

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

761032Orig1s000

REMS

BLA 761032 SILIQ® (brodalumab)

Human Interleukin-17 Receptor A (IL-17RA) Antagonist

Valeant Pharmaceuticals North America LLC

400 Somerset Corporate Boulevard, Bridgewater, NJ 08807

Phone: (908) 927-1400

RISK EVALUATION AND MITIGATION STRATEGY (REMS)

I. GOALS

The goal of the SILIQ REMS Program is to mitigate the observed risk of suicidal ideation and behavior, including completed suicides, which occurred in subjects treated with SILIQ by:

- Ensuring that prescribers are educated about the risk of suicidal ideation and behavior observed with SILIQ therapy and the need to counsel patients about this risk.
- Ensuring that patients are informed about the risk of suicidal ideation and behavior observed with SILIQ therapy and the need to seek medical attention for manifestations of suicidal thoughts and behavior, new onset or worsening depression, anxiety, or other mood changes.

II. ELEMENTS

A. Elements to Assure Safe Use

1. Healthcare providers who prescribe SILIQ must be certified.

- a. To become certified to prescribe SILIQ, prescribers must:
 - i. Review the Prescribing Information (PI) for SILIQ.
 - ii. Enroll in the SILIQ REMS Program by completing the *SILIQ REMS Program Prescriber Enrollment Form*
- b. As a condition of certification, prescribers must:
 - i. Enroll each patient in the SILIQ REMS Program by performing the following:
 - 1) Prior to providing the first prescription, counsel the patient that suicidal ideation and behavior (SIB), including completed suicides, have occurred in patients treated with SILIQ by informing the patient of the following key safety information:
 - i. Suicidal ideation and behavior (SIB) events and symptoms may occur at any time during treatment with SILIQ.
 - ii. To be aware of symptoms of suicidal ideation and behavior (SIB) events and steps to take if SIB symptoms occur..
 - 2) Complete the *SILIQ REMS Program Patient-Prescriber Agreement Form* for each patient. Submit the completed form to the SILIQ REMS Program and store a copy in the patient's records.
 - 3) Provide the patient with the *SILIQ REMS Program Patient Wallet Card*
 - i. Understand that patients with new or worsening symptoms of depression or suicidality should be referred to a mental health professional, as appropriate.

- ii. Inform SILIQ REMS Program if an enrolled patient has discontinued therapy or is no longer under your care.
- c. Valeant Pharmaceuticals North America LLC (Valeant) must:
- i. Ensure that healthcare providers who prescribe SILIQ are certified, in accordance with the requirements described above.
 - ii. Provide all the following mechanisms for prescribers to complete the certification process for the SILIQ REMS Program: online, by email, and by fax.
 - iii. Ensure that prescribers are notified when they have been certified by the SILIQ REMS Program.
 - iv. Maintain a validated, secure database of prescribers who are certified to prescribe SILIQ in the SILIQ REMS Program.
 - v. Ensure that prescribers meet the REMS requirements and de-certify prescribers who do not maintain compliance with REMS requirements.
 - vi. Ensure that certified prescribers are provided access to the database of certified pharmacies and enrolled patients.
 - vii. Provide the *SILIQ REMS Program Prescriber Enrollment Form*, *SILIQ REMS Program Patient-Prescriber Agreement Form*, *SILIQ REMS Program Patient Wallet Card*, and the Prescribing Information to healthcare providers who (1) attempt to prescribe SILIQ and are not yet certified, or (2) inquire about how to become certified.

The following materials are part of the REMS and are appended:

- *SILIQ REMS Program Prescriber Enrollment Form*
- *SILIQ REMS Program Patient-Prescriber Agreement Form*
- *SILIQ REMS Program Patient Wallet Card*

2. Pharmacies that dispense SILIQ must be certified.

- a. To become certified to dispense SILIQ, pharmacies must:
 - i. Designate an authorized representative to complete the enrollment process by submitting the completed *SILIQ REMS Program Pharmacy Enrollment Form* on behalf of the pharmacy.
 - ii. Ensure that the authorized representative oversees implementation and compliance with the SILIQ REMS Program requirements by the following:
 - 1) Review and complete the *SILIQ REMS Program Pharmacy Enrollment Form*.
 - 2) Ensure all relevant staff involved in the dispensing of SILIQ are informed of the SILIQ REMS Program requirements as described in the *SILIQ REMS Program Pharmacy Enrollment Form*.
 - 3) Put processes and procedures in place to ensure the following requirements are completed prior to dispensing SILIQ:
 - 1. Verify the prescriber is certified and the patient is enrolled in the SILIQ REMS Program by calling the SILIQ REMS Program or by accessing the SILIQ REMS Program Website.
- b. As a condition of certification, the certified pharmacies must:

- i. Recertify in the SILIQ REMS Program if the pharmacy designates a new authorized representative.
 - ii. Dispense SILIQ to patients only after obtaining authorization by calling the SILIQ REMS Program or by accessing the SILIQ REMS Program Website. The authorization confirms the following:
 - 1) The prescriber is certified in the SILIQ REMS Program; and
 - 2) The patient is enrolled in the SILIQ REMS Program
 - iii. Maintain documentation that all processes and procedures are in place and are being followed for the SILIQ REMS Program and provide upon request to Valeant, FDA, or a third party acting on behalf of Valeant or FDA.
 - iv. Comply with audits by Valeant, FDA, or a third party acting on behalf of Valeant or FDA, to ensure that all processes and procedures are in place and are being followed for the SILIQ REMS Program.
- c. Valeant must:
- i. Ensure that pharmacies that dispense SILIQ are specially certified, in accordance with the requirements described above.
 - ii. Provide all the following mechanisms for pharmacies to complete certification for the SILIQ REMS Program: online, by email, and by fax.
 - iii. Ensure that pharmacies are notified when they have been certified by the SILIQ REMS Program.
 - iv. Ensure that certified pharmacies are provided access to the database of certified prescribers and enrolled patients.
 - v. Verify every year that the authorized representative's name and contact information correspond to those of the currently designated authorized representative for the certified pharmacy. If different, the pharmacy must be required to recertify with a new authorized representative.

The following materials are part of the REMS and are appended:

- *SILIQ REMS Program Pharmacy Enrollment Form*
- *SILIQ REMS Program Website* (www.SILIQREMS.com)

3. SILIQ must be dispensed to patients with evidence or other documentation of safe-use conditions.

- a. To become enrolled in the SILIQ REMS Program, a patient must sign a *SILIQ REMS Program Patient-Prescriber Agreement Form* indicating that he/she has:
 - i. Received and has read the *SILIQ REMS Program Patient-Prescriber Agreement Form* with their healthcare provider.
 - ii. Received counseling from the prescriber regarding:
 - 1) the observed risk of suicidal ideation and behavior (SIB)
 - 2) the importance of keeping the *SILIQ REMS Program Patient Wallet Card* with them at all times
 - 3) the need to seek medical attention should they experience emergence or worsening of suicidal ideation and behavior
 - iii. Received the *SILIQ REMS Program Patient Wallet Card*

- b. Valeant must:
 - i. Provide all of the following mechanisms for the certified prescribers to be able to submit the completed *SILIQ REMS Program Patient-Prescriber Agreement Form* to the SILIQ REMS Program: online, by email, and by fax.

