the first 3 days of each treatment course (see Warnings and Precautions (5.2)). Hematopoietic Use of hematopoietic Info therapy for hematopoietic cell infusion on the first day of each treatment course and continue for a minimum of 2 months following treatment with LEMTRADA or until the CD34+ lymphocyte count is ≥ 200 cells per microliter. Additional courses may be given (see Warnings and Precautions (5.2)). 2.3 Recommended Dosage The recommended dosage of LEMTRADA is 12 mg per day for 3 treatment courses: First Treatment Course: 12 mg per day on 5 consecutive days (60 mg total dose). Second Treatment Course: 12 mg per 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 course. 2.4 Preparation Instructions Follow the steps below to prepare the diluent 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 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. 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.
LEMTRADA REMS Training

Full Prescribing Information (5 of 27)  Total Training Screens: 5 of 41

- Gently insert the bag into the solution. Ensure the integrity of the prepared solution, because it contains no antimicrobial preservatives. Each vial is for single use only.
- Prior to administration, review 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

Define LEMTRADA over 5-15 minutes starting within 3 hours after dilution. Extend the duration of the infusion if clinically indicated.

Administer LEMTRADA in a setting in which equipment and personnel are appropriately prepared, as well as actively managing adverse events. If adverse events occur, they should be reported immediately. Safety information is available on the Sanofi Genzyme website.

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 during and periodically during the infusion. Provide appropriate supportive treatment for adverse events as needed. Consider immediate discontinuation of the intravenous infusion if severe adverse events occur.

Obese patients or 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 any adverse events occurring during and after each infusion because they may indicate sequelae for prompt medical intervention.

2.6 Laboratory Testing and Monitoring to Assess Safety

Measure the same protein in a nutrient ratio prior to initiation of treatment. Conduct the following laboratory tests at baseline and at periodic intervals until 6 months after the last treatment course of LEMTRADA to monitor for early signs of potentially serious adverse effects:

- Complete blood count with differential (CBC) with platelet count
- Serum creatinine levels (prior to treatment initiation and at monthly intervals thereafter)
- Urine dipstick and urinalysis
- Serum antibodies for antibodies to antibodies to antibodies to antibodies to antibodies (anti-LMBA)
- Urine albumin and creatinine ratio (AUC) and serum creatinine levels (prior to treatment initiation and monthly thereafter)

Conduct baseline and yearly skin exams to monitor for melanoma.

3 DOSAGE FORMS AND STRENGTHS

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

4 CONTRAINDICATIONS
LEMTTRADE REMS Training

Full Prescribing Information (6 of 27) Total Training Screens: 6 of 41

5 WARNINGS AND PRECAUTIONS

5.1 Autoimmunity

Treatment with LEMTTRADE can result in the formation of autoantibodies and increase the risk of various autoimmune conditions.

In clinical studies (controlled and open-label citations), LEMTTRADE-treated patients experienced thyroid disorders (36.8%), immune hemolytic anemia (2%), and glomerulonephritis (0.3%). In postmarketing surveillance data, the incidence of autoimmune events in clinical trials and observational studies was as follows:

- Thyroid disorders: 0.3% of patients
- Immune hemolytic anemia: 0.3% of patients
- Glomerulonephritis: 0.3% of patients

In postmarketing surveillance, immune-mediated hepatitis, pericarditis, and pleuritis have been reported.

Classic autoimmune diseases such as pemphigus vulgaris and pemphigus foliaceus have been reported in patients with LEMTTRADE. Chronic destructive demyelinating polyradiculoneuropathy has been reported in the treatment of patients with B-cell chronic lymphocytic leukemia (B-CLL), as well as other autoimmune disorders. Treatment of patients with autoimmune disorders with LEMTTRADE was generally safe and well tolerated. However, patients with autoimmune disorders should be monitored closely for adverse events.

If autoimmune disorders develop, treatment with LEMTTRADE may be discontinued.

5.2 Infusion Reactions

LEMTTRADE causes cytokine release syndrome resulting in infusion reactions, some of which may be severe and life-threatening. Infusion reactions occurred in 35% of LEMTTRADE-treated patients and were generally managed with simple supportive measures.

If you have questions about the LEMTTRADE REMS or need help enrolling, call 1-655-467-3326, Mon – Fri, 8:30 am – 8:00 pm ET.
LEMTRADA REMS Training

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Reference ID: 4512344
Thyroid Cancer

LEMTTRA® may increase the risk of thyroid cancer. In controlled clinical studies, 3 of 899 (0.3%) LEMTRA®-treated patients developed thyroid cancer, compared to none in the interferon beta-1a treated group. Therefore, monitoring for thyroid cancer was performed more frequently in the LEMTRA®-treated group, because of the higher incidence of autoimmune thyroid disorders in these patients. Two additional cases of thyroid cancer in LEMTRA®-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 voice change, trouble swallowing or breathing, or a consistent cough not due to an upper respiratory tract infection.

References

LEMTTRA® may increase the risk of malignancies. In 5% clinical studies (controlled and uncontrolled extremities), 3 of 899 (0.3%) LEMTRA®-treated patients developed malignancies or malignancy suspicious. Of these patients had evidence of locally advanced disease.

Perform baseline and yearly skin examinations to monitor for malignancies in patients receiving LEMTRA®.

Lymphoproliferative Disorders and Lymphoma

Cases of lymphoproliferative disorders and lymphoma have occurred in LEMTRA®-treated patients and includes, a SALT lymphoma, Caffey’s Disease, and a febrile following treatment of non-Hodgkin Lymphoma-associated Bkin’s lymphoma. These are postmarketing reports of cases with unmonitored lymphoproliferative disorders or non-M0 patients.

Because LEMTRA® is an immunomodulatory therapy, caution should be exercised in initiating LEMTRA® in patients with lymphocytosis or ongoing malignancies.

LEMTTRA® is available only through a restricted program under a REMS (see Warnings and Precautions 2.5).

5.5 LEMTRA® REMS Program

LEMTTRA® is available only through a restricted program under a REMS called the LEMTRA® REMS Program because of the risks of immune-mediated, infusional reactions, and malignancies (see Warnings and Precautions 2.5).

Notable requirements of this LEMTRA® REMS Program include the following:

- Physicians must be certified with the program by enrolling and completing training.
- Physicians must enroll in the program and comply with ongoing monitoring requirements (see Dosage and Administration 6.6).
- Physicians must be certified with the program and only dispense to certified healthcare facilities that are authorized to receive LEMTRA®.
- Healthcare facilities must enroll in the program and verify that patients are authorized before enrolling. LEMTRA® Healthcare facilities must have secure access to equipment and personnel trained to manage infusion reactions.

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

Immune thrombocytopenia (ITP) occurred in 2% of LEMTRADA-treated patients in six clinical studies (controlled and uncontrolled extensions).

In a controlled clinical study in patients with MS, one LEMTRADA-treated patient developed ITP that was uncontrolled prior to the implementation of regular blood monitoring requirements, and died from intracranial hemorrhage. A subsequent patient (2/200 cells per microliter) as a result of ITP occurred in 2% of all LEMTRADA-treated patients in clinical studies in MS. Antiplatelet antibodies did not precede ITP onset. ITP has been diagnosed more than 5 years after the last LEMTRADA dose.

Symptoms of ITP include bruising, petechiae, spontaneous mucocutaneous bleeding (e.g., epistaxis, hemoptysis), and bruising that normal or minimal trauma. Exceptions to any also be indicative of anti-glomerular basement membrane disease (see Warnings and Precautions (1.7) and an appropriate differential diagnosis list to be validated. Restart the patient to maintain vigilance for symptoms they may experience and to seek immediate medical help if they have any concern.

Obtain complete blood counts (CBCs) with differential prior to initiation of treatment and at monthly intervals thereafter until 40 months after the last infusion (see Dosage and Administration (2.6)) after the 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

Glomerulonephropathies occurred in 1.5% of LEMTRADA-treated patients in six clinical studies. There were 5 cases of mesangial proliferative glomerulonephritis and 2 cases of anti-glomerular basement membrane disease (anti-GBM)

disease.

In promoting cases, some LEMTRADA-treated patients with anti-GBM disease developed anti-brain disease requiring dialysis or renal transplantation. Urgent evaluation and treatment is required. Baseline treatment may improve the preservation of renal function. Anti-GBM disease can be life-threatening if left untreated. Abramson hematuria, transferrin is hemospermia, and is a common component of anti-GBM disease and has been reported in promoting cases. Cases of anti-GBM disease have been diagnosed up to 40 months after the last dose of LEMTRADA.

Symptoms of nephropathy may include oliguria, hematuria, change in urine color, increased urine output, edema, dyspnea, and hypertension. Patients and caregivers should be instructed to seek medical advice if any concerns.

Obtain serum creatinine levels, arterial blood gas analysis, and urinalysis to establish renal function prior to initiation of treatment. Obtain serum creatinine, blood pressure, and edema levels at monthly intervals thereafter until 40 months after the last infusion. After the period of time, testing should be performed based on clinical findings suggestive of nephropathy.
5.8 Thyroid Disorders

Thyroid-activated disorders, including autonomous thyroid disorders, occurred in 348 of 1,627 patients in US clinical studies (controlled and open-label extension). Newly diagnosed thyroid disorders occurred throughout the randomized clinical trials followed up to 3 years after the first LEMTRADA dose. Autonomous thyroid disorders included Graves’ disease, hyperthyroidism, hypothyroidism, autoimmune thyroiditis, and goiter. Graves’ disease was reported with decreased vision, eye pain, and exophthalmos occurring in 2% of LEMTRADA-treated patients. Seven patients required surgical or medical decompression. Increased thyroid events occurred in about 3.3% of LEMTRADA-treated patients; 3.3% underwent thyroidectomy.

Thyroid disease poses special risks in women who are pregnant (see Uses in Specific Populations) or in lactation.

Obtain thyroid function tests, such as T3, T4 levels, prior to initiation of treatment and every 6 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 Graft Rejection

Autoimmune cytopenias such as leukopenia (9%), hemolytic anemia (4%), and pericarditis (4%) occurred in LEMTRADA-treated patients in US clinical studies (controlled and open-label extension). In cases of autoimmune hemolytic anemia, patients tested positive for direct antiglobulin antibodies, and early hemoglobin levels ranged from 3.0-5.0 g/dL. Symptoms of autoimmune hemolytic anemia include weakness, shortness of breath, palpitations, dark urine, and leg edema. One LEMTRADA-treated patient with autoimmune pericarditis died from pericardial tamponade, with additional autoimmune cytopenias, including fatal autoimmune hemolytic anemia and septic shock, have been reported in patients treated with LEMTRADA in the postmarketing setting. Such patients develop clinical symptoms, including unexplained fever and organ dysfunction.

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5.11 Infections

Infections occurred in 7% of LEMTRADA-treated patients compared to 3% of patients treated with interferon beta-1a in controlled clinical studies in 36 weeks up to 2 years in duration. Infections that occurred more often in LEMTRADA-treated patients than interferon beta-1a patients included upper respiratory infections, urinary tract infections, sinusitis, pneumonia, herpes zoster, and tooth infection.

The administration of live viral vaccines following a course of LEMTRADA. Patients treated with LEMTRADA have reduced immunity and may be at increased risk of infection following administration of live viral vaccines.

Consider delaying LEMTRADA administration in patients with active infections until the infections are fully controlled.

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

 Opportunistic infections

In the postmarketing setting, serious, sometimes fatal, opportunistic infections have been reported in patients taking LEMTRADA, including Legionnaires disease, histoplasmosis, Pneumocystis pneumonia, aspergillosis, mycobacterial infections, and cytomegalovirus infections.

Legionnaires disease infection

Legionnaires disease infections (e.g., pneumonia, pleuritis, eosinophilia, and gastrointestinal). including the listed case of Legionnaires disease pneumonia, have occurred in LEMTRADA-treated patients. Legionnaires pneumonitis has occurred as early as 4 weeks after treatment and up to 8 months after the last LEMTRADA dose. The duration of successful led for Legionnaires infection after LEMTRADA treatment is unknown.

Advise patients to avoid or adequately heat foods that are potential sources of Legionnaires disease (e.g., chilled salad, leafy produce, milk, soft cheeses, or uncooked meats, seafood, or poultry). Initiate these Legionnaires pneumonitis prior to starting LEMTRADA treatment. The incubation period for Legionnaires disease ranges from 3 to 10 days, with weakness, fever, chills, cough, diarrhea, nausea, vomiting, headache, malaise, and in some cases, diarrhea and vomiting. LEMTRADA is more effective in treating LEMTRADA pneumonitis. Symptoms of Legionnaires disease infection include fever, chills, diarrhea, nausea, vomiting, headache, malaise, and in some cases, diarrhea and vomiting. LEMTRADA pneumonitis is more common than drug-induced reactions. However, diarrhea, nausea, vomiting, and other non-specific symptoms are also more common among patients taking LEMTRADA.

Reference ID: 4512344
patients to watch for symptoms of Leucon infection and seek prompt medical help if symptoms occur.

Herpes Viral Infections
In controlled clinical studies, 10% of LEMTRADA-treated patients developed herpes viral infection compared to 3% of interferon beta-1a patients. These events included oral herpes (1.0%), herpes zoster (2.2%), herpetic simplex (1.8%) and genital herpes (1.1%). Human immunodeficiency infections in LEMTRADA-treated patients included primary varicella (0.5%), herpes zoster (0.2%) and herpes gestitans (0.1%). Administration of antiviral agents for herpes viral infections at appropriate dosages for treating symptoms, antiviral prophylaxis for herpes zoster-like lesions during the first 6 months of treatment course and treatment for post-dose-6 months following treatment with LEMTRADA or until the CD4+ lymphocyte count is > 200 cells per microliter, whichever occurs later (see Drug Interactions). (2.2).

Human Papilloma Virus
Cervical human papilloma virus (HPV) infections, including cervical dysplasia, occurred in 3% of LEMTRADA-treated patients. Human papilloma virus screening is recommended for female patients.

Tuberculosis
Tuberculosis occurred in patients treated with LEMTRADA and interferon beta-1b in controlled clinical studies. Active and latent tuberculosis cases occurred in 3% of LEMTRADA-treated patients and 3% of interferon beta-1a patients. Sputum culture results were not available. Tuberculosis screening according to local guidelines prior to initiation of LEMTRADA. For patients testing positive in tuberculin screening, test by standard medical practice prior to therapy with LEMTRADA.

Fungal Infection
Fungal infections, especially oral and vaginal candidiasis, occurred more commonly in LEMTRADA-treated patients (12%) than in patients treated with interferon beta-1a (9%) in controlled clinical studies in MS.

Infections in Non-MS Patients
During postmarketing use, severe 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 RCCM, as well as other disorders, generally at higher and more frequent doses than recommended in MS.

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

5.12 Progressive Multifocal Leuкоencephalopathy (PML)}
LEMTTRADE REMS Training

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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 in a short time. PML was diagnosed two months after the second course of LEMTTRADE. 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 significant medical problems and had been previously treated with natalizumab, which has a benign 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 LEMTRAD and perform an appropriate diagnostic evaluation. Typical symptoms associated with PML are diverse, progressive, and nonspecific and may vary in severity. Symptoms can include headache, fatigue, weakness, numbness, and changes in vision, speech, and coordination, leading to cognitive and psychosocial changes.

MRI findings may be apparent before clinical signs or symptoms. Cases of PML diagnosis based on MRI findings and the detection of JC Virus DNA in the cerebral spinal 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 become symptomatic with PML. Therefore, monitoring with MRI is essential that may be associated with PML may be needed in patients treated with LEMTRADA. Any significant worsening of a previously stable disease or unexpected unexpected findings as significant as those that have been reported in patients treated with other MS medications associated with PML. In some cases, PML-related mortality and morbidity have been reported in patients who were initially asymptomatic at diagnosis. This diagnosis was made by clinical and MRI findings. Therefore, patients treated with LEMTRADA should be monitored closely for the development of PML.

5.13 Acute Acalcemic Cholecystitis

LEMTTRADE 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 0.0% 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 initiation.

Typical risk factors for acute acalculous cholecystitis include surgical or traumatic injury to the abdomen, or the use of drugs known to cause cholecystitis, such as nonsteroidal anti-inflammatory drugs. The symptoms of acute acalculous cholecystitis include abdominal pain, fever, nausea, and vomiting. Although ultrasound and computed tomography were used to support the diagnosis of acute acalculous cholecystitis in some cases, some patients were treated conservatively with antibiotics and recovered without surgical intervention. However, others required cholecystectomy.

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5.14 Pneumonitis
In clinical studies, 4 of 127 (3.1%) LEMTRADA-treated patients had pneumonitis of varying severity. Cases of hypersensitivity pneumonitis and pneumonitis with diathesis occurred in clinical studies. Patients should be advised to report symptoms of pneumonitis, which may include shortness of breath, cough, wheezing, chest pain, or itchy eyes, and hoarseness.

5.15 Drug Products with Same Active Ingredient
LEMTTRA 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放大 efficacy effects on the immune system.

6 ADVERSE REACTIONS
The following systemic adverse reactions are described below and elsewhere in the labeling:
- Autoimmune: Autoimmune Thrombocytopenia (see Warnings and Precautions (5.2))
- Infections: Herpes Zoster (see Warnings and Precautions (5.4))
- Malignancies (see Warnings and Precautions (5.6))
- Gonococcal Osteomyelitis (see Warnings and Precautions (5.7))
- Thyroid Disorders (see Warnings and Precautions (5.8))
- Other: Autoimmune Cytopenias (see Warnings and Precautions (5.9))
- Autoimmune Reactivity (see Warnings and Precautions (5.10))
- Infections (see Warnings and Precautions (5.11))
- Prophylactic Multifocal Leukocapillaryitis (see Warnings and Precautions (5.12))
- Acute Aplastic Cholecystitis (see Warnings and Precautions (5.13))
- Pneumonitis (see Warnings and Precautions (5.14))

6.1 Clinical Trials Experience
In clinical trials, adalimumab was used under widely varying conditions, adverse reaction rates observed in the clinical trials of adalimumab directly compared to rates in the clinical trials of another drug or not represent the rates observed in practice.
In clinical trials (Study 1 and Study 2), a total of 81I patients with relapsing forms of MS received LEMTRADA. The population was 18 to 55 years of age, 69% were female, and 95% were Caucasian. A total of 81I patients received 1 dose of therapy, and 78I patients received a second course of therapy in 12 months. The overall follow-up in the clinical trials was approximately 9182 patient-years.
In US clinical trials controlled and open-label extensions, overall, a total of 1277 patients received LEMTRADA. Approximately 17% of patients received a total of 2 treatment courses and approximately 24% of patients received 1 dose of 3 treatment courses, others received a total of 4 or more treatment courses, although data beyond 3 treatment course are limited. This

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0.2 Lymphopenia

Nearly all (99.9%) patients treated with LEMTRADA in MS clinical trials experienced lymphopenia. The lowest lymphocyte counts occurred approximately 1 month after each course of treatment. The mean lymphocyte count at 1 month after LEMTRADA treatment was 0.25 × 10^9/L (range: 0.02-2.30 × 10^9/L) and 0.32 (0.02-1.51 × 10^9/L) for treatment courses 1 and 2, respectively. Total lymphocyte counts increased to near the baseline level of normal in approximately 40% of patients by 4 months after each LEMTRADA treatment course and approximately 80% of patients by 12 months after each course (see General Pharmacology).

0.3 Mental Behavior or Irritability

In clinical studies, 6.8% of patients in both the LEMTRADA and interferon beta-naive groups had events of altered behavior or mood disturbance. These events were generally mild or moderate. There were no apparent trends in either study treatment group. Mental behavior or irritation occurred in patients with or without a history of psychiatric or behavioral disorder. Advice to patients to report immediately any symptoms of depression or suicidal ideation to the prescribing physician.

0.4 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 structural identity of antibody (including inhibitory antibody positivity) may vary by assay used. A total of 32 patients developed an antibody to LEMTRADA. Of these 32 patients, 27 had no evidence of the antibody to interferon beta. The remaining 5 developed antibodies to interferon beta. Of these 5 patients, 4 were found to have antibodies to LEMTRADA with the incidence of antibodies to interferon beta.

Using an enzyme-linked immunosorbent assay (ELISA), and a competitive binding assay, anti-lemtrada binding antibodies were detected in 42%, 67%, and 79% of LEMTRADA-treated patients.
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patients, at months 1, 3, and 12 (Course 1) as well as 100%, 95%, and 99% of LEMTRADA-treated patients at months 15, 18, and 24 (Course 2). Samples that tested positive for binding antibodies were further evaluated for evidence of or neo-epitope using a flow cytometry assay. Neutralizing antibodies were detected in 0%, 40%, and 8% of positive binding antibody patients at months 1, 3, and 12 (Course 1) as well as 50%, 85%, and 85% of positive binding antibody patients at months 15, 18, and 24 (Course 2). Anti-leptomeningeal antibodies were not detected in any patients.

Through 2 treatment courses, there was no evidence from clinical trials that the presence of binding or neutralizing antibodies had a significant effect on clinical outcomes, total lymphocyte count, or adverse events. High titer anti-leptomeningeal antibodies, which were observed in 1 patient, were associated with incomplete lymphocyte depletion following a third or fourth treatment course. There was no clear effect of anti-leptomeningeal antibodies on the clinical efficacy or safety profile of LEMTRADA.

5.5 Postmarketing Experience

The following adverse reactions have been identified during post approval use of letermofor.

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 Experiences with LEMTRADA

Blood and Lymphatic System Disorders: Anemia, thrombocytopenia (see Warnings and Precautions 5.2)

Cardiovascular Disorders: Stroke, including hemorrhagic and ischemic stroke and cardiovascular arterial disease (see Warnings and Precautions 5.1)

Gastrointestinal System Disorders: Chest discomfort, including acute cholecystitis and acute exacerbation cholecystitis (see Warnings and Precautions 5.3)

Hepatobiliary Disorders: Hemorrhagic hepatic (see Warnings and Precautions 5.2)

Infections and Infestations: Opportunistic infections (see Warnings and Precautions 5.1)

Nervous System Disorders: Altered mental status, transient, Guillain-Barre syndrome (see Warnings and Precautions 5.1)

Polyneuropathy Disorders: Polyneuropathy hemorrhage (see Warnings and Precautions 5.2)

Postmarketing Experiences 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., 90mg) than recommended in the treatment of MS.

Cardiovascular 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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LEMTTRADE REMS Training

Pregnancy Excremen Risk

There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to LEMTRADE during pregnancy. Prescriptions are encouraged to register patients by calling 1-846-798-2000.

Risk Summary

There are no adequate data on the developmental risk associated with the use of LEMTRADA in pregnant women. LEMTRADE was not studied in pregnant hamsters in transgenic mice when administered during organogenesis [see Animal Data]. Antihumanized anti-CD20 monoclonal antibodies are known to induce an immunogenic response in mice and monkeys. The immunogenic response is not neutralizing, and a minimal background of anti-CD20 antibodies has been reported in humans.

Clinical Considerations

LEMTTRADE induces persistent thyroid disorders [see Warnings and Precautions (5.6)]. Untreated hypothyroidism in pregnant women increases the risk for miscarriage and poor neonatal outcomes. Neonatal hypothyroidism, if left untreated, can cause serious harm to the developing brain and permanent neurological damage. Neonatal hypothyroidism can be prevented by administration of levothyroxine to the mother during pregnancy or shortly after delivery.[5.7]

Data

Animal data

When LEMTRADA was administered to pregnant hamsters (transgenic mice) during organogenesis (gestational day 6-18 or 11-14) at doses of 7 or 15 mg/kg, no teratogenic effects were observed. However, there was an increase in malformations (increased postimplantation loss and the number of days with all viscera intact) in pregnant animals treated during GD 12-15. In a separate study in pregnant hamsters (transgenic mice), administration of LEMTRADA during organogenesis (GD 15-19 or GD 14-16) at doses of 5 or 10 mg/kg IV, dosed in 36- and 72-hourly treatments, was observed in the offspring at both doses tested.

In pregnant hamsters (transgenic mice), administration of LEMTRADA at doses of 7 or 10 mg/kg IV throughout gestation and lactation, there was an increase in topical dermal reactions during the postnatal period at 5 mg/kg. In addition to those in 72-hourly treatments, no antibodies were observed in the offspring at both doses tested.

8.2 Lactation

Risk Summary

There are no data on the presence of letrastuzumab in human milk, the effects on the breastfed infant, or the effects on milk production. Levetiracetam was detected in the milk of lactating hamsters in transgenic mice administered LEMTRADA [see Animal Data].

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The development 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

Alumunumab was detected in the milk of lactating beCD52 transgenic mice following intravenous administration of LEMTRADA to a dose of 10 mg/kg on postpartum days 16-17. Some levels of alumunumab were similar in lactating mother and offspring on postpartum day 13 and were associated with evidence of pharmacological activity (decreases in myelin basic protein) in the offspring.

8.3 Perinatal and Neonatal Use

Continuance

Before initiation of LEMTRADA treatment, women of childbearing potential should be counselled on the potential for serious adverse effects in the fetus. To avoid unintended pregnancy, LEMTRADA should not be administered to women of childbearing potential who are planning to conceive or for at least 10 months following the last course of treatment (see Use in Specific Populations: 8.4).

Impairment

In beCD52 transgenic mice, administration of LEMTRADA prior to and during the mating period resulted in adverse effects on various parameters in male and female offspring of variable severity and implications. The data are summarized in Table 3.4.1.

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 autoimmunity, infection reactions, and anaphylaxis, and because it may increase the risk of malignancies (infections, lymphomatoid granulomatosis, lymphoproliferative disorders, and lymphoma) (see Warnings and Precautions: 5.2, 5.4, 5.5).

8.5 Geriatric Use

Clinical evidence 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 10 mg/kg transgenic beCD52 transgenic mice, treated with and without high-dose beCD52, were monitored for 14 days after a single accidental infusion up to 10 mg/kg of LEMTRADA. Doses of LEMTRADA greater than those administered may increase the intensity and duration of infusion reactions or its/its effects. There is no known antidote for alumunumab overdose.

11 DESCRIPTION

Alumunumab is a recombinant humanized IgG1 kappa monoclonal antibody directed against the cell surface glycoprotein, CD52. Alumunumab has an approximate molecular weight of 150 kDa.
LEMTTRADA REMS Training

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Alumunium is produced in mammalian cell (Chinese hamster ovary) suspension culture in a constant medium containing antibiotics. Neomycin is not detectable in the final product.

LEMTTRADA (alemtuzumab) injection is sterile, clear and colorless to slightly yellow, solution (pH 7.2-7.4) for intravenous infusion.

Each 1 mL of solution contains 50 mg alumunium, sodium dihydrogen phosphate (0.35 mg), sodium chloride (4.04 mg), magnesium chloride (1.6 mg), potassium chloride (1.6 mg), potassium polyethylene glycol (2.2 mg), potassium chloride (0.5 mg), sodium chloride (0.05 mg), and Water for Injection USP.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

The precise mechanism by which alunumunium costs in therapeutic efficacy in multiple sclerosis is unknown. It is possible because it involves 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, alumunumium results in antibody-dependent cellular cytotoxicity and complement-mediated lysis.

