

# Risk Evaluation and Mitigation Strategy (REMS) Document

## SILIQ® (brodalumab) REMS Program

### I. Administrative Information

Application Number: BLA 761032  
Application Holder: Bausch Health US, LLC  
Initial REMS Approval: 02/2017  
Most Recent REMS Update: 01/2021

### II. REMS Goal

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:

1. 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.
2. 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.

### III. REMS Requirements

**Bausch Health US, LLC must ensure that healthcare providers, patients, pharmacies, and wholesalers-distributors comply with the following requirements:**

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#### 1. Healthcare providers who prescribe SILIQ must:

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To become certified to prescribe

1. Review the drug's Prescribing Information.
  2. Enroll in the REMS by completing the [Prescriber Enrollment Form](#) and submitting it to the REMS Program.
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Before treatment initiation (first dose)

3. Counsel the patient on the risk of suicidal ideation and behavior including that completed suicides have occurred with patients treated with SILIQ, symptoms may occur at any time during treatment, the need to seek medical attention for suicidal thoughts and behavior, new onset or worsening symptoms of depression, anxiety, or other mood changes, and the importance of keeping the [Patient Wallet Card](#) with them at all times.
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**1. Healthcare providers who prescribe SILIQ must:**

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|              | 4. Provide the patient with the <a href="#">Patient Wallet Card</a> .                                                                                                       |
|              | 5. Enroll the patient by completing and submitting the <a href="#">Patient Enrollment Form</a> to the REMS Program.<br>Provide a completed copy of the form to the patient. |
| At all times | 6. Report treatment discontinuation or transfer of care to the REMS Program.                                                                                                |
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**2. Patients who are prescribed SILIQ:**

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| Before treatment initiation | 1. Receive counseling from the prescriber on the risk of suicidal ideation and behavior including that completed suicides have occurred with patients treated with SILIQ, symptoms may occur at any time during treatment, the need to seek medical attention for suicidal thoughts and behavior, new onset or worsening symptoms of depression, anxiety, or other mood changes, and the importance of keeping the <a href="#">Patient Wallet Card</a> with you at all times. |
|                             | 2. Enroll in the REMS Program by completing the <a href="#">Patient Enrollment Form</a> with the prescriber. Enrollment information will be provided to the REMS Program.                                                                                                                                                                                                                                                                                                     |
|                             | 3. Receive the <a href="#">Patient Wallet Card</a> .                                                                                                                                                                                                                                                                                                                                                                                                                          |
| At all times                | 4. Have the <a href="#">Patient Wallet Card</a> with you.                                                                                                                                                                                                                                                                                                                                                                                                                     |
|                             | 5. Inform the prescriber if you have suicidal thoughts or behavior, or any new or worsening symptoms of depression, anxiety, or other mood changes.                                                                                                                                                                                                                                                                                                                           |
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**3. Pharmacies that dispense SILIQ must:**

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| To become certified to dispense | 1. Designate an authorized representative to carry out the certification process and oversee implementation and compliance with the REMS Program on behalf of the pharmacy. |
|                                 | 2. Have the authorized representative enroll in the REMS by completing the <a href="#">Pharmacy Enrollment Form</a> and submitting it to the REMS Program.                  |
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**3. Pharmacies that dispense SILIQ must:**

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	3. Train all relevant staff involved in dispensing SILIQ on the REMS Program requirements as described on the <a href="#">Pharmacy Enrollment Form</a> .
Before dispensing	4. Obtain authorization to dispense each prescription by contacting the REMS Program to verify the prescriber is certified and the patient is enrolled.
To maintain certification to dispense	5. Have a new authorized representative enroll in the REMS program by completing and submitting the <a href="#">Pharmacy Enrollment Form</a> to the REMS.
At all times	6. Maintain records that all processes and procedures are in place and being followed.  7. Comply with audits by Bausch Health US, LLC or third party acting on behalf of Bausch Health US, LLC to ensure that all processes and procedures are in place and are being followed.

