

# **BLENREP Risk Evaluation and Mitigation Strategy (REMS)**

## **Education Program for Healthcare Settings**



BLMPPT200026  
0002-0008-14

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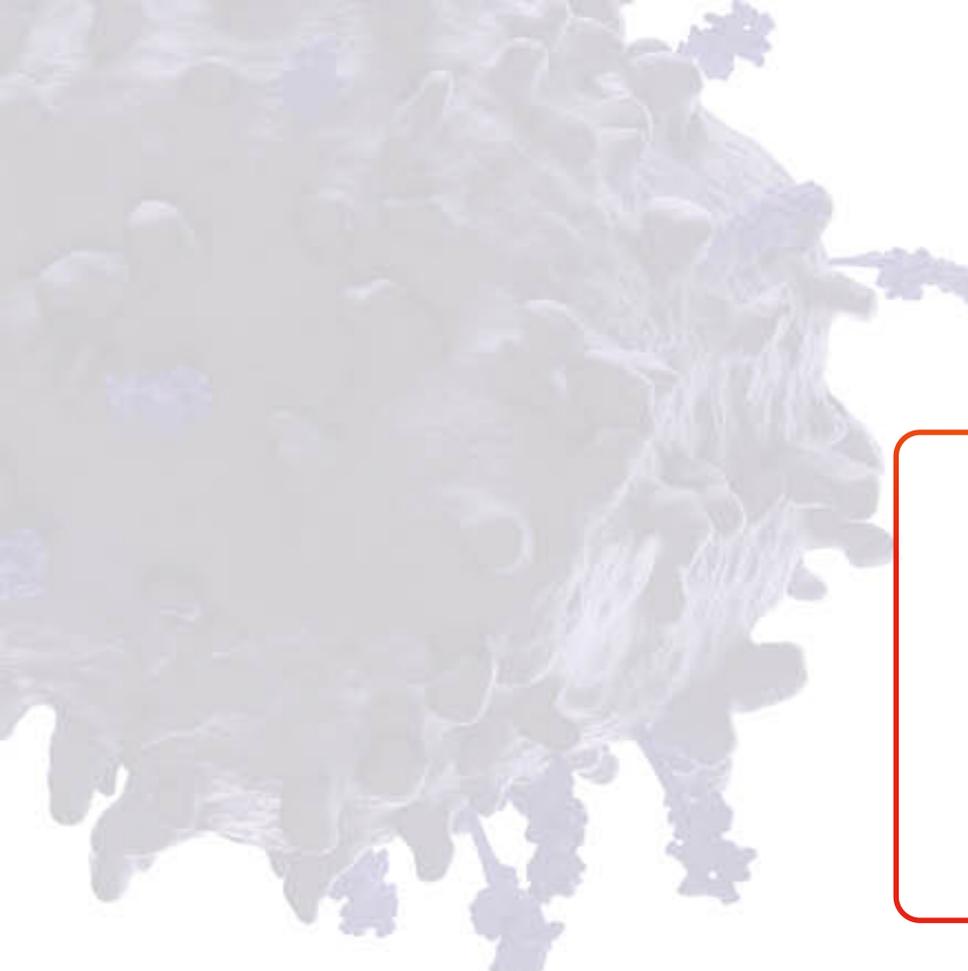
Healthcare Setting Training, Enrollment, and Setup