12.2 Pharmacodynamics

Effects of REMS on the Lymphocyte Population

LEMTTRADA was administered to 1% and 2 B lymphocytes after each treatment course. In clinical trials, the lowest cell count occurred 1 month after a course of treatment at the time of the first post-treatment (post-EC) lymphocyte count. Lymphocyte counts then increased over time. It is common for counts to reach a peak after treatment and return to baseline levels over the next 3 months. Approximately 80% of patients had normal lymphocyte counts at 3 months after each treatment course and 70% had counts below the lower limit of normal after 12 months. Lymphocyte counts normalized in the majority of patients with lymphopenia by 3 months after each treatment course, but some patients had persistent lymphopenia.

Cardiac Electrophysiology

In a study of 27 506 patients, alunumunium 12 mg was given to subjects with a history of cardiovascular disease.

12.3 Pharmacokinetics

The pharmacokinetics of LEMTRADA were evaluated in a total of 141 patients with two-time points per patient on 3 consecutive days, followed by 12 mg on 3 consecutive days 12 months following the first treatment course.

Absorption

A single dose of 1 mg was given to patients with high-dose corticosteroid treatment within 7 days of starting the first treatment course.

13.1 LMTTRADA or need help enrolling, call 1-855-667-6336, Mon - Fri, 8:30 am - 8:00 pm ET.
Patients were randomized to receive LEMTRADA (n=426) or interferon beta-1a (n=282). At baseline, the mean age was 50.3 years, the mean disease duration was 6.3 years, and the mean EDSS score was 2.7.

The clinical outcome measure was the annualized relapse rate (ARR) over 2 years and the time to confirmed disability progression. Confirmed disability progression was defined as a 1 point increase above baseline EDSS (1.0 point increase for patients with baseline EDSS of 0) sustained for 6 months. The ARR 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

<table>
<thead>
<tr>
<th>Outcome</th>
<th>LEMTRADA (n=426)</th>
<th>Interferon beta-1a (n=282)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Annualized relapse rate</td>
<td>0.06</td>
<td>0.12</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Relative risk reduction</td>
<td>0.40</td>
<td>0.12</td>
<td></td>
</tr>
<tr>
<td>Burden of disease progression in Year 2</td>
<td>0.00</td>
<td>0.27</td>
<td></td>
</tr>
<tr>
<td>% of patients improving relapse in Year 2</td>
<td>0.00</td>
<td>0.47</td>
<td></td>
</tr>
<tr>
<td>MRI Outcomes</td>
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<td></td>
</tr>
<tr>
<td>Percent change in T2 lesion volume from baseline</td>
<td>-0.5</td>
<td>-0.12</td>
<td>0.014</td>
</tr>
</tbody>
</table>

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

Study 2 was a 5-year randomized, open-label, active-controlled, non-blinded trial comparing intravenous infliximab 5 mg/kg at weeks 0, 2, and 6, with or without LEMTRADA. Patients were randomized to receive LEMTRADA (n=372) or intravenous infliximab (n=187). At baseline, the mean age was 35 years, the mean disease duration was 2 years, and the mean EDSS score was 3.

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 ARR 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 intravenous infliximab. There was no significant difference between the treatment groups for the time to confirmed disability progression or the primary ARR endpoint (change in T2 lesion volume). The results for Study 2 are shown in Table X.

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.
**LEMTRADA REMS Training**

Full Prescribing Information (24 of 27)  
Total Training Screens: 24 of 41

<table>
<thead>
<tr>
<th>Clinical Outcome</th>
<th>LEMTRADA (N=366)</th>
<th>comparator (N=352)</th>
<th>p-value</th>
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</thead>
<tbody>
<tr>
<td>Proportion of patients with relapse on or after Week 2</td>
<td>10%</td>
<td>12%</td>
<td>0.32</td>
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<tr>
<td>Proportion of patients with relapse on or after Month 6</td>
<td>36%</td>
<td>40%</td>
<td>0.38</td>
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</tbody>
</table>

**Table 3: Clinical and MRI Results of Study 2**

19 **HOW SUPPLIED/STORAGE AND HANDLING**

19.1 How Supplied

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

Each LEMTRADA vial (NDC: 59503-888-01) contains one single-dose vial that delivers 12 mg (1 ml; 10 mg/ml). The vial stopper is not made with natural rubber latex.

19.2 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 episodes of potential autoimmune diseases. Give examples of important symptoms such as blood disorders, chest pain, pancreatitis, pneumonitis, skin disorders, urticaria, or lupus-like conditions.
- 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. Early detection and prompt treatment can help prevent serious and potentially fatal infections associated with these events. Advise patients that monitoring may need to continue post-therapy if they have signs or symptoms of autoimmunity.

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
LEMTTRADE REMS Training

Full Prescribing Information (25 of 27)  Total Training Screens: 25 of 41

- Advise patients that LEMTRADE may cause hyperthyroidism or hypothyroidism.
- Advise patients to contact their healthcare provider if they experience symptoms suggestive of a potential thyroid disorder such as unexplained weight loss or gain, fast heartbeat or palpitations, nervousness, worsening headache, eye swelling, constipation, or feeling cold.
- Advise women of childbearing potential of the risks of pregnancy with concurrent thyroid disease. Advise women of childbearing potential to discuss pregnancy planning with their doctor.
- Cases of adenoma and cancer have been reported in patients treated with LEMTRADE. 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 itching or bruising more easily than normal.


dation Reactions
- Advise patients that infusion reactions can occur at the time of infusion or after they leave the infusion center (see Warnings and Precautions). 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:
  - Severe or moderate abdominal pain or cramping, abdominal swelling, abnormal heart rate (fast, slow, or irregular), nausea, shortness of breath, or coughing up blood
  - Instruct the patient to remain at the infusion center for 2 hours after each LEMTRADE infusion, or longer if directed by the physician.

 Stroke and Cerebrovascular Arterial Disease
- Educate patients on the symptoms and instruct patients to seek immediate medical attention if symptoms of stroke or cerebrovascular arterial disease occur (e.g., numbness or weakness on one side, facial droop, difficulty with speech, sudden severe headache) (see Warnings and Precautions).

Malignancies
- Advise patients that LEMTRADE may increase their risk of malignancies, including thyroid cancer and melanoma and lymphoma (see Warnings and Precautions).
- 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 breast and yearly skin examinations.

LEMTTRADE REMS Program
- LEMTRADE is available only through a restricted program called the LEMTRADE REMS Program (see Warnings and Precautions). Informs the patient of the following wallet requires:
  - Patients and providers must be certified in the program.

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

Full Prescribing Information (26 of 27)

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. If you are unsure about treating a side effect, please contact the LEMTRADA program at 1-877-952-1659.
- Familiarize patients to carry the LEMTRADA REMS Patient Safety Information Card with them in case of an emergency.

Hypersensitivity

- Advise patients to contact their healthcare provider if they develop symptoms of anaphylaxis such as hives or swelling in the mouth (see Warnings and Precautions (1.2)).
- Advise patients to complete any necessary hematologic monitoring at least 4 weeks prior to treatment with LEMTRADA (see Dosage and Administration (2.5)). Advise patients that they should talk to their healthcare provider before taking any vaccine after recent treatment with LEMTRADA (see Warnings and Precautions (1.3)).
- Advise patients to complete adequate hemoglobin levels and potential presence of Leterud syndrome pre-surgery prior to starting LEMTRADA and if they had a recent status of LEMTRADA. The duration of increased risk for Leterud syndrome after LEMTRADA administration at higher doses known. Inform patients that Leterud syndrome can lead to significant complications or death (see Warnings and Precautions (1.3)).
- Advise patients to take their prescribed medication for hypothyroidism as directed by their healthcare provider (see Warnings and Precautions (1.3)).
- Advise patients that you guide to morcellation is recommended (see Warnings and Precautions (1.3)).

Progression Multifocal Leukodystrophy

- Inform patients that progression multifocal leukodystrophy (PML) has occurred in a patient who received LEMTRADA. Inquire the patient that PML is characterized by a progression of deficits and usually leads to death or severe disability over weeks or months. Inform the patient of the importance of contacting their doctor if they develop any symptoms suggestive of PML. Inquire the patient that typical symptoms associated with PML are dramatic, progress over days to weeks, and include progressive weakness on one side of the body or symptoms of numbness, disturbance of vision, and changes in thinking, memory, and elimination leading to confusion and personality changes (see Warnings and Precautions (1.3)).

Assess Anabiosis Cisclavula

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.
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.
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

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.
What is the LEMTRADA REMS?

LEMTTRA REMS is a Risk Evaluation and Mitigation Strategy (REMS) that is designed 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, anaphylaxis, and malignancy, LEMTRADA is only available through a restricted program called the LEMTRADA REMS.

The LEMTRADA REMS is a tool to help healthcare professionals manage risks associated with LEMTRADA and how to help mitigate these risks through effective monitoring and prompt identification and management of these events.

- Prescribers are required to enroll 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 Patients
   - Complete the 8-question knowledge assessment
   - 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.LemtradaE prescribing.com or by contacting the LEMTRADA REMS at 1-855-676-4336.

To enroll in the LEMTRADA REMS Program, call 1-855-676-4336 or go to www.LemtradaE prescribing.com to review the LEMTRADA REMS Program, including the requirements for certification. All healthcare professionals who prescribe LEMTRADA are required to enroll and become certified 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.

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.
Overview of Important Safety Information

INDICATION AND USAGE

LEMTTRA® 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 LEMTRA® 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

LEMTTRA® 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 LEMTRA®.

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

SERIOUS RISKS ASSOCIATED WITH LEMTRA®

Autoimmune Conditions

LEMTTRA® has been associated with risk of autoimmune conditions, including immune thrombocytopenia, other connective tissue disorders, including myasthenia gravis, and pericarditis, 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 LEMTRA®-treated patients in clinical studies controlled and open-label extensions in HD. 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, weakness, spontaneous mucosal bleeding (nosebleeds, hemoptysis), and hives, or other non-normal or irregular mucocutaneous 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 40 weeks after patient’s last infusion of LEMTRA®, 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 40 weeks 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 LEMTRA® following the occurrence of ITP is unknown.
LEMTTRADE REMS Training

LEMTTRADE REMS Education Program for Prescribers (4 of 12)  Total Training Screens: 33 of 41

Potential Clinical Presentations of ITP

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

2. This is an example of large, scattered "purpura" spots under the skin that are not painful or tender. Petechiae can occur anywhere on the patient’s body, not just on the legs.

3. This is an example of easy or spontaneous bruising. This could occur anywhere on the patient’s body.

4. This is an example of purpura under the tongue.

Images © 2019 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 extensions) in A0. One LEMTRADa-treated patient with autoimmune pancytopenia died from sepsis. Symptoms of autoimmune hemolytic anemia may include weakness, chest pain, jaundice, dark urine, and jaundice. Use the morbilliform CBC results to monitor for cytopenia. If a cytopenia is confirmed, appropriate medical intervention should be promptly initiated.

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.
Glomerular Nephropathies

Glomerular nephropathies, including anti-glomerular basement membrane (GBM) disease, have been reported after treatment with LBMT3 in multiple sclerosis patients in clinical trials. Cases of anti-GBM disease have been diagnosed up to 12 months after the last dose of LBMT3.

In postmarketing cases, some LBMT3-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 LBMT3. 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 managing hematuria, consider the timing of urinalysis to avoid false positives. The observation of clinically significant changes from baseline is serum 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 disorders including Graves’ disease, hyperthyroidism, hypothyroidism, autoimmune thyroiditis, and/or pituitary were reported. Thyroid endocrine disorders, including autoimmune thyroid disorders occurred in 3.5% of LBMT3-treated patients in clinical studies associated and open-label extension.

Harvey- and Hashimoto thyroid disorders occurred throughout the uncontrolled clinical study follow-up period, more than 7 years after the first LBMT3 dose. New thyroid disorders occurred in 3.2% of patients. Of 68 LBMT3-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 LBMT3 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 for signs and symptoms of thyroid disorders, which may include excessive sweating, unexplained weight loss, fear of cold, weight gain, and/or palpitations.

If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6336, Mon – Fri, 8:30 am – 8:00 pm ET.
- Thyroid disease poses special risk 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 health professional 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 transplantation. The basic approach is similar, including corticosteroids, which are the cornerstone of treatment. If there is clinical suspicion of liver dysfunction (e.g., unexplained nausea, vomiting, abdominal pain, fatigue, anorexia, or jaundice) or in 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 transaminase (ALT and AST) and total bilirubin levels. Obtain transaminase levels and total bilirubin levels periodically week 4-6 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 all 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, clarify the need to know about LEMTRADA Treatment. A Patient Guide to 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 risks and the length of required follow-up, please refer to the diagrams below titled Overview of LEMTRADA Treatment and Overview of LEMTRADA Monitoring.

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.
Overview of LEMTRADA Treatment

Overview of LEMTRADA Monitoring

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.
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 not more than 2 hours after LEMTRADA infusion. Serious reactions occurred in 3% of patients, including cases of anaphylactic shock, angioedema, laryngospasm, hypotension, shortness of breath, laryngitis, vomiting, chest pain, and flushing. Other infusion reactions included nausea, anaphylaxis, arthralgia, myalgia, chest pain, dyspnea, pruritus, urticaria, chills, laryngospasm, hypotension, headache, rash, and tachycardia.

- Infusion reactions occurred in 3% of patients during or after 1st infusion of LEMTRADA.

- Consider additional monitoring in patients with medical conditions that predispose them to cardiovascular or pulmonary compromise. Physicians should alert patients that an infusion reaction could occur within 4 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. Inform patients that they must be observed for at least 2 hours after each infusion, and they should not drive or operate machinery until they are fully recovered from the infusion.

- If infusion reactions occur, immediate discontinuation of the infusion should be considered.

Stroke and Cerebrovascular Arterial Dissection

Young new onset focal neurological signs or stroke-like symptoms or transient ischemic attack should be reported within 3 days of the last LEMTRADA administration.

- Cerebrovascular Arterial Dissection

- Educate patients on the symptoms of stroke and cerebrovascular (e.g., carotid, vertebral) arterial dissection. Instruct patients to seek immediate medical attention if symptoms of stroke or cerebrovascular arterial dissection occur.
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 thyroid studies, 0.2% 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 these 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 extensive data, 0.1% Lemtrada treated patients developed melanomas or melanomas in situ. Of those patients, no evidence of locally advanced disease.

Lymphoproliferative Disorders and Lymphoma
Cases of lymphoproliferative disorders and lymphoma have occurred in Lemtrada treated patients with no, including a HCL Lymphoma, Cutaneous B-cell, and a relapsing treatment of non-Hodgkin Lymphoma-associated Burkitt's Lymphoma. There are postmarketing reports of Epstein Barr Virus associated lymphoproliferative disorders in non-IB 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 change, 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 record.
- Enrollment forms can be obtained online at www.LemtradaREMS.com or by phone (1-855-676-6326).
- Enrollment forms should be faxed to 1-855-937-2748.
- GetGCyne 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 risk 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 patients on the risks associated with LEMTRADA.
- Review this guide with your patient on an ongoing basis. You must provide each patient with a copy of the guide and a LEMTRADA Patient Safety Information Card.
- Perform the baseline and periodic monitoring described above and in the prescribing information for LEMTRADA.

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 at www.LemtradaREMS.com or by phone (1-855-676-6326).

Completed forms should be faxed to 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.
Administering LEMTRADA

As part of the LEMTRADA REMS, a healthcare facility must be enrolled in the LEMTRADA REMS to be able to dispense and 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 andbaseline Lab form to the LEMTRADA REMS indicating completion of each patient’s baseline lab tests within 30 days of the infusion date.

PRIOR TO EACH TREATMENT COURSE OF LEMTRADA

- Administer certolizumab alpha (100 mg methylprednisolone or equivalent) immediately prior to LEMTRADA administration for the first 3 days of any treatment course.
- Administer anti-viral prophylaxis for herpes zoster once a day 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 prophylaxis with antibiotics and/or antivirals prior to LEMTRADA administration as needed.

Adverse Event Reporting

Report suspected adverse events to Genzyme Medical Information at 1-800-746-4447 (option 2) or via fax at 1-800-250-1883 or www.fda.gov/medwatch.

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.
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.
LEMTRADA REMS Training Complete
You have completed your review of the training materials.
You may now answer the Knowledge Assessment questions.

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.
LEMTTRADE REMS Knowledge Assessment

To confirm that prescribers understand the LEMTRADE REMS requirements, you must successfully complete the Knowledge Assessment below. You must answer ALL 8 questions correctly in order to become enrolled in the LEMTRADE 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 LEMTRADE 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 proteins to creatinine ratio
- D. Thyroid function test
- E. All of the above

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

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.
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

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.
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

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.
LEMTARA 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 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

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.
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

Submit.

If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-4326, Mon – Fri, 8:30 am – 8:00 pm ET.
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

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.
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.*
LEMTTRA REMS Knowledge Assessment

To confirm that prescribers understand the LEMTTRA REMS requirements, you must successfully complete the Knowledge Assessment below. You must answer ALL 8 questions correctly in order to become enrolled in the LEMTTRA 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 8**

The healthcare facility that will administer LEMTTRA 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

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

To confirm that prescribers understand the LEMTRAIDE REMS requirements, you must successfully complete the Knowledge Assessment below. You must answer ALL 8 questions correctly in order to become enrolled in the LEMTRAIDE 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 LEMTRAIDE 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 LEMTRAIDE REMS or need help enrolling, call 1-855-676-6326, Mon – Fri, 8:30 am – 8:00 pm ET.
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 1-855-876-6326, Mon – Fri, 8:30 am – 8:00 pm ET.
LEMTRADA REMS Desktop - Prescriber Training, Failed the Assessment 6 Times

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 Contact a Genzyme Representative

You have reached the maximum number of attempts to complete the Knowledge Assessment. Please contact a Genzyme representative.

Please call 1-855-676-6326 to speak with a Genzyme representative.

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.
LEMTREDA REMS Knowledge Assessment Complete
You have successfully completed all of the Knowledge Assessment questions.
You may now review and submit your LEMTRADE REMS Enrollment Form.

If you have questions about the LEMTRADE REMS or need help enrolling, call 1-855-676-6326, Mon – Fri, 8:30 am – 8:00 pm ET.
Enrollment Is 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 an appointment to verify enrollment.

If you do not receive a confirmation email after the representative's visit, please contact a LEMTRADA REMS Specialist at 1-855-676-6326.

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.

Download and print a copy of your LEMTRADA REMS Prescriber Enrollment Form for your records.

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.
LEMTARDA 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:

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

INFUSION REACTIONS
LEMTARDA 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
LEMTARDA may cause an increased risk of malignancy including thyroid cancer, melanoma, and lymphoproliferative disorders. Perform baseline and yearly 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.

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

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 1-855-676-8326, Mon – Fri, 8:30 am – 8:00 pm ET.
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AUTOIMMUNE CONDITIONS
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INFUSION REACTIONS
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STROKE
Serious and life-threatening stroke (including ischemic and hemorrhagic stroke) has been reported within 3 days of LEMTRADE administration. Instruct patients to seek immediate medical attention if symptoms of stroke occur.

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

Complete Enrollment in the LEMTRADE REMS
You have not completed answering the LEMTRADE REMS Knowledge Assessment questions.

Find a REMS Certified Prescriber or Healthcare Facility
Search for prescribers or healthcare facilities that are certified by the LEMTRADE REMS to prescribe, dispense, or administer LEMTRADE.

Enter ZIP Code

LEMTTRADE REMS Requirements

Prescribers must be enrolled in the LEMTRADE REMS to prescribe LEMTRADE for patients with multiple adenomas. Learn about Prescriber Enrollment.

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If you have questions about the LEMTRADE REMS or need help enrolling, call 1-855-676-8326, Mon – Fri, 8:30 am – 8:00 pm ET.

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SANOFI GENZYME
LEMTTRADEX (Risk Evaluation and Mitigation Strategy)

**What is the LEMTTRADEX?**
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 LEMTTRADEX is to inform prescribers, pharmacies, healthcare facilities, and patients about the risks of:

- **Autoimmune Conditions**
  LEMTTRADEX 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 LEMTTRADEX.

- **Infusion Reactions**
  LEMTTRADEX causes serious and life-threatening infusion reactions. LEMTTRADEX 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 LEMTTRADEX administration. Instruct patients to seek immediate medical attention if symptoms of stroke occur.

- **MALIGNANCIES**
  LEMTTRADEX may cause an increased risk of malignancy including thyroid cancer, melanomas, and lymphoproliferative disorders. Perform baseline and yearly exams.

**Complete Enrollment in the LEMTTRADEX**

You must review the training materials in order to complete your enrollment in the LEMTTRADEX. Please call MG 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 LEMTTRADEX to prescribe, dispense, or administer LEMTTRADEX.

Enter ZIP Code

- REMS Certified Prescriber
- REMS Certified Healthcare Facility

**Find**

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

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U.S. 449 LEM, 14.11.015.01-07 Last Updated 09719

Reference ID: 4512344
**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.

---

**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]

---

**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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Enter ZIP Code

- REMS Certified Prescriber
- REMS Certified Healthcare Facility

Find

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If you have questions about the LEMTRADE REMS or need help enrolling, call 1-855-676-8326, Mon – Fri, 8:30 am – 8:00 pm ET.
LEMTRADA® REMS Training

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

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

Reference ID: 4512344
PREScriber DASHBOARD PAGES
## 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.

### You have 10 LEMTRADA patients

<table>
<thead>
<tr>
<th>Last Name</th>
<th>First Name</th>
<th>Year of Birth</th>
<th>REMS ID</th>
<th>Last infusion</th>
<th>Checklist</th>
<th>REMS Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Doe</td>
<td>John</td>
<td>1980</td>
<td>129604352</td>
<td>5/16/2013</td>
<td>View Checklist</td>
<td>Authorized</td>
</tr>
<tr>
<td>Doe</td>
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<td>1980</td>
<td>129604352</td>
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</tbody>
</table>

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If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-670-4326, Mon – Fri, 8:30 am – 8:00 pm ET.
You have 10 LEMTRADA patients

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.
You have 10 LEMTRADA patients

- Doe, John 1980 129641652 3/16/2013 View Checklist Authorized
- Doe, John 1980 129641652 3/16/2013 View Checklist Authorized
- Doe, John 1980 129641652 3/16/2012 View Checklist Authorized
- Doe, John 1980 129641652 3/16/2013 View Checklist Authorized
- Doe, John 1980 129641652 3/16/2012 View Checklist Authorized
- Doe, John 1980 129641652 3/16/2013 View Checklist Authorized
- Doe, John 1980 129641652 3/16/2013 View Checklist Authorized
- Doe, John 1980 129641652 3/16/2013 View Checklist Authorized

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.
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.

Go Back  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 Austria, 4010 Linz, Austria, and Genzyme Corporation, 900 Falmouth Street, Falmouth, MA 02540, USA. LEMTRADA (alemtuzumab). Updated 01/19.

Reference ID: 4512344
My Profile

Adam Smith
(REMS ID 123456)
7776 Golden Blossom Run
Zoek, IL 60056-3530
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

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.
Welcome, Adam Smith!

My Profile

Adam Smith

(REMS ID 123456)
7776 Golden Blossom Run
Zoek, IA 62066-3630
Office Phone: xxx-xxx-xxxx
Mobile Phone: xxx-xxx-xxxx
Fax: xxx-xxx-xxxx

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Current Password

Password not provided. 

New Password

Password not provided.

Please enter a valid password. 

Confirm Password

Password not provided.

Please confirm your new password.

Change Password

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SANOFI GENZYME
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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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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SANOFI GENZYME
Support for You

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 Prescriber 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.
**LEMTTRA 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 each 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**: [Input]
- **Last Name**: [Input]
- **Office Phone Number**: [Input]
- **Address Line 1**: [Input]
- **Address Line 2**: [Input]
- **City**: [Input]
- **State**: [Input]
- **ZIP Code**: [Input]

### PATIENT INFORMATION
- **First Name**: [Input]
- **Last Name**: [Input]
- **Patient Lemtrada REMS Identification Number**: [Input]
- **Date of Birth (MM/DD/YYYY)**: [Input]
- **Date of Last LEMTRADA Infusion (MM/DD/YYYY)**: [Input]
- **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**

(If 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 1-800-743-5447 (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 I need to know about LEMTRADA (Brand Name):

A Patient Guide with this patient and counseled the patient about the serious risks associated with the use of LEMTRADA, and how to manage these risks through periodic monitoring.

By providing my signature, I attest that I have filled out the Patient Status Form to the best of my knowledge. I understand that my signature will be used to verify my enrollment in the LEMTRADA REMS.

By entering my name, AHP 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:

Authorized Provider Identification (API) Number:

Password:

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).

Previous Page

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.
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.

IF YES, please complete the following information

The patient has completed the periodic monitoring within the last 6 months:

- [ ] Yes
- [x] No

Please select an option:

- [ ] Yes
- [ ] No

If the above-named patient still under your care?

- [ ] Yes
- [x] No

Please select an option:

In signing this form, I acknowledge that I have reviewed what you think of LEMTRADA treatment and how you will be informed about the use of LEMTRADA and how your treatment will be monitored and recorded:

- [ ] Yes
- [ ] No

Please make a selection.

This adverse event has already been reported to the patient’s physician.
- [ ] Yes
- [ ] No

Please make a selection.

In signing this form, I understand that I have reviewed the Patient Status Form and this patient’s condition and have completed the form with the information available.
- [ ] Yes
- [ ] No

Please make a selection.

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.
LEMTTRADE REMS PATIENT STATUS FORM

This form must be completed every 6 months for each LEMTRADE patient under your care. Please complete this form 6 months after your patient’s first infusion with LEMTRADE, 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 LEMTRADE REMS Identification Number
- Date of Birth (MM/DD/YYYY)
- Date of Last LEMTRADE Infusion (MM/DD/YYYY)

Is the above-named patient still under your care?
- [ ] Yes
- [x] No

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 LEMTRADE Treatment: A Patient Guide with this patient and counseled the patient about the serious risks associated with the use of LEMTRADE, 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 LEMTRADE REMS.

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

Full Name

National Provider Identification (NPI) Number

Password

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).

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

- Please enter healthcare provider's name.

**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 personal monitoring.

By providing my signature, I attest that I have filled out the Patient Status Form to the best of my knowledge. I understand that my 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 valid NPI number.

**Password**

- Please enter your 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.
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 - 6:00 pm ET.

Download and print a copy of the LEMTRADA REMS Patient Status Form for your records.

