

Initial REMS approval: 02/2017

Last modified/revised: 12/2019

BLA 761032 SILIQ™ (brodalumab)

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

Bausch Health US, 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:
      - a) Suicidal ideation and behavior (SIB) events and symptoms may occur at any time during treatment with SILIQ.
      - b) 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*.
  - a) Understand that patients with new or worsening symptoms of depression or suicidality should be referred to a mental health professional, as appropriate.
  - b) Inform SILIQ REMS Program if an enrolled patient has discontinued therapy or is no longer under your care.
- c. Bausch Health US, LLC. (Bausch Health) must:
  - i. Ensure that prescribers 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 prescribers 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:

- a) 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 Bausch Health, FDA, or a third party acting on behalf of Bausch Health or FDA.
  - iv. Comply with audits by Bausch Health, FDA, or a third party acting on behalf of Bausch Health or FDA, to ensure that all processes and procedures are in place and are being followed for the SILIQ REMS Program.
- c. Bausch Health 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](http://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 prescriber.
  - 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. Bausch Healthmust:
  - 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. Bausch Healthmust 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 Bausch Health, FDA, or a third party acting on behalf of Bausch Health 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 Bausch Health to verify compliance with the REMS.
  - b. Ensuring that wholesalers/distributors maintain distribution records of all shipments of SILIQ and provide the data to Bausch Health.
2. Bausch Health 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. Bausch Health 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. Bausch Health must maintain a validated, secure database of prescribers and pharmacies that are certified to dispense SILIQ in the SILIQ REMS Program. Bausch Health will make the list of certified prescribers available to patients via the SILIQ REMS Program Website ([www.SILIQREMS.com](http://www.SILIQREMS.com)).
5. Bausch Health must maintain a validated, secure database of patients who are enrolled in the SILIQ REMS Program.
6. Bausch Health must maintain records of SILIQ certified prescribers, certified pharmacies, and enrolled patients to meet REMS requirements.
7. Bausch Health must maintain a SILIQ REMS Program Call Center (855-511-6135) and *SILIQ REMS*

- Program Website* (www.SILIQREMS.com). The *SILIQ 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. Bausch Health 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. Bausch Health must monitor on an ongoing basis the certified pharmacies to ensure the requirements of the SILIQ REMS Program are being met. Bausch Health must institute corrective action if noncompliance is identified and decertify pharmacies that do not maintain compliance with the REMS requirements.
  10. Bausch Health must maintain an ongoing annual audit plan that involves certified pharmacies.
  11. Bausch Health 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 Bausch Health's ongoing annual audit plan. Bausch Health must institute corrective action if noncompliance is identified.
  12. Bausch Health 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**

Bausch Health 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. Bausch Health 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](http://www.SILIQREMS.com), or email it to [SILIQ@SILIQREMS.com](mailto: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 Bausch Health 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](http://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) *:	
Address*:	City*:	State*:	Zip Code*:
Race*: <input type="checkbox"/> African American <input type="checkbox"/> Asian <input type="checkbox"/> Caucasian <input type="checkbox"/> Hispanic <input type="checkbox"/> Other _____		Phone Number*:	
Patient Signature*:		Date*:	

**Prescriber Acknowledgement**

I acknowledge that prior to prescribing SILIQ:

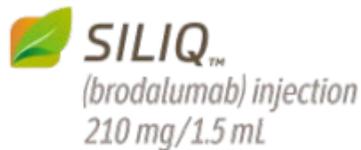
- I have counseled my patient about the importance of seeking medical advice should signs of suicidal ideation or behavior, new onset or worsening depression, anxiety, or other mood changes emerge.
- I have evaluated the risks and benefits of continuing treatment with SILIQ if such events occur.

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

 <p><b>SILIQ™</b> (brodalumab) injection 210 mg/1.5 mL</p>	<b>SILIQ Patient Information</b>
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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](http://www.SILIQREMS.com)**



## 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.**

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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.<sup>1,2</sup>

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## 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 dying<sup>2</sup>.

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](http://www.suicidelifeline.org).**

For more information, visit [www.SILIQREMS.com](http://www.SILIQREMS.com) or call 1-855-511-6135.

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

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

**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](http://www.SILIQREMS.com), or email it to [SILIQ@SILIQREMS.com](mailto: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 Bausch Health, the US Food and Drug Administration (FDA), or a designated third party acting on behalf of Bausch Health 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 REMS Program Website Screen Captures

April 10, 2019  
Version 10.0

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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

[Sign in](#)

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 potential 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.

