

BLENREP Risk Evaluation and Mitigation Strategy (REMS)

Education Program for Healthcare Settings



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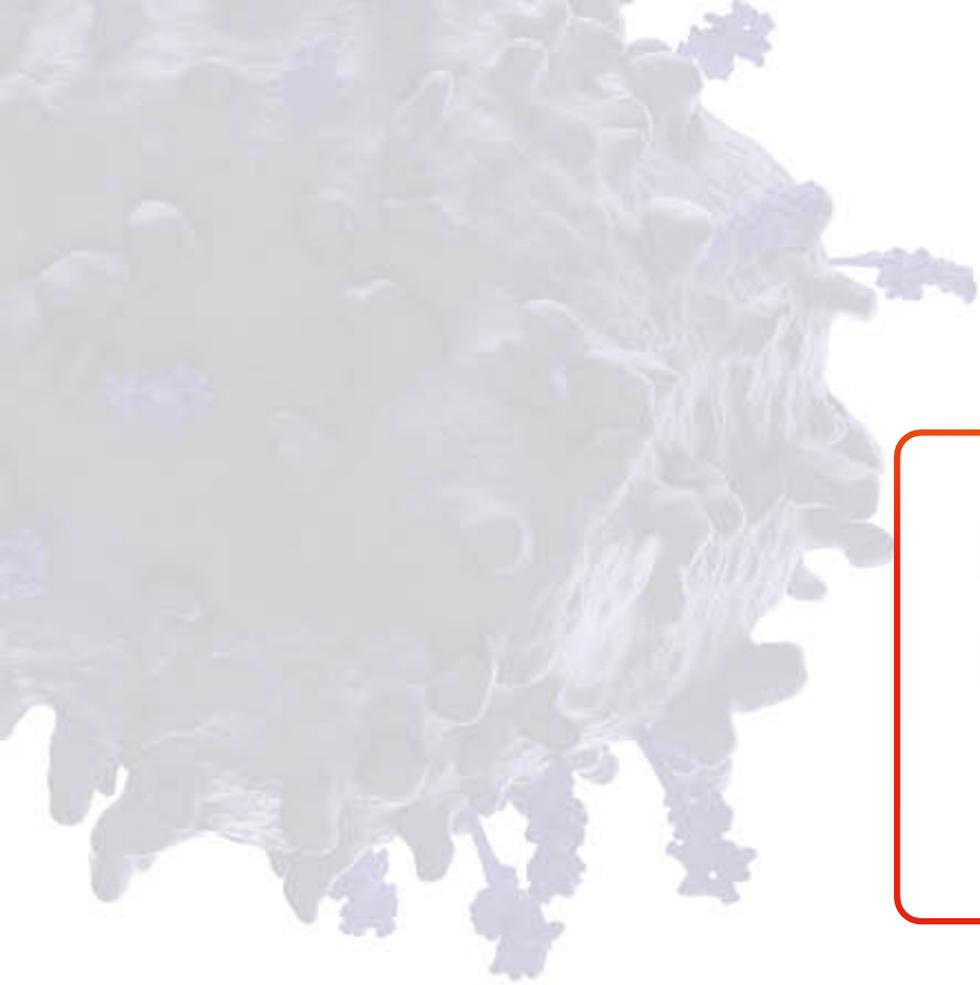
Healthcare Setting Training, Enrollment, and Setup