The following materials are part of the REMS and are appended:

- *SILIQ REMS Program Patient Wallet Card*
- *SILIQ REMS Program Patient-Prescriber Agreement Form*

B. Implementation System

1. Valeant must ensure that SILIQ is only distributed to certified pharmacies by:
 - a. Ensuring that wholesalers/distributors who distribute SILIQ comply with the program requirements for wholesalers/distributors. The wholesalers/distributor must:
 - i. Put processes and procedures in place to verify, prior to distributing SILIQ, that the pharmacies are certified.
 - ii. Train all relevant staff on the SILIQ REMS Program requirements.
 - iii. Comply with audits by Valeant, FDA, or a third party acting on behalf of Valeant or FDA to ensure that all processes and procedures are in place and are being followed for the SILIQ REMS Program. In addition, wholesalers/distributors must maintain documentation to support that all processes and procedures are in place, being followed, and make the documentation available for audits.
 - iv. Provide distribution data to Valeant to verify compliance with the REMS.
 - b. Ensuring that wholesalers/distributors maintain distribution records of all shipments of SILIQ and provide the data to Valeant.
2. Valeant must monitor distribution data to ensure all the processes and procedures are in place and functioning to support the requirements of the SILIQ REMS Program.
3. Valeant must audit the wholesalers/ distributors within 90 calendar days after the wholesaler/distributor is authorized to ensure that all processes and procedures are in place and functioning to support the requirements of the SILIQ REMS Program.
4. Valeant must maintain a validated, secure database of prescribers and pharmacies that are certified to dispense SILIQ in the SILIQ REMS Program.
5. Valeant must maintain a validated, secure database of patients who are enrolled in the SILIQ REMS Program.
6. Valeant must maintain records of SILIQ certified prescribers, certified pharmacies, and enrolled patients to meet REMS requirements.
7. Valeant must maintain a SILIQ REMS Program Call Center (855-511-6135) and SILIQ REMS Program Website (www.SILIQREMS.com). The REMS Program Website must include the capability to confirm patient authorization status, and the option to print the Prescribing Information, Medication Guide, and SILIQ REMS materials. The SILIQ product website must include a prominent REMS-specific link to the

SILIQ REMS Program Website. The SILIQ REMS Program Website must not link back to the product website(s).

8. Valeant must ensure that the SILIQ REMS Program Website is fully operational, including the capability to complete prescriber and pharmacy certification and patient enrollment online; online confirmation of patient authorization functionality; and the REMS materials listed in or appended to the SILIQ REMS document are available through the SILIQ REMS Program Website and by calling the SILIQ REMS Program Call Center.
9. Valeant must monitor on an ongoing basis the certified pharmacies to ensure the requirements of the SILIQ REMS Program are being met. Valeant must institute corrective action if noncompliance is identified and decertify pharmacies that do not maintain compliance with the REMS requirements.
10. Valeant must maintain an ongoing annual audit plan that involves certified pharmacies.
11. Valeant must audit 20% or one, whichever is greater, of the certified pharmacies within 90 calendar days after the pharmacy places its first order of SILIQ to ensure that all processes and procedures are in place and functioning to support the requirements of the SILIQ REMS Program. The certified pharmacies must be identified in Valeant's ongoing annual audit plan. Valeant must institute corrective action if noncompliance is identified.
12. Valeant must take reasonable steps to improve implementation of and compliance with the requirements in the SILIQ REMS Program based on monitoring and evaluation of the SILIQ REMS Program.

III. Timetable for Submission of Assessments

Valeant must submit REMS assessments to the FDA at 6 months and 12 months and annually thereafter from the date of the initial approval of the REMS (February 15, 2017). 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. Valeant must submit each assessment so that it will be received by the FDA on or before the due date.

Instructions

Please fax this completed form to the **SILIQ Risk Evaluation Mitigation Strategy (REMS) Program at 1-866-227-9451**, submit online at www.SILIQREMS.com, or email it to SILIQ@SILIQREMS.com.

SILIQ (brodalumab) is available only through the SILIQ REMS Program. The SILIQ REMS Program is available to answer questions regarding this program and initiating treatment with SILIQ. Please call 1-855-511-6135 for more information.

Only prescribers, pharmacies, and patients enrolled in the SILIQ REMS Program are able to prescribe, dispense and receive SILIQ.

1. Review the one-time SILIQ REMS Enrollment Information for Prescribers, including the Prescribing Information (PI).
2. Complete and submit this *SILIQ REMS Program Prescriber Enrollment Form* via the program website, email, or the fax number provided.
3. Send your patient's prescription to a pharmacy that is enrolled in the SILIQ REMS Program by utilizing the Pharmacy Certification Look Up function on the SILIQ REMS Program website.

You will receive enrollment confirmation via your preferred method of communication (email or fax) within 2 business days.

SILIQ Prescriber Information (*Required)

First Name*:	Last Name*:	Degree*: <input type="checkbox"/> MD <input type="checkbox"/> DO <input type="checkbox"/> PA <input type="checkbox"/> NP <input type="checkbox"/> Other
National Provider Identification (NPI) Number*:		DEA Number:
Name of Institution or Healthcare Facility*:		Specialty*:
Street Address*:		
City*:	State*:	Zip Code*:
Office Phone Number*:	Office Fax Number*:	Mobile Phone Number:
Email Address:	Preferred Method of Communication*: <input type="checkbox"/> Email <input type="checkbox"/> Fax	

Prescriber Agreement

By completing this form, I attest that:

1. I have read and understand the SILIQ Prescribing Information.
2. I understand that I must comply with the Program requirements in order to prescribe SILIQ.
3. I understand that by signing this *SILIQ REMS Program Prescriber Enrollment Form* (one time only), I will be enrolled in the SILIQ REMS Program and may prescribe SILIQ.
4. I understand that, prior to authorizing the first prescription, I am responsible for counseling each patient that suicidal ideation and behavior (SIB), including completed suicides, have occurred in patients treated with SILIQ. I will inform the patient of the following key safety information:
 - Suicidal ideation and behavior (SIB) events and symptoms may occur at any time during treatment with SILIQ.
 - To be aware of symptoms of suicidal ideation behavior (SIB) events and steps to take if SIB symptoms occur.
5. I understand that I must submit a completed *SILIQ REMS Program Patient-Prescriber Agreement Form* for each patient before I prescribe SILIQ for the first time, and store a copy of the completed form in the patient's record.
6. I will provide each patient with a *SILIQ REMS Program Patient Wallet Card* and instruct each patient to carry this card with them at all times.
7. I understand that patients with new or worsening symptoms of depression or suicidality should be referred to a mental health professional, as appropriate.
8. I will inform the SILIQ REMS Program if an enrolled patient has discontinued therapy or is no longer under my care.
9. I understand Valeant and its agents may contact me via phone, mail, fax, email, or in person to support administration of the SILIQ REMS Program.

Prescriber Signature*:	Date*:
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Instructions for Prescribers

1. Sign this form along with your patient and place it in the patient's chart.
2. Tear off the bottom portion and provide it to your patient to take home as a reference.
3. Submit this completed form to the SILIQ Risk Evaluation and Mitigation Strategy (REMS) Program online at www.SILIQREMS.com or by fax at 1-866-227-9451.