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.
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

Authorized LEMTRADA REMS Identification Number

AUTHORIZED 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

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.
LEMTTRADE REMS PATIENT AUTHORIZATION AND BASELINE LAB FORM

This form must be completed within 30 days prior to the first infusion date of each LEMTRADE 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**
- **City**
- **ZIP Code**
- **Prescriber Identification Number**

**PATIENT INFORMATION**

- **First Name**
- **Last Name**
- **Date of Birth (MM/DD/YYYY)**
- **Valid Drivers License**

**PRESCRIPTION INFORMATION**

- **Select dose**
  - **Initial dose** (160 mg [52.5 mg/kg]) X 3 consecutive days
  - **Subsequent dose** (160 mg [52.5 mg/kg]) X 3 consecutive days

**AUTHORIZATION AND BASELINE LABS**

- **Do you authorize LEMTRADE treatment for the above referenced patient?**
  - 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 LEMTRADE REMS.

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

- **Full Name**
- **NPI Number**
- **Password**

If you have questions about the LEMTRADE REMS or need help enrolling, call 1-855-676-6326, Mon – Fri, 8:30 am – 8:00 pm ET.
LEMTTRA REMS Patient Authorization and Baseline Lab 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 and print a copy of the LEMTRADA REMS Patient Authorization and Baseline Lab Form for your records.

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.
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.

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 Authentication 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.
Frequently Asked Questions

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 copy 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, 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 Provider & 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 Inpatient Authorization and Readmission Form?

The LEMTRADA REMS Patient Authorization and Readmission 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 every 8 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 reviewed 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 Profile tab. To see alerts for a specific patient, click the link to the LEMTRADA REMS Support Tools to view the individual 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.
LEMTTRADA REMS Desktop - Prescriber Dashboard, REMS Certified Prescriber and Healthcare Facility Locator

REMST 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

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.
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

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.
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

<table>
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<tr>
<th>Steps</th>
<th>Activity</th>
<th>Progress</th>
</tr>
</thead>
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<td>1</td>
<td>Account Registration</td>
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<tr>
<td>2</td>
<td>Training</td>
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</tr>
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<td>3</td>
<td>Assessment Test</td>
<td>Completed</td>
</tr>
<tr>
<td>4</td>
<td>Enrollment Form Submission</td>
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</tr>
<tr>
<td>5</td>
<td>Enrollment Processed</td>
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<td>REMS ID Assigned</td>
<td>Completed</td>
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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).

If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-670-6326, Mon – Fri, 8:30 am – 8:00 pm ET.
LEMTTRADE REMS Prescriber Enrollment

1. Prescribers must be enrolled in the LEMTRADE REMS to be able to prescribe LEMTRADE for patients with relapsing forms of multiple sclerosis (MS). Because of its safety profile, the use of LEMTRADE should generally be reserved for patients who have had an inadequate response to two or more drugs indicated for the treatment of MS.

2. Note that your healthcare facility must be separately enrolled in the LEMTRADE REMS to dispense/administer LEMTRADE.

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

1. Register with the LEMTRADE REMS Online Training Center
2. Review the LEMTRADE REMS Education Program for Prescribers, including the LEMTRADE REMS Program Overview and the LEMTRADE FAQ, 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 LEMTRADE REMS Prescriber Enrollment Form.

If you have questions about the LEMTRADE REMS or need help enrolling, call 1-833-676-6326, Mon – Fri, 8:30 am – 8:00 pm ET.
LEMTRADAR 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 1-855-678-6326, Mon – Fri, 8:30 am – 8:00 pm ET.
BOTH PRESCRIBER AND HEALTHCARE FACILITY USER
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<th>First Name</th>
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<th>Last Infusion</th>
<th>Checklist</th>
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<td>3/16/2013</td>
<td>View Checklist</td>
<td>Authorized</td>
</tr>
</tbody>
</table>
LEMTRADA REMS DESKTOP
REMS Certified Healthcare Facility Pages Only
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

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.

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.
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*

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.
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.

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.
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.

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.
Are You Sure You Want to Exit?

You will lose your session and will need to begin again.

Yes  No, Continue

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.

If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-4326, Mon – Fri, 8:30 am – 8:00 pm ET.
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

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.

If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-4326, Mon – Fri, 8:30 am – 8:00 pm ET.

Continue
Your Session Has Timed Out

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

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.
LEMRADRA REMS TRAINING

LEMRADRA REMS PROGRAM OVERVIEW

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

LEMRADRA REMS is a strategy to manage known or potential risks associated with LEMTRADA. It is required by the FDA to ensure that the benefits of the drug outweigh its risks. Due to serious risks of autoimmune conditions, initiation and ongoing use of LEMTRADA are restricted to a controlled program only available through a restricted REMS provider.

LEMRADRA 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 certified to 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 Pharmacist Enrollment Form, which acknowledges their understanding of the REMS and commitment to ensure the proper handling and dispensing of LEMTRADA.
2. Pharmacy must maintain a personnel file for each prescriber, including copies of all remitted, signed enrollment forms and any other relevant documentation.
3. The pharmacy will verify that a LEMTRADA REMS Prescriber Enrollment Form is completed for each prescriber.
4. The pharmacy will verify that prescriber and healthcare facility are certified and patients are authorized to receive LEMTRADA prior to dispensing LEMTRADA.
5. Enrollment in the LEMTRADA REMS must be renewed every 2 years from initial enrollment.
6. Submit the completed and signed LEMTRADA REMS Pharmacy Enrollment forms to the LEMTRADA REMS.

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.
LEMTREADA REMS Training
LEMTREADA REMS Program Overview (2 of 2)

**HEALTHCARE FACILITY ENROLLMENT INSTRUCTIONS**

1. An authorized representative must enroll on behalf of the healthcare facility by completing the LEMTREADA REMS Enrollment Form. Enrollments are submitted through the LEMTREADA REMS website.
2. The enrolled healthcare facility will provide a copy of the LEMTREADA Patient Information Card to each patient that receives LEMTREADA. You must verify that all staff are aware of LEMTREADA and its requirements.
3. The healthcare facility will provide a copy of the LEMTREADA Patient Information Card to each patient that receives LEMTREADA. You must verify that all staff are aware of LEMTREADA and its requirements.
4. The healthcare facility will provide a copy of the LEMTREADA Patient Information Card to each patient that receives LEMTREADA. You must verify that all staff are aware of LEMTREADA and its requirements.

**PATIENT ENROLLMENT INSTRUCTIONS**

1. Complete the LEMTREADA Patient Enrollment Form, which contains information on the enrollment process for each patient.
2. Provide a copy of the LEMTREADA Patient Information Card to each patient. You must verify that all staff are aware of LEMTREADA and its requirements.
3. Submit the completed and signed LEMTREADA Patient Enrollment Form to the LEMTREADA REMS Technical Support Center.
4. Provide a copy of the LEMTREADA Patient Information Card to each patient. You must verify that all staff are aware of LEMTREADA and its requirements.

If you have questions about the LEMTREADA REMS or need help enrolling, call 1-855-576-6366, Mon – Fri, 8:30 am – 8:00 pm ET.

Reference ID: 4512344
LEMTTRA 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, death, malignancies
- Proper administration of LEMTRADA® (alemtuzumab)

If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-575-6326, Mon - Fri, 8:30 am - 8:00 pm ET.
Who Can Be An Authorized Representative?

An authorized representative at the healthcare facility can be:

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

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

One representative needs to enroll per healthcare facility site (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 prescribing or administering LEMTRADA.

Overview of Important Safety Information

INDICATION AND USAGE

LEMTTRA 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 LEMTRA should generally be reserved for patients who have had an inadequate response to or intolerance to disease-modifying therapies.

Limitations of Use:

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

The Prescribing Information includes a BOXED WARNING for LEMTRA.

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

SERIOUS RISKS ASSOCIATED WITH LEMTRADA

Infusion Reactions

Most patients treated with LEMTRA is reported to develop clinical signs of infusion reactions during or after LEMTRA administration. Some of these reactions were serious and life-threatening. In some patients, infusion reactions were reported more than 24 hours after LEMTRA infusion. Serious reactions occurred in less than 1% of patients, including cases of anaphylactic shock in 2 patients, including anaphylactoid shock, angioedema, bronchoconstriction, hypotension, chest pain, laryngitis, dyspnea, and rash. Other infusion reactions included nausea, urticaria, pruritus, urticaria, chills, flushing, fatigue, dyspnea, pulmonary edema, dyspnea, hypotension, and pain. In clinical studies, all patients with infusion reactions received treatment or supportive care. Certain pulmonary adverse events and myocardial ischemia have been reported in post-approval users of LEMTRA infusion.

Presumed patients with high-risk biologics should be monitored for signs of infusion-reaction, such as the first 3 days of each treatment cycle. Consider pretreatment with antihistamines and for antiinflammatory prior to LEMTRA administration.

Allergic reactions may occur in patients despite pretreatment.

If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-4326, Mon - Fri, 8:30 am - 8:00 pm ET.
Consider additional monitoring in patients with medical conditions which predispose them to cardiovascular or pulmonary complications. Prescriptions should alert patients that an infusion reaction could occur within 48 hours of initiation.

LEMTRADA can only be administered in certified healthcare settings that base on-site access to equipment and personnel trained to manage infusion reactions (including anaphylaxis and anaphylactoid reactions 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. West signs should be monitored before and during infusion. If an infusion reaction occurs, the infusion should be terminated. Treatment of infusion-reaction-related symptoms, as provided in the product labeling, should be administered if needed. If the infusion is to be continued, the duration of the infusion may be extended. If severe infusion reactions occur, immediate discontinuation of the infusion should be considered.

Stroke and Cerebrovascular Arterial Occlusion

Stroke

In the postmarketing setting, serious and life-threatening strokes (including subarachnoid hemorrhage) have been reported within 3 days of LEMTRADA administration, with most cases occurring within 1 day.

Cerebrovascular Arterial Occlusion

In the postmarketing setting, cases of cerebrovascular occulsion (e.g., stroke, cerebral arterial dissection) have also been reported within 3 days of LEMTRADA administration. However, stroke was reported in one of these cases.

Discontinue patients on the sympatholytic stroke and cerebrovascular (e.g., vasodilators) arterial dissection. Discontinue patients to seek immediate medical attention if symptoms of stroke or cerebrovascular arterial dissection occur.

Autoimmune Conditions

LEMTRADA has been associated with a risk of autoimmune conditions, including severe thrombocytopenia, other cytopenias (including neutropenia, lymphopenia, anemia, and thrombocytopenia), thyroid disorders, and glomerulonephritis, 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 lifethreatening conditions 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 antiplatelet antibodies. Patients depletion the ability of the bone to clot.

ITP was reported in 26 of patients in clinical trials in MS. ITP can be a serious condition leading to morbidity and mortality, and may occur among several years after the drug. There have been reports of mortality in patients with ITP, and the risk of death in patients with ITP is still unknown. The risk of death in patients with ITP is still unknown. It is recommended that patients with ITP be monitored closely, and be treated appropriately with corticosteroids, immunoglobulins, or splenectomy when appropriate. The risk of death in patients with ITP is still unknown.
LEMTRADA REMS Training

LEMTRADA REMS Education Program for Healthcare Facilities (5 of 8) Total Training Screens: 7 of 10

irregular menstrual bleeding. These clinical signs of ITP may be apparent before serious bleeding develops.

POTENTIAL CLINICAL PRESENTATIONS OF ITP

- Fatigue
- Petechiae (petite, scattered "pinpoint" spots on the skin that are red, pink, or purple)
- Petechiae seen anywhere on the patient's body, not just the legs

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

Autoimmune cytophenias such as neutropenia, hemolytic anemia, and pancytopenia have been reported in clinical studies in IL-10. In one study of patients treated with aminoside, patients reported fatigue, arthralgia, and myalgia.

If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-576-6326, Mon - Fri, 8:30 am - 8:00 pm ET.

Reference ID: 4512344
Initiate treatment. Obtain seven 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 disorders, including autoimmune thyroid disorders, occur in 1.3% 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. In total, thyroid disorders occurred in 4.5% of patients. Prescribers are required to monitor all patients for thyroid disorders by ordering thyroid function tests, such as thyroid-stimulating hormone (TSH) levels, 90 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, age swelling, nervousness, and fast heartbeat (hyperthyroidism), or unexplained weight gain, feeling cold, worsening tremors, and nervousness occurring constellation (hypothyroidism).

Autoimmune Hepatitis
Autoimmune hepatitis is causing clinically significant liver injury. Including acute liver failure requiring transplantation, 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, such as, unexplained nausea, vomiting, abdominal pain, fatigue, anorexia, or jaundice and dark urine, prescribers should promptly measure serum transaminases and total bilirubin and consider an immunomodulatory treatment with LEMTRADA as appropriate.

Prior to starting treatment with LEMTRADA, prescribers are advised 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.

Hypersensitivities
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 malignancy. Prescribers should perform baseline and yearly skin examination to monitor for incidence in patients receiving LEMTRADA. Cases of lymphoproliferative disorders and lymphoma have occurred in LEMTRADA treated patients with NMO.

If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-4326, Mon – Fri, 8:30 am – 8:00 pm ET.
Strategies to Implement in Your Healthcare Facility to Mitigate Risk of Infusion Reactions

- Ensure the infusion site is equipped with the necessary equipment and supplies to manage infusion reactions (including antihistamines and cardiac and respiratory emergencies).
- Premedicate 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 prophylactic use of 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 to a patient if the patient has a history of a serious or life-threatening infusion reaction.

Proper Storage and Administration

STORAGE OF LEMTRADA
- LEMTRADA is packaged in 12 mg/L 2 mL (10 mg/mL) single-dose vials.
- LEMTRADA vials should be stored at 2°C to 8°C (36°F to 46°F), protected 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 Infusion Reaction Guide prior to administering LEMTRADA.
  - Administer corticosteroids immediately prior to LEMTRADA administration for the first 3 days of each treatment course.
  - Ensure and patients for high dose corticosteroids are not prescribed or have been prescribed to start on the first day of each treatment course. Consider prophylactic use of antihistamines and/or antipyretics prior to LEMTRADA administration as needed.
  - Monitor vital signs before and periodically during the infusion.

If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-876-6368, Mon - Fri, 8:30 am - 8:00 pm ET.
ADMINISTRATION OF LEMTRADA

1. Inspect vial for particulate matter/contamination prior to use.
2. Withdraw 1.2 mL of LEMTRADA from the vial into a syringe using aseptic technique.
3. Ingest any 1 mL of the LEMTRADA, mix 0.9% Sodium Chloride, USP or 0.9% Sterile Water for Injection, USP. Gently invert the bag to mix the solution.
4. Cover IV infusion bag to protect from light.
5. Administer 12 mg/day over approximately 4 hours.
6. Store infusion as IV push over 1 hour. 
7. If infusion is not well tolerated, infusion duration may be extended.
8. Use the LEMTRADA diluted product within 4 hours after dilution. LEMTRADA diluted product may be stored at room temperature (15° to 30°C) or refrigerated conditions (2° to 8°C).
9. Protect from light. Store infusion as IV push over 1 hour.
10. Monitor patient vital signs before and periodically during the infusion, and provide appropriate symptomatic treatment for infusion reactions as needed.
11. 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 or email to the LEMTRADA REMS at lemtbradarems@sanofi.com or submit online at www.LemtradaREMS.com within 5 business days of the last infusion.
- Return unused vials of LEMTRADA to Genzyme within 30 days of receipt of the LEMTRADA REMS Patient Authorization and Disposal Label Form.
LEMTTRADE REMS Desktop - HCF Training - Training Confirmation

LEMTTRADE REMS Training Complete
You have completed your review of the training materials.

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

LEMTTRA is only available through the CONTINUED REMS, a restricted distribution program. Only practitioners, pharmacies, healthcare facilities, and patients enrolled in the program are able to receive LEMTRADA. An authorized representative of the healthcare facility must enroll the facility in the LEMTRA REMS.

Please review the following information and submit to Sanofi by clicking the submit button. Complete any missing information and correct any errors prior to submission. All fields are required.

Name of Institution/Healthcare Facility: [Name]
Optional Provider Identification (NPI) Number: [NPI]
Institution Facility Address: [Address]
City: [City]
State: [State]
ZIP Code: [ZIP]
Phone Number: [Phone]
Fax Number: [Fax]
Site Affiliation: [Affiliation]

Other Information: [Other]

I, the undersigned, declare that the information contained herein is true and correct. I have read and understand the requirements for enrollment in the LEMTRA REMS Healthcare Facility Enrollment Program and agree to comply with all requirements.

Full Name: [Name]
NPI Number: [NPI]
Password: [Password]

Reference ID: 4512344
LETRADA REMS HEALTHCARE FACILITY ENROLLMENT FORM

Please refer to the following information and review the LEMTRADA REMS nerd faqs for details on how to submit. Follow the instructions and complete the required information. Submit this form via our secure website to enroll your facility.

Reference ID: 4512344
Enrollment is 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 an appointment to verify enrollment.

If you do not receive a confirmation email after the representative’s visit, please contact a LEMTRADA REMS Specialist at 1-855-676-6326.

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.

Download and print a copy of your LEMTRADA REMS Healthcare Facility Enrollment Form for your records.

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.
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
LEMTTRADA 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
LEMTTRADA can cause 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
LEMTTRADA may cause an increased risk of malignancy including thyroid cancer, melanoma, and lymphoproliferative disorders. Perform baseline and yearly 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

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 1-855-676-8326, Mon – Fri, 8:30 am – 8:00 pm ET.
LEMTTRADE REMS (Risk Evaluation and Mitigation Strategy)

What is the LEMTRADE REMS?
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AUTOIMMUNE CONDITIONS
LEMTTRADE causes serious, sometimes fatal, autoimmune conditions such as immune thrombocytopenia and anti-gliomerular 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 LEMTRADE.

INFUSION REACTIONS
LEMTTRADE causes serious and life-threatening infusion reactions. LEMTRADE 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 LEMTRADE administration. Instruct patients to seek immediate medical attention if symptoms of stroke occur.

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

Complete Enrollment in the LEMTRADE REMS
You must review the training materials in order to complete your enrollment in the LEMTRADE REMS.
Please call MD One to One® at 1-855-676-6226 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 LEMTRADE REMS to prescribe, dispense, or administer LEMTRADE.

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

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Genzyme, LEMTRADE and LEMTRADE REMS are trademarks of Genzyme Corporation.
LEMTTRA® REMS Desktop - HCF Training - Pre-REMS Cert, Enrollment Incomplete

LEMTTRA® REMS (Risk Evaluation and Mitigation Strategy)

What is the LEMTRA® 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 LEMTRA® REMS is to inform prescribers, pharmacies, healthcare facilities, and patients about the risks of:

AUTOTHEMUNE CONDITIONS
LEMTTRA® causes serious, sometimes fatal, autottheumne 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 LEMTRA®.

INFUSION REACTIONS
LEMTTRA® causes serious and life-threatening infusion reactions. LEMTRA® 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 LEMTRA® administration. Instruct patients to seek immediate medical attention if symptoms of stroke occur.

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

Complete Enrollment in the LEMTRA® REMS

You have not completed your review and submission of the LEMTRA® REMS Healthcare Facility Enrollment Form.

Review Enrollment Form

LEMTTRA® REMS Requirements

HEALTHCARE FACILITIES

Healthcare facilities must be enrolled in the LEMTRA® REMS to dispense/administer LEMTRA® for patients with multiple sclerosis. One representative needs to enroll per healthcare setting.

Learn about Healthcare Facility Enrollment +

Find a REMS Certified Prescriber or Healthcare Facility

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

Enter ZIP Code

Submit

LEMTTRA® REMS Healthcare Facility

LEMTTRA® REMS Certified Prescriber

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

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LEMTTRA® (alemtuzumab) injection; for subcutaneous use.

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

LEMTTRADA 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.

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

LEMTTRADA REMS Requirements
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.

If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-8326, Mon – Fri, 8:30 am – 8:00 pm ET.

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LEMTTRA REMS Training
LEMTTRA REMS Program Overview (1 of 2)

LEMTTRA REMS PROGRAM OVERVIEW

What is the LEMTRA REMS Risk Evaluation and Mitigation Strategy (REMS)?
LEMTTRA 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. This training module offers guidance on how to enroll in the LEMTRA REMS Program Overview. LEMTRA REMS is only available through a comprehensive REMS program.

LEMTTRA REMS Requirements:
- Prescribers must be enrolled in the LEMTRA REMS to be able to prescribe LEMTRA.
- Pharmacies must be enrolled in the LEMTRA REMS to be able to dispense LEMTRA.
- Healthcare facilities must be enrolled in the LEMTRA REMS to be able to dispense LEMTRA.
- Patients must be enrolled and authorized in the LEMTRA REMS in order to receive LEMTRA.

PRESCRIBER ENROLLMENT INSTRUCTIONS:
1. Complete the training program, which includes reviewing the following:
   - LEMTRA REMS Program Overview
   - LEMTRA REMS Program Overview for Prescribers
   - LEMTRA REMS Education Program for Prescribers
   - Succeed in completing the 8-question LEMTRA REMS Knowledge assessment.
   - Enroll in the program by completing a LEMTRA REMS Prescriber Enrollment Form.
   - Submit the completed and signed forms to the LEMTRA REMS.

PHARMACY ENROLLMENT INSTRUCTIONS:
1. Your pharmacy must be enrolled as part of the pharmacy by reviewing the LEMTRA REMS Program Overview and completing the LEMTRA REMS Pharmacy Enrollment Form, which acknowledges the risks and provides instructions for a pharmacy and its staff to manage them.
2. All pharmacy staff must be trained on the LEMTRA REMS.
3. The pharmacy must verify that a LEMTRA REMS Prescription Ordering Form is received by each pharmacy.
4. The pharmacy must verify that prescribers and healthcare facilities are certified and approved to receive LEMTRA prior to dispensing LEMTRA.
5. Enrollees in the LEMTRA REMS must be reviewed every 2 years after initial enrollment.
6. Submit the completed and signed LEMTRA REMS Pharmacy Enrollment Form to the LEMTRA REMS.

If you have questions about the LEMTRA REMS, or need help enrolling, call 1-855-676-6365, Mon - Fri, 8:30 am - 8:00 pm ET.
REMS CERTIFIED HEALTHCARE FACILITY DASHBOARD PAGES
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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LEMTRADA, My Ride To Life, Sanofi and Genzyme registered in U.S. Patent and Trademark Office.
DEC 4, 2018 11:23 PM / Last Updated 09/18
Your Re-enrollment Is Due in Less Than a Month

- Re-enroll Now
- Return to Dashboard

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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Reference ID: 4512344
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.

- **MALIGNECANCES**
  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 click the link below to re-enroll in the LEMTRADA REMS.

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

Search by:
- REMS Certified Prescriber
- REMS Certified Healthcare Facility

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.
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

You have 10 LEMTRADA patients

Re-enroll in the LEMTRADA REMS

Healthcare Facilities must renew their enrollment every 2 years, and authorized representatives must renew their enrollment every year.

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If you have questions about the LEMTRADA REMS or need help enrolling, call 1-833-676-6326, Mon – Fri, 8:30 am – 8:00 pm ET.
LEMTRADA REMS Desktop - HCF Dashboard - Single Patient Detail, Infusion Verification Alert

Alert
This patient is due for infusion verification. Please complete and submit patient’s infusion verification. Your patient must be verified before infusion.

John Doe
(REMS ID 129684352)
Year of Birth: 1982
7778 Golden Blossom Run
Zook, IL 62056-3639
Home Phone: xxx-xxx-xxxx
Mobile Phone: xxx-xxx-xxxx

Previous Page

Preventative Medicine

Insurance
Provider: BlueCross BlueShield of Kansas City
Coverage: Completed

Infusion Information
Next Infusion Date: 6/10/12
Infusion Facility: Facility 01

Prescriber Information
Prescriber: Adam Smith, MD
REMS ID: 0125405789

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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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SCULIPREM 14 10 03 31/1 LEMTRADA 05/12

SANOFI GENZYME
LEMTTRADA 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/YYYY. 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

☑ Yes, I have verified my patient is ready for infusion.

Confirm

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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LEMTRADA REMS INFUSION VERIFICATION

Patients cannot be infused until the patient, their prescriber, and the healthcare facility are verified under the LEMTRADA REMS. If the 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

☐ Yes, I have verified my patient is ready for infusion.

Please indicate verification.

[Confirm]

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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.
LEMTTRADEX REMS INFUSION VERIFICATION COMPLETE

Please allow 1 business day for this form to be processed. If you have questions about your form submission, please contact the LEMTRADA REMS at 1-855-676-6326, Mon - Fri, 9:00 am - 8:00 pm ET. If this patient is not infused by XX/XX/XXXX, you must reverify this patient.

Download and print a copy of the LEMTRADA REMS Infusion Verification for the patient's medical record.

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.
Welcome, Robert Clark! My Profile | Log Out

Previews Page

John Doe
(REMS ID 129684352)

Year of Birth: 1982
7778 Golden Blossom Run
Zook, IL 62056-3630
Home Phone: xxx-xxx-xxxx
Mobile Phone: xxx-xxx-xxxx

Previous Page

REM Authorize

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

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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.
LEMTTRADE REMS INFUSION CHECKLIST SAVED

Your progress on the LEMTRADE REMS Infusion Checklist has been saved.

Bank

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If you have questions about the LEMTRADE REMS or need help enrolling, call 1-855-676-6328, Mon – Fri, 8:30 am – 8:00 pm ET.
LEMTRADA REMS INFUSION CHECKLIST

As a condition of your healthcare facility’s authorization to infuse LEmtrada, 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. The 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**

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<thead>
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<th>Field</th>
<th>Value</th>
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<tr>
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<tr>
<td>Patient Last Name</td>
<td>Doe</td>
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<td>Patient LEMTRADA REMS ID</td>
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**PRESCRIBER INFORMATION**

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<td>Prescriber First Name</td>
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<tr>
<td>Prescriber Last Name</td>
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<td>Prescriber LEMTRADA REMS ID</td>
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**HEALTHCARE FACILITY INFORMATION**

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<td>Facility ID</td>
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<td>Healthcare Facility LEMTRADA REMS ID</td>
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**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 [x] No

**Step 2: CONFIRM that the patient has been counseled and has received when 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 a copy of the “When You Need to Know About LEMTRADA Treatment and Infusion Reactions: A Patient Guide” prior to the first infusion of each treatment course. May the patient have counseled and received the guide? [ ] Yes [x] No

**Step 3: CONFIRM appropriate medical measures available for infusion**

Appropriate medical support measures are available:

1. Does the patient have a Bentall’s or similar risk? [ ] Yes [x] No
2. Does the patient have a history of adverse reactions? [ ] Yes [x] No

**Step 4: RECORD infusion information**

Was patient infused with LEMTRADA? [ ] Yes [x] No

**Step 5: RECORD infusion details of LEMTRADA**

Infusion of LEMTRADA must be reported within 40 days of administration 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 signature, I certify that I have filled out the infusion checklist to the best of my knowledge. I understand that my signature will be used to verify my involvement in the LEMTRADA REMS. By signing my name, NPI number, and password, I confirm my involvement in this form.

Name of staff member completing checklist:

Password:

NPI Number:

**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.**
LETRADA 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 Sanofi by clicking the button below.

All fields are required.

PATIENT INFORMATION

Patient First Name

Patient Last Name

Patient LEMTRADA REMS Identification Number

Full Patient Record

Are patient’s vital signs normal?

Are patient’s medications normal?