Authorization and REMS Checklist



Important Reminders and the REMS Portal



BLENREP: REMS Summary

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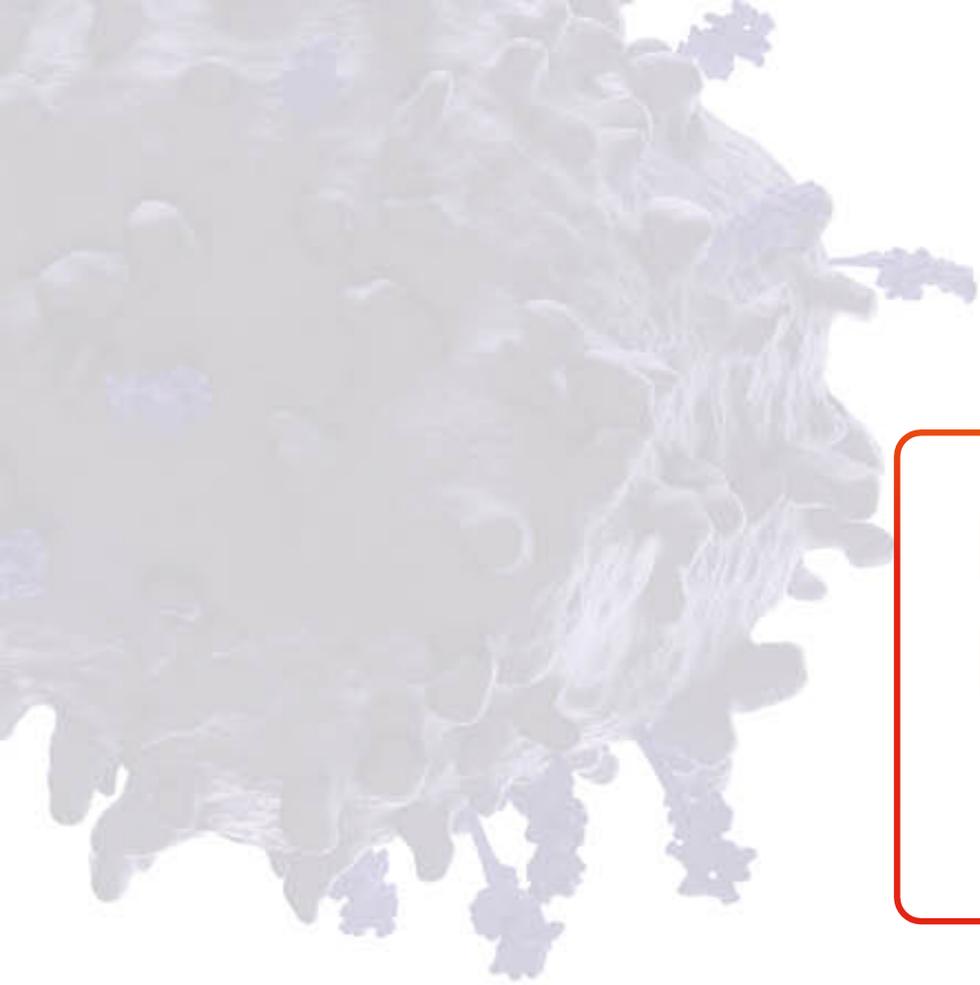
Indications and Usage

- BLNREP is a B-cell maturation antigen (BCMA)-directed antibody and microtubule inhibitor conjugate indicated for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least 4 prior therapies including an anti-CD38 monoclonal antibody, a proteasome inhibitor, and an immunomodulatory agent.
- This indication is approved under accelerated approval based on response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

BLNREP: Key US Prescribing Information

WARNING: OCULAR TOXICITY

- BLNREP caused changes in the corneal epithelium resulting in changes in vision, including severe vision loss and corneal ulcer, and symptoms, such as blurred vision and dry eyes.
- Conduct ophthalmic exams at baseline, prior to each dose, and promptly for worsening symptoms. Withhold BLNREP until improvement and resume, or permanently discontinue, based on severity.
- Because of the risk of ocular toxicity, BLNREP is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the BLNREP REMS.



BLENREP: REMS Overview

Due to the risk of ocular toxicity, BLENREP is available only through a restricted program called the BLENREP REMS

What is the BLENREP REMS?



- A Risk Evaluation and Mitigation Strategy, or REMS, is a strategy to manage known or potential risks associated with a product. It is required by the Food and Drug Administration (FDA) to ensure the benefits of the drug outweigh its risks.
- Because of the risk of ocular toxicity, BLENREP is available only through a restricted program called the BLENREP REMS.