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# **BLENREP: REMS Summary**

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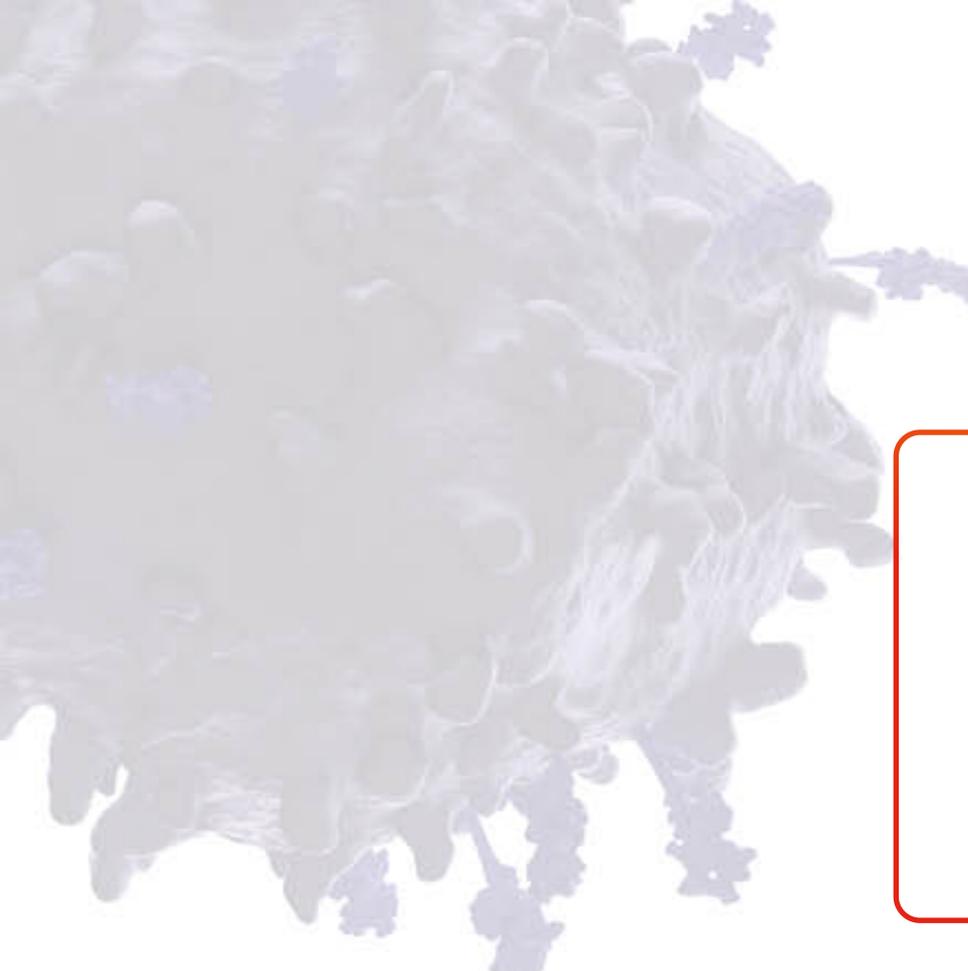
## Indications and Usage

- 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.



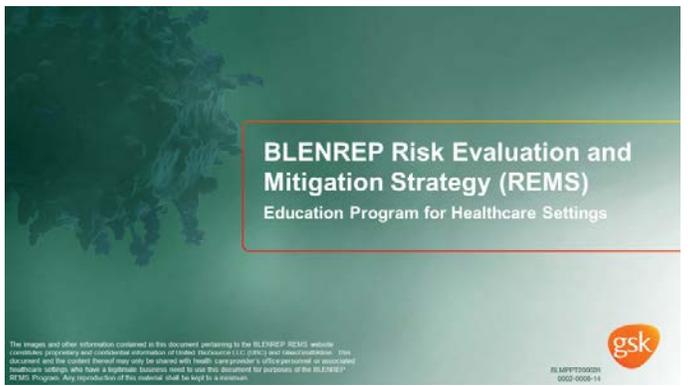
**Wholesalers and distributors** must only distribute BLENREP to certified healthcare facilities.

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

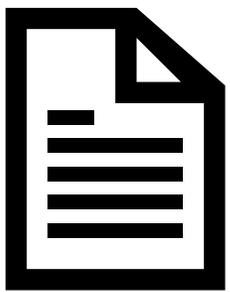
1. Designate an Authorized Representative to Review Training Materials

2. Authorized Representative Completes Online Enrollment

3. Healthcare Setting Establishes REMS Processes and Trains Staff



Education Program for Healthcare Settings (this presentation)