HEALTHCARE FACILITY INFORMATION

Healthcare Facility Name

HEALTHCARE FACILITY REMS Identification Number

Are healthcare facility’s protocols followed?

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 (1-855-876-0252) prior to initiation of each treatment course.

Is the patient authorized to receive LEMTRADA?

Yes

No

Alert!

STOP – DO NOT INFUSE. Notify patient back to the LEMTRADA prescribing.

Step 2: CONFIRM that the patient has been counseled and has received all that has been advised about LEMTRADA’s Development and Inclusion of a Patient Guide.

The patient must be informed about the risks for infusion reactions and provided with what you need to know about LEMTRADA’s Treatment and Monitor Overview. A Patient Guide is to be infused at the first infusion of LEMTRADA.

Has the patient been counseled and received the guide?

Yes

No

Alert!

Provide the patient with the Patient Guide and ensure that the patient has reviewed the guide and has been counseled.

Step 2: CONFIRM appropriate medical measures available during infusion

Appropriate medical support measures are available:

1. I.V. access

2. I.V. access

Are the appropriate medical measures listed above available?

Yes

No

Alert!

STOP – DO NOT INFUSE. Appropriate medical support measures are not available. Please contact the LEMTRADA REMS information line.

Step 4: RECORD infusion data

Was patient infused with LEMTRADA?

Yes

No

Alert!

Proceed to step 5.

Step 3: REPORT infusion site review

Infusion data of LEMTRADA must be reported within 30 days of administration of the LEMTRADA REMS Patient Authorization and Lab Form. Contact the LEMTRADA REMS at 1-855-876-0252 for additional information.

Step 5: SIGNATURE

By providing my signature, I attest that I have filled out the Infusion Checklist to the best of my knowledge. I understand that my signature will be used to verify my enrollment in the LEMTRADA REMS. By submitting this form, I agree to the terms of the LEMTRADA REMS.

Name of staff member completing checklist

Signature

Role

Alert!

If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-876-0252. Mon – Fri, 8:30 am – 8:00 pm ET.
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 30 calendar 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:** John
- **Patient Last Name:** Doe
- **Drug (LVV):** LEMTRADA
  - **Product Number:** 1234567890123
  - **Date:** 05/10/2018

**Prescriber Information**
- **Prescriber First Name:** Alex
- **Prescriber Last Name:** Smith

**Healthcare Facility Information**
- **Healthcare Facility Name:** John Doe Hospital
- **Facility ID:** 123456

**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 (after you read) “About LEMTRADA Treatment and Holder’s Guide,” Prescriber Guide**
This patient must be counseled about the risk for infusion reactions and provided with the “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 resources 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**

Date of Infusion:
- **Date:** 10/9/2007
- **Date:** 11/10/2007
- **Date:** 02/10/2007

**Step 5: RETURN of unopened vials of LEMTRADA**
Unused vials of LEMTRADA must be returned within 30 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 signature, I declare that I have filled out the Infusion Checklist to the best of my knowledge. I understand that my signature will be used to verify my endorsement of the LEMTRADA REMS. By entering my name, NPI number, and password, I confirm my endorsement of this form.

- **Name of staff member completing checklist:** Robert Clark
- **Password:** 
- **NPI Number:** 1234567890

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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.
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 30 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**

<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
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<td>Smith</td>
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<td>Date of Birth</td>
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<td>LEMTRADA REMS Identification Number</td>
<td>125558900</td>
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<td>1/21/1983</td>
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**PRESCRIBER INFORMATION**

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**HEALTHCARE FACILITY INFORMATION**

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**Step 1: CONFIRM that the patient is authorized to receive LEMTRADA**

- In the patient authorized to receive LEMTRADA: Yes

**Step 2: CONFIRM that the patient has been counseled and has received ADEs if you had prior to ADEs.**

- Has the patient been counseled and received the guide: Yes

**Step 3: CONFIRM that appropriate medical measures available during infusion**

- Are the appropriate medical measures listed above available: Yes

**Step 4: RECORD infusion information**

<table>
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<tr>
<th>Field</th>
<th>Value</th>
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<td>Infusion Date</td>
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<tr>
<td>Infusion Time</td>
<td>3:00 PM</td>
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</table>

**Step 5: RETURN of unused vials of LEMTRADA**

- Unused vials of LEMTRADA must be returned within 30 days of submission of the LEMTRADA REMS Patient Authorization and Label Form. Contact the LEMTRADA REMS at 1-855-676-6326 for additional information.

**Step 6: SIGNATURE**

- By completing this form, I certify that I have reviewed the information on the site and am familiar with the use and administration of LEMTRADA REMS, and I understand that the information on the site is subject 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.**

Reference ID: 4512344
LEMTRADE 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 LEMTRADE REMS at 1-855-676-6326, Mon - Fri, 8:30 am - 8:00 pm ET.

Download and print a copy of the LEMTRADE REMS Infusion Checklist for the patient's medical record.

If you have questions about the LEMTRADE REMS or need help enrolling, call 1-855-676-6326, Mon – Fri, 8:30 am – 8:00 pm ET.
Lemtrada REMS Desktop - HCF Dashboard - Single Patient Detail, Checklist Saved

Welcome, Robert Clark! My Profile | Log Out

Forms & FAQs | REMS Authorized

Previous Page

John Doe
(REMS ID 129684352)

Year of Birth: 1982
7779 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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LEMTTRADE REMS Desktop - HCF Dashboard - Single Patient Detail, Patient Status Form Alert

Alert

This patient is overdue for authorization by the LEMTRADA REMS Patient Status Form. Please contact the prescriber, who must complete the necessary form.

LEMTTRADE REMS Infusion Checklist

Insurance

Provider: BlueCross BlueShield of Kansas City
Coverage: Completed (View)

Infusion Information

First Course: 6/11/12 - 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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If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6320, Mon – Fri, 8:30 am – 8:00 pm ET.

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Reference ID: 4512344
Previous Page

John Doe
(REMS ID 129684352)

**REMS Authorized**
Year of Birth: 1982
7779 Golden Blossom Run
Zook, IL 62056-3830
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)
Second Course: 6/10/13 - 6/12/13 (View Checklist)

**Prescriber Information**
Prescriber: Adam Smith, MD
REMS ID: 812441878

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SECURITY 1.1.4.3.01.31.10. Last Updated 2018

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Reference ID: 4512344

VV-REG-0833078 0.1
You have 5 patient alerts!

You have 13 LEMTRADA prescribers associated with your patients:

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<th>Last Name</th>
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<td>Adam</td>
<td>0123456789</td>
<td>Certified</td>
<td></td>
</tr>
<tr>
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<td>Adam</td>
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<td></td>
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</tbody>
</table>

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.
LEMTRADA REMS Desktop - HCF Dashboard - Prescribers, Tool Tip Expanded

You have 5 patient alerts!

Our Patients  Prescribers  Manage Users

You have 13 LEMTRADA prescribers associated with your patients

<table>
<thead>
<tr>
<th>Last Name</th>
<th>First Name</th>
<th>Status</th>
<th>Patient Alerts</th>
</tr>
</thead>
<tbody>
<tr>
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</tr>
<tr>
<td>Smith</td>
<td>Adam</td>
<td>Certified</td>
<td></td>
</tr>
</tbody>
</table>

Search, sort, and navigate information about your prescribers below. Click on a name to view their individual profile.

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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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09/4565.CEN.14.12.01.03.97 12/21 Updated 09/19

SANOFI GENZYME

Reference ID: 4512344
Patients Seeing This Prescriber

You have 10 LEMTRADA patients associated with this prescriber.

<table>
<thead>
<tr>
<th>Last Name</th>
<th>First Name</th>
<th>Year of Birth</th>
<th>REMS ID</th>
<th>REMS Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Doe</td>
<td>John</td>
<td>1980</td>
<td>126684352</td>
<td>Authorized</td>
</tr>
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</tr>
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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.
Adam Smith, MD
(REMS ID 129684352)

Patients Seeing This Prescriber

You have 10 LEMTRADA patients associated with this prescriber.

<table>
<thead>
<tr>
<th>Last Name</th>
<th>First Name</th>
<th>REMS ID</th>
<th>REMS Status</th>
</tr>
</thead>
<tbody>
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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.
You have 10 LEMTRADA patients associated with this prescriber.

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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.
Patients Seeing This Prescriber

You have 1 patient alerts!

You have 10 LEMTRADA patients associated with this prescriber

<table>
<thead>
<tr>
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<th>Year of Birth</th>
<th>REMS ID</th>
<th>REMS Status</th>
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<tbody>
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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.
As a Facility 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.

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.
As aFacility 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.

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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.
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
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
Edit User

First Name
Robert

Last Name
Clark

Email
clark@abc123.com

- User has received the required LEMTRADA REMS training.
- Require password reset.

Cancel  Save

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 1-855-676-0326 Mon - Fri, 8:30 am - 8:00 pm ET.
Are You Sure You Want to Delete User?

Cancel  Delete
My Profile

Robert Clark
(REMS ID 123456)
7776 Golden Blossom Run
Zoob, IL 62050-3830
Office Phone: xxx-xxx-xxxx
Fax: xxx-xxx-xxxx

If any of your information is incorrect or has recently changed, please call 1-855-676-4326, 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

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 1-855-676-4326, Mon – Fri, 8:30 am – 8:00 pm ET.
My Profile

Robert Clark

(REMS ID 123456)
7776 Golden Blossom Run
Zoob, IL 62056-3830
Office Phone: xxx-xx-xxxx
Fax: xxx-xx-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 alerts about the status of your LEMTRADEX patients. Please note that you will continue to receive important communications from Genzyme, if warranted.

Patient Alert Emails

As a part of the LEMTRADEX REMS you will automatically receive emails to update you on the status of your LEMTRADEX 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 monthly 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
Password does not match

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

Adobe® Reader® is required to view all of these PDFs. If you do not have it installed, download it 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.
**LEMTRADA REMS INFUSION CHECKLIST**

As a condition of your healthcare facility’s authorization to invoice 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. The 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

<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
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</thead>
<tbody>
<tr>
<td>Patient First Name</td>
<td>John</td>
</tr>
<tr>
<td>Patient Last Name</td>
<td>Doe</td>
</tr>
<tr>
<td>Patient LEMTARDA REMS</td>
<td>Identification Number 1:20000800</td>
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<td></td>
<td>DOD (MM/DD/YYYY)</td>
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### PRESCRIBER INFORMATION

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<tbody>
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<tr>
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<td>Doe</td>
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<tr>
<td>Prescriber LEMTARDA REMS Identification Number</td>
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### HEALTHCARE FACILITY INFORMATION

<table>
<thead>
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<tr>
<td>Healthcare Facility LEMTARDA REMS Identification Number</td>
<td>0907000676</td>
</tr>
</tbody>
</table>

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**Step 1: CONFIRM that the patient is authorized to receive LEMTARDA**

You must complete the LEMTARDA REMS infusion notification online or contact the LEMTARDA REMS by phone (1-855-676-4320) prior to initiation of each treatment course.

Is the patient authorized to receive LEMTARDA? **Yes** | **No**

**Step 2: CONFIRM that the patient has been counseled and has received What You Need to Know About LEMTARDA Treatment and infusion Resistant A Patient Guide**

The patient must be counseled about the risks for infusion reactions and provided with What You Need to Know About LEMTARDA Treatment and Infusion Reactions: A Patient Guide prior to the first infusion of each treatment course. Have the patient been counseled and received the guide? **Yes** | **No**

**Step 3: CONFIRM appropriate medical measures available for infusion**

Are the appropriate medical measures listed above available? **Yes** | **No**

**Step 4: RECORD infusion information**

Was patient infused with LEMTARDA? **Yes** | **No**

**Step 5: RETURN all unused vials of LEMTARDA**

Unused vials of LEMTARDA must be returned within 5 days of administration to the LEMTARDA REMS Patient Authorization and Life Form. Contact the LEMTARDA REMS at 1-855-676-4320 for additional information.

**Step 6: SIGNATURE**

By providing my signature, I attest that I have filled out the Infusion Checklist is the best of my knowledge. I understand that my signature will be used to verify my involvement in the LEMTARDA REMS. By entering my name, MP number, and password, I affirm my signature of this form.

Name of staff member completing checklist:

Password:

MP Number:

---

If you have questions about the LEMTARDA REMS or need help enrolling, call 1-855-676-4320, Mon – Fri, 8:30 am – 8:00 pm ET.

---

Reference ID: 4512344
The form consists of multiple sections with various inputs and fields. The details are too extensive to summarize concisely, but it appears to be a comprehensive medical document related to the patient information, prescriber information, and healthcare facility information. There are sections for confirming the patient's authorization to receive LEMTRADA, preparing for infusion, and recording infusion information.

There is a note at the bottom of the form regarding the availability of this resource as a reference for prescribers and not intended as medical advice. It also provides contact information for LEMTRADA REMS support.

Reference ID: 4512344
### LEMTRADA REMS INFUSION CHECKLIST

As a condition of your healthcare facility’s authorization to infuse LEMTRADA® (abatacept), this infusion checklist must be completed for each patient by the last day of each patient’s treatment course and submitted within 30 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 Denosumab by clicking the button below.

All fields are required.

<table>
<thead>
<tr>
<th><strong>PATIENT INFORMATION</strong></th>
<th><strong>PRESCRIBER INFORMATION</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Patient First Name</strong></td>
<td>Prescriber First Name</td>
</tr>
<tr>
<td>John</td>
<td>44th</td>
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<tr>
<td><strong>Patient Last Name</strong></td>
<td>Prescriber Last Name</td>
</tr>
<tr>
<td>Doe</td>
<td>Sarah</td>
</tr>
<tr>
<td><strong>Patient LMRTRADA</strong></td>
<td>Prescriber LMRTRADA</td>
</tr>
<tr>
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<td>123456789 (VVVVVV)</td>
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</table>

<table>
<thead>
<tr>
<th><strong>HEALTHCARE FACILITY INFORMATION</strong></th>
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<tr>
<td>Healthcare Facility Name</td>
</tr>
<tr>
<td>Facility 1</td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>

**Step 1:** CONFIRM that the patient is authorized to receive LEMTRADA

You must complete the LMRTRADA REMS infusion verification online or contact the LMRTRADA REMS by phone (1-855-476-4226) prior to initiation of each treatment course.

Is the patient authorized to receive LMRTRADA? **Yes** **No**

**Step 2:** CONFIRM that the patient has been counseled and has received After You Read to know about Contraindications and Precautions. A Patient Guide

**Step 3:** CONFIRM that appropriate medical records are available during infusion.

Are the appropriate medical records listed above available? **Yes** **No**

**Step 4:** RECORD all infusion information

<table>
<thead>
<tr>
<th>Date</th>
<th>Time</th>
<th>Infusion Type</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>1/6/2007</td>
<td>1:00</td>
<td>Completed</td>
<td>1/6/2007</td>
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<tr>
<td>1/6/2007</td>
<td>2:00</td>
<td>Completed</td>
<td>1/6/2007</td>
</tr>
</tbody>
</table>

**Step 5:** RETURN of unused vials of LMRTRADA

Unused vials of LMRTRADA must be returned within 30 days of submission of the LMRTRADA REMS Patient Authorization and Lab Form. Contact the LMRTRADA REMS at 1-855-476-4226 for additional information.

**Step 6:** SIGNATURE

By providing my signature, I certify that I have filled out the Infusion Checklist to the best of my knowledge. I understand that any signatures will be used to verify my enrollment in the LMRTRADA REMS. By entering my name, NPI number, and password, I confirm my signature at file form.

**Note:**

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 15 hours).

If you have questions about the LMRTRADA REMS or need help enrolling, call 1-855-476-4226. Mon – Fri, 8:30 am – 8:00 pm ET.

---

**Reference ID:** 4512344

**VVM-REG-0833078 0.1**
**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 3 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.

<table>
<thead>
<tr>
<th><strong>PATIENT INFORMATION</strong></th>
<th><strong>PRESCRIBER INFORMATION</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Patient First Name</strong></td>
<td>Prescriber First Name</td>
</tr>
<tr>
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<td>44am</td>
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<tr>
<td><strong>Patient Last Name</strong></td>
<td>Prescriber Last Name</td>
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<td>598</td>
</tr>
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<td>Prescribe LEMTRADA REMS</td>
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<tr>
<td>123456789</td>
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<tr>
<td><strong>DOB (MM/DD/YYYY)</strong></td>
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**HEALTHCARE FACILITY INFORMATION**

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</thead>
<tbody>
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</table>

**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.

In the patient authorized to receive LEMTRADA?

**Yes**  **No**

**Step 2: CONFIRM that the patient has been counseled and has received After You Read to Know About CIPROFLOXACIN Treatment and Inhaler Reactivation.**

This patient must be counseled about the risk of infusion reactions and provided with After You Read to Know About LEMTRADA Treatment and Inhaler Reactivation. 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 that appropriate medical resources are available during infusion:**

Are the appropriate medical resources listed above available?

**Yes**  **No**

**Step 4: RECORD infusion information:**

Was patient infused with LEMTRADA?

**Yes**  **No**

FIll in Details of Infusion below and then proceed to Step 5.

**LEMTRADA Infusion**

<table>
<thead>
<tr>
<th><strong>Date</strong></th>
<th><strong>Date</strong></th>
<th><strong>Date</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Step 5: RETURN of unused vials of LEMTRADA**

Unused vials of LEMTRADA must be returned within 5 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 any signature will be used to verify my enrollment in the LEMTRADA REMS. By entering my name, NPI number, and password, I confirm my signature at the form.

**Name of staf member completing checklist:**

Robert Clark

**Password:**

**NPI Number:** 123456789

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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 – 5:00 pm ET.
LEMTTRA® 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 LEMTRA® REMS at 1-855-674-6328, Mon - Fri, 8:00 am - 8:00 pm ET.

Download and print a copy of the LEMTRA® REMS Infusion Checklist for the patient’s medical record.

Back
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 - 4:00 pm ET.

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.

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.
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.

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. The patient cannot be infused until the patient, their prescriber, and the healthcare facility are enrolled 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 a reauthorization 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 list of a patient’s completed and infusion checklist by clicking “View Checklist” on their patient’s profile page.

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 prescriber’s identification is ‘Not REMS Authorized’ or ‘Not REMS Certified’, DO NOT administer LEMTRADA to that patient or dispense LEMTRADA pursuant to that prescription. Contact a LEMTRADA REMS Specialist at 1-855-676-6326 if you have questions about the LEMTRADA REMS eligibility.

6. 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.

7. How can I update contact information on this site?

To update your contact information, contact the LEMTRADA REMS at 1-855-676-6326.

8. How do I request my password?

Patients 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.

9. How do I request my log in information?

Patients can request their log in information by clicking the "Forgot Password" button on their dashboard.

10. What should I do if the Healthcare Facility account manager (HCF REMS authorized representative) needs to change their log in information?

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.
REMTRADA REMS Desktop - HCF Dashboard - REMS Certified Prescriber & Healthcare Facility Locator

Welcome, Robert Clark! My Profile | Log Out

Prescribing Information | Medication Guide

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

REMTRADA REMS Desktop - HCF Dashboard - REMS Certified Prescriber & Healthcare Facility Locator

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

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

New Search: Street address, city, state, or ZIP Code

REMTRADA REMS Desktop - HCF Dashboard - REMS Certified Prescriber & Healthcare Facility Locator

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

Genzyme is providing this search feature to help patients find prescribers and healthcare facilities that have been certified by the REMTRADA 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).

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Sanofi Genzyme

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REMTRADA, MS One In One, Sanofi and Genzyme registered in U.S. Patent and Trademark Office.

Sanofi-Aventis
1-855-676-6326
2015-08-20
REMSTRADE REMS Desktop - HCF Dashboard - REMS Certified Prescriber & Healthcare Facility Locator

REMST Certified Prescriber & Healthcare Facility Locator

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

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

New Search: Street address, city, state, or ZIP Code

Genzyme is providing this search feature to help patients find prescribers and healthcare facilities that have been certified by the REMSTRADE 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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If you have questions about the REMSTRADE 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
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

LEMTTRADEX REMS Activity

<table>
<thead>
<tr>
<th>Steps</th>
<th>Activity</th>
<th>Progress</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Account Registration</td>
<td>Completed</td>
</tr>
<tr>
<td>2.</td>
<td>Training</td>
<td>Completed</td>
</tr>
<tr>
<td>3.</td>
<td>Enrollment Form Submission</td>
<td>Completed</td>
</tr>
<tr>
<td>4.</td>
<td>Enrollment Processed</td>
<td>Completed</td>
</tr>
<tr>
<td>5.</td>
<td>REMS ID Assigned</td>
<td>Completed</td>
</tr>
</tbody>
</table>

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If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6328, Mon – Fri, 8:30 am – 8:00 pm ET.
LEMTTRADE REMS Requirements

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

LEMTTRADE 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 LEMTRADE REMS Training Center
3. Authorized representative must review the LEMTRADE REMS Education Program for Healthcare Facilities and the LEMTRADE REMS Program Overview through the online module on this site
4. After completing the online module, complete and sign the LEMTRADE 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 LEMTRADE REMS requirements

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

Below are materials that help inform patients about treatment with LEMTRADE.

- **PDF** What You Need to Know About LEMTRADE Treatment: A Patient Guide
- **PDF** What You Need to Know About LEMTRADE 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 LEMTRADE REMS or need help enrolling, call 1-855-676-6326, Mon – Fri, 8:30 am – 8:00 pm ET.
DASHBOARD PAGES FOR HCF USERS WHO ARE NON-MANAGERS
### You have 10 LEMTRADEA patients

<table>
<thead>
<tr>
<th>Last Name</th>
<th>First Name</th>
<th>Year of Birth</th>
<th>REMS ID</th>
<th>Prescriber ID</th>
<th>Prescriber Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Doe</td>
<td>John</td>
<td>1980</td>
<td>129684352</td>
<td>Adam Smith (01234567)</td>
<td>Authorized</td>
</tr>
<tr>
<td>Doe</td>
<td>John</td>
<td>1980</td>
<td>129684352</td>
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</tbody>
</table>

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If you have questions about the LEMTRADEA REMS or need help enrolling, call 1-855-676-6326, Mon - Fri, 8:30 am - 8:00 pm ET.
LEMTREDA REMS (Risk Evaluation and Mitigation Strategy)

What is the LEMTREDA 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 LEMTREDA REMS is to inform prescribers, pharmacies, healthcare facilities, and patients about the risks of:

AUTOIMMUNE CONDITIONS
LEMTREDA 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 LEMTREDA.

INFUSION REACTIONS
LEMTREDA causes serious and life-threatening infusion reactions. LEMTREDA 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 LEMTREDA administration. Instruct patients to seek immediate medical attention if symptoms of stroke occur.

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

Re-enroll in the LEMTREDA REMS
You have been locked out due to incomplete re-enrollment. Please locate the Healthcare Facility manager, re-enroll in the LEMTREDA 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 LEMTREDA REMS to prescribe, dispense, or administer LEMTREDA.

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 LEMTREDA REMS or need help enrolling, call 1-855-676-8326, Mon – Fri, 8:30 am – 8:00 pm ET.

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LEMTREDA® is a registered trademark of Genzyme Corporation. LEMTREDA is a registered trademark of Genzyme Corporation and is manufactured and distributed in the U.S. by Genzyme Corporation in Framingham, MA, U.S.A. (SAS304882).

LV-REG-0833078 0.1
You have 13 LEMTRADA prescribers associated with your patients.

<table>
<thead>
<tr>
<th>Last Name</th>
<th>First Name</th>
<th>REMS ID</th>
<th>REMS Status</th>
<th>Patient Alerts</th>
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</thead>
<tbody>
<tr>
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Sanofi Genzyme
You have 5 patient alerts!

You have 13 LEMTRADA prescribers associated with your patients.

<table>
<thead>
<tr>
<th>Last Name</th>
<th>First Name</th>
<th>Last4 SSN</th>
<th>Status</th>
<th>Patient Alerts</th>
</tr>
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<tbody>
<tr>
<td>Smith</td>
<td>Adam</td>
<td>0123456789</td>
<td>Certified</td>
<td>Not Certified</td>
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<tr>
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SANOFI GENZYME
BOTH A PRESCRIBER AND HEALTHCARE FACILITY USER
Welcome, Robert Clark! My Profile | Log Out

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

- Doe John 1980 129684352 Adam Smith 01/2345678 Authorized
- Doe John 1980 129684352 Adam Smith 01/2345678 Authorized
- Doe John 1980 129684352 Adam Smith 01/2345678 Authorized
- Doe John 1980 129684352 Adam Smith 01/2345678 Authorized
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- Doe John 1980 129684352 Adam Smith 01/2345678 Authorized
- Doe John 1980 129684352 Adam Smith 01/2345678 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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If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-567-6326, Mon – Fri, 8:30 am - 8:00 pm ET.

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DOCUREM 14.8.23177 / Last Updated 09/12

Reference ID: 4512344

VV-REG-0833078 0.1
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

©2017 Genzyme Corporation. All rights reserved. LEMTRADA, Sanofi and Genzyme registered in U.S. Patent and Trademark Office GZUS.LEMT.16.01.0031(1). Last Updated 01/17

PO BOX 220790 • CHARLOTTE, NC, 28222-0790 • PHONE: 1-855-676-6326 • FAX: 1-855-557-2478
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

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.

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.
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*

Select

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.
Pharmacy Registration for LEMTRADA REMS Training

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

*Required

Email Address*

Password* 
Create a Password*

Confirm Password*

Name of Pharmacy*

National Provider Identification (NPI) Number*

Pharmacy Address*

City*

State* 
ZIP Code* 
Please select a state. 
Please enter a 5-digit ZIP Code.

Name of Authorized Pharmacy Representative*

Phone Number*

Fax Number*


Terms and conditions not selected.

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.
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 must be 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., !, #, &).

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* 

Please select 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.

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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LP, MS-Dx, MS, and MS-Dx are registered trademarks of Genzyme Corporation.

SANOFI GENZYME
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.
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/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 30 minutes of inactivity and your training progress may be lost.

If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-4326, Mon – Fri, 8:30 am – 8:00 pm ET.
Are You Sure You Want to Exit?
You will lose your session and will need to begin again.

Yes  No, Continue

If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-4336, Mon – Fri, 8:30 am – 8:00 pm ET.

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U.S. MS.HV.1A-1G.013-27 Last Updated 09/19
Your Session Has Timed Out

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

If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-4326, Mon – Fri, 8:30 am – 8:00 pm ET.
What is the LEMTRADA REMS (Risk Evaluation and Mitigation Strategy)?

LEMTRADA is a strategy to manage known or potential risks associated with a drug. It is employed by the FDA to ensure that the benefits of the drug exceed its risks. Due to various risks of immunizations such as infections, multiple sclerosis, stroke, and malignancy, LEMTRADA (remslegacy) is only available through a special program called the LEMTRADA REMS.