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**4. Wholesalers-distributors that distribute SILIQ must:**

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To be able to distribute	1. Establish processes and procedures to ensure that the drug is distributed only to certified pharmacies.  2. Train all relevant staff involved in distribution on the REMS requirements.
At all times	3. Distribute only to certified pharmacies.  4. Maintain and submit records of all drug distribution to the REMS Program.  5. Maintain records that all processes and procedures are in place and being followed.  6. Comply with audits by Bausch Health US, LLC or a third party acting on behalf of Bausch Health US, LLC to ensure that all processes and procedures are in place and are being followed.

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**To support REMS Program operations, Bausch Health US, LLC must:**

1. Establish and maintain a REMS Program website ([www.SILIQREMS.com](http://www.SILIQREMS.com)). The REMS Program website must include the capability to complete prescriber and pharmacy certification online, to enroll patients online, to confirm patient authorization status, and the option to print the Prescribing Information, Medication Guide, and SILIQ REMS

materials. All product websites for consumers and healthcare providers must include prominent REMS-specific links to the REMS Program website. The REMS Program website must not link back to the promotional product website(s).

2. Make the REMS Program website fully operational and all REMS materials available through the call center and [www.SILIQREMS.com](http://www.SILIQREMS.com) within 90 calendar days of REMS modification (01/22/2021).
3. Establish and maintain a REMS Program Call Center for REMS participants at 855-511-6135.
4. Establish and maintain a validated, secure database of all REMS participants who are enrolled and/or certified in the SILIQ REMS Program.
5. Ensure prescribers are able to become certified online, by email, and by fax.
6. Ensure that prescribers are able to enroll patients in the REMS online, by email, and by fax.
7. Ensure that pharmacies are able to become certified in the REMS online, by email, and by fax.
8. Ensure pharmacies are able to obtain authorization to dispense online and by phone.
9. Provide the [Prescriber Enrollment Form](#), [Patient Enrollment Form](#), [Patient Wallet Card](#), and Prescribing Information to healthcare providers who (1) attempt to prescribe or dispense SILIQ and are not yet certified, or (2) inquire about how to become certified.
10. Provide the [Pharmacy Enrollment Form](#) to pharmacies who (1) attempt to order SILIQ and are not yet certified, or (2) inquire about how to become certified.
11. Notify pharmacies and prescribers within one business day after they become certified in the REMS Program.
12. Provide certified prescribers access to the database of certified pharmacies and enrolled patients.
13. Provide certified pharmacies access to the database of certified prescribers and enrolled patients.

**To ensure REMS participants' compliance with the REMS Program, Bausch Health US, LLC must:**

14. Verify annually that the authorized representative's name and contact information correspond to those of the current designated authorized representative for the pharmacy. If different, the pharmacy must be required to recertify with a new authorized representative.
15. Maintain adequate records to demonstrate that REMS requirements have been met, including, but not limited to records of: SILIQ distribution and dispensing; certification of prescribers, pharmacies; enrolled patients; and audits of REMS participants. These records must be readily available for FDA inspections.
16. Establish a plan for addressing noncompliance with REMS Program requirements.
17. Monitor prescribers, pharmacies, and wholesalers-distributors on an ongoing basis to ensure the requirements of the REMS are being met. Take corrective action if non-compliance is identified, include de-certification.
18. Audit 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. Certified pharmacies must be identified in Bausch Health's ongoing annual audit plan.

19. Audit wholesalers-distributors that have distributed SILIQ no later than 90 calendar days after they become authorized to distribute the drug and annually thereafter to ensure that all REMS processes and procedures are in place, functioning, and support the REMS requirements.
20. Take reasonable steps to improve implementation of and compliance with the requirements of the SILIQ REMS Program based on monitoring and evaluation of the SILIQ REMS Program.

#### **IV. REMS Assessment Timetable**

Bausch Health US, LLC must submit REMS assessments at 6 months, 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 US, LLC must submit each assessment so that it will be received by the FDA on or before the due date.

#### **V. REMS Materials**

The following materials are part of the SILIQ REMS:

##### **Enrollment Forms**

Prescriber:

1. [Prescriber Enrollment Form](#)

Patient:

2. [Patient Enrollment Form](#)

Pharmacy:

3. [Pharmacy Enrollment Form](#)

##### **Training and Educational Materials**

Patient:

4. [Patient Wallet Card](#)

##### **Other Materials**

5. [REMS Program Website](#)