[Start Prescriber Certification](#)   [Start Pharmacy Certification](#)

Materials for Prescribers

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

Materials for Pharmacies

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

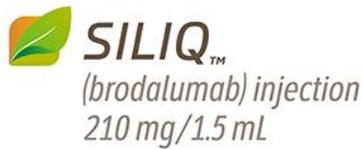
Materials for Patients

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

Email: [SILIQ@SILIQREMS.com](mailto:SILIQ@SILIQREMS.com)  
Phone: 855-511-6135  
Fax: 866-227-9451

[Contact Us](#) | [Privacy Policy](#) | [Terms and Conditions](#) | [Site Map](#)

## 1.2 Prescriber Landing Page



Prescribing Information | Medication Guide

Sign in

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

Prescribers

Pharmacies

Patients

### Prescriber Certification

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

#### To complete prescriber certification:

**READ** the *SILIQ REMS Program 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 REMS Program Patient-Prescriber Agreement Form \(Spanish\)](#)
- [SILIQ Prescribing Information](#)

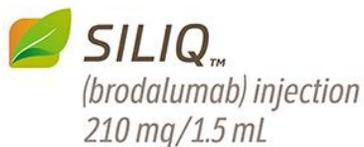
#### Materials for Patients

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

Email: [SILIQ@SILIQREMS.com](mailto:SILIQ@SILIQREMS.com)  
Phone: 855-511-6135  
Fax: 866-227-9451

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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*

Materials for Pharmacies

[SILIQ REMS Program Pharmacy Enrollment Form](#)

[SILIQ Prescribing Information](#)

[Start Pharmacy Certification](#)

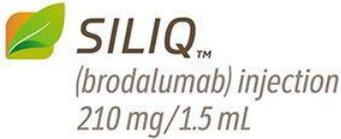
Email: [SILIQ@SILIQREMS.com](mailto:SILIQ@SILIQREMS.com)

Phone: 855-511-6135

Fax: 866-227-9451

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## 1.4 Patient Landing Page



Prescribing Information | Medication Guide

Username  Password  [Sign in](#)

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

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

Email: [SILIQ@SILIQREMS.com](mailto:SILIQ@SILIQREMS.com)  
Phone: 855-511-6135  
Fax: 866-227-9451

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# 1.5 Pharmacy Staff Landing Page



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

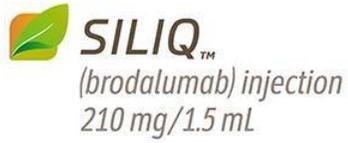
[Forgot Username?](#) [Forgot Password?](#) [Need an Account?](#)

Prescribers	Pharmacies	Patients
<h3>Pharmacy Staff</h3> <p><b>Steps for Pharmacy Staff Enrollment</b></p> <p>Pharmacy staff may include pharmacists or other individuals who assist in dispensing SILIQ. If your pharmacy is certified to dispense SILIQ, pharmacy staff can enroll in the SILIQ REMS Program to have access to the SILIQ REMS Program Website. Pharmacy staff can associate to one or more pharmacy locations.</p> <p>Pharmacy staff must complete the following steps to enroll in the SILIQ REMS Program:</p> <ol style="list-style-type: none"><li>1. <b>Create</b> an online account</li><li>2. <b>Associate</b> to a Pharmacy</li><li>3. <b>Certify</b> by completing and submitting the pharmacy staff member information and attestation</li></ol> <p><a href="#">Start Pharmacy Staff Enrollment</a></p>	<ul style="list-style-type: none"><li>Pharmacy Certification</li><li>Certified Pharmacies</li><li>Pharmacy Staff Enrollment</li></ul>	

Email: [SILIQ@SILIQREMS.com](mailto:SILIQ@SILIQREMS.com)  
Phone: 855-511-6135  
Fax: 866-227-9451

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## 1.6 Site Map



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

[Sign in](#)

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

[Prescribers](#)

[Pharmacies](#)

[Patients](#)

### Site Map

#### Prescriber

[Prescriber Certification](#)

#### Pharmacy

[Pharmacy Certification](#)

#### Patient

[Patient Information](#)

#### General

[Contact Us](#)

[Prescribing Information](#)

[Privacy](#)

[Terms of Use](#)

#### Account

[Forgot Password](#)

[Forgot Username](#)

[Need an Account](#)

Email: [SILIQ@SILIQREMS.com](mailto:SILIQ@SILIQREMS.com)

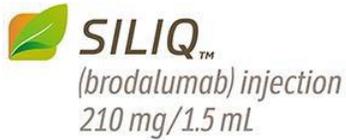
Phone: 855-511-6135

Fax: 866-227-9451

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## 1.7 Prescriber Search Page – with results



Prescribing Information | Medication Guide

Username  Password

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

**Prescribers**      Pharmacies      Patients

### User Search

If you began or completed certification through a fax process, you may already be certified in the SILIQ REMS Program. To determine your certification status, please complete the fields below and press Search. If you are a New User, please click [here](#). All fields listed below are required unless otherwise indicated.

At least one identifier is required

NPI <input type="text"/>		DEA (Optional) <input type="text"/>
or		
First Name <input type="text"/>	Last Name <input type="text"/>	Certification ID (Optional) <input type="text"/>
Phone <input type="text"/>	Fax <input type="text"/>	Email (Optional) <input type="text"/>

If the search results have returned your record, please highlight the row and press **Submit**. If you do not see your record, you can either try your search again or press the **New User** button to begin your certification process in the SILIQ REMS Program.

First Name	Last Name	Phone
John	Doe	555-555-5555

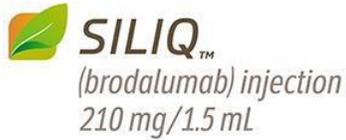
Showing 1 to 1 of 1 entries 1 >> 10 ▾

Email: [SILIQ@SILIQREMS.com](mailto:SILIQ@SILIQREMS.com)  
Phone: 855-511-6135  
Fax: 866-227-9451



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# 1.8 Prescriber Search Page – with no results found



Prescribing Information | Medication Guide

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

**Prescribers**      **Pharmacies**      **Patients**

## User Search

If you began or completed certification through a fax process, you may already be certified in the SILIQ REMS Program. To determine your certification status, please complete the fields below and press Search. If you are a New User, please click [here](#). All fields listed below are required unless otherwise indicated.