**LEMTTRADA REMS Requirements**
- Prescriptions may be written to 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**
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 in 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 pharmacists and healthcare facilities are certified and patients are authorized to receive LEMTRADA prior to dispensing LEMTRADA.
2. Enroll in the LEMTRADA REMS must be renewed every 2 years from the date of enrollment.
3. Submit the completed and signed LEMTRADA REMS Pharmacy Enrollment Form to the LEMTRADA REMS.

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.

Reference ID: 4512344
**HEALTHCARE FACILITY ENROLLMENT INSTRUCTIONS**

1. An authorized representative must enroll on behalf of the healthcare facility by completing the LEMTRADA REMS Education Program for Healthcare Facilities and completing the LEMTRADA REMS Framework of Agreement (FOA) form. The healthcare facility must 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 confirm 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 the PATIENT INFORMATION FOLDER to the patient at the first dose of LEMTRADA.
   - The healthcare facility will complete a LEMTRADA REMS Information Checklist for each patient at the conclusion of each treatment course and submit it to the LEMTRADA REMS within 7 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 Enrolment Form, which contains information to be completed by both the prescriber and the patient.

2. Provide a copy of the PATIENT INFORMATION FOLDER to each patient who will receive LEMTRADA. You must also give him/her/it the information about LEMTRADA, including:
   - The serious risks and REMS requirements of the use of LEMTRADA.
   - The patient needs to complete and sign LEMTRADA REMS Patient Enrolment Form to the LEMTRADA REMS.

3. Provide the patient with a copy of the LEMTRADA REMS Patient Enrolment Form and keep a copy in the patient’s medical record.

Where to Find REMS Information and Resources

To enrol in LEMTRADA, call 1-855-676-5435. For additional information about the LEMTRADA REMS, visit www.LEMTRADA.com.

**FOLIO**
Welcome, Patricia Washington!

LEMTTRADE REMS Training Complete

You have completed your review of the training materials.

Go To Enrollment

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

LEMTTRA 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 Sanofi 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: 123456789
- Pharmacy Address: 70 Oak Street, Apartment 7C, Santa Monica, CA 90401
- Phone Number: 555-655-5555
- Fax Number: 555-655-5555
- Email Address: 123abc1234@email.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 ensure 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 audit processes and procedures, to ensure the following requirements 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.
  - 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 Sanofi, 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 this module and adhere to the requirements of the LEMTRADA REMS. I understand that I must complete the 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

If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-476-6526, Mon – Fri, 8:30 am – 8:00 pm ET.
LEMTTRADE REMS Pharmacy Enrollment Form

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

Please review the following information and submit to Genzyme by clicking the button below. Complete any missing information and resubmit 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

ZIP Code: 90403

Name of Authorized Pharmacist Representative: Jane Doe

Title: Pharmacist

Phone Number: 123-456-7890

Fax Number: 123-456-7891

Email Address: jane.doe@pharmacy.com

PHARMACY AGREEMENT

I am the authorized representative signing this form, I agree:
- I understand that my pharmacy will be registered as a REMS participating pharmacy; LEMTRADE by completing the LEMTRADE REMS registration form.
- I will ensure that all safe dispensing of LEMTRADE is conducted by trained and competent pharmacists.
- The LEMTRADE REMS program will be monitored by Genzyme and the REMS Brand Monitor.

I have verified that all states in which I will dispense LEMTRADE are listed above.

I understand that the information submitted is true and complete.

By entering my name, I certify that I am a pharmacist authorized to dispense LEMTRADE.

Full Name: Jane Doe

NPI Number: 0123456789

I certify that I have completed the LEMTRADE REMS training.

If you have questions about the LEMTRADE REMS or need help enrolling, call 1-855-476-6326, Mon – Fri, 8:30 am – 8:00 pm ET.
LEMTTRA 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 LEMTRADA.

AUTOIMMUNE CONDITIONS
LEMTTRA 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
LEMTTRA causes severe 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
LEMTTRA may cause an increased risk of malignancy including thyroid cancer, melanoma, and lymphoproliferative disorders. Perform baseline and yearly exams.

LEMTTRA 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

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 1-855-676-8328, Mon – Fri, 8:30 am – 8:00 pm ET.

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US 445,549 and US 9,559,313. Last Updated 09/12

SANOFI GENZYME
LEMTREDA REMS (Risk Evaluation and Mitigation Strategy)

What is the LEMTREDA 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 LEMTREDA REMS is to inform prescribers, pharmacies, healthcare facilities, and patients about the risks of:

AUTOIMMUNE CONDITIONS
LEMTREDA causes serious, sometimes fatal, autoimmune conditions such as immune thrombocytopenia and anti-gliomerular 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 LEMTREDA.

INFUSION REACTIONS
LEMTREDA causes serious and life-threatening infusion reactions. LEMTREDA 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 LEMTREDA administration. Instruct patients to seek immediate medical attention if symptoms of stroke occur.

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

Complete Enrollment in the LEMTREDA REMS

You must review the training materials in order to complete your enrollment in the LEMTREDA 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 LEMTREDA REMS to prescribe, dispense, or administer LEMTREDA.

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

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LEMTREDA is a registered trademark of Genzyme Corporation and is registered in the United States, Australia, Canada, China, Colombia, the European Union, and India. Sanofi is the owner of LEMTREDA in the United States.
LEMTTRADE REMS (Risk Evaluation and Mitigation Strategy)

**What is the LEMTTRADE 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 LEMTTRADE REMS is to inform prescribers, pharmacies, healthcare facilities, and patients about the risks of:

- **Autoimmune Conditions**
  LEMTTRADE 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 LEMTTRADE.

- **Infusion Reactions**
  LEMTTRADE causes serious and life-threatening infusion reactions. LEMTTRADE 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 LEMTTRADE administration. Instruct patients to seek immediate medical attention if symptoms of stroke occur.

- **Malignancies**
  LEMTTRADE may cause an increased risk of malignancy including thyroid cancer, melanoma, and lymphoproliferative disorders. Perform baseline and yearly exams.

**Find a REMS Certified Prescriber or Healthcare Facility**

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

Enter ZIP Code:

- REMS Certified Prescriber
- REMS Certified Healthcare Facility

**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 LEMTTRADE REMS or need help enrolling, call 1-855-676-8326, Mon – Fri, 8:30 am – 8:00 pm ET.
LEMTTRADE REMS (Risk Evaluation and Mitigation Strategy)

**What is the LEMTRADE 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 LEMTRADE REMS is to inform prescribers, pharmacies, healthcare facilities, and patients about the risks of:

**AUTOIMMUNE CONDITIONS**
LEMTTRADE 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 LEMTRADE.

**INFUSION REACTIONS**
LEMTTRADE causes serious and life-threatening infusion reactions. LEMTRADE 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 LEMTRADE administration. Instruct patients to seek immediate medical attention if symptoms of stroke occur.

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

---

**LEMTTRADE REMS Enrollment Complete**

You have successfully completed online enrollment at the LEMTRADE REMS. You will receive a confirmation email with your LEMTRADE REMS identification number. A Genzyme representative will also follow up with you to schedule your appointment to verify enrollment.

**Find a REMS Certified Prescriber or Healthcare Facility**

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

- Enter ZIP Code
- [REMS Certified Prescriber]
- [REMS Certified Healthcare Facility]
- Find

---

If you have questions about the LEMTRADE REMS or need help enrolling, call 1-855-676-8326, Mon – Fri, 8:30 am – 8:00 pm ET.
LEMTTRA REMS PROGRAM OVERVIEW

What is the LEMTRA 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 unique risks of anemia, infections, severe skin reactions, stroke, and malignancies, LEMTRA (lemtuzumab) is only available through a restricted program called the LEMTRA REMS.

LEMTTRA REMS Requirements:
- Prescribers must be enrolled in the LEMTRA REMS to be able to prescribe LEMTRA.
- Pharmacists must be enrolled in the LEMTRA REMS to be able to dispense LEMTRA.
- Healthcare facilities must be enrolled in the LEMTRA REMS to be able to dispense and administrate LEMTRA.
- Patients must be enrolled and authorized in the LEMTRA REMS in order to receive LEMTRA.

PRESCRIBER ENROLLMENT INSTRUCTIONS
1. Complete the training program, which includes reviewing the following:
   a. LEMTRA Prescribing Information
   b. LEMTRA REMS Program Overview
   c. LEMTRA REMS Education Program for Prescribers
2. Successfully complete the 8-question LEMTRA REMS Knowledge assessment.
3. Enroll in the program by completing a LEMTRA REMS Prescriber Enrollment Form.
4. Submit the completed and signed forms to the LEMTRA REMS.

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

If you have questions about the LEMTRA REMS or need help enrolling, call 1-855-875-6326, Mon - Fri, 8:30 am - 8:00 pm ET.

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PHARMACY DASHBOARD PAGES
Lemtrada Rems Pharmacy Dashboard

Authorized representatives of pharmacies can use this site to coordinate fulfilling the Lemtrada REMS requirements.

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.

Re-enroll Now

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Vv-reg-0833078 0.1

Reference ID: 4512344
Your Re-enrollment Is Due in Less Than a Month

Re-enroll Now  Return to Dashboard

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.
LEMRADA REMS (Risk Evaluation and Mitigation Strategy)

What is the LEMRADA 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 LEMRADA REMS is to inform prescribers, pharmacies, healthcare facilities, and patients about the risks of:

AUT IMMUNE CONDITIONS
LEMRADA 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 LEMRADA.

INFUSION REACTIONS
LEMRADA causes serious and life-threatening infusion reactions. LEMRADA 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 LEMRADA administration. Instruct patients to seek immediate medical attention if symptoms of stroke occur.

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

Re-enroll in the LEMRADA REMS

You have been locked out due to incomplete re-enrollment. Please click the link below to re-enroll in the LEMRADA REMS.

Re-enroll Now

Find a REMS Certified Prescriber or Healthcare Facility

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

Enter ZIP Code

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 LEMRADA REMS or need help enrolling, call 1-855-676-8326, Mon – Fri, 8:30 am – 8:00 pm ET.

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UCS 190 LEM 1.4.16.01S-17 Last Updated 09/19

SANOFI GENZYME
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

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.
My Profile

Patricia Washington

(REMS ID 123456)

7776 Golden Blossom Run
Zoob, IL 60065-3202
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
- Please enter password.
- New Password
- Please enter 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.
My Profile

Patricia Washington

(REMS ID 123456)
7776 Golden Blossom Run.
Zool, IL 02056-3602
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

Password is incorrect
New Password
Password does not meet strength requirements
Confirm Password
Password are not match

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.
Required LEMTRADA REMS Forms & Materials

Refer to these materials for information about the safe use of LEMTRADA through the LEMTRADA REMS.

- Online
- LEMTRADA REMS Program Overview
- PDF
- LEMTRADA REMS Pharmacy Enrollment Form.

Adobe® Reader® is required to view all of these PDF's. If you do not have it installed, download it from 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.
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.

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?

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.
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.

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?
   Please call the LEMTRADA REMS at 1-855-676-6326 to verify if a healthcare facility is REMS certified to administer LEMTRADA.

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?
   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.
REM 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 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

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.
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 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

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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.
### LEMTRADA REMS Requirements

Welcome to the LEMTRADA REMS. Here you can:
- Retrain and enroll in the LEMTRADA REMS every 2 years
- Manage and track your progress through the LEMTRADA REMS training and enrollment
- Download materials to help support implementation of the LEMTRADA REMS

### LEMTRADA REMS Activity

<table>
<thead>
<tr>
<th>Step</th>
<th>Activity</th>
<th>Progress</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Account Registration</td>
<td>Completed</td>
</tr>
<tr>
<td>2</td>
<td>Training</td>
<td>Completed</td>
</tr>
<tr>
<td>3</td>
<td>Enrollment Form Submission</td>
<td>Completed</td>
</tr>
<tr>
<td>4</td>
<td>Enrollment Processed</td>
<td>Completed</td>
</tr>
<tr>
<td>5</td>
<td>REMS ID Assigned</td>
<td>Completed</td>
</tr>
</tbody>
</table>

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If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-3226, Mon – Fri, 8:30 am – 8:00 pm ET.
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 procedures to comply with the LEMTRADA REMS

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.
LEMTRADA REMS MOBILE
PUBLIC and Prescriber Pages Only
PUBLIC FACING PAGES
LEMTTRA SD Requirements

PRESCRIBERS

Prescribers must be enrolled in the LEMTRA SD to prescribe LEMTRA for patients with multiple sclerosis. Learn about Prescriber Enrollment.

HEALTHCARE FACILITIES

Healthcare facilities must be enrolled in the LEMTRA SD to dispense/administer LEMTRA 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 LEMTRA SD to be able to dispense LEMTRA for patients with multiple sclerosis. Learn about Pharmacy Enrollment.

If you have questions about the LEMTRA SD or need help enrolling, call 1-866-973-0352. Mon - Fri, 8:30 am - 8:00 pm ET.

Enroll in the LEMTRA SD

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

Find a REMS Certified Prescriber or Healthcare Facility

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

Enter ZIP Code:

- REMS Certified Prescriber
- REMS Certified Healthcare Facility

Find
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, pharmacists, healthcare facilities, and patients about the risks of LEMTRADA.

AUTOMMUNE CONDITIONS
LEMTRADA REMS /Hecasea accura sometime fatal

LEMTRADA REMS Requirements

PRESCRIBERS

HEALTHCARE FACILITIES

PHARMACIES
LEMTTRADE REMS Requirements

PRESCRIBERS

Prescribers must be enrolled in the LEMTRADE REMS to prescribe LEMTRADE for patients with multiple sclerosis.
Learn about Prescriber Enrollment »

HEALTHCARE FACILITIES

Healthcare facilities must be enrolled in the LEMTRADE REMS to dispense an administer LEMTRADE 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 LEMTRADE REMS to be able to dispense LEMTRADE for patients with multiple sclerosis.
Learn about Pharmacy Enrollment »

If you have questions about the LEMTRADE REMS or need help enrolling, call 1-888-678-6332
Mon - Fri, 8:30 am - 8:00 pm ET.

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Enroll in the LEMTRADE REMS

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

Information for Prescribers »
Information for Healthcare Facilities »
Information for Pharmacies »
Already registered? Log in »

Find a REMS Certified Prescriber or Healthcare Facility

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

Enter ZIP Code

Find
LEMTTRADE REMS Requirements

PRESCRIBERS

Prescribers must be enrolled in the LEMTRADE REMS to prescribe LEMTRADE for patients with multiple sclerosis. Learn more about Prescriber Enrollment →

HEALTHCARE FACILITIES

Healthcare facilities must be enrolled in the LEMTRADE REMS to dispense and administer LEMTRADE for patients with multiple sclerosis. Learn more about Healthcare Facility Enrollment →

PHARMACIES

Pharmacists must be enrolled in the LEMTRADE REMS to be able to dispense LEMTRADE for patients with multiple sclerosis. Learn more about Pharmacy Enrollment →

If you have questions about the LEMTRADE REMS or need help enrolling, call 1-888-378-5320 Mon – Fri, 8:30 am – 8:00 pm ET.

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Reference ID: 029733078 0.1
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 1-855-478-1524.
Mon - Fri, 8:30 am - 8:00 pm ET.
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

Password does not meet strength requirements

Confirm Password

Password does not match.

Log In

If you have questions about the LEMTRADA REMS or need help enrolling, call 1-833-679-5582.
Mon - Fri, 8:30 am - 8:30 pm ET.
Reset Your Password
Please enter your email address and you will receive a link to reset your password.

Cancel Reset 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.
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 1-855-879-4320, Mon – Fri, 8:30 am – 8:00 pm ET.

Return to Home

If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-879-4320, 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). Based on 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

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

If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-576-4320, Mon - Fri, 8:30 am - 8:30 pm ET.
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

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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LEMTTRA Patient Guides

Below are materials that help inform patients about treatment with LEMTRADA:

- What You Need to Know About LEMTRADA Treatment: A Patient Guide
- 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 1-855-478-4326, Mon - Fri, 8:30 am - 8:00 pm ET.

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Leimbrud, MA One In CIle. Sarah and Genzyme 994010 8669 800 Phone: 1-866-800 E-mail: LEM NURSING 001 last updated: 06/19

SANOFI GENZYME
LEMTTRADE REMS Mobile - Public / Prescriber Home, REMS Certified Prescriber and Healthcare Facility Locator

REM Certified Prescriber & Healthcare Facility Locator

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

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

New Search:

Street address, city, state, or ZIP Code

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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 LEMTTRADE REMS at 1-855-676-6426.

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

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US Mfg. Lemtra 14-10-010a / Last Updated 0919

SANOFI GENZYME
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:

Certified Prescriber

Address
Ph: (800) - 888 - 8888

Certified Prescriber

Address
Ph: (800) - 888 - 8888

Certified Prescriber

Address
Ph: (800) - 888 - 8888

Certified Prescriber

Address
Ph: (800) - 888 - 8888

Certified Prescriber

Address
Ph: (800) - 888 - 8888

Certified Prescriber

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If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6426.

M-F 8:30 am – 8:00 pm ET.

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Sanofi Genzyme

Reference ID: 4512344
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If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-974-6370, Mon - Fri, 8:30 am - 8:00 pm ET.

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SANOFI GENZYME
Contact Us

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

Phone: 1-866-571-6330
Call Center Hours: Mon – Fri, 8:00 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

Submit
Contact Us
For any questions about LEMTRADA, please contact LEMTRADA Support. Services by phone or complete the form below.
Phone: 1-800-699-6325
Call Center Hours: Mon – Fri, 8:00 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

Submit

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Contact Us

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

Phone: 1-855-576-6320
Call Center Hours: M-F, 8:00 am – 6:00 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?

Select One

How would you like to be contacted?

Email

Phone

Please enter a valid email address.

Submit

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Contact Us

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

Phone: 1-800-578-6320
Call Center Hours: Mon – Fri, 8:00 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?

Submit

How would you like to be contacted?

Email

Phone

Please enter a valid phone number.

Submit

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Sanofi Genzyme

Reference ID: 4512344
Thank You

Thank you for contacting us. Please remember that the information you provided will be kept strictly confidential and will not be shared with other parties.

You will be contacted by a Genzyme representative to address your concern. We will contact you by your choice of email or phone. If your issue has not been resolved in a timely manner, please call us at 1-850-596-9224, Mon – Fri, 8:30 am – 8:00 pm ET.
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 1-855-678-6320.

If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-678-6320. Mon - Fri, 8:30 am - 8:00 pm ET.
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

Selected:
- 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

Mobile Phone 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 1-855-679-6326. Mon – Fri, 8:30 am – 5:00 pm ET.

Reference ID: 4512344
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 LEMTRADA.

☐ I have passed an assessment test and am REMS enrolled.

Continue

If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-5176-6226, Mon – Fri, 8:30 am – 8:00 pm ET.
LEMTTRA REMS Online Training Module

If inactive on the training module for 30 minutes, you will be automatically logged off the LEMTRA REMS website and lose your training progress.

- Please review the LEMTRA REMS Training Materials, including the full Prescribing Information, the LEMTRA REMS Program Overview, and the LEMTRA 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 material 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 LEMTRA REMS and will not be certified to prescribe/dispenser LEMTRA REMS.

Online training will take approximately 20 minutes. Please allow enough time to view the entire module. You will be automatically logged out after 30 minutes of inactivity and your training progress may be lost.

Continue

If you have questions about the LEMTRA REMS or need help enrolling, call 1-855-407-4326, Mon – Fri, 8:30 am – 8:00 pm ET.

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0818-00351 01 12-02-2021 020 006-2021 020 006-2021

Reference ID: 4512344

VV-REG-0833078 0.1
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

If you have questions about the
LEMTRADA REMS or need help
enrolling, call 1-855-876-6526.
Mon - Fri, 8:30 am - 8:00 pm ET.

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ULS-ME-1MA-11-0916a-v1 and submitted 07/19.

SANOFI GENZYME
Your Session Has Timed Out

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

Accept

If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-976-6326, Mon – Fri, 8:30 am – 8:00 pm ET.

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SANOFI GENZYME

Reference ID: 4512344
If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6226. Mon – Fri, 8:30 am – 8:00 pm ET.
If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-976-6326. Mon – Fri, 8:30 am – 8:00 pm ET.
If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6305, Mon – Fri, 8:30 am – 8:00 pm ET.
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.
If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-776-6325, Mon – Fri, 8:30 am - 8:00 pm ET.
If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-8265, Mon – Fri, 8:30 am - 8:00 pm ET.
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.
If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-774-6226, Mon – Fri, 8:30 am – 8:00 pm ET.
LEMTRADA REMS Training

Full Prescribing Information (16 of 27)
Total Training Screens: 16 of 41

If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-976-6306, Mon – Fri, 8:30 am - 8:00 pm ET.
If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6206, Mon – Fri, 8:30 am – 8:00 pm ET.
If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6226. Mon – Fri, 8:30 am – 8:00 pm ET.
If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-976-8202, Mon – Fri, 8:30 am – 8:00 pm ET.
If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-956-6236.
Mon – Fri, 8:30 am - 8:00 pm ET.

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If you have questions about the LEMTRADE REMS or need help enrolling, call 1-855-576-6226. Mon – Fri, 8:30 am – 8:00 pm ET.
LEMTRADA REMS Training

LEMTRADA REMS Education Program for Prescribers (1 of 2)
Total Training Screens: 30 of 41

If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-876-6326.
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Reference ID: 4512344
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If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-876-6326.
Mon – Fri, 8:30 am – 8:00 pm ET.
If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-877-6326.
Mon – Fri, 8:30 am – 8:00 pm ET.
If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-876-6326. Mon – Fri, 8:30 am – 8:00 pm ET.
LEMTRADA REMS Training

Overview of LEMTRADA Treatment

If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-876-6326. Mon – Fri, 8:30 am – 5:00 pm ET.
LEMTTRA REMS Training

LEMTTRA REMS Education Program for Prescribers (3 of 12)
Total Training Screens: 32 of 41

LEMTTRA REMS Training

LEMTTRA REMS Education Program for Prescribers (3 of 12)
Total Training Screens: 32 of 41

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

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LEMTTRA REMS Education Program for Prescribers (3 of 12)
If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-876-6326. Mon – Fri, 8:30 am – 8:00 pm ET.
LEMTTRADE REMS Training Complete

You have completed your review of the training materials. You may now answer the Knowledge Assessment questions.

Answer Knowledge Assessment Questions

If you have questions about the LEMTRADE REMS or need help enrolling, call 1-855-676-6226, Mon – Fri, 8:30 am – 8:00 pm ET.
LEMTRADA REMS Mobile - Prescriber Training, Assessment Question 1

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

Submit

If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-476-6326, Mon – Fri, 8:30 am – 8:00 pm ET.

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SANOFI GENZYME

VV-REG-0833078 0.1
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)**

What is the following information 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

If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-476-6326. Mon - Fri, 8:30 am - 8:00 pm ET.
LEMTTRADE REMS Mobile - Prescriber Training, Assessment Question 2

LEMTTRADE REMS Knowledge Assessment
To confirm that prescribers understand the LEMTRADE REMS requirements, you must successfully complete the knowledge Assessment below. You must answer ALL 8 questions correctly in order to become enrolled in the LEMTRADE 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 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

If you have questions about the LEMTRADE REMS or need help enrolling, call 1-855-476-6326, Mon - Fri, 8:30 am - 8:00 pm ET.
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 3

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

- True
- False

Submit

If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-476-6326, Mon – Fri, 8:30 am – 8:00 pm ET.
LEMTRADA REMS - Prescriber Training, Assessment Question 4

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 4 (select one)

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

- A. Headache, rash, pain, nausea
- B. Easy bruising, petechiae, purpura, spontaneous mucocutaneous bleeding
- C. Weight gain, fatigue, constipation
- D. Pyrosis, chilli, swollen glands

Submit

If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-476-6326, Mon – Fri, 8:30 am – 8:00 pm ET.

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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 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

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.
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 6 (select one)

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

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

Submit

If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-476-6326.
Mon - Fri, 8:30 am - 8:00 pm ET.
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 strokes) 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 1-855-678-6326, Mon – Fri, 8:30 am – 8:00 pm ET.
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 8

This 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

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.
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 as 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.
LEMTTRADE REMS Mobile - Prescriber Training, Failed Assessment 3 Times

LEMTTRADE REMS Knowledge Assessment

To confirm that prescribers understand the LEMTRADE REMS requirements, you must successfully complete the knowledge Assessment below. You must answer ALL 8 questions correctly in order to become enrolled in the LEMTRADE 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 LEMTRADE REMS or need help enrolling, call 1-855-676-6326, Mon – Fri, 8:30 am – 8:00 pm ET.

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May 2015 U.S. LTR 0.7.0 US1 US2 (Last updated 05/15)

SANOFI GENZYME

Reference ID: 4512344
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 Contact A Genzyme Representative

You have reached the maximum number of attempts to complete the Knowledge Assessment. Please contact a Genzyme representative.

Please call 1-855-476-6326 to speak with a Genzyme representative.

If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-476-6326, Mon – Fri, 8:30 am – 8:00 pm ET.
LEMTRADA REMS Mobile - Prescriber Training, Assessment Complete

You have successfully completed all of the Knowledge Assessment questions. You may now review and submit your LEMTRADA REMS Enrollment Form.

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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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 Enrolment 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) 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 record.

I will provide enrolled patients with a LEMTRADA Patient Safety Information Card and instruct patients to carry it with them at all times in the case of an emergency.

I understand that I must submit to LEMTRADA REMS Prescriber Ordering Form for each LEMTRADA prescription.

I understand that I am responsible for completing baseline lab monitoring within 30 days prior to initiation of LEMTRADA. I understand that I must submit to a LEMTRADA REMS Patient Authorization and Baseline Lab Form indicating completion of each patient’s baseline lab within 30 days prior to the patient’s infusion date.

I understand the risk of autoimmunity 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.
- Untyped, white 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 urine examinations.

I understand the risk of osteoporosis and the following administration of LEMTRADA.

I will report any adverse events of serious, unexpected, conditional reactions, or malignancies to Geoxyme.

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 Geoxyme 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 Geoxyme 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 administering LEMTRADA and consent to the foregoing.

I understand that I am waiving the right to impact my Contact Information prior to its inclusion on the website, and I agree to hold harmless and release the LEMTRADA REMS and Geoxyme 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.

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.

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

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. Because of its safety profile, the use of LEMTRADA should be reserved for patients who have had an inadequate response to two or more drugs prescribed 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 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 record.

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 initiation of LEMTRADA. I understand that I must submit a LEMTRADA REMS Patient Authorization and Baseline Lab Form indicating completion of each patient’s baseline lab within 30 days prior to the patient’s infusion date.

I understand the risks of Serious Illnesses, 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.
- Urea and electrolyte levels 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 visual acuity examinations.

I understand the risk of death during and following the administration of LEMTRADA.

I will report any adverse events associated with LEMTRADA.

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.

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 LEMTRADA REMS.
# LEMTRADA REMS Prescriber Enrollment, State Selection

**LEMTTRADA REMS Prescriber Enrollment Form**

LEMTTRADA 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, administrate, 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.