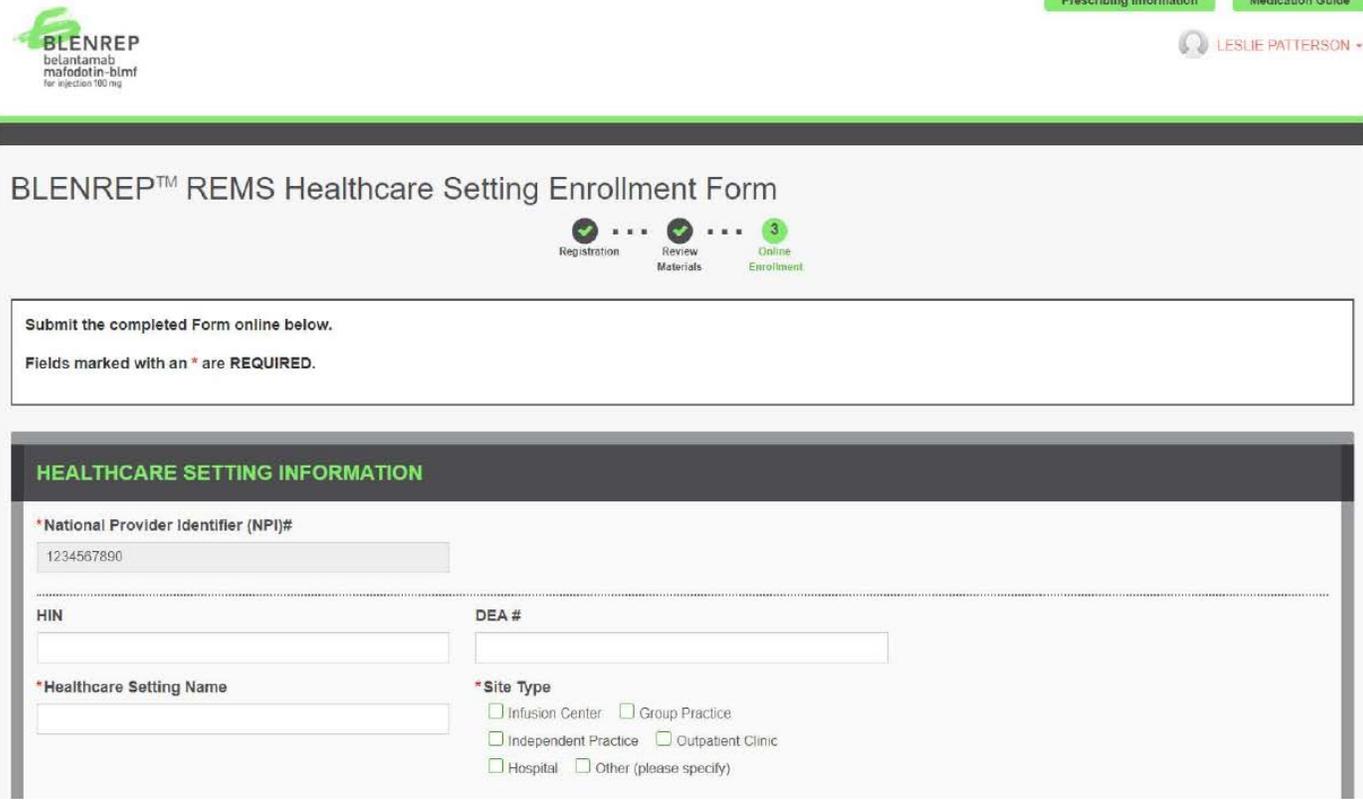
US Prescribing Information



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-bimf  
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

Loretta Mayby lmayby@hcs1.com <span>REMOVE ASSOCIATION</span>	Steve Mason smason@hcs1.com <span>REMOVE ASSOCIATION</span>
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**Add/Associate Delegate**

**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

The screenshot shows the 'REMS Verification' page in the BLENREP system. It includes sections for 'HEALTHCARE SETTING INFORMATION', 'PRESCRIBER INFORMATION', and 'PATIENT INFORMATION'. Each section contains input fields for NPI, name, address, and date of birth. A 'SUBMIT' button is visible at the bottom right.



The screenshot shows the 'REMS Checklist' page, which is a summary of the information entered in the verification step. It lists patient, prescriber, and healthcare setting details. A 'SUBMIT' button is visible at the bottom right.

PATIENT INFORMATION	
First Name: Peggy	Date of Birth (MM/DD/YYYY): 9/2/2000
Last Name: Sue	Patient BLENREP REMS Identification #: 12345
PRESCRIBER INFORMATION	
First Name: Maria	National Provider Identifier (NPI) #: 123456789
Last Name: Sun	
HEALTHCARE SETTING INFORMATION	
Healthcare Setting Name: Professional Associates HCS	Healthcare Setting BLENREP REMS Identification #: 12345
National Provider Identifier (NPI) #: 2345678901	Phone: 555-555-5434

# 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 REMS Verification portal interface. At the top left is the BLENREP logo (belantamab mafodotin-bimf for injection 100 mg). At the top right are tabs for 'Prescribing Information' and 'Medication Guide', and a user profile for 'Jones, Mark'. Below the navigation bar, the 'REMS VERIFICATION' tab is highlighted with a red circle. The main heading is 'REMS Verification', followed by the instruction 'Please enter the information below to verify enrollment.' and a note 'Fields marked with \* are required.' The form is divided into three sections: 'HEALTHCARE SETTING INFORMATION' with a text input for '\*Healthcare Setting'; 'PRESCRIBER INFORMATION' with a text input for '\*Prescriber'; and 'PATIENT INFORMATION' with text inputs for '\*First Name', '\*Last Name', and '\*Date of Birth' (with a calendar icon). 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 Prescriber REMS ID: 12345	Certified
Patient	✓ Janet Bowers Patient REMS ID: 987374	Enrolled - Cleared for Infusion