Patient Acknowledgement (*Required)

By signing this form, I acknowledge that:

- I understand that suicidal thoughts and behavior, including completed suicides, have occurred in patients treated with SILIQ.
- I will call my doctor or the **National Suicide Prevention Lifeline at 1-800-273-8255** if:
 - I feel new or worsening feelings of withdrawal, depression, anxiety, hopelessness, or other mood changes beginning.
 - I am thinking about hurting or killing myself; seeking access to firearms, pills or other means for the purpose of self-harm; or am talking or writing about death and dying.
- I will **call 911** if I feel an **immediate threat of death or self-injury**.
- My doctor has given me a *SILIQ REMS Patient Wallet Card* to carry with me at all times.

Printed First and Last Name*		Date of Birth (Month/Day/Year):*
Phone Number*:	State*:	Zip Code*:
Patient Signature*:		Date*:

Prescriber Acknowledgement

I acknowledge that prior to prescribing SILIQ:

- I have counseled my patient about the importance of seeking medical advice should signs of suicidal ideation or behavior, new onset or worsening depression, anxiety, or other mood changes emerge.
- I have evaluated the risks and benefits of continuing treatment with SILIQ if such events occur.

Printed First and Last Name*:		
Phone Number*	DEA:	NPI*
Prescriber Signature*		Date*:

 <p>SILIQ™ (brodalumab) injection 210 mg/1.5 mL</p>	SILIQ Patient Information
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- I understand that suicidal thoughts and behavior, including completed suicides, have occurred in patients treated with SILIQ.
- I will call my doctor or the **National Suicide Prevention Lifeline at 1-800-273-8255** if:
 - I feel new or worsening feelings of withdrawal, depression, anxiety, hopelessness, or other mood changes beginning.
 - I am thinking about hurting or killing myself; seeking access to firearms, pills or other means for the purpose of self-harm; or am talking or writing about death and dying.
- I will **call 911** if I feel an **immediate threat of death or self-injury**.

For more information about the SILIQ REMS Program please visit
www.SILIQREMS.com

Instructions

To become enrolled, the pharmacy must designate an Authorized Pharmacy Representative to ensure compliance with the SILIQ Risk Evaluation and Mitigation Strategy (REMS) Program.

Please fax this completed form to the SILIQ REMS Program at 1-866-227-9451, submit online at www.SILIQREMS.com, or email it to SILIQ@SILIQREMS.com.

SILIQ (brodalumab) is available only through the SILIQ REMS Program. The SILIQ REMS Program is available to answer questions regarding this program and initiating treatment with SILIQ. Please call 1-855-511-6135 for more information.

Authorized Pharmacy Representative Responsibilities

I am the authorized representative designated by my pharmacy to coordinate the activities of the SILIQ REMS Program. By signing this form, I agree, on behalf of myself and my pharmacy, to comply with the following program requirements:

1. I understand that by signing this form, and upon confirmation from the SILIQ REMS Program, this pharmacy will be enrolled in the SILIQ REMS Program, and will be able to order and dispense SILIQ.
2. This pharmacy will re-enroll in the SILIQ REMS Program if the name and contact information for the Authorized Pharmacy Representative changes.
3. This pharmacy will ensure that all relevant staff involved in the dispensing of SILIQ is trained on the SILIQ REMS Program requirements.
4. This pharmacy will maintain and make available appropriate documentation reflecting that all processes and procedures are in place and being followed.
5. I understand that non-compliance with the requirements of the SILIQ REMS Program will result in decertification of my pharmacy and termination of authorization to dispense SILIQ.
6. I will ensure that, prior to dispensing SILIQ, my pharmacy will verify that the prescriber is certified and the patient is enrolled to receive SILIQ by contacting the SILIQ REMS Program.
7. This pharmacy will comply with audits by Valeant, the US Food and Drug Administration (FDA), or a designated third party acting on behalf of Valeant or FDA to ensure compliance with the SILIQ REMS Program.

Pharmacy Information (*Required)

Pharmacy Name*:		Pharmacy Type*: <input type="checkbox"/> Inpatient <input type="checkbox"/> Outpatient	
Address*:		City*:	State*:
		Zip Code*:	
Pharmacy Identifier* (at least one required):	NPI:	NCPDP:	DEA:

Authorized Pharmacy Representative Information (*Required)

First Name*:	Last Name*:	MI:
Telephone Number*:	Alternate Telephone Number:	Office Fax*:
Email*:	Preferred Method of Communication*: <input type="checkbox"/> Email <input type="checkbox"/> Fax	
Authorized Pharmacy Representative Signature*:		Date*:

By completing and submitting this form and receiving enrollment confirmation, your pharmacy will be certified in the SILIQ REMS Program. You will receive confirmation of your enrollment via your preferred method of communication.

 **SILIQ™**
(brodalumab) injection
210 mg/1.5 mL

SILIQ™ REMS Program
Patient Wallet Card

SILIQ is indicated for the treatment of moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy and have failed to respond or have lost response to other systemic therapies.

WARNING: Suicidal thoughts and behavior, including completed suicides, have occurred in patients treated with SILIQ.

Taking SILIQ has proven effective for the treatment of moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy. However, if you are experiencing sudden feelings of withdrawal, anxiety, depression or hopelessness, call your doctor immediately. Suicide warning signs also include thinking about hurting or killing yourself; seeking access to firearms, pills or other means for the purpose of self-harm; and talking or writing about death and dying when these actions are out of the ordinary.^{1,2}

Reference ID: 4056898

You are not alone. Help is available.

I will call my doctor or the **National Suicide Prevention Lifeline at 1-800-273-8255 (TALK)** if:

- I feel new or worsening feelings of withdrawal, depression, anxiety, hopelessness, or other mood changes beginning.
- I am thinking about hurting or killing myself; seeking access to firearms, pills or other means for the purpose of self-harm; or am talking or writing about death and dying².

I will **call 911** if I feel an **immediate threat of death or self-injury**.

Learn about the signs of suicide at www.suicidelifeline.org.

For more information, visit www.SILIQREMS.com or call 1-855-511-6135.

¹ American Association of Suicidology. Know the Warning Signs of Suicide. <http://www.suicidology.org/resources/warning-signs>.

² American Foundation for Suicide Prevention. Suicide Warning Signs. <http://www.afsp.org/understanding-suicide/suicide-warning-signs>.

SILIQ REMS Program Website Screen Captures

**February 13th, 2017
Version 5.0**

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1. General Pages

1.1 Home Page

[Important Program Updates »](#)



SILIQ™
(brodalumab) injection
210 mg/1.5 mL

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

[Forgot Username?](#) [Forgot Password?](#) [Need an Account?](#)

PrescribersPharmaciesPatients

What is the SILIQ REMS Program?

A Risk Evaluation and Mitigation Strategy (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 goal of the SILIQ REMS Program is to mitigate the observed risk of suicidal ideation and behavior, including completed suicides, which occurred in subjects treated with SILIQ by:

- Ensuring that prescribers are educated about the risk of suicidal ideation and behavior observed with SILIQ therapy and the need to counsel patients about this risk.
- Ensuring that patients are informed about the risk of suicidal ideation and behavior observed with SILIQ therapy and the need to seek medical attention for manifestations of suicidal thoughts and behavior, new onset or worsening depression, anxiety, or other mood changes.