What are the BLENREP REMS requirements?



Prescribers must be certified with the program by enrolling and completing training in the BLENREP REMS, and they must counsel patients receiving BLENREP about the risk of ocular toxicity and the need for ophthalmic examinations prior to each dose.



Patients must be enrolled in the BLENREP REMS and comply with monitoring.



Healthcare facilities must be certified with the program and verify that patients are authorized to receive BLENREP.



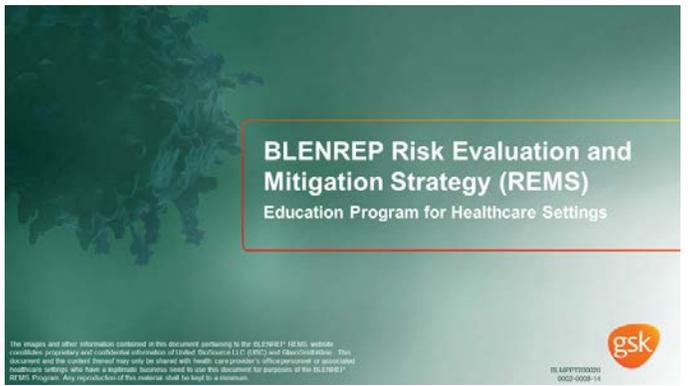
Wholesalers and distributors must only distribute BLENREP to certified healthcare facilities.

Prior to first patient infusion, the Healthcare Setting will designate an Authorized Representative to review training, enroll in the REMS, establish REMS processes and train staff

1. Designate an Authorized Representative to Review Training Materials

2. Authorized Representative Completes Online Enrollment

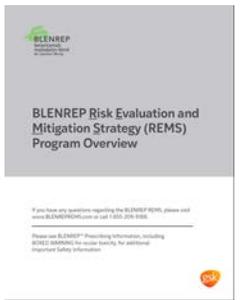
3. Healthcare Setting Establishes REMS Processes and Trains Staff



Education Program for Healthcare Settings (this presentation)