**Prescribed Stevens Information**

<table>
<thead>
<tr>
<th>First Name*</th>
<th>Adam</th>
</tr>
</thead>
<tbody>
<tr>
<td>Last Name*</td>
<td>Smith</td>
</tr>
<tr>
<td>Degree*</td>
<td>Medical Doctor</td>
</tr>
<tr>
<td>Street Address*</td>
<td>730-04 Maple Lane</td>
</tr>
<tr>
<td>City*</td>
<td>Beacon</td>
</tr>
<tr>
<td>State*</td>
<td>New York</td>
</tr>
</tbody>
</table>

**I understand that I must submit a LEMTRADA REMS Patient Authorization and Baseline Lab Form indicating completion of each patient’s baseline lab within 30 days prior to the patient’s infusion date.**

- 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.
- Urea nitrogen and creatinine 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 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 urine examinations.

- I understand the risk of esophageal and gastrointestinal perforation.

- 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 I will notify Genzyme if I fail to comply with the requirements of the LEMTRADA REMS.

- I understand that the LEMTRADA REMS will publish my name, business address, and phone number (“Contact Information”) on its website as 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.

- I have verified that all details are correct.

By providing my 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 signature will be used to verify my enrollment in the LEMTRADA REMS.

By printing 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.

<table>
<thead>
<tr>
<th>Full Name*</th>
<th>Adam Smith</th>
</tr>
</thead>
<tbody>
<tr>
<td>NPI Number*</td>
<td>1234567890</td>
</tr>
<tr>
<td>Password*</td>
<td>password123</td>
</tr>
</tbody>
</table>

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.

---

Reference ID: 4512344
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 the 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 record.

I will provide enrolled patients with a LEMTRADA Patient Safety Information Card and instruct patients to carry the card with them at all times in case of an emergency.

I understand that I must submit a LEMTRADA REMS Prescribing 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 to the LEMTRADA REMS Patient Authorization and Baseline Lab Form indicating completion of these procedures at least within 30 days prior to the patient’s infusion date.

I understand the risks of autologous 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 at and 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.
- Urea nitrogen and creatinine on renal dysfunction obtained within 30 days prior to initiation of treatment and at monthly intervals thereafter until 48 months after the last infusion.
- Measure the International Normalized 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 every 6 months thereafter until 48 months after the last infusion.
- Baseline and yearly urine examinations.

I understand the risks of osteoarthritis following the administration of LEMTRADA.

I will report any adverse events of autologous conditions, infestations, reactions, or malignancies to Genesis.

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 Genesis 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 LEMTRADA REMS is available only through the LEMTRADA REMS and that I must enroll all patients being prescribed LEMTRADA into the LEMTRADA REMS.
Enrollment Is Complete!

You have successfully completed the 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.

If you do not receive a confirmation email after the representative's visit, please contact a LEMTRADA REMS Specialist at 1-855-576-6529.

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.

Download a copy of your LEMTRADA REMS Prescriber Enrollment Form for your records.

If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-576-6529, Mon – Fri, 8:30 am – 9:00 pm ET.
LEMTTRA REMS Mobile - Pre-REMS Certification, Prescriber Training Incomplete

LEMTTRA REMS (Risk Evaluation and Mitigation Strategy)

What is the LEMTRA 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 LEMTRA REMS is to inform prescribers, pharmacies, healthcare facilities, and patients about the risks of:

- Autoimmune Conditions
  LEMTRA may cause 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 urinal cell counts at periodic intervals for 48 months after the last dose of LEMTRA.

- Infusion Reactions
  LEMTRA may cause serious or life-threatening infusion reactions. LEMTRA 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 intracerebral hemorrhage) has been reported within 3 days of LEMTRA administration. Instruct patients to seek immediate medical attention if symptoms of stroke occur.

- Malfunctions
  LEMTRA may cause an increased risk of malignancy including thyroid cancer, melanoma, and lymphoproliferative disorders. Perform baseline and yearly skin exams.

Complete Enrollment in the LEMTRA 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 LEMTRA REMS.

Find a REMS Certified Prescriber or Healthcare Facility

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

LEMTTRA REMS Requirements

Prescribers must enroll in the LEMTRA REMS to prescribe LEMTRA for patients with multiple sclerosis.

Reference ID: 4512344
LEMTTRADEX REMS Mobile - Pre-REMS Certification, Prescriber Assessment Incomplete

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 LEMTRADEX REMS or need help enrolling, call 1-855-676-6336. Mon - Fri, 8:30 am - 8:00 pm ET.

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Last Updated 08/19

Complete Enrollment in the LEMTRADEX REMS

You have not completed answering the LEMTRADEX 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 LEMTRADEX REMS to prescribe, dispense, or administer LEMTRADEX.

Enter ZIP Code

- REMS Certified Prescriber
- REMS Certified Healthcare Facility

Find

LEMTTRADEX REMS Requirements

Prescribers must be enrolled in the LEMTRADEX REMS to prescribe LEMTRADEX for patients with multiple sclerosis.

Learn about Prescriber Enrollment

Reference ID: 4512344

VV-REG-0833078 0.1
LEMTRADE REMS Mobile - Pre-REMS Certification, Prescriber Enrollment Incomplete

If you have questions about the LEMTRADE REMS or need help enrolling, call 1-855-876-8326, Mon - Fri, 8:30 am - 8:00 pm ET.

Complete Enrollment in the LEMTRADE REMS

You have not completed your review and submission of the LEMTRADE REMS Prescriber Enrollment Form. Complete your enrollment and gain access to the online tools and resources available to help you manage your LEMTRADE patients.

Find a REMS Certified Prescriber or Healthcare Facility

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

Enter ZIP Code

- REMS Certified Prescriber
- REMS Certified Healthcare Facility

LEMTRADE REMS Requirements

Prescribers

Prescribers must be enrolled in the LEMTRADE REMS to prescribe LEMTRADE for patients with multiple sclerosis.

Learn about Prescriber 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).
Prescribers must be enrolled in the LEMTRADA REMS to prescribe LEMTRADA for patients with multiple sclerosis. Learn about Prescriber 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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SANOBI GENZYME

LEMTTRADA REMS Mobile - Pre-REMS Certification, Prescriber Enrollment Complete

LEMTTRADA 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:

AUTONOMIC CONDITIONS

LEMTRADA causes sudden, sometimes fatal, autonomic conditions such as immune thrombocytopenia and anti-glucagon-like peptide-1 receptor antibodies, which may cause symptoms such as weakness, sweating, dizziness, or unexplained blood loss.

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

Sudden and life-threatening stroke (including intracerebral hemorrhage) has been reported within 3 days of LEMTRADA administration. Report any stroke to the nearest emergency department immediately.

MAJOR NAVIGATION

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

LEMTTRADA REMS Enrollment Complete

You have successfully completed the 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 receive enrollment. Once your enrollment is verified, you gain access to the online tools and resources available to help you manage your LEMTRADA patients.

Find a REMS Certified Prescriber or Healthcare Facility

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

Enter ZIP Code

○ REMS Certified Prescriber
○ REMS Certified Healthcare Facility

Find

LEMTTRADA REMS Requirements

PRESCRIBERS

Reference ID: 4512344

VV-REG-0833078 0.1
LEMTTRADE 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.

You have 10 LEMTRADA patients.

<table>
<thead>
<tr>
<th>Patient (REMS ID)</th>
<th>REMS Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>John Doe (123456789)</td>
<td>Authorized</td>
</tr>
<tr>
<td>John Doe (123456789)</td>
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<td>John Doe (123456789)</td>
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<tr>
<td>John Doe (123456789)</td>
<td>Authorized</td>
</tr>
</tbody>
</table>

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 1-855-876-6330. Mon - Fri, 8:30 am - 8:00 pm ET.
**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 patient authorization status, infusion records, and monitoring program activity.

You have 10 LEMTRADA patients

<table>
<thead>
<tr>
<th>Patient ID</th>
<th>REMS Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>1234567890</td>
<td>Authorized</td>
</tr>
<tr>
<td>1234567890</td>
<td>Authorized</td>
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<td>Authorized</td>
</tr>
<tr>
<td>1234567890</td>
<td>Authorized</td>
</tr>
</tbody>
</table>

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If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-876-8526, Mon – Fri, 8:30 am – 8:00 pm ET.
You have 4 patient alerts!

- 1 patient is overdue for authentication 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.

LEMTTRA REMS Support Tools

View individual profiles of your LEMTRADA patients and the healthcare facilities they visit. These resources can help you learn more about patient authentication status, infusion records, and monitoring program activity.

LEMTTRA REMS Support Tools

You have 4 LEMTRADA patients

Search, edit, and navigate information about your patients' timeline. Click on a box to complete authentication requirements.

Patient Status Form

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 1-855-676-8336, Mon – Fri, 8:30 am – 8:00 pm ET.
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.

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.
My Profile

Adam Smith

Address: 1234 Main St, Anytown, USA 99999
Phone: 123-456-7890
Fax: 123-456-7890

If any of your information is incorrect or has recently changed, please call 1-855-676-3042.

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

Change Your Password

Current Password

New Password

Confirm 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 1-855-676-3042.

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My Profile

Adam Smith

(VREA) 123-456-7890
7777 Golden Blossom Run
Zeek, IN 31056-2030
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 1-351-455-6324, Mon - Fri, 8:00 am – 5:00 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 uppercase letter, a lowercase letter, a special character (e.g., $, @, #, %, etc.)

Current Password

[Input field for current password]

New Password

[Input field for new password]

Confirm Password

[Input field to confirm new 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 1-855-479-6222, Mon – Fri, 8:00 am – 8:00 pm ET.

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U.S. NDA #04-40369 v7 Last Updated 10/19
LEMTRADA REMS Mobile - Prescriber Dashboard, My Profile, Passwords do not match Error

My Profile

Adam Smith

(908) 321-5432
7276 Goldenson Blvd
Avenel, NJ 07001-2530
Office Phone: xxx-x-x-xxxx
Mobile Phone: xxx-x-x-xxxx
Fax: xxx-x-x-xxxx

If any of your information is incorrect or has recently changed, please call 1-888-476-9332, Mon - Fri, 8:30 am – 5:00 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 combination of upper case letters, lower case letters, special characters (e.g., $, #, @, etc.)

Current Password

Password is incorrect

New Password

Password does not meet strength requirements

Confirm Password

Passwords do not match

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 1-888-476-A328, Mon - Fri, 8:30 am – 5:00 pm ET.
Required LEMTRADA REMS Forms & Materials

Refer to these materials for information about the safe use of LEMTRADA through the LEMTRADA REMS.

- 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
- 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 833-676-8378, Mon – Fri, 8:30 am – 8:00 pm ET.
LEMTRADA REMS Mobile - Patient Status Form, Yes Selected, Error

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 those 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-EHE 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:

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:

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 1-800-299-9346 Mon - Fri, 8:30 am - 8:00 pm ET.

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U.S. REPS: 1-800-745-4447 (option 2) or www.FDA.gov/medwatch

SANOFI GENZYME

Reference ID: 4512344
LEMTARA REMS PATIENT STATUS FORM

This form must be completed every 6 months for each LEMTARA patient under your care. Please complete this form 6 months after your patient’s first infusion with LEMTARA, 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
Date of Birth (MM/DD/YYYY)
Date of Last LEMTARA 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 LEMTARA Treatment: A Patient Guide with this patient and counseled the patient about the serious risks associated with the use of LEMTARA, 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 LEMTARA REMS.

By entering my name, NPI number, and password, I confirm that I have completed the LEMTARA 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 healthcare providers and is not intended as medical advice. Information on the site is updated periodically (approximately every 12 hours).

If you have questions about the LEMTARA REMS or need help enrolling, call 1-855-875-6320. Mon - Fri, 8:30 am - 8:00 pm ET.

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Sanofi Genzyme

Reference ID: 4512344
LEMTRADA REMS Mobile - Patient Status Form, No Selected, Error

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**: [Name]
- **Last Name**: [Name]
- **Office Phone Number**: [Phone number]
- **Address Line 1**: [Address]
- **Address Line 2**: [Address]
- **City**: [City]
- **State**: [State]
- **ZIP Code**: [ZIP Code]

**PATIENT INFORMATION**

- **First Name**: [Name]
- **Last Name**: [Name]
- **Patient’s LEMTRADA REMS Identification Number**: [Number]
- **Date of Birth**: [Date]
- **Date of Last LEMTRADA Infusion**: [Date]

If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-670-6320, Mon - Fri, 8:30 am - 8:00 pm ET.

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Reference ID: 4512344
LETRADA 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 LETRADA REMS at 1-855-676-6325, Mon – Fri., 8:30 am - 8:00 pm ET.

Download a copy of your LETRADA REMS Patient Status Form for your records.

If you have questions about the LETRADA REMS or need help enrolling, call 1-855-676-6325.
Mon – Fri., 8:30 am - 8:00 pm ET.
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/kg]) X 5 consecutive days

Total number of vials ordered

Subsequent course (1 vial [12 mg/kg]) 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.
LEMTRADA REMS Mobile - Patient Status Form, Patient Authorization and Baseline Lab Form, Error

Full Name
Please enter your name.

Authorized Provider Identification (NPI) Number
Please enter a valid NPI number.

Password
Please enter a valid password.

Submit
Cancel

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 1-855-686-6325.

Mon - Fri, 8:30 am - 8:00 pm ET.

Please read all of the information on the site to determine if you qualify for the LEMTRADA REMS program. If you do not qualify for the LEMTRADA REMS program, please do not enroll or submit a request for enrollment.

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Sanofi Genzyme

LEMTREDA 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 it to Genzyme using the button below. All fields are required.

Prescriber Information

First Name
Please enter your first name.

Last Name
Please enter your last name.

Office Phone Number
Please enter a 10-digit phone number.

Address Line 1
Please enter your address.

Address Line 2
Please enter your address.

City
Please enter your city.

State
Please enter your state.

ZIP Code
Please enter a valid ZIP Code.

Prescriber [LEMTTRADE REMS Identification Number]
Please enter a valid NPI number.

Patient Information

First Name
Please enter your first name.

Last Name
Please enter your last name.

Patient LEMTRADA REMS Identification Number
Please enter the patient’s LEMTRADA REMS Identification Number.

Date of Birth (MM/DD/YYYY)
Please enter the date of birth.

Authorization and Baseline Labs

Do you authorize LEMTRADA treatment for this 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

Initial course (1 vial [12 mg/kg]): X 5 consecutive days

Total number of vials ordered
Please enter the total number of vials ordered.

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

Total number of vials ordered
Please enter the 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.

Reference ID: 4512344
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.

1. How do I add a patient to this portal?

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 patient?

4. What is the LEMTRADA REMS Patient Authorization and Informed Consent 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. How do I view alerts?

8. How can I change the frequency of Patient alert reminders?

9. How can I access my portal?

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.
1. How do I add a patient to this record?

This site displays information about patients enrolled in the LEMTRADEX REMS. REMS certified prescribers can enroll new patients in the LEMTRADEX REMS by submitting a completed LEMTRADEX Patient Enrollment Form to Genzyme. A PDF of the LEMTRADEX Patient Enrollment Form is available in the Forms & FAQs section. Once patients are enrolled in this program, their information will be available.

Please contact the LEMTRADEX REMS at 1-855-676-6026 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 LEMTRADEX REMS Training Center after registration, the representative must review the LEMTRADEX REMS education program for healthcare professionals, complete the online module, complete and sign the LEMTRADEX REMS healthcare facility enrollment form, and implement the necessary staff training and processes.

For further information, contact the LEMTRADEX REMS Specialist at 1-855-676-6026.

3. How can I find an infusion center for my patient?

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 LEMTRADEX REMS to dispense/administer LEMTRADEX. You can also contact the LEMTRADEX REMS at 1-855-676-6026 to speak with a LEMTRADEX REMS Specialist.

4. What is the LEMTRADEX REMS Patient Authorization and Baseline Lab form used for?

The LEMTRADEX 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 LEMTRADEX patient's treatment course. The form can be found in the Forms section.

5. What is the LEMTRADEX REMS Patient Status Form used for?

The LEMTRADEX REMS Patient Status Form is a mandatory form that must be filled out every 6 months after a patient's first infusion with LEMTRADEX and at 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 parent is not REMS Authorized?

Alerts are generated when patients are overdue for authorization by the LEMTRADEX REMS Patient Authorization Form and/or the LEMTRADEX REMS Patient Status Form. Authorization forms that have not been completed by the LEMTRADEX REMS team 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 LEMTRADEX 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 Profile tab. To see alerts for a specific patient, click the link to the LEMTRADEX REMS Support tools to view the individual Patient Profile page.

8. How can I change the frequency of Patient alerts?

To change the frequency of Patient alerts, first click My Profile in the navigation bar. Under the “Manage My Alert Preferences” section, you may adjust 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 LEMTRADEX REMS at 1-855-676-6026.

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 LEMTRADEX REMS or need help enrolling, call 1-855-676-6026, Mon - Fri, 8:30 am – 8:00 pm ET.

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SANOFI GENZYME

Reference ID: 4512344
REMTRADE REMS Mobile - Prescriber Dashboard, REMS Certified Prescriber and Healthcare Facility Locator

REMTRADE REMS Mobile - Prescriber Dashboard, REMS Certified Prescriber and Healthcare Facility Locator

REMSP Certified Prescriber & Healthcare Facility Locator

Search for prescribers or healthcare facilities that are enrolled and certified in the LEMTRADE REMS and able to prescribe or dispense administration REMTRADE.

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

New Search:

Street address, city, state, or ZIP Code

LETRADE REMS Mobile - Prescriber Dashboard, REMS Certified Prescriber and Healthcare Facility Locator

REMSP Certified Prescriber & Healthcare Facilities

Certified Prescriber Name
Address
P: (000) - 0000

Certified Prescriber Name
Address
P: (000) - 0000

Certified Prescriber Name
Address
P: (000) - 0000

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Certified Prescriber Name
Address
P: (000) - 0000

Genzyme is providing this search feature to help patients find prescribers and healthcare facilities that have been certified by the LEMTRADE REMS. Genzyme does not assume liability for providing this feature, and does not endorse, recommend, have jurisdiction over, or accept responsibility for the websites 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 LEMTRADE 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 LEMTRADE REMS or need help enrolling, call 1-855-676-6326.

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Sanofi Genzyme
LEMTTRADE REMS Mobile - Prescriber Dashboard, REMS Certified Prescriber and Healthcare Facility Locator

Search for prescribers or healthcare facilities that are enrolled and certified in the LEMTRADE REMS and able to prescribe or dispense lemtarada. Please enter street address, city, state, or zip code you would like to search for.

New Search:

Certified Prescriber Healthcare Facilities

Certified Center Name Address E: (0000) - 0000 - 0000

Certified Center Name Address E: (0000) - 0000 - 0000

Certified Center Name Address E: (0000) - 0000 - 0000

Certified Center Name Address E: (0000) - 0000 - 0000

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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 LEMTRADE REMS at 1-855-4-LEMTRED.

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

Reference ID: 4512344
LEMTTRA DA REMS Requirements

Welcome to the LEMTRA DA REMS.
Here’s what you can:
- Track and enroll in the LEMTRA DA REMS when indicated by a Genzyme representative
- Manage and track your progress through the LEMTRA DA REMS training and enrollment
- Download materials to help inform your patients about treatment with LEMTRA

LEMTTRA DA REMS Activity

<table>
<thead>
<tr>
<th>Step</th>
<th>Activity</th>
<th>Progress</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>Account Setup</td>
<td>Completed</td>
</tr>
<tr>
<td>2</td>
<td>Training</td>
<td>Completed</td>
</tr>
<tr>
<td>3</td>
<td>Assessment</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Patient Track</td>
<td>Completed</td>
</tr>
<tr>
<td>5</td>
<td>EHR Integration</td>
<td>Completed</td>
</tr>
</tbody>
</table>

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 LEMTRA REMS or need help enrolling, call 1-855-627-6326, Mon – Fri, 8:30 am – 8:00 pm ET.

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Reference ID: 4512344
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

If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-9336, 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

If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-876-6326, Mon – Fri, 8:30 am – 8:00 pm ET.
BOTH A PRESCRIBER AND HEALTHCARE FACILITY USER
LEMTTRA REMS Support Tools

View individual profiles of your LEMTRA REMS patients and the healthcare facilities they visit. These resources can help you learn more about patients’ authorization status, infusion records, and monitoring program activity.

You have 10 LEMTRA REMS patients

<table>
<thead>
<tr>
<th>Patient (REMS ID)</th>
<th>REMS Status</th>
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<tbody>
<tr>
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<td>Authorized</td>
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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).

If you have questions about the LEMTRA REMS or need help enrolling, call 1-833-875-6325, Mon – Fri, 8:30 am – 8:00 pm ET.
HEALTHCARE FACILITY TRAINING PAGES
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.
Healthcare Facility Registration for LEMTRADE REMS Training

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

*Required

Email Address*

Create a Password*

Passwords must be at least 8 characters in length and contain a combination of at least one letter, one number, and one 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* (Select One)

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 Register

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

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

*Required

Email Address*

Create a Password*

Passwords must be at least 12 characters in length and contain a minimum of 3 out of the following: A lowercase letter, an uppercase letter, a number, and 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
Healthcare Facility Registration for LEMTRADA REMS Training

To complete your enrolling 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 1 out of the following 3 categories: a lowercase letter, an uppercase 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*

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

Register

If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-476-6532
Mon - Fri, 8:30 am - 8:00 pm ET.

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<tr>
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Reference ID: 4512344
Healthcare Facility Registration for LEMTRADA REMS Training
To complete your tracking for the LEMTRADA REMS, please set up an account.

*Required

Email Address*
Please enter a valid email address.

Create a Password*

Password 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 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*

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 Site

Ship-to is the same as facility address

Ship-to Address*

City*

Please enter ship-to address.

State*

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.

Title*

Please enter 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 1-855-878-6328.

Reference ID: 4512344

VY-REG-0833078 0.1
Healthcare Facility Registration for LEMTRADA REMS Training

To complete your step for the LEMTRADA REMS, please set up an account:

*Required

Email Address*

Please enter a valid email address.

Create a Password*

Password must be at least 8 characters in length and contain at least one of the following: A number, an upper- and/or lowercase letter, and a special character (e.g., !, $, #, %, etc.).

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 a facility address.

City*

Please enter city.

State*  ZIP Code*

Please select a state and enter 5-digit ZIP Code.

Phone Number*

Please enter a 10-digit phone number.

Fax Number*

Please enter a 10-digit fax number.

Site Administrator*

Select One

Please select a site administrator.

Ship-to Address*

Please enter ship-to address.

City*

Please enter city.

State*  ZIP Code*

Please select a state and enter 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.

If you have any questions about the LEMTRADA REMS or need help enrolling, call 866-861-3232.

Reference ID: 4512344
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 1-855-876-6206, Mon – Fri, 8:30 am – 8:00 pm ET.
LEMTTRADA REMS Online Training Module

If inactive on the training module for 30 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 Providers. 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 Accreditation 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 30 minutes. Please allow enough time to view the entire module. You will be automatically logged out after 30 minutes of inactivity and your training progress may be lost.

Continue

If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6320. Mon – Fri, 8:30 am – 8:00 pm ET.

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Sanofi Genzyme

Reference ID: 4512344
Are You Sure You Want to Exit?
You will lose your session and will need to begin again.

Yes  No, 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.
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

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.

Please return to Terms and Conditions | Contact Us

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U.S. LEM-14.10.016a of Last Updated 09/19.

SANOFI GENZYME
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 1-855-876-6326. Mon – Fri, 8:30 am – 8:00 pm ET.

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If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-877-6326.
Mon - Fri, 8:30 am - 8:00 pm ET.
LEMTTRADE REMS Program Overview (2 of 2)
Total Training Screens: 2 of 10

If you have questions about the LEMTRADE REMS or need help enrolling, call 1-855-976-6326.
Mon – Fri, 8:30 am – 8:00 pm ET.
LEMTTRADEX REMS Training
LEMTTRADEX REMS Education Program for Healthcare Facilities (3 of 10)
Total Training Screens: 5 of 10

If you have questions about the LEMTRADEX REMS or need help enrolling, call 1-855-436-6328. Mon – Fri, 8:30 am – 8:00 pm ET.
LEMTTRADE REMS Training
LEMTTRADE REMS Education Program for Healthcare Facilities (5 of 10)
Total Training Screens: 7 of 10

If you have questions about the LEMTRADE REMS or need help enrolling, call 1-855-876-6326. Mon – Fri, 8:30 am – 8:00 pm ET.
LEMTRADA REMS Training
LEMTRADA REMS Education Program for Healthcare Facilities (6 of 10)
Total Training Screens: 8 of 10

If you have questions about the LEMTRADA REMS or need help enrolling, call 1-833-676-6326, Mon – Fri, 8:30 am – 8:00 pm ET.

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Reference ID: 4512344
LEMTRADA REMS Mobile - HCF Training, Training Confirmation

You have completed your review of the training materials.

Go to Enrollment

If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6320, Mon – Fri, 8:30 am – 8:00 pm ET.

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US 10 016 519 B1 Last Updated 01/02/19

SANOFI GENZYME

Reference ID: 4512344

VV-REG-0833078 0.1
LEMTTRA REMS HEALTHCARE FACILITY ENROLLMENT FORM

LEMTTRA is only available through the LEMTRA REMS, a restricted distribution program. Only prescribers, pharmacists, healthcare facilities, and patients enrolled in the program are able to prescribe, dispense, administer, and receive LEMTRA. An authorized representative of the healthcare facility must enroll the facility in the LEMTRA REMS.

Please review the following information and submit to Genzyme by clicking the submit below. Complete any missing information and correct any errors prior to submission.

All fields are required.

HEALTHCARE FACILITY AGREEMENT

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

- I understand that my healthcare facility must be certified with the LEMTRA REMS to receive or administer LEMTRA.
- I have completed the review of the LEMTRA REMS Education Program for Healthcare Facilities and the LEMTRA REMS Program Overview.
- I understand that my healthcare facility must confirm that the patient is authorized to receive LEMTRA by contacting the LEMTRA REMS enrollment office at 1-855-676-2442 or www.lemtraREMsis.com prior to initiation of each treatment course.
- I understand the risk of serious infusion reactions during and following the administration of LEMTRA.
- I understand the need to monitor patients for infusion reactions during and for at least 2 hours after each LEMTRA 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 site equipment and personnel to manage anaphylaxis or serious infusion reactions.
- I understand that my healthcare facility must receive enrollment in the LEMTRA 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 LEMTRA REMS, including the following:
  - Ensure that a LEMTRA REMS Prescription Ordering Form is received for each prescription.
  - Ensure that the prescription is filled and the patient is enrolled and authorized by either calling the LEMTRA REMS or verifying this information via the LEMTRA REMS website prior to dispensing and administering LEMTRA.
  - Ensure that all staff members from the site are trained in the safe use of LEMTRA.
- LEMTRA 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 LEMTRA. Treatment and Informatino Restraint: A Patient Guide to each patient to inform them about the risk of serious infusion reactions.
- Observe each patient administered LEMTRA at my healthcare facility during and for at least 2 hours after each LEMTRA infusion, in order to provide appropriate medical treatment in the event of serious infusion reactions following LEMTRA infusion.
- For each patient, complete and return the LEMTRA REMS infusion Checklist to the LEMTRA REMS within 5 business days from the patient’s last infusion of LEMTRA within a specific treatment course.
- Review enrollment into the LEMTRA 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 LEMTRA REMS.
- To return to Genzyme any unused vials of LEMTRA within 50 days from the date of receipt of the LEMTRA REMS Patient Authorization Baseline Lab Form.
- To ensure that a LEMTRA REMS Patient Authorization and BasiLine Lab Form is received for each prescription by either calling the LEMTRA REMS or verifying this information via the LEMTRA REMS website.
- To ensure that all non-prescribing HCPs who administer LEMTRA in my healthcare facility are trained using the LEMTRA REMS Education Program for Healthcare Facilities and a second report regarding such training must be maintained.
- I have verified that all details are correct.
- I acknowledge that I have completed the educational training required for LEMTRA for healthcare facilities and I understand the benefits and risks of LEMTRA.
- 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 LEMTRA REMS.
- I understand that I must complete the LEMTRA 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 LEMTRA REMS training and that I will comply with the requirements of the program.