Materials for Prescribers

- [SILIQ REMS Program Prescriber Enrollment Form](#)
- [SILIQ REMS Program Patient-Prescriber Agreement Form](#)
- [SILIQ REMS Program Medication Guide](#)
- [SILIQ REMS Program Prescribing Information](#)

Materials for Pharmacies

- [SILIQ REMS Program Pharmacy Enrollment Form](#)
- [SILIQ REMS Program Pharmacy Education Brochure](#)

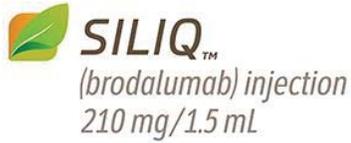
Materials for Patients

- [SILIQ REMS Program Patient-Prescriber Agreement Form](#)
- [SILIQ REMS Program Patient Wallet Card](#)
- [SILIQ REMS Program Medication Guide](#)

Email: Siliq@SILIQREMS.com
Phone: 855-511-6135
Fax: 866-227-9451

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1.2 Prescriber Landing Page



Prescribing Information | Medication Guide

Username Password [Sign in](#)

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[Prescribers](#) [Pharmacies](#) [Patients](#)

Prescriber Certification

Prescribers must be certified in the SILIQ REMS Program to prescribe SILIQ.

To complete prescriber certification:

READ the *SILIQ Prescribing Information*, to understand the risks of SILIQ and to learn about the SILIQ REMS Program

COMPLETE a *SILIQ REMS Program Prescriber Enrollment Form*

To complete enrollment for SILIQ patients:

EDUCATE & COUNSEL all patients about the risks of SILIQ and how to monitor them

SIGN a *SILIQ REMS Program Patient-Prescriber Agreement Form* for each new patient before prescribing SILIQ and submit the completed form to the SILIQ REMS Program and store a copy in the patient's records

[Start Prescriber Certification](#)

Materials for Prescribers

- [SILIQ REMS Program Prescriber Enrollment Form](#)
- [SILIQ REMS Program Patient-Prescriber Agreement Form](#)
- [SILIQ Prescribing Information](#)

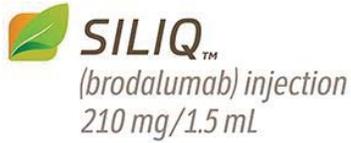
Materials for Patients

- [SILIQ REMS Program Patient-Prescriber Agreement Form](#)
- [SILIQ REMS Program Patient Wallet Card](#)

Email: Siliq@SILIQREMS.com
Phone: 855-511-6135
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1.3 Pharmacy Landing Page



Prescribing Information | Medication Guide

Sign in

[Forgot Username?](#) [Forgot Password?](#) [Need an Account?](#)

Prescribers Pharmacies Patients

Pharmacy Certification

All pharmacies must certify in the SILIQ REMS Program to purchase and dispense SILIQ.

To become certified, pharmacies must designate an authorized representative to complete certification. In general an authorized representative for a pharmacy:

- Coordinates the activities required for the pharmacy in the SILIQ REMS Program
- Establishes and implements processes and procedures to ensure compliance with the safe use conditions of the SILIQ REMS Program

The authorized representative for each pharmacy must complete the following steps to certify in the SILIQ REMS Program:

READ the *SILIQ Prescribing Information* to understand the risks of SILIQ and to learn about the SILIQ REMS Program

CERTIFY by completing and submitting the *SILIQ REMS Program Pharmacy Enrollment Form*

Start Pharmacy Certification

Materials for Pharmacies

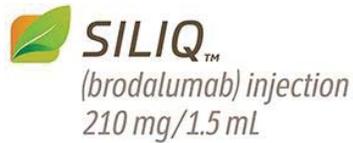
- [SILIQ REMS Program Pharmacy Enrollment Form](#)
- [SILIQ Prescribing Information](#)

Email: Siliq@SILIQREMS.com
Phone: 855-511-6135
Fax: 866-227-9451



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1.4 Patient Landing Page



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

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[Prescribers](#)

[Pharmacies](#)

[Patients](#)

Patient's Role in the SILIQ REMS Program:

Only patients who are enrolled and counseled on the safe use of SILIQ by their prescriber should be prescribed SILIQ. Patients will be counseled on the SILIQ REMS Program by certified prescribers. Patients will have the opportunity to discuss any questions or concerns they have with their prescriber. The prescriber will provide and review the *SILIQ REMS Program Patient-Prescriber Agreement Form*.

Materials for Patients

-  [SILIQ REMS Program Patient-Prescriber Agreement Form](#)
-  [SILIQ REMS Program Patient Wallet Card](#)

Email: Siliq@SILIQREMS.com

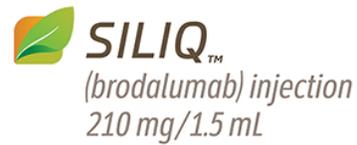
Phone: 855-511-6135

Fax: 866-227-9451

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1.5 Coming Soon Page



Coming Soon!

The SILIQ REMS Program website is currently under construction. Please check back soon for program updates.

What is the SILIQ REMS Program?

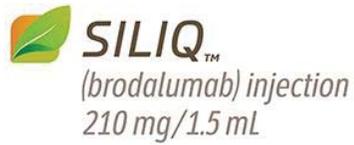
A Risk Evaluation and Mitigation Strategy (REMS) is a strategy to manage known or potential serious risks associated with a drug product, and is required by the FDA to ensure the benefits of a drug outweigh its risks.

The goal of the SILIQ REMS Program is to mitigate the observed risk of suicidal ideation and behavior, including completed suicides, which occurred in subjects treated with SILIQ by:

- Ensuring that prescribers are educated about the risk of suicidal ideation and behavior observed with SILIQ therapy and the need to counsel patients about this risk.
- Ensuring that patients are informed about the risk of suicidal ideation and behavior observed with SILIQ therapy and the need to seek medical attention for manifestations of suicidal thoughts and behavior, new onset or worsening depression, anxiety, or other mood changes.



1.6 Site Map



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[Prescribers](#)

[Pharmacies](#)

[Patients](#)

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[Prescriber Certification](#)

Pharmacy

[Pharmacy Certification](#)

Patient

[Patient Information](#)

General

[Contact Us](#)
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[Terms of Use](#)

Account

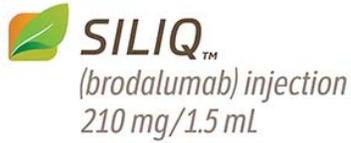
[Forgot Password](#)
[Forgot Username](#)
[Need an Account](#)

Email: Siliq@SILIQREMS.com
Phone: 855-511-6135
Fax: 866-227-9451

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1.7 Account Registration Page



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

[Forgot Username?](#) [Forgot Password?](#) [Need an Account?](#)

[Prescribers](#) [Pharmacies](#) [Patients](#)

Create an Account

To create your web account for the SILIQ REMS Program, please complete the fields below. The Username you specify must be unique within the SILIQ REMS Program website. Once you have submitted this form successfully, you will be logged in on the website. All fields below are required unless otherwise indicated.