At least one identifier is required

NPI <input type="text"/>		DEA (Optional) <input type="text"/>
or		
First Name <input type="text"/>	Last Name <input type="text"/>	Certification ID (Optional) <input type="text"/>
Phone <input type="text"/>	Fax <input type="text"/>	Email (Optional) <input type="text"/>

No results found. Please try your search again or contact the SILIQ REMS Program for assistance. Alternatively, You may also use the **New User** button below to begin your certification process in the SILIQ REMS Program.

First Name	Last Name	Phone
No matching records found		

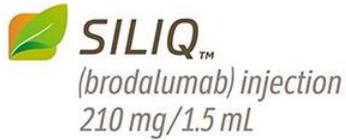
Showing 0 to 0 of 0 entries      1 >> 10 ▾

Email: [SILIQ@SILIQREMS.com](mailto:SILIQ@SILIQREMS.com)  
Phone: 855-511-6135  
Fax: 866-227-9451



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## 1.9 Pharmacy Search Page – with results



Prescribing Information | Medication Guide

Username  Password  [Sign in](#)

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

Prescribers

Pharmacies

Patients

### User Search

If you began or completed certification through a fax process, you may already be certified in the SILIQ REMS Program. To determine your certification status, please complete the fields below and press **Search**. If you are a New User, please click [here](#). All fields listed below are required unless otherwise indicated.

Pharmacy Information (at least one identifier is required):

Zip Code	DEA	NPI Number	NCPDP Number
<input type="text"/>	and <input type="text"/>	or <input type="text"/>	or <input type="text"/>
First Name	Last Name	Certification ID (Optional)	
<input type="text"/>	<input type="text"/>	<input type="text"/>	
Phone	Fax	Email (Optional)	
<input type="text"/>	<input type="text"/>	<input type="text"/>	

[Search](#)

If the search results have returned your record, please highlight the row and press **Submit**. If you do not see your record, you can either try your search again or press the **New User** button to begin your certification process in the SILIQ REMS Program.

First Name	Last Name	Pharmacy Name	Pharmacy Address	Pharmacy Phone	Pharmacy Type
John	Doe	ABC Pharmacy	1 New Street NY 10001	555-555-5555	Outpatient

Showing 1 to 1 of 1 entries

1 >> 10 ▾

[New User](#)

[Submit](#)

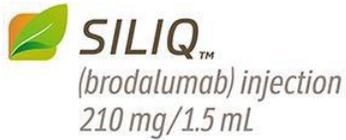
Email: [SILIQ@SILIQREMS.com](mailto:SILIQ@SILIQREMS.com)

Phone: 855-511-6135

Fax: 866-227-9451

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# 1.10 Pharmacy Search Page – with no results found



Prescribing Information | Medication Guide

Username  Password  [Sign in](#)

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

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

## User Search

If you began or completed certification through a fax process, you may already be certified in the SILIQ REMS Program. To determine your certification status, please complete the fields below and press **Search**. If you are a New User, please click [here](#). All fields listed below are required unless otherwise indicated.

Pharmacy Information (at least one identifier is required):

Zip Code	and	DEA	or	NPI Number	or	NCPDP Number
<input type="text"/>		<input type="text"/>		<input type="text"/>		<input type="text"/>
First Name		Last Name		Certification ID (Optional)		
<input type="text"/>		<input type="text"/>		<input type="text"/>		
Phone		Fax		Email (Optional)		
<input type="text"/>		<input type="text"/>		<input type="text"/>		

[Search](#)

No results found. Please try your search again or contact the SILIQ REMS Program for assistance. Alternatively, you may use the **New User** button below to begin your certification process in the SILIQ REMS Program.

First Name	Last Name	Pharmacy Name	Pharmacy Address	Pharmacy Phone	Pharmacy Type
No matching records found					

Showing 0 to 0 of 0 entries      1 >> 10 ▾

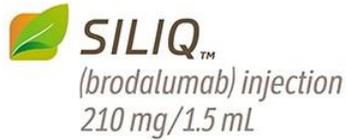
[New User](#)

Email: [SILIQ@SILIQREMS.com](mailto:SILIQ@SILIQREMS.com)  
Phone: 855-511-6135  
Fax: 866-227-9451



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# 1.11 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 you will receive a verification email that includes a link. Please use the link to complete the activation process for your new web account. 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  [Privacy - Terms](#)

Email: [SILIQ@SILIQREMS.com](mailto:SILIQ@SILIQREMS.com)  
Phone: 855-511-6135  
Fax: 866-227-9451

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# 1.12 Certified Pharmacies



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

Username  Password

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

Prescribers      Pharmacies      Patients

## SILIQ Certified Pharmacy Network

The SILIQ REMS Certified Pharmacy Network list includes all pharmacies listed are certified to dispense SILIQ.