Full Name
NPI Number
Password

If you have questions about the LEMTRA REMS or need help enrolling, call 1-855-676-2442 Mon - Fri, 8:30 am - 8:00 pm ET.

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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

Category: hospital

National Provider Identification (NPI) Number

0123456789

Infusion Facility Address

43 Blasco St

City: Los Angeles

State: CA

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

Pennsylvania

Puerto Rico

Rhode Island

South Carolina

South Dakota

Tennessee

Texas

Utah

Vermont

Virgin Islands

Washington

West Virginia

Wisconsin

Wyoming

I hereby certify that

I understand the benefits and risks of LEMTRADA.

I am enrolled and authorized by LEMTRADA REMS to dispense and administer LEMTRADA.

I understand that LEMTRADA REMS is required for healthcare facilities and that I must 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 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

Submit

If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-276-6349. Mon – Fri, 8:30 am – 8:00 pm ET.

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LEMTRADA UK: One of Genzyme’s, and SGEMZYME in U.S. Patient and Healthcare CPE US MS LEM-14-0313-17 (Last Updated 6/19)

SANO® GENZYMÉ
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 e-mailing list at www.lemtradaems.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 need to monitor patients for infusion reactions during and for at least 2 hours after each LEMTRADA infusion.
- To include the monitoring of patients 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 review 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, review 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 submit 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.
  - Remove patient from 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.

If you have questions about the LEMTRADA REMS or need help enrolling, call 1-888-779-6711. Mon – Fri, 8:30 am – 8:00 pm ET.
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
Wyoming

- The prescriber, pharmacist, or other healthcare provider caring for the patient should provide a Medication Guide to each patient to inform them about the risk of serious infusion reactions.
- If a patient requires LEMTRADA at their 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.
- If a patient is receiving the LEMTRADA REMS infusion infusion Check up 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 Geaygene documentation to verify understanding of, and adherence to, the requirements of the LEMTRADA REMS.
- To return to Geaygene any unused vials of LEMTRADA within 30 days of the date of receipt of the LEMTRADA REMS Patient Authorization 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 Professionals, and a record regarding such training must be maintained.

I have verified that all details are correct.
By providing my 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 this module and adhere to the requirements of the LEMTRADA REMS.

If you have questions about the LEMTRADA REMS or need help enrolling, call 1-888-807-6738, Mon - Fri, 8:30 am - 8:00 pm ET.
HEALTHCARE FACILITY AGREEMENT

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

- I understand that my healthcare facility must be certified with the LEMTRA DA REMS to receive or administer LEMTRA DA.
- I have completed the review of the LEMTRA DA REMS Information Program for Healthcare Facilities and the LEMTRA DA REMS Program Overview.
- I understand that my healthcare facility must confirm that the patient is authorized to receive LEMTRA DA by contacting the LEMTRA DA 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 LEMTRA DA.
- I understand the risk of stroke during and following the administration of LEMTRA DA.
- I understand the need to monitor patients for infusion reactions during and for at least 2 hours after each LEMTRA DA infusion.
- To include the monitoring of patients vital signs before the infusion is initiated and periodically during the infusion.
- I understand that my healthcare facility must be equipped with the necessary crash equipment and personnel to manage anaphylaxis or serious infusion reactions.
- I understand that my healthcare facility must receive enrollment notification from the LEMTRA DA 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 safety conditions required in the LEMTRA DA REMS, including the following:

- Ensure that a LEMTRA DA 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 LEMTRA DA REMS or verifying this information via the LEMTRA DA REMS website prior to dispensing and administering LEMTRA DA.
- Ensure that the infusion site is equipped to manage infusion reactions.
- Ensure that LEMTRA DA is not administered outside of the authorized representatives certified healthcare facility.
- Prior to the first day of each treatment course, counsel and provide a copy of the "Before You Need to Know About LEMTRA DA" Treatment and Infusion Reactions: A Patient Guide to each patient to inform them about the risk of infusion reactions.
- Observe each patient administered LEMTRA DA at my healthcare facility during and for at least 2 hours after each infusion. In order to provide appropriate medical treatment in the event of serious infusion reactions following LEMTRA DA infusion.
- For each patient, complete and return the LEMTRA DA REMS infusion checkoff to the LEMTRA DA REMS within 5 business days from the patient's last infusion of LEMTRA DA within a specific treatment course.

I have verified that all details are correct. Please include information was reviewed and corrected. By providing my signature, I acknowledge that I have completed the educational training required for LEMTRA DA healthcare facility enrollment and ensure that the LEMTRA DA REMS will be completed and referenced by all staff members from my site be trained on the information in the module and adhere to the requirements of the LEMTRA DA REMS.

I understand that I must complete this LEMTRA DA 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 LEMTRA DA REMS training and that I will comply with the requirements of the program.

Full Name

Please enter your ID/Name:
NPI Number

Please enter a valid NPI number:
Password

Please enter password:
Submit

If you have questions about the LEMTRA DA REMS or need help enrolling, call 1-855-317-6708 Mon.-Fri. 8:00 am - 8:00 pm ET.
Enrollment Is 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 an appointment to verify enrollment.

If you do not receive a confirmation email after the representative’s visit, please contact a LEMTRADA REMS Specialist at 1-855-876-6526.

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.

Download a copy of your LEMTRADA REMS Healthcare Facility Enrollment Form for your records.

If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-876-6526. Mon – Fri, 8:30 am – 8:00 pm ET.
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:

AUTOMATIC IMMUNE CONDITIONS
LEMTRADA causes serositis, sometimes fatal, autoimmune conditions such as immune thrombocytopenia and polyglomerulonephritis. 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.

INFECTION REACTIONS
LEMTRADA causes serious and life-threatening infection 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.

MAINTENANCE
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.

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 admit the patient.

Enter ZIP Code

LEMTRADA REMS Requirements

Healthcare facilities must be enrolled in the
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 more 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 1-855-870-6326, Mon - Fri, 8:30 am - 8:00 pm ET.

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LEMTRADA, MS One-to-One, Sanofi and Genzyme represent U.S. Patent and Trademark Office and/or Foreign Patent issued or pending. 061919
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.

If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-879-6323. Mon – Fri, 8:30 am – 8:00 pm ET.

This site is provided as a resource for providers and is not intended as medical advice. Information on the site is updated periodically (approximately every 13 hours).

LEMTTRADE REMS Mobile - HCF, Dropdown Navigation

LEMTTRADE 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 LEMTRADA patients.

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

LEMTTRADE REMS Requirements

HEALTHCARE FACILITIES

医疗机构必须加入 LEMTRADA REMS 以便分发 / 管理 LEMTRADA 用于多发性硬化症患者。每家医疗机构需要一名代表来完成注册。

如果您有关于 LEMTRADA REMS 的问题或需要帮助注册，请致电 1-855-879-6323。工作日 8:30 am – 8:00 pm ET。

此网站仅作为为医疗专业人员提供的资源，不作为医疗建议。网站上的信息会定期更新（大约每 13 小时一次）。
### LEMTRADA REMS Mobile - HCF Dashboard - Patient List, Alert On

#### Patient List

<table>
<thead>
<tr>
<th>Patient Name</th>
<th>Prescriber Name</th>
<th>Prescriber ID</th>
<th>REMS Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>John Doe</td>
<td>Smith</td>
<td>1234567890</td>
<td>Authorized</td>
</tr>
<tr>
<td>John Doe</td>
<td>Smith</td>
<td>1234567890</td>
<td>Authorized</td>
</tr>
<tr>
<td>John Doe</td>
<td>Smith</td>
<td>1234567890</td>
<td>Authorized</td>
</tr>
<tr>
<td>Adam Brown</td>
<td>Smith</td>
<td>1234567890</td>
<td>Authorized</td>
</tr>
<tr>
<td>John Doe</td>
<td>Smith</td>
<td>1234567890</td>
<td>Authorized</td>
</tr>
<tr>
<td>Adam Brown</td>
<td>Smith</td>
<td>1234567890</td>
<td>Authorized</td>
</tr>
</tbody>
</table>

#### 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 1-855-429-6329, Mon – Fri, 8:30 am – 8:00 pm ET.

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US MS LEM - 04.16.005-a1 Last Updated 04.19

Reference ID: 4512344
LETRADA REMS Mobile - HCF Dashboard - Patient List, Alert On, Re-enrollment Message

Your Re-enrollment is Due in Less Than a Month

- Re-enroll Now
- Return to Dashboard

If you have questions about the LEMTRADA REMS or need help enrolling, call 1-888-676-6376. Mon - Fri, 8:30 am - 8:00 pm ET.

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LEMTRADA, MyDay®, MyDate®, MyTime®, MyAlert®, and the L logo are trademarks of Genzyme Corporation or Sanofi and are registered in U.S. Patent and Trademark Office. All rights reserved. LEMTRADA is the only FDA-approved IVI A for multiple sclerosis (MS) in the U.S. View details of its use.

SANOFI GENZYME
LEMTTRADE REMS (Risk Evaluation and Mitigation Strategy)

What is the LEMTRADE 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 LEMTRADE REMS is to inform prescribers, pharmacies, healthcare facilities, and patients about the risks of:

AUTOIMMUNE CONDITIONS
LEMTTRADE causes systemic, sometimes fatal, autoimmune conditions such as immune thrombocytopenia and interstitial lung disease. Monitor complete blood counts with differentials, serum creatinine levels, and urinalysis with urine cell counts at periodic intervals for 6 months after the last dose of LEMTRADE.

INFUSION REACTIONS
LEMTTRADE can cause and life-threatening infusion reactions. LEMTRADE must be administered in a setting with appropriate equipment and personnel to manage anaphylaxis or severe infusion reactions.

STROKE
Serious and life-threatening stroke (including ischemic and hemorrhagic stroke) has been reported within 6 weeks of LEMTRADE administration. Instruct patients to seek immediate medical attention if symptoms of stroke occur.

MALE GONADAL
LEMTTRADE may cause an increased risk of malignancy including thyroid cancer, melanoma, and lymphoproliferative disorders. Perform baseline and yearly skin exams.

Re-enroll in the LEMTRADE REMS
You have been locked out due to incomplete re-enrollment. Please click the link below to re-enroll in the LEMTRADE REMS.

Find a REMS Certified Prescriber or Healthcare Facility
Search for prescribers or healthcare facilities that are certified by the LEMTRADE REMS to prescribe, dispense, or administer LEMTRADE.

Enter ZIP Code
- REMS Certified Prescriber
- REMS Certified Healthcare Facility

LEMTTRADE REMS Requirements
Healthcare facilities must be enrolled in the
You have 10 LEMTRADA patients

<table>
<thead>
<tr>
<th>Name</th>
<th>DOB</th>
<th>Sex</th>
<th>Authorized</th>
</tr>
</thead>
<tbody>
<tr>
<td>John</td>
<td>1/2/95</td>
<td>Male</td>
<td>Authorized</td>
</tr>
<tr>
<td>John</td>
<td>1/2/95</td>
<td>Male</td>
<td>Authorized</td>
</tr>
<tr>
<td>John</td>
<td>1/2/95</td>
<td>Male</td>
<td>Not Authorized</td>
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<tr>
<td>John</td>
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<td>Not Authorized</td>
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<td>John</td>
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<td>John</td>
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<td>Not Authorized</td>
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<td>Not Authorized</td>
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<td>Not Authorized</td>
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<tr>
<td>John</td>
<td>1/2/95</td>
<td>Male</td>
<td>Not Authorized</td>
</tr>
<tr>
<td>John</td>
<td>1/2/95</td>
<td>Male</td>
<td>Not Authorized</td>
</tr>
</tbody>
</table>

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 1-855-407-6324, Mon – Fri, 8:30 am – 8:00 pm ET.
You have 3 patients alerts:

- 2 patients are overdue for the LEMTRADA REMS Patient Status Form.
- 1 patient needs to be authorized by the LEMTRADA REMS Patient Status Form in 1 month.
- 1 patient needs to be verified before their infusion.

Manage your patient alert preferences

Our Patients

Use the list below to search and sort information about patients using your healthcare facility to renew 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

Re-enroll in the LEMTRADA REMS

Healthcare Facilities must renew their enrollment every 2 years and authorized representatives must renew their enrollment every year.

If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6325. Mon - Fri, 8:30 am - 8:00 pm ET.
Verified Patient Information

Patient Name: John Doe
(REMS ID 126684152)

- Date of Birth: 02/02/1982
- 777 Golden Blossom Run
- 10035, IL 60606-5639
- Home Phone: 800-800-0000
- Mobile Phone: 800-800-0000

Infusion Verification Alert

This patient is due for infusion verification. Please complete and submit patient's infusion verification. Your patient must be verified before infusion.

LEMTTRA RESE Infusion Checklist

Insurance
- Provider: BlueCross BlueShield of Kansas City
- Coverage: Complete (Fully)

Infusion Information
- Next Infusion Date: 1/10/12
- Infusion Facility: Facility 01

Prescriber Information
- Physician: Adam Smith, MD
- REMS ID: 0123456789

If you have questions about the LEMTTRA REMS or need help enrolling, call 1-855-275-0225, Mon – Fri, 8:30 am – 8:00 pm ET.

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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).
LEMTA RDA RE MS MOBILE - HCF DASHBOARD - Infusion Verification

LEMTA RDA RE MS INFUSION V E R I F I C AT I O N

Patients cannot be infused until the patient, their prescriber, and the healthcare facility are verified under the LEMTRA RDA REMS. This includes but is not limited to, the date of birth. If this date is incorrect or the date changes, please contact the LEMTRA RDA 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.
- [Verify]
- [Confirm]

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 LEMTRA RDA REMS or need help enrolling, call 1-855-871-8335, Mon - Fri, 8:30 am - 8:00 pm ET.

Please see Terms and Conditions/Contact Us.

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SANOFI GENZYME

Reference ID: 4512344
LETRADA REMS INJUSION VERIFICATION COMPLETE

Please allow 1 business day for the form to be processed. If you have questions about the LEMTRADA REMS, contact the LEMTRADA REMS at 1-855-676-6326, Mon-Fri, 8:30 am - 8:00 pm ET. If this patient is not infused by 10/32/2023, you must verify this patient.

Download and print a copy of the LEMTRADA REMS infusion verification for the patient's medical record.

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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, Inc. One Cambridge Center, Cambridge, MA 02140, USA. Last updated: 2023-10-23.
**LEMTRA REMS INFUSION CHECKLIST**

As a condition of your healthcare facility's authorization to infuse LEMTRA® (alemtuzumab), this Infusion Checklist must be completed for each patient by the last day of each patient's treatment course and submitted within 3 business days. This Infusion Checklist must also be completed and returned even if LEMTRA is not infused. Keep a copy of this checklist in the patient's medical record.

Please complete the form and submit by clicking the button below. All fields are required.

### PATIENT INFORMATION

<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient First Name</td>
<td>John</td>
</tr>
<tr>
<td>Patient Last Name</td>
<td>Doe</td>
</tr>
<tr>
<td>Patient LEMTRA REMS</td>
<td></td>
</tr>
<tr>
<td>Identification Number</td>
<td>1234567890</td>
</tr>
<tr>
<td>DOB (MM/DD/YYYY)</td>
<td>06/10/1965</td>
</tr>
</tbody>
</table>

### PRESCRIBER INFORMATION

<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prescriber First Name</td>
<td>Adam</td>
</tr>
<tr>
<td>Prescriber Last Name</td>
<td>Smith</td>
</tr>
<tr>
<td>Prescriber LEMTRA REMS</td>
<td></td>
</tr>
<tr>
<td>Identification Number</td>
<td>1234567890</td>
</tr>
</tbody>
</table>

### HEALTHCARE FACILITY INFORMATION

<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
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</thead>
<tbody>
<tr>
<td>Healthcare Facility Name</td>
<td></td>
</tr>
<tr>
<td>Facility Name</td>
<td>01</td>
</tr>
<tr>
<td>Healthcare Facility LEMTRA REMS</td>
<td></td>
</tr>
<tr>
<td>Identification Number</td>
<td>0987654321</td>
</tr>
</tbody>
</table>

### Step 1: CONFIRM that the patient is authorized to receive LEMTRA

You must complete the LEMTRA REMS infusion verification online or contact the LEMTRA REMS by phone (1-855-679-8329) prior to initiation of each treatment course.

Is the patient authorized to receive LEMTRA?

- Yes
- No

### Step 2: CONFIRM that the patient has been sponsored and has received What You Need to Know About LEMTRA 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 LEMTRA Treatment and Infusion Reactions: A Patient Guide prior to the first infusion of each treatment course.

Was the patient 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:
   - 1:00 AM - 6:00 AM: Call 911 or contact emergency medical service.
   - 6:00 AM - 6:00 PM: Call 911 or contact emergency medical service.
   - 6:00 PM - 1:00 AM: Call 911 or contact emergency medical service.

Are the appropriate medical measures listed above available?

- Yes
- No

### Step 4: RECORD infusion information

Was patient infused with LEMTRA?

- Yes
- No

### Step 5: RETURN of unused vials of LEMTRA

Unused vials of LEMTRA must be returned within 30 days of administration of the LEMTRA REMS Patient Authorization and Lab Form. Contact the LEMTRA REMS at 1-855-679-8329 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 signature will be used to verify my enrollment in the LEMTRA REMS. By entering my name, NPI number, and password, I confirm my signature of this form.

- Name of staff member completing checklist
- Password

### If you have questions about the LEMTRA REMS or need help enrolling, call 1-855-679-8329, Mon - Fri, 8:30 am – 8:00 pm ET.
LEMTARADA REMS INFUSION CHECKLIST SAVED

Your progress on the LEMTARADA REMS Infusion Checklist has been saved.

If you have questions about the LEMTARADA REMS or need help enrolling, call 1-855-876-6330, Mon - Fri, 8:30 am - 6:00 pm ET.

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LEMTARADA, Mf. Each by GlaxoSmithKline, are registered in U.S. Patent and Trademark Office.

Reference ID: 4512344
LEMRADA REMS INFUSION CHECKLIST

As a condition of your healthcare facility’s authorization to infuse LEMRADA® (cleratuzumab), 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. The Infusion Checklist must also be completed and returned even if LEMRADA 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: John
Patient Last Name: Doe
Patient LEMRADA REMS Identification Number: 123456789
DOB (MM/DD/YYYY): 06/10/1965
Date of Infusion:
Date 1: 10/1/2007
Date 2: 10/2/2007
Date 3: 10/3/2007

PRESCRIBER INFORMATION

Prescriber First Name: Adam
Prescriber Last Name: Smith
Prescriber LEMRADA REMS Identification Number: 123456789

HEALTHCARE FACILITY INFORMATION

Healthcare Facility Name: Facility 01
Healthcare Facility LEMRADA REMS Identification Number: 0987654321

Step 2: CONFIRM that the patient has been counseled and has received what You Need to Know About LEMRADA 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 LEMRADA 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 LEMRADA?

Yes / No

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

LEMRADA Infusions

Date of infusion:
Date 1: 10/1/2007
Date 2: 10/2/2007
Date 3: 10/3/2007

Step 5: RETURN of unused vials of LEMRADA

Unused vials of LEMRADA must be returned within 30 days of submission of the LEMRADA REMS Patient Authorization and Lab Form. Contact the LEMRADA REMS at 1-855-676-6350 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 signature will be used to verify my enrollment in the LEMRADA REMS. By entering my name, NPI number, and password, I confirm my signature of this form.

Name of staff member completing checklist:

Password:

NPI Number:

Verify
Submit
LEMTREDA REMS INFUSION CHECKLIST

As a condition of your healthcare facility’s authorization to infuse LEMTRADA (cladribine), 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. The 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 it 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: 1234567890
- DOB (MM/DD/YYYY): 06/10/1965

**PRESCRIBER INFORMATION**

- Prescriber First Name: Adam
- Prescriber Last Name: Smith
- Prescriber LEMTRADA REMS Identification Number: 1234567890

**HEALTHCARE FACILITY INFORMATION**

- Healthcare Facility Name: Facility 01
- Healthcare Facility LEMTRADA REMS Identification Number: 0987654321

**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 (1-866-676-5222) 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 a**

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 they 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 nervous 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:

**LEMTREDA 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 30 days of submission of the LEMTRADA REMS Patient Authorization and Lab Form. Contact the LEMTRADA REMS at 1-859-676-6226 for additional information.

**Step 6: SIGNATURE**

By providing my e-signature, I affirm 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

If you have questions about the LEMTRADA REMS or need help enrolling, call 1-866-676-6320. Mon – Fri, 8:30 am – 8:00 pm ET.

Reference ID: 4512344
LEMTRADA REMS INFUSION CHECKLIST

Do you wish to submit this form?

Yes  No

If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-876-6326, Mon - Fri, 8:30 am - 8:00 pm ET.

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SANOFI GENZYME

Reference ID: 4512344
John Doe
(REMS ID 129684352)

- Birth Date: 1982
- 7776 Golden Blossom Run
  Zionsville, IN 46079
  Home Phone: xxx-xxxx-xxxx
  Mobile Phone: xxx-xxxx-xxxx

REM Authorization

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: Blue Cross Blue Shield of Illinois
- Coverage: Compliant (Valid)

Infusion Information

- First Course: 5/10/12 - 6/14/12 (Male)
- Infusion Facility: Facility 01

Prescriber Information

- Physician: Alan 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 1-800-272-2839, Mon – Fri, 8:30 am – 8:00 pm ET.

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SANOFI GENZYME

Reference ID: 4512344
LEMTTRA MREMS Mobile - HCF Dashboard - Single Patient Detail, 2nd Infusion Checklist Completed

John Doe
(REMS ID 129684352)

Age at Birth: 58 yr
7776 Golden Blossom Run
Zwolle, LA 71488
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 - 6/17/13 (View)
Infusion Facility: Facility 02

Prescriber Information
Physician: Adam Smith, MD
REMS ID: 0123456789

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If you have questions about the LEMTTRA REMS or need help enrolling, call 1-800-8279-0225, Mon – Fri, 8:30 am – 8:00 pm ET.
You have 5 patient alerts!

You have 13 LEMTRADEX prescribers associated with your patients.

<table>
<thead>
<tr>
<th>Prescriber (REMS ID)</th>
<th>REMS Status</th>
<th>Patient Alerts</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acorn Smith (123456789)</td>
<td>Certified</td>
<td></td>
</tr>
<tr>
<td>Acorn Smith (123456789)</td>
<td>Certified</td>
<td></td>
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<tr>
<td>Acorn Smith (123456789)</td>
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<tr>
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If you have questions about the LEMTRADEX REMS or need help enrolling, call 1-833-876-8334, Mon - Fri, 8:30 am - 8:00 pm ET.

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SANOFI GENZYME
Patients Seeing This Prescriber

You have 10 LEMTRADA patients associated with this prescriber.

<table>
<thead>
<tr>
<th>Patient Name</th>
<th>REMS Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>John Doe</td>
<td>Authorized</td>
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<tr>
<td>John Doe</td>
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<td>Not Authorized</td>
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If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-879-8554, Mon – Fri, 8:30 am – 8:00 pm ET.

Reference ID: 4512344
**Patients Seeing This Prescriber**

You have 1 patient alert!

You have 10 LEMTRADA patients associated with this prescriber.

<table>
<thead>
<tr>
<th>Patient Name</th>
<th>REMS Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>John Doe</td>
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<tr>
<td>John Doe</td>
<td>Authorized</td>
</tr>
</tbody>
</table>

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If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-679-8326.

Mon – Fri, 8:30 am – 8:00 pm ET.
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

Certified Users | Last Logon
--- | ---
Robert Clark | 16/10/2014
Robert Clark | 16/10/2014
Robert Clark | 16/10/2014
Robert Clark | 16/10/2014
Robert Clark | 16/10/2014
Robert Clark | 16/10/2014

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If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-670-6376. Mon - Fri, 8:30 am - 8:00 pm ET.
As a Facility Manager, you have access to LEMTRADA REMS certified facility staff profiles. This portal will help you manage patient information and add users to the 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.

You have 6 certified users.

You must have completed LEMTRADA REMS training. Click on a name to update user information or remove users who no longer have access to your facility’s account.

Robert Clark 16/14/2014 Edit Delete
Robert Clark 16/14/2014 Edit Delete
Robert Clark 16/14/2014 Edit Delete
Robert Clark 16/14/2014 Edit Delete
Robert Clark 16/14/2014 Edit Delete
Robert Clark 16/14/2014 Edit Delete

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-RD5-8376. Mon - Fri, 8:30 am - 8:00 pm ET.
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.

Save

If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6376, Mon – Fri, 8:30 am – 8:30 pm ET.
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
Middle Name
Email
Confirm Email

User has received the required LEMTRADA REMS training.
User has been trained.
Cancel Save

If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-876-6370, Mon - Fri, 8:30 am - 8:00 pm ET.
Are You Sure You Want to Delete User?

Cancel Delete

If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-5526.
Mon – Fri, 8:30 am – 8:00 pm ET.

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On MT 12M N 16-00000 V1 Last Updated 09/15

SANOFIGENZYME
User Successfully Deleted

If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6320.
Mon - Fri, 8:30 am - 8:00 pm ET.
My Profile

Robert Clark
(REMS ID 01/13/14)  
3776 Golden Point Rd  
2950, 0, 29300-2020  
Office Phone: xxx-xxx-xxxx  
Fax: xxx-xxx-xxxx

If any of your information is incorrect or has recently changed, please call 1-855-976-9336, 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 alerts/sanctions?

- 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 2 out of the following: A number, an uppercase letter, a lowercase letter, a special character (e.g., @, #, $, etc.)

Current Password

New Password

Confirm Password

Change Password

If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-976-9336, Mon – Fri, 8:30 am – 8:00 pm ET.
My Profile

Robert Clark

VD REMS 9/17/2016

277 Dulin Bldg.

209-932-2222

Fax 209-932-2222

If any of your information is incorrect or has recently changed, please call 1-866-676-8325.