First Name

Last Name

Email Address

Confirm Email Address

Phone Number

Username

Use Email Address as Username [Suggest Username](#)

Password

Confirm Password

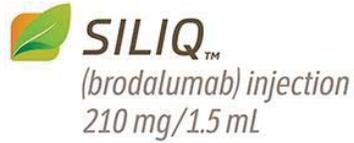
I'm not a robot 

Email: Siliq@SILIQREMS.com
Phone: 855-511-6135
Fax: 866-227-9451

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1.8 Certified Pharmacies



Prescribing Information | Medication Guide

Username Password

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Prescribers Pharmacies Patients

Pharmacy Certification

SILIQ Certified Pharmacy Network

Certified Pharmacies

The SILIQ REMS Certified Pharmacy Network list includes specialty pharmacies that are contracted to fill prescriptions for restricted distribution programs for SILIQ. All pharmacies listed are certified to dispense SILIQ.

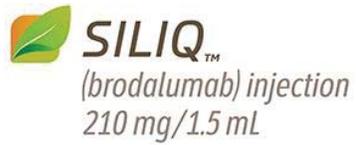
Pharmacy Name	Certification ID	Pharmacy Address	Pharmacy Phone	Pharmacy Fax
Uptown Drugs	FAC399878655	5228 N Roxie Drive DURHAM North Carolina 27704	919-333-7325	555-555-5555

Showing 1 to 2 of 2 entries 1 » 10

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1.9 Forgot Username



Prescribing Information | Medication Guide

Username Password

[Forgot Username?](#) [Forgot Password?](#) [Need an Account?](#)

Prescribers

Pharmacies

Patients

Forgot Username

Please enter your credentials in the spaces provided below. Your username will be sent to the email you registered with the SILIQ REMS Program.

First Name

Last Name

Email Address

Email: Siliq@SILIQREMS.com

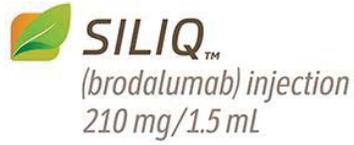
Phone: 855-511-6135

Fax: 866-227-9451

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1.10 Forgot Password



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

<input type="text" value="Username"/>	<input type="text" value="Password"/>	<input type="button" value="Sign in"/>
---------------------------------------	---------------------------------------	--

[Forgot Username?](#) [Forgot Password?](#) [Need an Account?](#)

[Prescribers](#)

[Pharmacies](#)

[Patients](#)

Forgot Password

Please enter your username and email address in the spaces provided below. Your username is the identification you established when creating your web account for the SILIQ REMS Program.

Username

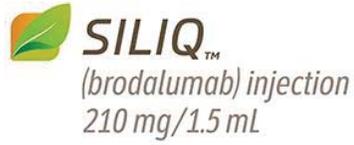
Email Address

Email: Siliq@SILIQREMS.com
Phone: 855-511-6135
Fax: 866-227-9451

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1.11 Contact Us



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Contact Us

If you have any questions or require additional information, please contact the SILIQ REMS Program utilizing the information provided below.

Phone Number

855-511-6135

Fax Number

866-227-9451

Email Address

Siliq@SILIQREMS.com

Mailing Address

SILIQ REMS Program

PO Box XXXX

XXXXX, XX XXXXX

Program Manufacturer

Valeant Pharmaceuticals North America LLC

Email: Siliq@SILIQREMS.com

Phone: 855-511-6135

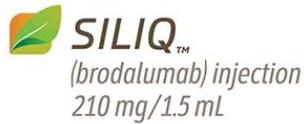
Fax: 866-227-9451

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2. Prescriber Online Certification

2.1 Prescriber Information Page



Prescribing Information | Medication Guide

Username

Prescribers	Pharmacies	Patients
-------------	------------	----------

1 INTAKE 2 ATTESTATION 3 CONFIRMATION

Prescriber Intake

To certify as a prescriber in the SILIQ REMS Program, please complete the required fields below and press **Next**. Once certified, you will receive a certification confirmation via your preferred method of communication. All fields listed below are required unless otherwise indicated.

Prescriber Information

First Name	<input type="text"/>
Last Name	<input type="text"/>
Email Address	<input type="text"/>
Degree	-- Please Select --
Specialty	<input type="text"/>
Name of Institution/Healthcare Facility	<input type="text"/>
Street Address	<input type="text"/>
City	<input type="text"/>
State	-- Please Select --
Zip Code	<input type="text"/>
Office Phone Number	<input type="text"/>
Mobile Phone Number (Optional)	<input type="text"/>
Office Fax Number	<input type="text"/>
Preferred Method of Communication	-- Please Select --

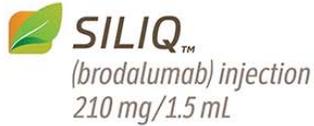
Prescriber Identifiers

NPI Number	<input type="text"/>
DEA Number (optional)	<input type="text"/>

Email: Siliq@SILIQREMS.com
Phone: 855-511-6135
Fax: 866-227-9451

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2.2 Prescriber Attestation Page



Prescribers	Pharmacies	Patients
-------------	------------	----------

1 INTAKE 2 **ATTESTATION** 3 CONFIRMATION

Prescriber Attestation

To complete the prescriber certification for **John Smith** into the SILIQ REMS Program online, please review the attestation section below to provide your acknowledgement along with signature and signature date.

Alternatively, you may print your online enrollment form using the print icon to the right and fax it to the SILIQ REMS Program at 866-227-9451.

As a prescriber, I attest that:

1. I have read and understand the *SILIQ Prescribing Information*.
2. I understand that I must comply with the Program requirements in order to prescribe SILIQ.
3. I understand that by signing this *SILIQ REMS Program Prescriber Enrollment Form* (one time only), I will be enrolled in the SILIQ REMS Program and may prescribe SILIQ.
4. I understand that, prior to authorizing the first prescription, I am responsible for counseling each patient that suicidal ideation and behavior (SIB), including completed suicides, have occurred in patients treated with SILIQ. I will inform the patient of the following key safety information:
 - Suicidal ideation and behavior (SIB) events and symptoms may occur at any time during treatment with SILIQ.
 - To be aware of symptoms of suicidal ideation and behavior (SIB) events and steps to take if SIB symptoms occur.
5. I understand that I must submit a completed *SILIQ REMS Program Patient-Prescriber Agreement Form* for each patient before I prescribe SILIQ for the first time, and store a copy of the completed form in the patient's record.
6. I will provide each patient with a *SILIQ REMS Program Patient Wallet Card* and instruct each patient to carry this card with them at all times.
7. I understand that patients with new or worsening symptoms of depression or suicidality should be referred to a mental health professional, as appropriate.
8. I will inform the SILIQ REMS Program if an enrolled patient has discontinued therapy or is no longer under my care.
9. I understand Valeant and its agents may contact me via phone, mail, fax, email, or in person to support administration of the SILIQ REMS Program.

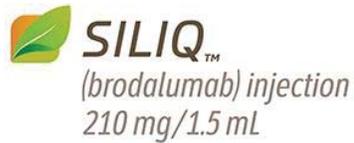
By checking this box, I agree to comply with the SILIQ REMS Program requirements.