- Pharmacy Certification
- Certified Pharmacies
- Pharmacy Staff Enrollment

Prescriptions for restricted distribution programs for 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

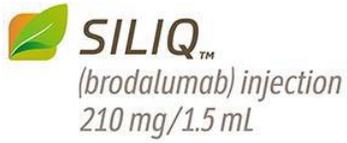
Showing 1 to 2 of 2 entries      1 » 10

Email: [SILIQ@SILIQREMS.com](mailto:SILIQ@SILIQREMS.com)  
Phone: 855-511-6135  
Fax: 866-227-9451



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# 1.13 Forgot Username



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

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

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

## Forgot Username

Please enter your First Name, Last Name and Email Address in the spaces provided below. Your username will be sent to the email you registered with the SILIQ REMS Program.

First Name

Last Name

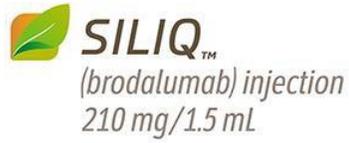
Email Address

Email: [SILIQ@SILIQREMS.com](mailto:SILIQ@SILIQREMS.com)  
Phone: 855-511-6135  
Fax: 866-227-9451



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## 1.14 Forgot Password



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

[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](mailto:SILIQ@SILIQREMS.com)

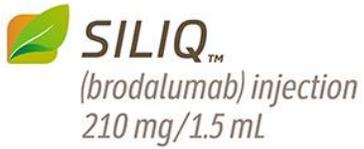
Phone: 855-511-6135

Fax: 866-227-9451

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## 1.15 Contact Us



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

[Sign in](#)

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

[Prescribers](#)

[Pharmacies](#)

[Patients](#)

### 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 52170**

**Phoenix, AZ 85072**

Program Manufacturer

**Bausch Health US, LLC**

Email: [SILIQ@SILIQREMS.com](mailto:SILIQ@SILIQREMS.com)

Phone: 855-511-6135

Fax: 866-227-9451

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## 2. Prescriber Online Certification

### 2.1 Prescriber Information Page

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

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](mailto:SILIQ@SILIQREMS.com)  
Phone: 855-511-6135  
Fax: 866-227-9451

Contact Us | Privacy Policy | Terms and Conditions | Site Map

## 2.2 Prescriber Attestation Page



### 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 Bausch Health 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

[Back](#)

[Submit](#)



## 2.3 Prescriber Confirmation Page



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

[Prescribing Information | Medication Guide](#)

Username ▾ [My Dashboard](#)

**Prescribers**      Pharmacies      Patients

1 INTAKE      2 ATTESTATION      3 CONFIRMATION

### Prescriber Certification Confirmation

 You are now certified in the SILIQ REMS Program.

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

Certification ID: **HCP123456879** 

Email: [SILIQ@SILIQREMS.com](mailto: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

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

Prescribing Information | Medication Guide

Username 

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

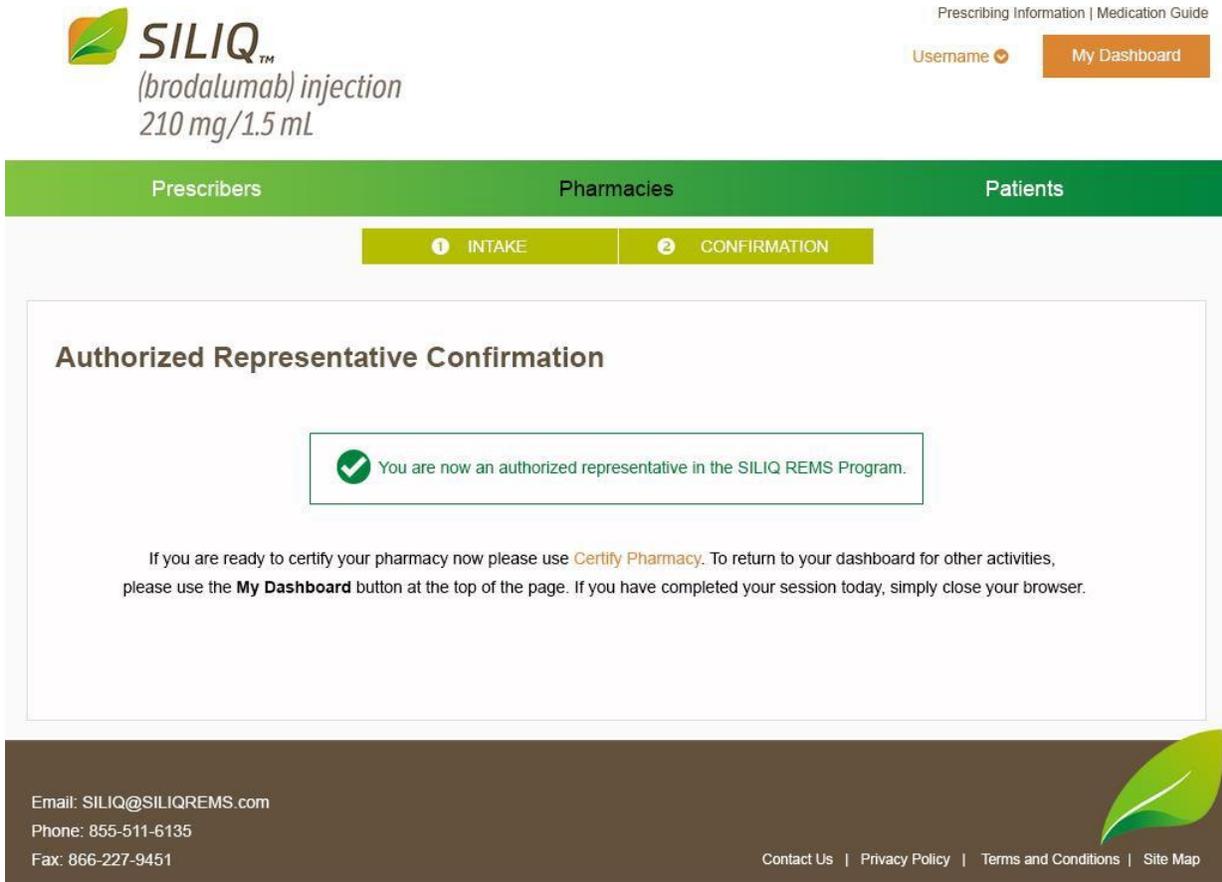
First Name	<input type="text"/>	MI (Optional)	<input type="text"/>
Last Name	<input type="text"/>		
Email Address	<input type="text"/>		
Confirm Email Address	<input type="text"/>		
Telephone Number	<input type="text"/>		
Alternate Telephone Number (Optional)	<input type="text"/>		
Office Fax	<input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