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 Prescriber REMS ID: 12345	Certified
Patient	✗ Janet Bowers Patient REMS ID: 987374	Enrolled - Pending Patient Status Form



# 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

*First Name <input type="text" value="Peggy"/>	*Last Name <input type="text" value="Sue"/>	*Credentials <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 <input type="checkbox"/> Other (please specify)
*Phone <input type="text"/>	*Fax <input type="text"/>	*Email <input type="text" value="a@abc.com"/>

### SEND INFUSION INFORMATION TO THE BLENREP REMS

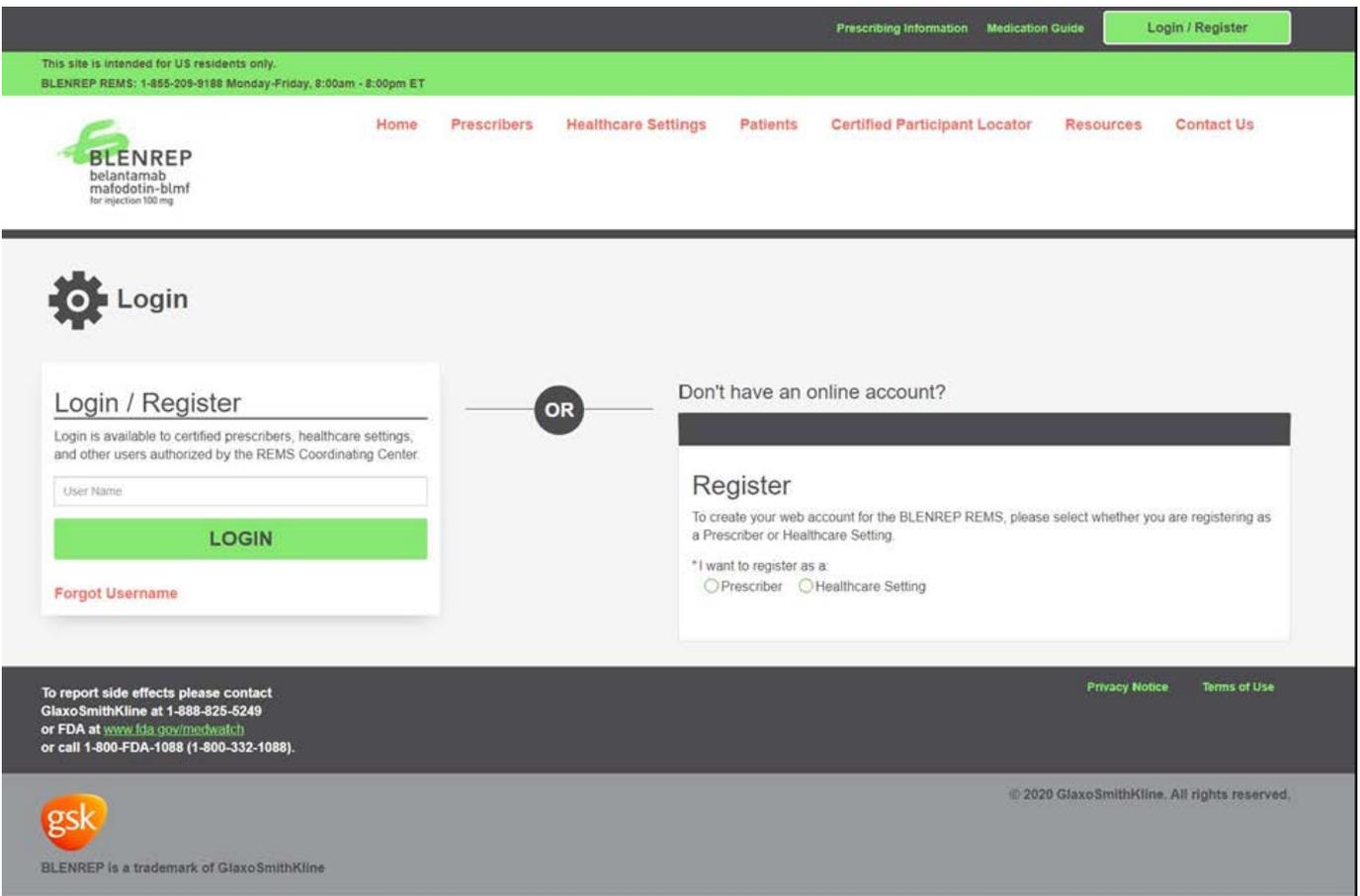
Please submit this completed form by clicking "Submit" below within 5 business days of infusion. You will receive a confirmation of receipt via e-mail.

# 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](http://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](http://www.BLNPREMS.com)