Signature Signature Date

Email: Siliq@SILIQREMS.com
Phone: 855-511-6135
Fax: 866-227-9451

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2.3 Prescriber Confirmation Page



Prescribing Information | Medication Guide

Username 

[My Dashboard](#)

Prescribers

Pharmacies

Patients

1 INTAKE

2 ATTESTATION

3 CONFIRMATION

Pharmacy Certification Confirmation

 Your pharmacy is now certified in the SILIQ REMS Program

Below is your SILIQ REMS Program Certification ID. Please retain this information for your records.

Certification ID: **FAC123456789** 

To add additional pharmacies or manage your pharmacies, please use the **My Dashboard** button at the top of the page.

Email: Siliq@SILIQREMS.com

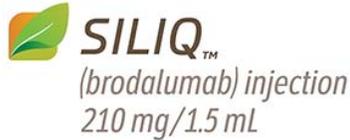
Phone: 855-511-6135

Fax: 866-227-9451

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3. Pharmacy Online Certification

3.1 Authorized Representative Information Page



Prescribers Pharmacies Patients

1 INTAKE 2 CONFIRMATION

Authorized Representative Intake

To begin the process as an authorized representative in the SILIQ REMS Program, please complete the required fields below and press **Next**. All fields listed below are required unless otherwise indicated.

Authorized Pharmacy Representative Information

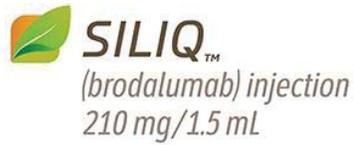
First Name	<input type="text"/>	MI (Optional)	<input type="text"/>
Last Name	<input type="text"/>		
Email Address	<input type="text"/>		
Confirm Email Address	<input type="text"/>		
Telephone Number	<input type="text"/>		
Alternate Telephone Number (Optional)	<input type="text"/>		
Office Fax	<input type="text"/>		
Preferred Method of Communication	<input type="text" value="-- Please Select --"/>		

Email: Siliq@SILIQREMS.com
Phone: 855-511-6135
Fax: 866-227-9451

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3.2 Authorized Representative Confirmation Page



Prescribing Information | Medication Guide

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My Dashboard

Prescribers

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1 INTAKE

2 CONFIRMATION

Authorized Representative Confirmation

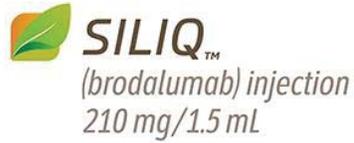
 You are now an authorized representative in the SILIQ REMS Program.

If you are ready to certify your pharmacy now please use [Certify Pharmacy](#). To return to your dashboard for other activities, please use the **My Dashboard** button at the top of the page. If you have completed your session today, simply close your browser.

Email: Siliq@SILIQREMS.com
Phone: 855-511-6135
Fax: 866-227-9451

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3.3 Pharmacy Information Page



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Prescribers Pharmacies Patients

1 INTAKE 2 ATTESTATION 3 CONFIRMATION

Pharmacy Intake

To certify your pharmacy, please complete the required fields below and press **Next**. Once certified, you will receive a certification confirmation via the contact preference you selected during your authorized representative intake. All fields listed below are required unless otherwise indicated.

Pharmacy Information

Pharmacy Name

Pharmacy Type

Address

City

State Zip Code

Pharmacy Identifiers

DEA Number

NPI Number

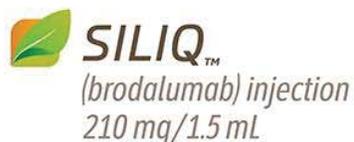
NCPDP Number

Email: Siliq@SILIQREMS.com
Phone: 855-511-6135
Fax: 866-227-9451

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3.4 Pharmacy Attestation Page



Prescribing Information | Medication Guide

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Prescribers

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1 INTAKE

2 ATTESTATION

3 CONFIRMATION

Pharmacy Attestation

To complete the Pharmacy Certification for **ABC Pharmacy** into the SILIQ REMS Program, please review the attestation section below to provide your acknowledgement along with signature and signature date.

Alternatively, you may print this form by clicking on the print icon on the right and fax it to the SILIQ REMS Program at 866-227-9451.

I am the authorized representative designated by my pharmacy to coordinate the activities of the SILIQ REMS Program. By signing this form, I agree, on behalf of myself and my pharmacy, to comply with the following program requirements:

1. I understand that by signing this form, and upon confirmation from the SILIQ REMS Program, this pharmacy will be enrolled in the SILIQ REMS Program, and will be able to order and dispense SILIQ.
2. This pharmacy will re-enroll in the SILIQ REMS Program if the name and contact information for the Authorized Pharmacy Representative(s) changes.
3. This pharmacy will ensure that all relevant staff involved in the dispensing of SILIQ is trained on the SILIQ REMS Program requirements.
4. This pharmacy will maintain and make available appropriate documentation reflecting that all processes and procedures are in place and being followed.
5. I understand that non-compliance with the requirements of the SILIQ REMS Program will result in decertification of my pharmacy and termination of authorization to dispense SILIQ.
6. I will ensure that, prior to dispensing SILIQ, my pharmacy will verify that the prescriber is certified and the patient is enrolled to receive SILIQ by contacting the SILIQ REMS Program.
7. This pharmacy will comply with audits by Valeant, the U.S. Food and Drug Administration (FDA), or a designated third party acting on behalf of Valeant or FDA to ensure compliance with the SILIQ REMS Program.

By checking this box, I agree, on behalf of myself and my pharmacy, to comply with the SILIQ REMS Program requirements.

Signature

Signature Date

[Back](#)

[Submit](#)

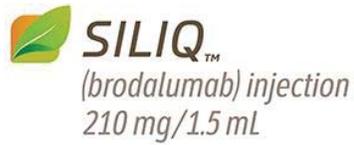
Email: Siliq@SILIQREMS.com

Phone: 855-511-6135

Fax: 866-227-9451

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3.5 Pharmacy Confirmation Page



Prescribing Information | Medication Guide

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Prescribers

Pharmacies

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1 INTAKE

2 ATTESTATION

3 CONFIRMATION

Pharmacy Certification Confirmation

Your pharmacy is now certified in the SILIQ REMS Program

Below is your SILIQ REMS Program Certification ID. Please retain this information for your records.

Certification ID: **FAC123456789**

To add additional pharmacies or manage your pharmacies, please use the **My Dashboard** button at the top of the page.

Email: Siliq@SILIQREMS.com

Phone: 855-511-6135

Fax: 866-227-9451

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4. Patient Online Enrollment

4.1 Patient Information Page



Prescribing Information | Medication Guide

Username My Dashboard

PrescribersPharmaciesPatients

1 PATIENT INTAKE2 ACKNOWLEDGEMENT3 CONFIRMATION

Patient Intake

To enroll your patient into the SILIQ REMS Program, please complete the required fields below and press **Next**. Once the patient enrollment is complete, you will receive an enrollment confirmation via fax.