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



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## 3.2 Authorized Representative Confirmation Page



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 are links for "Prescribing Information | Medication Guide", a "Username" dropdown, and a "My Dashboard" button. Below this is a navigation bar with "Prescribers", "Pharmacies", and "Patients" tabs. A progress indicator shows "1 INTAKE" and "2 CONFIRMATION". The main content area is titled "Authorized Representative Confirmation" and features a green checkmark icon with the text "You are now an authorized representative in the SILIQ REMS Program." Below this, instructions state: "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." 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

Prescribers Pharmacies Patients

1 INTAKE 2 CONFIRMATION

### Authorized Representative Confirmation

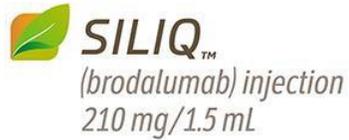
 You are now an authorized representative in the SILIQ REMS Program.

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

Contact Us | Privacy Policy | Terms and Conditions | Site Map

### 3.3 Pharmacy Information Page



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

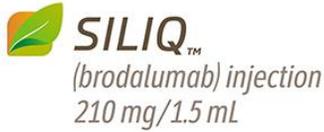
DEA Number:

NPI Number:

NCPDP Number:



## 3.4 Pharmacy Attestation Page



Prescribing Information | Medication Guide

Username

[My Dashboard](#)

Prescribers

Pharmacies

Patients

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 Bausch Health, the U.S. Food and Drug Administration (FDA), or a designated third party acting on behalf of Bausch Health 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](mailto:SILIQ@SILIQREMS.com)  
Phone: 855-511-6135  
Fax: 866-227-9451

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## 3.5 Pharmacy Confirmation Page



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

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[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** 

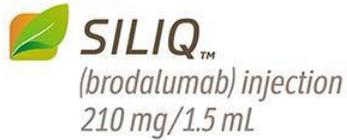
To add additional pharmacies or manage your pharmacies, please use the **My Dashboard** button at the top of the page.

Email: [SILIQ@SILIQREMS.com](mailto:SILIQ@SILIQREMS.com)  
Phone: 855-511-6135  
Fax: 866-227-9451

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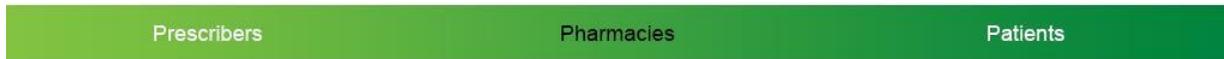


## 3.6 Pharmacy Staff Information Page



Prescribing Information | Medication Guide

Username



### Pharmacy Staff Intake

To enroll as a pharmacy staff member please complete the form below and select the **Next** button. Once enrolled, you will receive an enrollment confirmation via your preferred method of contact. All fields are required unless otherwise indicated.

#### Pharmacy Staff Information

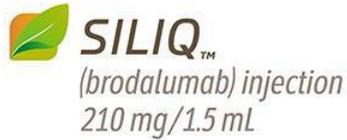
First Name	<input type="text"/>	MI (Optional)	<input type="text"/>
Last Name	<input type="text"/>		
Email Address	<input type="text"/>		
Confirm Email Address	<input type="text"/>		
Telephone Number	<input type="text"/>		
Alternate Telephone Number (Optional)	<input type="text"/>		
Fax	<input type="text"/>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

Email: [SILIQ@SILIQREMS.com](mailto:SILIQ@SILIQREMS.com)  
Phone: 855-511-6135  
Fax: 866-227-9451



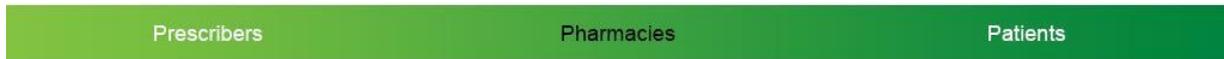
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## 3.7 Pharmacy Staff Attestation Page



Prescribing Information | Medication Guide

Username



### Pharmacy Staff Attestation

To complete pharmacy staff enrollment in the SILIQ REMS Program, please review the attestation section below to provide an acknowledgement along with signature and signature date.

