BLENREP Risk Evaluation and Mitigation Strategy (REMS)
Healthcare Setting Training
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BLENREP REMS Summary

BLENREP REMS Program

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BLENREP: REMS Summary
• BLENREP 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.
WARNING: OCULAR TOXICITY

- BLENREP 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 BLENREP until improvement and resume, or permanently discontinue, based on severity.

- Because of the risk of ocular toxicity, BLENREP is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the BLENREP REMS.
BLENREP: REMS Overview
Due to the risks 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
After reviewing training materials, the Healthcare Setting Authorized Representative will enroll in the BLENREP REMS via the online portal.

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

1. Establish Processes & Procedures

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

3. Maintain a list of trained staff for auditing, and add as delegates for portal access
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
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:

![REMS Verification Screen](image-url)

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**

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 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 |
| Last Name:  | Sue   |
| Date of Birth (MM/DD/YYYY): | 3/2/2000 |
| Patient BLENREP REMS Identification #: | 12345 |

### PRESCRIBER INFORMATION

| First Name: | Maura |
| Last Name:  | Barr  |
| National Provider Identifier (NPI) #: | 1234567890 |

### HEALTHCARE SETTING INFORMATION

| Healthcare Setting Name: | Professional/Associates HCS |
| National Provider Identifier (NPI) #: | 2345678901 |
| Healthcare Setting BLENREP REMS Identification #: | 12345 |
| 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)
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
BLENREPREMS.com provides rapid support for the BLENREP REMS program, with additional support available via the REMS Coordinating Center.

Key Features of BLENREPREMS.com

- Real-time enrollment verification
- Real-time authorization to dispense
- Real-time treatment checklist submission
- Automatic email notifications for REMS enrollment and treatment checklist submission that can be saved for record keeping and audits

For More Information

Call 1-855-209-9188

Visit www.BLENREPREMS.com