Patient Information (all fields required)

First Name

Last Name

Date of Birth

Phone Number

State ▼ Zip Code

By signing this form, I acknowledge that:

- I understand that suicidal thoughts and behavior, including completed suicides, have occurred in patients treated with SILIQ.
- I will call my doctor or the **National Suicide Prevention Lifeline at 1-800-273-8255** if:
 - I feel new or worsening feelings of withdrawal, depression, anxiety, hopelessness, or other mood changes beginning.
 - I am thinking about hurting or killing myself, seeking access to firearms, pills or other means for the purpose of self-harm; or am talking or writing about death and dying.
- I will call **911** if I feel an **immediate threat of death or self-injury**.
- My doctor has given me a *SILIQ REMS Program Patient Wallet Card* to carry with me at all times.

Patient Signature

Signature Date

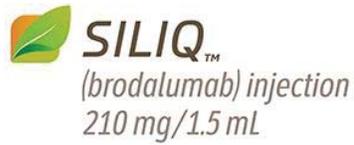
CancelNext

Email: Siliq@SILIQREMS.com
Phone: 855-511-6135
Fax: 866-227-9451

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4.2 Prescriber Acknowledgment Page



Prescribing Information | Medication Guide

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Prescribers

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1 PATIENT INTAKE

2 ACKNOWLEDGEMENT

3 CONFIRMATION

Prescriber Acknowledgement

I acknowledge that prior to prescribing SILIQ:

- I have counseled my patient about the importance of seeking medical advice should signs of suicidal ideation or behavior, new onset or worsening depression, anxiety, or other mood changes emerge.
- I have evaluated the risks and benefits of continuing treatment with SILIQ if such events occur.

Prescriber Signature

Signature Date

[Back](#)

[Submit](#)

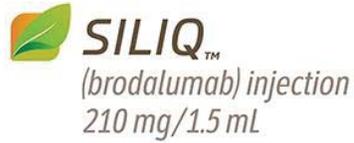
Email: Siliq@SILIQREMS.com

Phone: 855-511-6135

Fax: 866-227-9451

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4.3 Patient Enrollment Confirmation Page



Prescribing Information | Medication Guide

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My Dashboard

Prescribers Pharmacies Patients

1 PATIENT INTAKE 2 ACKNOWLEDGEMENT 3 CONFIRMATION

Patient Enrollment Confirmation

 Your patient is now enrolled in the SILIQ REMS Program.

Please print this information and tear off the bottom portion of the printed *SILIQ REMS Program Patient-Prescriber Agreement Form* and provide it to your patient to take home as a reference. You are responsible to retain this information for your records.

Enrollment ID: **PAT123456789** 

Email: Siliq@SILIQREMS.com
Phone: 855-511-6135
Fax: 866-227-9451


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5. Dashboard

5.1 Prescriber Dashboard



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Prescribers **Pharmacies** **Patients**

Prescriber Dashboard

Please search for your patient in the table below and take the appropriate action. If you need to add a new patient to your list, please use the **Add Patient** button. For taking actions, use the Actions list.

[Add Patient](#) Search 

First Name	Last Name	DOB	Enrollment ID	Enrollment Status	Actions
Joe	Doe	04/16/1967	PAT123456789	Enrolled	Please Select  Go
John	Smith	01/01/1964	PAT143443433	Enrolled	Please Select  Go View Patient Profile Manage Patient Status

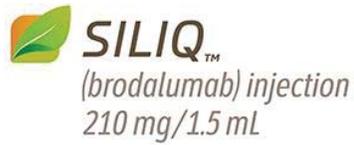
Showing 1 to 2 of 2 entries

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5.2 Manage Patient Status



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Manage Patient Status

Updating the patient status will deactivate the patient from the SILIQ REMS Program. The patient will no longer be eligible to receive SILIQ. The patient will no longer appear on the prescriber dashboard. To continue please select an option below and press **Submit**.

First Name: **John**

Last Name: **Smith**

Date of Birth: **02/02/1954**

Zip Code: **10001**

Update Patient Status:

Cancel

Submit

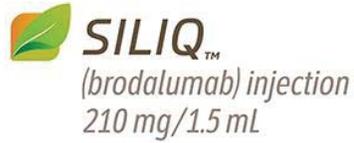
Email: Siliq@SILIQREMS.com

Phone: 855-511-6135

Fax: 866-227-9451

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5.3 View Patient Profile



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Patient Profile

[Edit](#)

Patient Information

First Name	<input type="text" value="John"/>		
Last Name	<input type="text" value="Smith"/>		
Date of Birth	<input type="text" value="05/02/1982"/>		
Phone	<input type="text" value="555-555-0011"/>		
State	<input type="text" value="New York"/>	Zip Code	<input type="text" value="10001"/>

Patient Enrollment Information

Enrollment ID: **PAT123456789** 

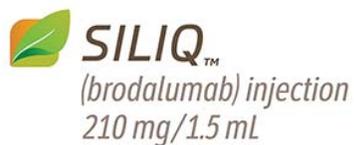
[Cancel](#)

[Save](#)

Email: Siliq@SILIQREMS.com
Phone: 855-511-6135
Fax: 866-227-9451

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5.4 Pharmacy Dashboard



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Prescribers

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Pharmacy Dashboard

Please search for your pharmacy in the table below and take the appropriate action. If you need to add a new pharmacy to your list, please use the **Add Pharmacy** button. For taking actions, use the Actions list.

Add Pharmacy					<input type="text" value="Search"/>	
Pharmacy Name	Address	Pharmacy Type	Certification ID	Status	Actions	
ABC Pharmacy	1234 West Pharmacy Lane Pheonix AZ 85008	Inpatient	FAC1000000000	Certified	<input type="text" value="Please Select"/>	<input type="button" value="Go"/>
XYZ Pharmacy	15 East Prescription Street Phoenix AZ 85008	Outpatient	FAC1000000001	Certified	<input type="text" value="Please Select"/>	<input type="button" value="Go"/>

Showing 1 to 2 of 2 entries 1 » 10

Email: Siliq@SILIQREMS.com

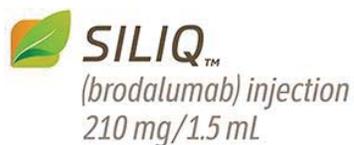
Phone: 855-511-6135

Fax: 866-227-9451

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5.5 Edit Authorized Pharmacy Representative Profile