As a pharmacy staff member:

1. I attest that I have been trained and will follow the requirements of the SILIQ REMS Program.
2. I understand I can access the SILIQ REMS Program Website to:
  - Verify the prescriber is certified and the patient is enrolled, prior to the patient receiving SILIQ
  - Edit my profile information
  - Associate my profile to one or more pharmacies
  - Disassociate my profile from one or more pharmacies

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

Signature

Signature Date

[Back](#)

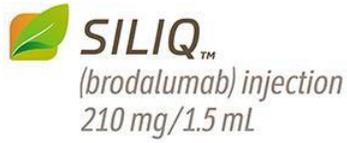
[Submit](#)

Email: [SILIQ@SILIQREMS.com](mailto:SILIQ@SILIQREMS.com)  
Phone: 855-511-6135  
Fax: 866-227-9451



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## 3.8 Pharmacy Staff Confirmation Page



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[Username](#)

[My Dashboard](#)

[Prescribers](#)

[Pharmacies](#)

[Patients](#)

1 INTAKE

2 ATTESTATION

3 CONFIRMATION

### Pharmacy Staff Confirmation



You are now an enrolled pharmacy staff member in the SILIQ REMS Program.

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

Enrollment ID: <Enrollment #>

[Print](#)

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

Email: [SILIQ@SILIQREMS.com](mailto:SILIQ@SILIQREMS.com)

Phone: 855-511-6135

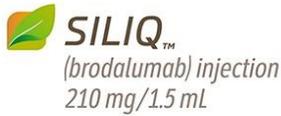
Fax: 866-227-9451

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## 4. Patient Online Enrollment

### 4.1 Patient Acknowledgement Page



Prescribing Information | Medication Guide

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Prescribers Pharmacies Patients

1 PATIENT INTAKE 2 ACKNOWLEDGEMENT 3 CONFIRMATION

#### Patient Acknowledgement

To enroll your patient into the SILIQ REMS Program, please complete the required fields below with the patient 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

Race

Address

City

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-TALK(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

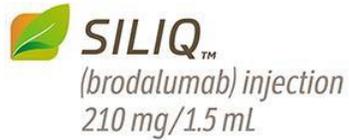
Please enter your name as your electronic signature

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

Username

My Dashboard

Prescribers

Pharmacies

Patients

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

Please enter your name as your electronic signature

Back

Submit

Email: [SILIQ@SILIQREMS.com](mailto:SILIQ@SILIQREMS.com)

Phone: 855-511-6135

Fax: 866-227-9451

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## 4.3 Patient Enrollment Confirmation Page

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

Prescribing Information | Medication Guide

Username

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

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

[Prescribing Information](#) | [Medication Guide](#)  
Username  [My Dashboard](#)

[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](#)



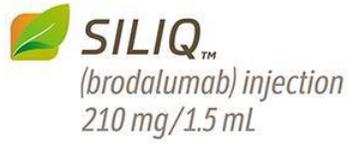
First Name	Last Name	DOB	Enrollment ID	Enrollment Status	Actions
Joe	Doe	04/16/1967	PAT123456789	Enrolled	<div style="border: 1px solid #ccc; padding: 2px;"><span>Please Select</span>  <span>Go</span></div>
John	Smith	01/01/1954	PAT143443433	Enrolled	<div style="border: 1px solid #ccc; padding: 2px;"><span>Please Select</span>  <span>Go</span> <a href="#">View Patient Profile</a> <a href="#">Manage Patient Status</a></div>

Showing 1 to 2 of 2 entries

Email: [SILIQ@SILIQREMS.com](mailto:SILIQ@SILIQREMS.com)  
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Fax: 866-227-9451

  
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## 5.2 Manage Patient Status



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[Username](#)

[My Dashboard](#)

[Prescribers](#)

[Pharmacies](#)

[Patients](#)

### 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](#)

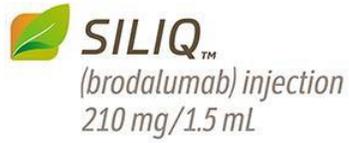
Email: [SILIQ@SILIQREMS.com](mailto:SILIQ@SILIQREMS.com)

Phone: 855-511-6135

Fax: 866-227-9451

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## 5.3 View Patient Profile



Prescribing Information | Medication Guide

Username

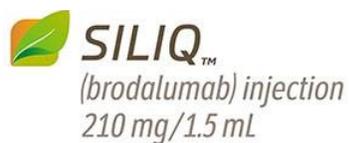
My Dashboard

Prescribers	Pharmacies	Patients												
<h3>Patient Profile</h3> <p style="text-align: right;"><a href="#">Edit</a></p> <h4>Patient Information</h4> <table><tr><td>First Name</td><td><input type="text" value="John"/></td></tr><tr><td>Last Name</td><td><input type="text" value="Smith"/></td></tr><tr><td>Date of Birth</td><td><input type="text" value="05/02/1982"/></td></tr><tr><td>Phone</td><td><input type="text" value="555-555-0011"/></td></tr><tr><td>State</td><td><input type="text" value="New York"/></td><td>Zip Code</td><td><input type="text" value="10001"/></td></tr></table> <h4>Patient Enrollment Information</h4> <p>Enrollment ID: <b>PAT123456789</b> </p> <p style="text-align: center;"><a href="#">Cancel</a> <a href="#">Save</a></p>			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"/>
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"/>											

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Fax: 866-227-9451

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## 5.4 Pharmacy Dashboard



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

Username

[My Dashboard](#)

Prescribers      Pharmacies      Patients

### 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. Actions available are *View Pharmacy Profile* and *Request Predispense Authorization*.