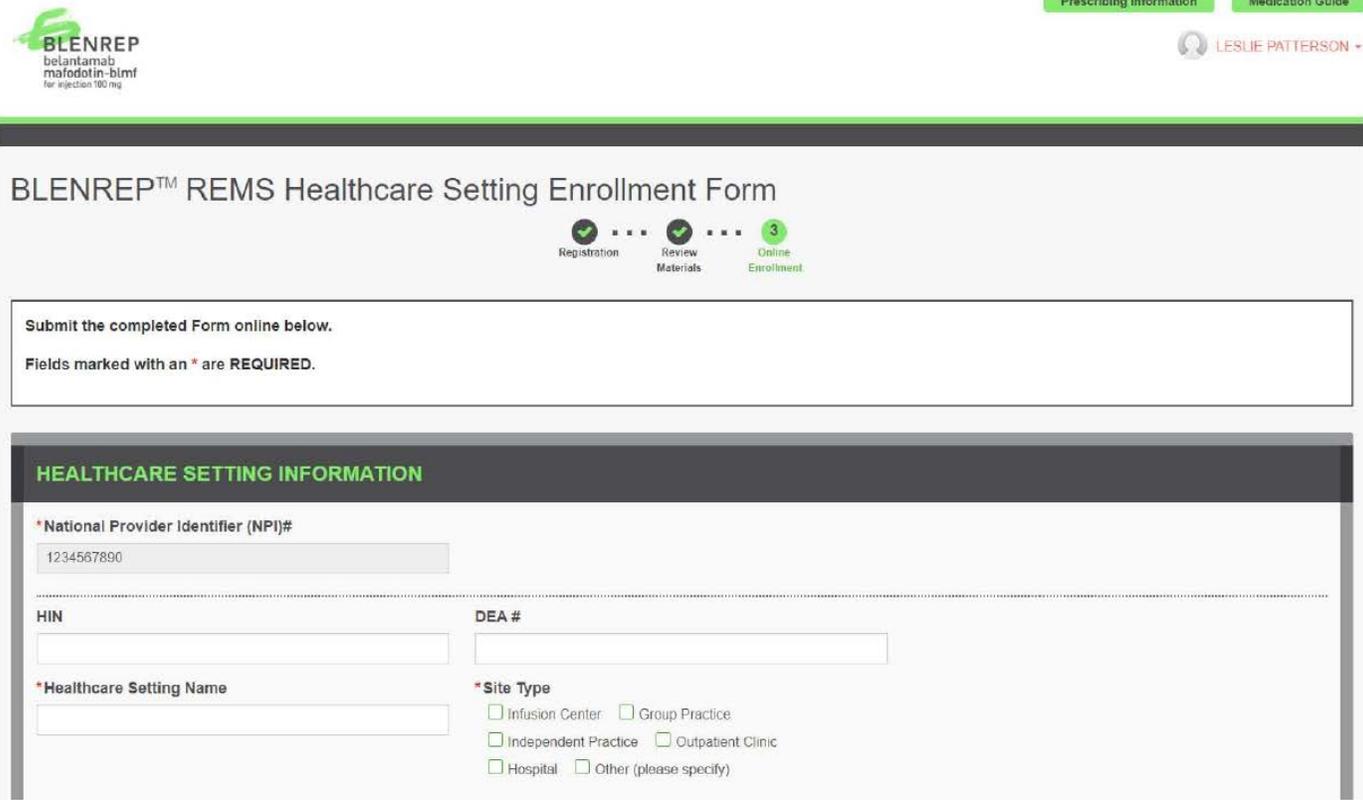
US Prescribing Information



REMS Program Overview



After reviewing training materials, the Healthcare Setting Authorized Representative will enroll in the BLENREP REMS via the online portal



BLENREP
belantamab mafodotin-blmf
for injection 100 mg

Prescribing Information Medication Guide

LESLIE PATTERSON

BLENREP™ REMS Healthcare Setting Enrollment Form

Registration Review Materials **3 Online Enrollment**

Submit the completed Form online below.
Fields marked with an * are REQUIRED.

HEALTHCARE SETTING INFORMATION

*National Provider Identifier (NPI)#
1234567890

HIN DEA #

*Healthcare Setting Name *Site Type

Infusion Center Group Practice
 Independent Practice Outpatient Clinic
 Hospital Other (please specify)

- ### You will need to provide:
- Healthcare Setting NPI
 - Healthcare Setting Name and Type
 - Healthcare Setting Address
 - Authorized Representative contact information

During enrollment, you may designate one Authorized Representative for multiple healthcare settings (e.g. multiple affiliated infusion centers), if relevant

Paper form available for fax submission

Following REMS enrollment, each Healthcare Setting must establish processes to support REMS Compliance and Train Staff; trained staff may be added as Delegates within the REMS Portal



1. Establish Processes & Procedures



2. Train Relevant Team Members using the Education Program for Healthcare Settings, and the REMS Program Overview

3. Maintain a list of trained staff for auditing, and add as delegates for portal access (remove any users that no longer require access)

REMS VERIFICATION | **HEALTHCARE SETTING MANAGEMENT** | REMS CHECKLIST

Healthcare Setting Management

Below is a list of your associated Delegates/Users who require access to the BLENREP REMS portal.

As the Authorized Representative, you are responsible to manage user access for the BLENREP REMS Portal and should immediately remove any users that no longer require access.

Healthcare Settings [ADD HEALTHCARE SETTING](#)

HCS 1
123 Main Street
City, State Zip
NPI #: 1234567890

DELEGATES [ADD/ASSOCIATE DELEGATE](#)

<div style="background-color: #333; color: white; padding: 2px;">Loretta Mayby</div> <div style="padding: 2px;"> imably@hcs1.com </div> <div style="text-align: right; padding: 2px;">REMOVE ASSOCIATION</div>	<div style="background-color: #333; color: white; padding: 2px;">Steve Mason</div> <div style="padding: 2px;"> smason@hcs1.com </div> <div style="text-align: right; padding: 2px;">REMOVE ASSOCIATION</div>
---	---

Add/Associate Delegate x

ENTER DELEGATE INFORMATION

Please enter the information below and click "Add".