Prescribing Information | Medication Guide

Username

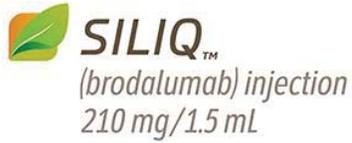
My Dashboard

Prescribers	Pharmacies	Patients																												
<h3>My Profile</h3> <p>Edit</p> <h4>My Information</h4> <table><tr><td>First Name</td><td><input type="text" value="John"/></td><td>MI (Optional)</td><td><input type="text" value="T"/></td></tr><tr><td>Last Name</td><td colspan="3"><input type="text" value="Doe"/></td></tr><tr><td>Email Address</td><td colspan="3"><input type="text" value="johndoe@email.com"/></td></tr><tr><td>Telephone Number</td><td colspan="3"><input type="text" value="555-555-5555"/></td></tr><tr><td>Alternate Telephone Number (Optional)</td><td colspan="3"><input type="text" value="555-555-4444"/></td></tr><tr><td>Office Fax</td><td colspan="3"><input type="text" value="555-555-0000"/></td></tr><tr><td>Preferred Method of Communication</td><td colspan="3"><input type="text" value="Email"/></td></tr></table> <p><input type="button" value="Cancel"/> <input type="button" value="Save"/></p>			First Name	<input type="text" value="John"/>	MI (Optional)	<input type="text" value="T"/>	Last Name	<input type="text" value="Doe"/>			Email Address	<input type="text" value="johndoe@email.com"/>			Telephone Number	<input type="text" value="555-555-5555"/>			Alternate Telephone Number (Optional)	<input type="text" value="555-555-4444"/>			Office Fax	<input type="text" value="555-555-0000"/>			Preferred Method of Communication	<input type="text" value="Email"/>		
First Name	<input type="text" value="John"/>	MI (Optional)	<input type="text" value="T"/>																											
Last Name	<input type="text" value="Doe"/>																													
Email Address	<input type="text" value="johndoe@email.com"/>																													
Telephone Number	<input type="text" value="555-555-5555"/>																													
Alternate Telephone Number (Optional)	<input type="text" value="555-555-4444"/>																													
Office Fax	<input type="text" value="555-555-0000"/>																													
Preferred Method of Communication	<input type="text" value="Email"/>																													

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5.6 View Pharmacy Profile



Prescribing Information | Medication Guide

Username

[My Dashboard](#)

Prescribers

Pharmacies

Patients

Pharmacy Profile

[Edit](#)

Pharmacy Information

Pharmacy Name:

Pharmacy Type:

Address:

City:

State: Zip Code:

Pharmacy Identifiers

DEA Number:

NPI Number:

NCPDP Number:

Pharmacy Certification

Certification ID: **FAC123456789**

[Cancel](#)

[Save](#)

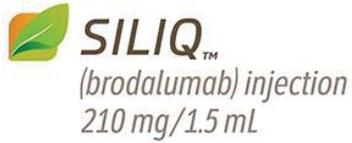
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5.7 Predispense Authorization (PDA) Intake



Prescribing Information | Medication Guide

Username

[My Dashboard](#)

Prescribers

Pharmacies

Patients

Predispense Authorization

To determine if the safe use conditions have been met to receive SILIQ, please complete the Predispense Authorization information below and **Submit**. The results of the Predispense Authorization will be displayed after the information is submitted. All fields listed below are required unless otherwise indicated.

Patient Information

First Name	<input type="text"/>
Last Name	<input type="text"/>
Date of Birth	<input type="text" value="MM/DD/YYYY"/>
Zip Code	<input type="text"/>

Predispense Authorization Request

Date of Service	<input type="text" value="MM/DD/YYYY"/>		
NDC Number	<input type="text" value="-- Please Select --"/>		
Days Supply	<input type="text"/>	Quantity	<input type="text"/>

Prescriber Identifiers (at least one identifier is required)

Prescriber NPI Number	<input type="text"/>
Prescriber DEA Number	<input type="text"/>

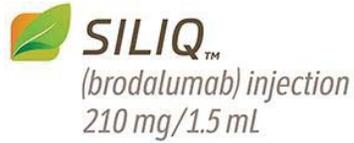
[Cancel](#)

[Submit](#)

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5.8 Predispense Authorization (PDA) Confirmation



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Predispense Authorization Result



This Predispense Authorization Request has been Approved

Authorization Number: **AUTH-1234-5678-9100**

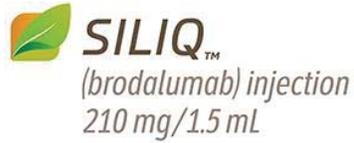
Email: Siliq@SILIQREMS.com

Phone: 855-511-6135

Fax: 866-227-9451

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5.9 Predispense Authorization (PDA) Rejection



Prescribing Information | Medication Guide

Username

My Dashboard

Prescribers

Pharmacies

Patients

Predispense Authorization Result

Do NOT dispense SILIQ.

<Reject Reason>

Please call the SILIQ REMS Program at 855-511-6135 for more information.

Email: Siliq@SILIQREMS.com

Phone: 855-511-6135

Fax: 866-227-9451

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6. Account

6.1 Change Password

The screenshot shows the SILIQ website interface. At the top left is the SILIQ logo with the text "(brodalumab) injection 210 mg/1.5 mL". At the top right, there are links for "Prescribing Information | Medication Guide", a "Username" dropdown menu, and a "My Dashboard" button. Below these is a green navigation bar with "Prescribers", "Pharmacies", and "Patients" tabs. The main content area is titled "Change Password" and contains the instruction "To change your password, please complete fields below." followed by three input fields: "Current Password", "New Password", and "Confirm New Password". At the bottom of the form are "Cancel" and "Save" buttons. The footer contains contact information: "Email: Siliq@SILIQREMS.com", "Phone: 855-511-6135", "Fax: 866-227-9451", and links for "Contact Us", "Privacy Policy", "Terms and Conditions", and "Site Map".

Prescribing Information | Medication Guide

Username  [My Dashboard](#)

[My Profile](#)
[Change Username](#)
[Change Password](#)
[Sign Out](#)

Prescribers Pharmacies Patients

Change Password

To change your password, please complete fields below.

Current Password

New Password

Confirm New Password

[Cancel](#) [Save](#)

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6.2 Change Username



Prescribing Information | Medication Guide

Username  [My Dashboard](#)

- My Profile
- Change Username
- Change Password
- Sign Out

Prescribers Pharmacies Patients

Change Username

To change your username, please provide your new username below. The information you provide for your username must be unique within the SILIQ REMS Program Website.

Username

Use Email Address as Username Suggest Username

[Cancel](#) [Save](#)

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6.3 Edit Prescriber Profile

[Prescribing Information | Medication Guide](#)

[Username](#)

[My Dashboard](#)

- My Profile
- Change Username
- Change Password
- Sign Out

Prescribers Pharmacies Patients

My Profile

[Edit](#)

My Information

First Name	<input type="text" value="John"/>		
Last Name	<input type="text" value="Doe"/>		
Email Address	<input type="text" value="johndoe@email.com"/>		
Degree	<input type="text" value="MD"/>		
Specialty	<input type="text" value="General"/>		
Name of Institution/Healthcare Facility	<input type="text" value="Good Health Clinic"/>		
Street Address	<input type="text" value="1 Main Street"/>		
City	<input type="text" value="New York"/>		
State	<input type="text" value="New York"/>	Zip Code	<input type="text" value="10001"/>
Office Phone Number	<input type="text" value="555-555-5555"/>		
Mobile Phone Number (Optional)	<input type="text" value="555-555-5111"/>		
Office Fax Number	<input type="text" value="555-555-0000"/>		
Preferred Method of Communication	<input type="text" value="Email"/>		

Prescriber Identifiers

DEA Number (Optional)	<input type="text" value="AB23423412"/>
NPI Number	<input type="text" value="23423423423"/>

My Certification

Certification ID: **HCP123546789**

[Cancel](#)

[Save](#)

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Phone: 855-511-6135
Fax: 866-227-9451

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This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

KENDALL A MARCUS
02/15/2017