Manage My Alert Preferences

Customize how often you would like to receive email alerts about the status of your LEMTRADA patient. 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 summary of alerts

Please provide a weekly summary of alerts

Please do not provide a summary of alerts

Change Your Password

Passwords must be at least 8 characters in length and must contain a minimum of 2 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 healthcare professionals 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 1-866-676-8325.

Mon – Fri, 8:30 am - 8:00 pm ET.

Reference ID: 4512344
My Profile

Robert Clark

If any of your information is incorrect or has recently changed, please call 1-855-716-3334, 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 samplers?

- 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. !, #, $, %, 

Current Password

New Password

Confirm Password

If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-716-3334, Mon – Fri, 8:30 am – 8:00 pm ET.
Forms

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
- LEMTRADA REMS Education Program for Healthcare Facilities
- LEMTRADA REMS Healthcare Facility Enrollment Form

PDF
- LEMTRADA REMS Infusion Checklist

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 1-855-876-6328, Mon – Fri, 8:30 am – 8:00 pm ET.
**LEMTTRADE REMS INFUSION CHECKLIST**

As a condition of your healthcare facility’s authorization to infuse LEMTRADA® (clinalumab-gibr), 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

<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient First Name</td>
<td>John</td>
</tr>
<tr>
<td>Patient Last Name</td>
<td>Doe</td>
</tr>
<tr>
<td>LEMTRADA REMS Identification Number</td>
<td>1236698909</td>
</tr>
<tr>
<td>DOB (MM/DD/YYYY)</td>
<td>06/10/1985</td>
</tr>
</tbody>
</table>

### PRESCRIBER INFORMATION

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<tr>
<td>Prescriber First Name</td>
<td>Adam</td>
</tr>
<tr>
<td>Prescriber Last Name</td>
<td>Smith</td>
</tr>
<tr>
<td>LEMTRADA REMS Identification Number</td>
<td>1236698909</td>
</tr>
</tbody>
</table>

### HEALTHCARE FACILITY INFORMATION

<table>
<thead>
<tr>
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<tr>
<td>Healthcare Facility Name</td>
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</tr>
<tr>
<td>LEMTRADA REMS Identification Number</td>
<td>099709978</td>
</tr>
</tbody>
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---

**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 1-855-676-6333 prior to initiation of each treatment course.

Is the patient authorized to receive LEMTRADA?

- [ ] Yes
- [x] No

---

**Step 2: STOP — DO NOT INFUSE.**

Refer patient back to the LEMTRADA prescriber.

---

**Step 3: CONFIRM that this patient has been counseled and has reviewed the**

*You Need to Know About LEMTRADA Prevention and Infusion Reaction: A Patient Guide.*
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 this 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

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.

PHARMACIST INFORMATION

Prescriber First Name

Please enter prescriber’s first name.

Prescriber Last Name

Please enter prescriber’s last name.

Prescription 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 (1-855-076-6326) 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 the patient has been counseled and has received the patient guide

The patient must be counseled about the risk for infusion reactions and provided with the 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 concluded

Step 3: CONFIRM appropriate medical measures available for infusion

Appropriate medical support measures are available.

STEP: To monitor the patient’s vital signs before, during, and after 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

STOP – Proceed to Step 5.

Step 5: RETURN of unused vials of LEMTRADA

Unused vials of LEMTRADA must be returned within 30 days of submission of the LEMTRADA REMS Patient Authorization and Lab Form. Contact the LEMTRADA REMS at 1-855-076-6326 for additional information.

Step 6: SIGNATURE

By providing my signature, I attest that I have filled out the Infusion Checklist to the best of my knowledge. I understand that my signature will be used to verify my enrollment in the LEMTRADA REMS. By entering my name, NPI number, and password, I confirm my signature on this form.

Name of staff member completing checklist

Please enter name of staff member completing checklist.

Password

Please enter password.

NPI number

Please enter valid NPI number.

Cancel

Reference ID: 4512344
Step 2: CONFIRM that the patient has been counseled and has received the fact sheet: Have You Need to Know About LEMTRADA: Treatment and Injection Reactions: A Patient Guide

The patient must be counseled about the risk for infusion reactions and provided with a fact sheet: Have You Need to Know About LEMTRADA: Treatment and Injection 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 severe 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

Date of infusion:

Date:

Date:

Date:

Step 5: RETURN of unused vials of LEMTRADA

Unused vials of LEMTRADA must be returned within 30 days of submission of the LEMTRADA REMS Patient Authorization and Label Form. Contact the LEMTRADA REMS at 1-855-676-6325 for additional information.

Step 6: SIGNATURE

By providing my signature, I attest that I have filled out the Infusion Checklist to the best of my knowledge. I understand that my signature will be used to verify my enrollment in the LEMTRADA REMS. By entering my name, NPI number, and password, I confirm my signature of this form.

Name of staff member completing checklist

Robert Clark

Password

********

NPI Number

1234567890

Submit
LEMTRADA REMS Infusion Checklist Form - “Yes” Selected, Infusion Dates Added

Step 3: CONFIRM appropriate medical measures available for infusion

Appropriate medical support measures are available:
1. In case of serious infusion reaction.
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: 10/1/2017
- Date: 10/2/2017
- Date: 10/3/2017
- Date: 10/4/2017
- Date: 10/9/2017

Step 5: RETURN of unused vials of LEMTRADA

Unused vials of LEMTRADA must be returned within 30 days of submission of the LEMTRADA REMS Patient Authorization and Lab Form. Contact the LEMTRADA REMS at 1-855-676-6335 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

Reference ID: 4512344
Step 2: CONFIRM that the patient has been counseled and has received all
You Need to Know About LEMTRADA Treatment and Infusion Reaction: 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 Reaction: 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 after 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

Date of infusion:

Please enter valid date (MM/DD/YYYY)

Date:

Date:

Date:

Date:

Step 5: RETURN of unused vials of LEMTRADA

Unused vials of LEMTRADA must be returned within 30 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 signature of this form.

Name of staff member completing checklist:

Robert Clark

Password:

********

NPI Number:

1234567890

If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6326.

Man – Fri, 8:30 am – 8:00 pm ET.

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10909 Genzyme Corporation, Waltham, Massachusetts

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LEMTRADA REMS INFUSION CHECKLIST

Do you wish to submit this form?

Yes  No

If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-876-8325, Mon – Fri, 8:30 am – 8:00 pm ET.
LEMTTRADE 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 LEMTRADE REMS at 1-855-876-6325, Mon - Fri, 8:30 am - 8:00 pm ET.

Download a copy of the LEMTRADE REMS Infusion Checklist for the patient’s medical record.

If you have questions about the LEMTRADE REMS or need help enrolling, call 1-855-876-6325, Mon – Fri, 8:30 am – 8:00 pm ET.
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 1-855-676-5326. 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-eligible 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 1-855-676-5326 if you have questions about the enrollment process or if an enrolled patient’s information is missing or incorrect.

2. How do 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 Infused/Informed” 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 [ACF REMS-characterized representation] needs to change?

If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-5326, Mon – Fri, 8:30 am – 8:00 pm ET.
Frequently Asked Questions

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 add new patients to the LEMTRADA REMS by submitting a completed LEMTRADA Patient Enrolment Form to Genzyme. A PDF of the LEMTRADA Patient Enrolment 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 1-855-676-6329 if you have questions about the enrolment process or if you need patients’ information or missing or incorrect.

2. How can I verify that prescribers are eligible to prescribe LEMTRADA?

"REM S Certified" prescribers are enrolled in the LEMTRADA REMS and eligible to prescribe LEMTRADA. You can verify whether a prescriber is "REM S Certified" by using the "Prescribers" tab on your dashboard.

3. How do I verify that patients are authorized to access LEMTRADA?

Prior to your patients’ treatment course, you will receive notification on your dashboard with instructions to verify that your patient is authorized to receive LEMTRADA. Patients cannot be treated until the patient, their prescriber, and the healthcare facility are verified under the LEMTRADA REMS.

When you receive a notification 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 "Non REM S Authorized"?

If your patient is "Non REM S Authorized" please check the individual’s Pharmacy Profile in the LEMTRADA REMS. The Pharmacy Profile provides information on why a prescriber is not REM S Certified. The Pharmacy Profile is generated when patients are authorized for access to the LEMTRADA REMS. The Pharmacy Profile must be reviewed by the LEMTRADA REMS Prescriber. If the Pharmacy Profile is updated, the patient’s access to LEMTRADA REMS will be updated. If you have questions about a patient, please contact the LEMTRADA REMS at 1-855-676-6329 or the LEMTRADA REMS Specialized at 1-855-676-6330.

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 completed by the patient or a designated person and validates the patient’s infusion history. You can access the checklist by clicking "Start Infusion" on the patient’s profile.

6. What do I do if I receive an alert that a patient has never received LEMTRADA?

If a patient has never received LEMTRADA, please check the individual’s Pharmacy Profile in the LEMTRADA REMS. If the Pharmacy Profile is updated, the patient’s access to LEMTRADA REMS will be updated. If you have questions about a patient, please contact the LEMTRADA REMS at 1-855-676-6329 or the LEMTRADA REMS Specialized at 1-855-676-6330.

7. How do I access my profile?

You can recover your profile from anywhere by clicking on the "My Profile" link 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 1-855-676-6329.
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

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 here.

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 1-800-274-8326, Mon – Fri, 8:30 am – 8:00 pm ET.

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LEMTRADA, MYD-NerLN, Ch-o, Sanofi and Genzyme, registered WJ/2, Patent and Trademark Office. US-REG-LEA-14.10.01a-v9 Last Updated 08/19
LEMTTRADE REMS Requirements

Welcome to the LEMTRADE REMS. Here you can:

- Return and enroll in the LEMTRADE REMS every 2 years
- Manage and track your progress through the LEMTRADE REMS training and score tests
- Download materials to help support implementation of the LEMTRADE REMS

LEMTTRADE REMS Activity

<table>
<thead>
<tr>
<th>Steps</th>
<th>Activity</th>
<th>Progress</th>
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<tbody>
<tr>
<td>1.</td>
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<tr>
<td>2.</td>
<td>Training</td>
<td>Completed</td>
</tr>
<tr>
<td>3.</td>
<td>Identification Successors</td>
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<td>4.</td>
<td>Excellence Program</td>
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</tr>
<tr>
<td>5.</td>
<td>Monthly Follow-up</td>
<td>Completed</td>
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If you have questions about the LEMTRADE REMS or need help enrolling, call 1-855-679-6326. Mon – Fri, 8:30 am – 8:00 pm ET.

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Reference ID: 4512344
LEMTTRADE REMS Requirements
• Healthcare facilities must be enrolled in the LEMTTRADE REMS to be able to dispense/administer LEMTTRADE for patients with relapsing forms of multiple sclerosis (MS). Because of its safety profile, the use of LEMTTRADE should generally be reserved for patients who have had an inadequate response to two or more drugs included for the treatment of MS.

LEMTTRADE 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 LEMTTRADE REMS Training Center
3. Authorized representative must review the LEMTTRADE REMS Education Program for Healthcare Facilities and LEMTTRADE REMS Program Overview through the online module on this site
4. After completing the online module, complete and sign the LEMTTRADE 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 LEMTTRADE REMS requirements.

If you have questions about the LEMTTRADE REMS or need help enrolling, call 1-855-670-6320. Mon – Fri, 8:30 am – 8:00 pm ET.
LEMTTRA REMS Patient Guides

Below are materials that help inform patients about treatment with LEMTTRA.

PDF: What You Need to Know About LEMTTRA. Treatment: A Patient Guide

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

If you have questions about the LEMTTRA REMS or need help enrolling, call 1-855-876-6324, Mon - Fri, 8:30 am - 8:00 pm ET.

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LEMTTRA. MP One St. One Sanofi and Genzyme registered in U.S. Patent and Trademark Office. US NDA: 040,505a v.9 Last Updated 8/5/19
DASHBOARD PAGES FOR HCF USERS WHO ARE NON-MANAGERS
You have 5 patient alerts!

Our Patients

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

<table>
<thead>
<tr>
<th>Patient (REMS ID)</th>
<th>Prescriber (REMS ID)</th>
<th>REMS Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>John</td>
<td>Adam John</td>
<td>Authorized</td>
</tr>
<tr>
<td></td>
<td>(123450789)</td>
<td></td>
</tr>
<tr>
<td>John</td>
<td>Dick Smith</td>
<td>Authorized</td>
</tr>
<tr>
<td></td>
<td>(123450789)</td>
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</tr>
<tr>
<td>John</td>
<td>Adam John</td>
<td>Authorized</td>
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<td>(123450789)</td>
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<tr>
<td></td>
<td>(123450789)</td>
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<tr>
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<td>Adam John</td>
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If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6376. Mon – Fri, 8:30 am – 8:00 pm ET.

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LEMTTRADE REMS (Risk Evaluation and Mitigation Strategy)

What is the LEMTRADE 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 LEMTRADE REMS is to inform prescribers, pharmacies, healthcare facilities, and patients about the risks of:

AUTOIMMUNE CONDITIONS
LEMTTRADE causes or exacerbates autoimmune conditions such as immune thrombocytopenia and interstitial lung disease. Monitor complete blood counts (CBCs) with differential, serum creatinine levels, and urinalyses with urine cell counts at periodic intervals for 6 months after the last dose of LEMTRADE.

INFUSION REACTIONS
LEMTTRADE causes serious and life-threatening infusion reactions. LEMTRADE must be administered in the setting with appropriate equipment and personnel to manage anaphylaxis or serious infusion reactions.

STROKE
Serious and life-threatening stroke (including ischemic and hemorrhagic strokes) has been reported within 5 days of LEMTRADE administration. Instruct patients to seek immediate medical attention if symptoms of stroke occur.

MAJOR NEOPLASMS
LEMTTRADE may cause an increased risk of malignancy including thyroid cancer, melanoma, and lymphoproliferative disorders. Perform baseline and yearly skin exams.

Re-enroll in the LEMTRADE REMS
You have been booted out due to incomplete re-enrollment. Please have the Healthcare facility manager re-enroll in the LEMTRADE 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 LEMTRADE REMS to prescribe, dispense, or administer LEMTRADE.

Enter ZIP Code
- REMS Certified Prescriber
- REMS Certified Healthcare Facility

LEMTTRADE REMS Requirements
Healthcare facilities must be enrolled in the LEMTRADE REMS system.
You have 5 patient alerts!

Our Patients
Prescribers

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
Certified
(1234567890)

Adam Smith
Certified
(1234567890)

Adam Smith
Certified
(1234567890)

Adam Smith
Certified
(1234567890)

Adam Smith
Certified
(1234567890)

Adam Smith
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Adam Smith
Certified
(1234567890)

Adam Smith
Certified
(1234567890)

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If you have questions about the LEMTRADA REMS or need help enrolling, call 1-833-479-8326. Mon – Fri, 8:30 am – 8:00 pm ET.

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SANOFI GENZYME
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
LEMTRADA REMS MOBILE
Pharmacy Pages Only
PHARMACY TRAINING PAGES
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 1-855-676-6329.

Cancel  Next

If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6329, Mon – Fri, 8:30 am – 8:00 pm ET.
Pharmacy Registration

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

*Required

Email Address*

Create a Password*

Password must be at least 8 characters in length and contain a minimum of 2 out of the following: A number, an uppercase letter, a lowercase 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.

Register

If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-076-6320. Mon – Fri, 8:30 am – 8:00 pm ET.
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*

Password must be at least 8 characters in length and contains a maximum of 5 out of the following: a number, an upper-case letter, a lower-case letter, a special character (eg. !, #, $, 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

Reference ID: 4512344
Pharmacy Registration for LEMTRADA REMS Training

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

*Required

Email Address*

Password does not meet strength requirements

Password must be at least 8 characters in length and contain a minimum of 2 out of the following: a number, an upper-case letter, a lower-case letter, a symbol. (e.g. #, $, %, etc.)

Confirm Password*

Name of Pharmacy*

National Provider Identification (NPI) Number*

Pharmacy Address*

Pharmacy phone number.

City*

Select City

Pharmacy representative Title*

Pharmacy representative Phone Number*

Fax Number*

*By checking this box, you indicate you will comply with our terms and conditions. Terms and conditions not selected.

If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-876-6330, Mon – Fri, 8:30 am – 8:00 pm ET.
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 1-833-876-6320, Mon – Fri, 8:30 am – 8:00 pm ET.

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US MS UFM 11.10.014a of Last Updated 06/19

SANOFI GENZYME
LEMTARA REMS Online Training Module

If you choose to complete Module 1 for 10 minutes, you will be automatically logged off the LEMTARA website and lose your training progress.

1. Please review the LEMTARA REMS Training Materials, including the LEMTARA 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.

2. After reviewing the material in the module, you will be asked to review and sign the LEMTARA REMS Pharmacy Enrollment Form to complete your enrollment.

3. All staff at your site will be involved with the dispensing/administration of LEMTARA must be trained on the information in the module and adhere to the requirements of the LEMTARA 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 LEMTARA REMS or need help enrolling, call 1-855-676-6326. Mon – Fri, 8:30 am – 5:00 pm ET.
Are You Sure You Want to Exit?
You will lose your session and will need to begin again.

Yes  No, Continue

If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-871-6326.
Mon – Fri, 8:00 am – 8:00 pm ET.

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Sanofi Genzyme Corporation, 6230 Library Road, Malvern, PA 19355, USA and/or its affiliate(s) or licensor(s).
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

If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6326.
Mon – Fri, 8:00 am – 8:00 pm ET.
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 1-855-876-6320.
Mon – Fri, 8:30 am – 8:50 pm ET.
LEMTTRADE REMS Training
LEMTTRADE REMS Program Overview (2 of 2)
Total Training Screens: 2 of 2

If you have questions about the LEMTRADE REMS or need help enrolling, call 1-855-876-6326.
Mon – Fri, 8:30 am – 8:00 pm ET.

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SANOFI GENZYME
LEMTRADA REMS Training Complete
You have completed your review of the training materials.

Go To Enrollment

If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6320, Mon – Fri, 8:30 am – 8:00 pm ET.

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Sanofi Genzyme

Reference ID: 4512344
LEMTRADA REMS Pharmacy Enrollment Form

LEMTRADA REMS Pharmacy Enrollment Form

I understand that my pharmacy must be certified with the LEMTRADA REMS to dispense LEMTRADA.
I will ensure 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 not prescribe and dispense LEMTRADA.

Reference ID: 4512344
LEMTTRADE REMS Pharmacy Enrollment Form

LEMTTRADE is only available through the LEMTRADE REMS, a restricted distribution program. Only prescribers, pharmacies, healthcare facilities, and patients enrolled in the program are able to prescribe, dispense, administer, and receive LEMTRADE. An authorized representative of the pharmacy must enroll the pharmacy in the LEMTRADE 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: [Field]

NPI Number: [Field]

Pharmacy Address: [Field]

City: [Field]

State: [Field]

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 LEMTRADE REMS training and that I will comply with the requirements of the program.

Full Name: [Field]

NPI Number: [Field]

Password: [Field]

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

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.
Enrollment Is Complete!

You have successfully completed 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.

If you do not receive a confirmation email after the representative’s visit, please contact a LEMTRADA REMS Specialist at 1-888-306-6124.

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.

Download a copy of your LEMTRADA REMS Pharmacy Enrollment Form for your records.

If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6226, Mon – Fri, 8:30 am – 8:00 pm ET.
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:

AUTOMMUNE CONDITIONS
LEMTRADA causes serous, sometimes fatal, autoimmune conditions such as immune thrombocytopenia purpura (ITP) 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 24 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 12 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 (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:

AUTONOMIC CONDITIONS
LEMTTRADE causes serum, sometimes fatal, autonomic conditions such as immune thrombocytopenia and anti-gliomaerelator basement membrane disease. Monitor complete blood counts with differentials, serum creatinine levels, and urea levels at periodic intervals for 48 months after the last dose of LEMTRADA.

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

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

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

Complete Enrollment in the LEMTRADA REMS
You must complete the training materials in order to complete your enrollment in the LEMTRADA REMS.

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

Find

LEMTTRADE REMS Requirements

PHARMACIES
Pharmacies must be enrolled in the

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, Temporary Homepage - Training Invalid

Reference ID: 4512344
LEMENTRA REMS (Risk Evaluation and Mitigation Strategy)

What is the LEMENTRA 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 LEMENTRA REMS is to inform prescribers, pharmacies, healthcare facilities, and patients about the risks of:

- AUTIMMUNE CONDITIONS: LEMENTRA 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 LEMENTRA.

- INFUSION REACTIONS: LEMENTRA causes serious and life-threatening infusion reactions. LEMENTRA must be administered in a setting with appropriate equipment and personnel to manage anaphylactic or serious infusion reactions.

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

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

Complete Enrollment in the LEMENTRA REMS

You have not completed your review and submission of the LEMENTRA 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 LEMENTRA REMS to prescribe, dispense, or administer LEMENTRA.

Enter ZIP Code

- REMS Certified Prescriber
- REMS Certified Healthcare Facility

Find

LEMENTRA REMS Requirements

PHARMACIES
Pharmacies must be enrolled in the
LEMTRADA REMS Mobile - Pharmacy, Temporary Homepage - Enrollment Complete, Menu Dropdown

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 1-855-476-6326. Mon - Fri, 8:30 am - 8:00 pm ET.

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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.

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
PHARMACY DASHBOARD PAGES
Authorized representatives of pharmacies can use this site to coordinate fulfilling the LEMTRADA REMS requirements.

Have you verified all prescription requests?

- Please call 1-800-271-9376, 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

Pharmacists must renew their enrollment every 2 years and authorized representatives must renew their enrollment every year.

If you have questions about the LEMTRADA REMS or need help enrolling, call 1-800-271-9376, Mon – Fri, 8:30 am – 8:00 pm ET.

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ALL USA MS-14.10.2019-122-300004 (L4/19-09) Reference ID: 4512344
Your Re-enrollment is Due in Less Than a Month

Re-enroll Now

Return to Dashboard

If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-0325. Mon – Fri, 8:30 am – 8:00 pm ET.
LEMTTRADEX (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:

AUTOMATIC CONDITIONS
LEMTTRADEX 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
LEMTTRADEX 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 2 days of LEMTRADA administration. Instruct patients to seek immediate medical attention if symptoms of stroke occur.

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

Re-enroll in LEMTRADA REMS

You have been locked out due to incomplete re-enrollment. Please click the link below to re-enroll in the LEMTRADA REMS.

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

LEMTRADA REMS Requirements

PHARMACIES
Pharmacies must be enrolled in the
My Profile

Patricia Washington

1212 Golden Glades Blvd
Zion, IL 60096-3530
Office Phone: 333-333-3333
Fax: 333-333-3333

If any of your information is incorrect or has recently changed, please call 1-333-333-3333, 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 uppercase letter, a lowercase letter, or 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 1-800-676-5226, Mon – Fri, 8:30 am – 8:00 pm ET.

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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.)

Current Password

Please enter password:
New Password

Please enter new password:
Confirm Password

Please confirm new password:

Change Password:

If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6226, Mon – Fri, 8:30 am – 8:00 pm ET.

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

Reference ID: 4512344
My Profile

Patricia Washington

(1-888-769-9372)
Address: 320 Golden Glades Blvd
Salt Lake City, UT 84103
Phone: 800-123-4567
Fax: 123-456-7890

If any of your information is incorrect or has recently changed, please call 1-800-123-4567.

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

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 1-800-123-4567.

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Reference ID: 4512344
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

If you have questions about the LEMTRADA REMS or need help enrolling, call 1-855-676-6236,
Mon – Fri, 8:30 am – 8:00 pm ET.
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 1-856-676-6326, Mon - Fri, 8:30 am - 8:00 pm ET.

1. How can I verify that prescribers are eligible to prescribe LEMTRADA?

Please call the LEMTRADA REMS at 1-856-676-6326 to verify if a prescriber is REMS certified to prescribe LEMTRADA.

2. How can I verify that a healthcare facility is eligible for dispensing administration?

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 1-856-676-6326, Mon - Fri, 8:30 am - 8:00 pm ET.
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.

1. How can I verify that a prescriber is enrolled in REMS?
   Please call the LEMTRADA REMS at 1-855-676-6326 to verify if a prescriber is enrolled in REMS.

2. How can I verify that a healthcare facility is enrolled in REMS?
   Please call the LEMTRADA REMS at 1-855-676-6326 to verify if a healthcare facility is enrolled in REMS.

3. How do I verify that patients are authorized to receive a LEMTRADA injection?
   Please call the LEMTRADA REMS at 1-855-676-6326 to verify if a patient is authorized to receive a LEMTRADA injection.

4. What do I do if the patient/physician or healthcare facility that is associated with 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 do I access my profile?
   You can access your profile from any page by clicking on the Profile icon in the top right corner of the site.

6. How can I update my 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 entering 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 a prescription?
   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.
LEMTTRADEX REMS Mobile - Pharmacy, Support - REMS Certified Prescriber & Healthcare Facility Locator

LEMTTRADEX REMS Mobile - Pharmacy, Support - REMS Certified Prescriber & Healthcare Facility Locator

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

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

New Search:

Street address, city, state, or ZIP Code

LEMTTRADEX REMS Mobile - Pharmacy, Support - REMS Certified Prescriber & Healthcare Facility Locator

Certified Center Name
Address
Phone

Certified Center Name
Address
Phone

Certified Center Name
Address
Phone

Certified Center Name
Address
Phone

Certified Center Name
Address
Phone

Certified Center Name
Address
Phone

Genzyme is providing this search feature to help patients find prescribers and healthcare facilities that have been certified by the LEMTTRADEX 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 10 hours).

If you have questions about the LEMTTRADEX REMS or need help enrolling, call 1-855-B79-REMS, Mon – Fri, 8:30 am – 8:00 pm ET.

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LEMTTRADE REMS
Requirements

Welcome to the LEMTRADE REMS. Here you can:
- Return and track in the LEMTRADE REMS every 2 years
- Manage and/or track your progress through the LEMTRADE REMS training and enrollment
- Download materials to help support the implementation of the LEMTRADE REMS

LEMTTRADE REMS Activity

<table>
<thead>
<tr>
<th>Steps</th>
<th>Activity</th>
<th>Progress</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Account Registration</td>
<td>Completed</td>
</tr>
<tr>
<td>2</td>
<td>Training</td>
<td>Completed</td>
</tr>
<tr>
<td>3</td>
<td>Enrollment Assistance</td>
<td>Completed</td>
</tr>
<tr>
<td>4</td>
<td>CheckHandbookRead</td>
<td>Completed</td>
</tr>
<tr>
<td>5</td>
<td>REMS B Assignment</td>
<td>Completed</td>
</tr>
</tbody>
</table>

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 LEMTRADE REMS or need help enrolling, call 1-866-476-8328, Mon – Fri, 8:30 am – 8:00 pm ET.

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Ref: VV-REG-0833078 0.1
LEMTTRADE REMS Pharmacy Enrollment

Pharmacists must be registered 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

If you have questions about the LEMTRADA REMS or need help enrolling, call 1-800-676-6326, 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

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

LEMTTRADA REMS
This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

NICHOLAS A KOZAUER
10/29/2019 09:02:32 AM