Healthcare Facility Name 1

*First Name

*Last Name

*Email

[CANCEL](#) [ADD](#)

Prior to Patient Infusion: obtain authorization to dispense; Following infusion: complete the REMS Checklist

1. Obtain Authorization to Dispense

2. Infusion

3. Complete and Submit REMS Checklist within 5 Business Days

REMS Verification

Please enter the information below to verify enrollment.
Fields marked with * are required.

HEALTHCARE SETTING INFORMATION

You may enter the Healthcare Setting NPI#, Name or Address/City/State/Zip, then select the healthcare setting

*Healthcare Setting

PRESCRIBER INFORMATION

You may enter the Prescriber NPI#, First Name or Last Name, then select the prescriber.

*Prescriber

PATIENT INFORMATION

*First Name *Last Name *Date of Birth

CLEAR SUBMIT



REMS Checklist

Submit the completed form online below.

As a condition of your authorization to dispense BLENREP, this checklist must be completed for each patient within 5 business days of infusion. You will receive a confirmation of receipt via an automatic email notification after submission of this checklist. Keep a copy of the notification in the patient's medical record.

Fields marked with an * are REQUIRED.

PATIENT INFORMATION	
First Name: Peggy	Date of Birth (MM/DD/YYYY): 3/2/2000
Last Name: Sue	Patient BLENREP REMS Identification #: 12345
PRESCRIBER INFORMATION	
First Name: Abana	National Provider Identifier (NPI) #: 1234567890
Last Name: Ben	
HEALTHCARE SETTING INFORMATION	
Healthcare Setting Name: Professional Associates HCS	Healthcare Setting BLENREP REMS Identification #: 12345
National Provider Identifier (NPI) #: 2345678901	Phone: 555-555-5434

CLEAR SUBMIT

Select REMS Verification tab in the online portal to verify Patient eligibility and obtain an authorization to dispense

Enter requested information about the Healthcare Setting, Prescriber, and Patient into the REMS Portal:

The screenshot shows the BLMPPT200026 REMS Verification portal. At the top left is the BLMPPT logo with the text "BLMPPT belantamab mafodotin-biml for injection 100 mg". At the top right are two tabs: "Prescribing information" and "Medication Guide". Below these is a user profile for "Jones, Mark". A navigation bar contains three tabs: "REMS VERIFICATION" (highlighted with a red circle), "HEALTHCARE SETTING MANAGEMENT", and "REMS CHECKLIST". The main content area is titled "REMS Verification" and includes the instruction "Please enter the information below to verify enrollment." and "Fields marked with * are required." The form is divided into three sections: "HEALTHCARE SETTING INFORMATION" with a text input field for "Healthcare Setting"; "PRESCRIBER INFORMATION" with a text input field for "Prescriber"; and "PATIENT INFORMATION" with three text input fields for "First Name", "Last Name", and "Date of Birth". At the bottom right are "CLEAR" and "SUBMIT" buttons.



The REMS Coordinating Center
(1-855-209-9188) can also provide
authorization information

REMS Verification will indicate if it is okay to infuse the Patient or not

If Patient is eligible, you will receive the “OK TO INFUSE” message noted below; **select “Generate Authorization Code”** and note the code for the REMS Checklist:

Verification Results

You must generate an authorization code to complete this verification.

GENERATE AUTHORIZATION CODE

REMS Authorization Code:
32327



OK TO INFUSE
REMS verification successful.
Authorization Code needed

Prescriber ✓ Susan Gold Certified
Prescriber REMS ID: 12345

Patient ✓ Janet Bowers Enrolled - Cleared for Infusion
Patient REMS ID: 987374



If Patient is not eligible, **do not proceed; contact the REMS Coordinating Center (1-855-209-9188)**

Verification Results

PLEASE CALL FOR ASSISTANCE
1-855-209-9188

PLEASE CALL FOR ASSISTANCE
1-855-209-9188



DO NOT INFUSE
REMS verification failed.