[Add Pharmacy](#)      Search

Pharmacy Name	Address	Pharmacy Type	Certification ID	Status	Actions
ABC Pharmacy	1234 West Pharmacy Lane Pheonix AZ 85008	Inpatient	FAC100000000	Certified	Please Select <input type="button" value="Go"/>
XYZ Pharmacy	15 East Prescription Street Phoenix AZ 85008	Outpatient	FAC100000001	Certified	Please Select <input type="button" value="Go"/>

Showing 1 to 2 of 2 entries 1 » 10

Email: [SILIQ@SILIQREMS.com](mailto:SILIQ@SILIQREMS.com)

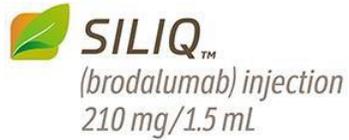
Phone: 855-511-6135

Fax: 866-227-9451



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## 5.5 Edit Authorized Pharmacy Representative Profile



Prescribing Information | Medication Guide

Username

[My Dashboard](#)

Prescribers

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Patients

### My Profile

[Edit](#)

#### My Information

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"/>		

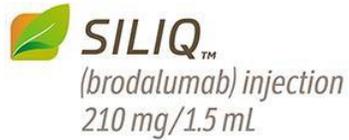
[Cancel](#)

[Save](#)

Email: [SILIQ@SILIQREMS.com](mailto:SILIQ@SILIQREMS.com)  
Phone: 855-511-6135  
Fax: 866-227-9451

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## 5.6 View Pharmacy Profile



Prescribing Information | Medication Guide

Username

My Dashboard

Prescribers

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Patients

### Pharmacy Profile

Edit

#### Pharmacy Information

Pharmacy Name	Pharmacy ABC		
Pharmacy Type	Inpatient Pharmacy		
Address	1 Main Street		
City	New York		
State	New York	Zip Code	10001

#### Pharmacy Identifiers

DEA Number	AB23423412
NPI Number	23423423423
NCPDP Number	123546879

#### Pharmacy Certification

Certification ID: **FAC123456789**

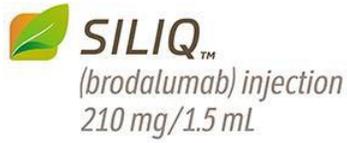
Cancel

Save

Email: [SILIQ@SILIQREMS.com](mailto:SILIQ@SILIQREMS.com)  
Phone: 855-511-6135  
Fax: 866-227-9451

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## 5.7 Pharmacy Staff Dashboard



Prescribing Information | Medication Guide

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Prescribers

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### My Dashboard

The table below contains all of your associated pharmacies. If you need to associate yourself to a new pharmacy, use the **Associate to Pharmacy** button. For taking actions, use the Actions list.

				<a href="#">Associate to Pharmacy</a>	<input type="text" value="Search"/>
Pharmacy Name	Address	Pharmacy Type	Status	Actions	
ABC Pharmacy	1234 West Pharmacy Lane Phoenix AZ 85008	Inpatient	Certified	Please Select	<input type="button" value="Go"/>
XYZ Pharmacy	15 East Prescription Street Phoenix AZ 85008	Inpatient	Certified	Please Select	<input type="button" value="Go"/>

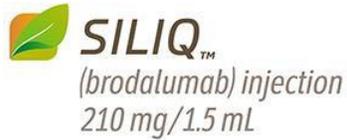
Showing 1 to 2 of 2 entries 1 » 10

Email: [SILIQ@SILIQREMS.com](mailto:SILIQ@SILIQREMS.com)  
Phone: 855-511-6135  
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## 5.8 Pharmacy Staff Associate to Pharmacy



Prescribing Information | Medication Guide

Username

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Patients

### Associate to Pharmacy

To identify your certified pharmacy, please complete the fields below and select **Search**. All fields are required unless otherwise indicated.

Pharmacy Information (at least one identifier is required):

Pharmacy Zip Code		and	Identifiers		
<input type="text"/>			DEA Number	NPI Number	NCPDP Number
			<input type="text"/>	or <input type="text"/>	or <input type="text"/>

[Search](#)

If the search results have returned your record, please highlight the row and select the **Submit** button. If you do not see your record, please try your search again or contact the SILIQ REMS Program for assistance.