Prescriber ✓ Susan Gold Certified
Prescriber REMS ID: 12345

Patient ✗ Janet Bowers Enrolled - Pending Patient Status Form
Patient REMS ID: 987374



Complete the REMS Checklist within 5 business days of infusion by entering the date of administration, actual dose, and by electronically signing the checklist (1/2)

REMS VERIFICATION

HEALTHCARE SETTING MANAGEMENT

REMS CHECKLIST

REMS Checklist

Submit the completed form online below.

As a condition of your authorization to dispense BLENREP, this checklist must be completed for each patient within 5 business days of infusion. You will receive a confirmation of receipt via an automatic email notification after submission of this checklist. Keep a copy of the notification in the patient's medical record.

Fields marked with an * are REQUIRED.

> PATIENT INFORMATION

First Name: Peggy

Date of Birth (MM/DD/YYYY): 3/2/2000

Last Name: Sue

Patient BLENREP REMS Identification #: 12345

> PRESCRIBER INFORMATION

First Name: Maura

National Provider Identifier (NPI) #: 1234567890

Last Name: Barr

> HEALTHCARE SETTING INFORMATION

Healthcare Setting Name: Professional Associates HCS

Healthcare Setting BLENREP REMS Identification #: 12345

National Provider Identifier (NPI) #: 2345678901

Phone: 555 555-3434

Complete the REMS Checklist within 5 business days of infusion by entering the date of administration, actual dose, and by electronically signing the checklist (2/2)

AUTHORIZATION CODE PRIOR TO DISPENSING

Authorization: **32327**

DOSING INFORMATION

*Date of Infusion: (MM/DD/YYYY) *Actual dose (mg)

SIGNATURE OF STAFF COMPLETING CHECKLIST

*Signature

<p>*First Name</p> <input type="text" value="Peggy"/>	<p>*Last Name</p> <input type="text" value="Sue"/>	<p>*Credentials</p> <p><input checked="" type="checkbox"/> DO <input type="checkbox"/> MD <input type="checkbox"/> PharmD <input type="checkbox"/> RN <input type="checkbox"/> NP <input type="checkbox"/> PA</p> <p><input type="checkbox"/> Other (please specify)</p>
<p>*Phone</p> <input type="text" value=""/>	<p>*Fax</p> <input type="text" value=""/>	<p>*Email</p> <input type="text" value="a@abc.com"/>

SEND INFUSION INFORMATION TO THE BLENREP REMS

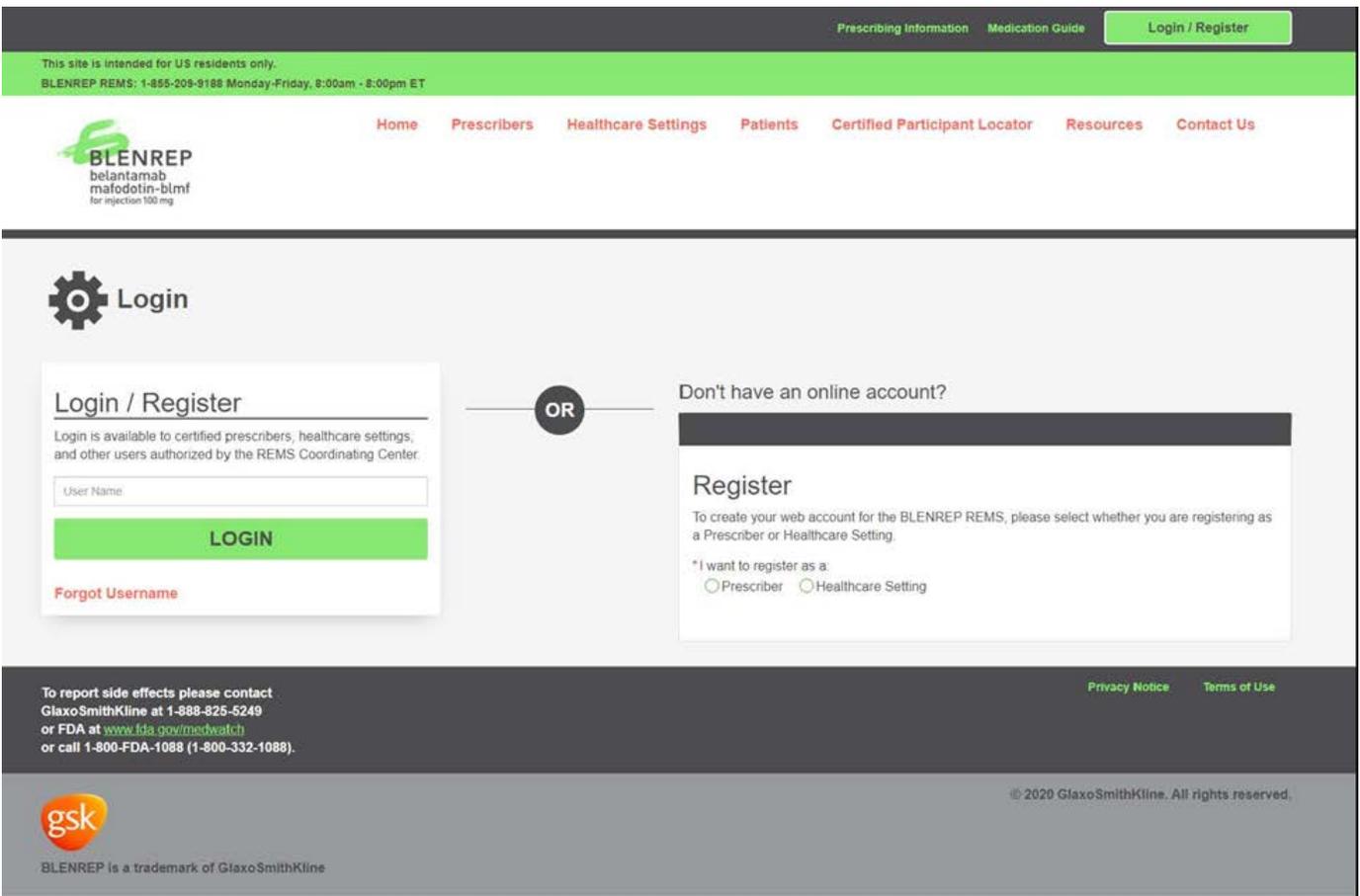
Please submit this completed form by clicking "Submit" below within 5 business days of infusion. You will receive a confirmation of receipt via e-mail.

Important Reminders

- Ensure the training, enrollment, authorization to dispense and REMS checklist procedures in this document are followed
- Notify the REMS Coordinating Center (1-855-209-9188) if the authorized representative designated by the healthcare setting changes
- Maintain records to demonstrate all processes and procedures are in place and being followed, and to document staff completion of REMS training
- Comply with all audits carried out by GSK or third parties acting on behalf of GSK to ensure all processes and procedures are in place and are being followed
- BLENREP may not be administered outside of the certified healthcare setting administering the infusion
- BLENREP must not be distributed, transferred, loaned, or sold

This educational module for Healthcare Settings is not intended to be a comprehensive description of the complete safety information for BLENREP. For complete safety information, please see the full Prescribing Information, including Boxed Warning, available at www.BLENREPREMS.com

BLNPREMS.com provides rapid support for the BLNREP REMS program, with additional support available via the REMS Coordinating Center



Key Features of BLNPREMS.com

- ✓ real-time enrollment certification
- ✓ real-time authorization to dispense
- ✓ real-time REMS checklist submission
- ✓ Automatic email notifications for REMS enrollment and REMS checklist submission that can be saved for record keeping and audits

For More Information



Call 1-855-209-9188



Visit www.BLNPREMS.com