Pharmacy Name	Pharmacy Address	Pharmacy Phone
ABC Pharmacy	5228 N Roxie Drive DURHAM North Carolina 27704	919-333-7325

Showing 1 to 2 of 2 entries 1 > 10 ▾

[Cancel](#)

[Submit](#)

Email: [SILIQ@SILIQREMS.com](mailto:SILIQ@SILIQREMS.com)  
Phone: 855-511-6135  
Fax: 866-227-9451

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## 5.9 Pharmacy Staff Disassociate from Pharmacy

The screenshot shows the SILIQ (brodalumab) injection website interface. At the top left is the SILIQ logo and product name. At the top right, there are links for 'Prescribing Information | Medication Guide', a 'Username' dropdown, and a 'My Dashboard' button. Below the header is a navigation bar with 'Prescribers', 'Pharmacies', and 'Patients' tabs. The 'Pharmacies' tab is active, displaying a 'My Dashboard' section with a table of pharmacies. A modal dialog box titled 'Disassociate from Pharmacy' is overlaid on the table, containing the text: 'Please select the **Confirm** button to remove this pharmacy from the list of pharmacies on your dashboard.' The dialog has 'Cancel' and 'Confirm' buttons. The background table lists two pharmacies: ABC Pharmacy and XYZ Pharmacy, with columns for Pharmacy Name, Address, Inpatient/Outpatient status, and Certification status. To the right of the table is an 'Associate to Pharmacy' section with a search bar and a dropdown menu.

Prescribing Information | Medication Guide

Username My Dashboard

SILIQ™  
(brodalumab) injection  
210 mg/1.5 mL

Prescribers Pharmacies Patients

My Dashboard

The table below contains all of the pharmacies associated with your dashboard. For taking actions, use the buttons in the table.

Disassociate from Pharmacy

Please select the **Confirm** button to remove this pharmacy from the list of pharmacies on your dashboard.

Cancel Confirm

Pharmacy Name	Address	Inpatient/Outpatient	Certification
ABC Pharmacy	1234 West Pharmacy Lane Phoenix AZ 85008	Inpatient	Certified
XYZ Pharmacy	15 East Prescription Street Phoenix AZ 85008	Inpatient	Certified

Showing 1 to 2 of 2 entries

Associate to Pharmacy

Search

Actions

Please Select Go

Please Select Go

1 » 10

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

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## 5.10 Pharmacy Staff Edit Profile



Prescribing Information | Medication Guide

Username 

[My Dashboard](#)

- Change Username
- Change Password
- Edit Profile
- Sign Out

Prescribers Pharmacies Patients

### My Profile [Edit](#)

#### My Information

First Name	<input type="text" value="John"/>	MI (Optional)	<input type="text"/>
Last Name	<input type="text" value="Doe"/>		
Email Address	<input type="text" value="jDoe@gmail.com"/>		
Telephone Number	<input type="text" value="555-555-5555"/>		
Alternate Telephone Number (Optional)	<input type="text"/>		
Fax	<input type="text" value="555-555-3434"/>		
Preferred Method of Communication	<input type="text" value="Fax"/>		

#### My Enrollment

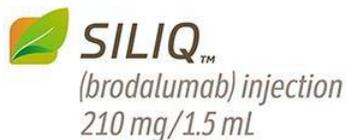
Enrollment ID: [<Enrollment ID>](#)

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

Email: [SILIQ@SILIQREMS.com](mailto:SILIQ@SILIQREMS.com)  
Phone: 855-511-6135  
Fax: 866-227-9451

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## 5.11 Predispense Authorization (PDA) Intake



Prescribing Information | Medication Guide

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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"/>	Number of Packs	<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

Email: [SILIQ@SILIQREMS.com](mailto:SILIQ@SILIQREMS.com)

Phone: 855-511-6135

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## 5.12 Predispense Authorization (PDA) Confirmation



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

Prescribing Information | Medication Guide

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Prescribers Pharmacies Patients

### Predispense Authorization Result

 This Predispense Authorization Request has been Approved

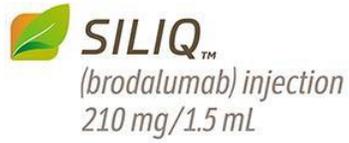
Authorization Number: **AUTH-1234-5678-9100** 

Patient Enrollment ID: <XXXXXXXXXX>  
Prescriber Certification ID: <XXXXXXXXXX>  
Pharmacy Certification ID: <XXXXXXXXXX>

Email: [SILIQ@SILIQREMS.com](mailto:SILIQ@SILIQREMS.com)  
Phone: 855-511-6135  
Fax: 866-227-9451

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## 5.13 Predispense Authorization (PDA) Rejection



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[Username](#) 

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[Patients](#)

### Predispense Authorization Result

 **Do NOT dispense SILIQ.**

<Reject Reason>

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

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Phone: 855-511-6135

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## 6. Account

### 6.1 Change Password

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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](#)

Email: [SILIQ@SILIQREMS.com](mailto:SILIQ@SILIQREMS.com)  
Phone: 855-511-6135  
Fax: 866-227-9451

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## 6.2 Change Username

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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](#)

Email: [SILIQ@SILIQREMS.com](mailto:SILIQ@SILIQREMS.com)  
Phone: 855-511-6135  
Fax: 866-227-9451

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## 6.3 Edit Prescriber Profile



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Username ▼ [My Dashboard](#)

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

Prescribers Pharmacies Patients

### My Profile Edit

#### My Information

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

#### Prescriber Identifiers

DEA Number (Optional)	AB23423412		
NPI Number	23423423423		

#### My Certification

Certification ID: **HCP123546789** 

Cancel Save

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

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