

BLENREP Risk Evaluation and Mitigation Strategy (REMS) Education Program for Healthcare Settings

This education program includes information about:

- Overview of the BLENREP REMS
- Healthcare setting certification requirements
- REMS verification and authorization code generation



Please see full Prescribing Information, including Boxed Warning, Warnings and Precautions, and Adverse Reactions, for further information regarding the use of BLENREP.

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BLENREP REMS Education Program for Healthcare Settings

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Boxed Warning

▶	What is BLENREP?
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	Healthcare Setting Certification
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WARNING: OCULAR TOXICITY

- **BLENREP causes changes in the corneal epithelium resulting in changes in vision, including severe visual impairment, and symptoms such as blurred vision and dry eyes. In the clinical study, corneal ulcers, including cases with infection, also occurred.**
- **Conduct ophthalmic exams at baseline, before each dose, promptly for new or worsening symptoms, and as clinically indicated. In the clinical study, 83% of patients required a dosage modification due to ocular toxicity. 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 called the BLENREP Risk Evaluation and Mitigation Strategy (REMS).**

▶ What is BLENREP?
BLENREP REMS
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Indications and Usage



BLENREP, a B-cell maturation antigen (BCMA)-directed antibody and microtubule inhibitor conjugate, is indicated in combination with bortezomib and dexamethasone for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least two prior lines of therapy, including a proteasome inhibitor and an immunomodulatory agent.

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What is BLENREP?

▶ BLENREP REMS
Healthcare Setting Certification
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What is the BLENREP REMS?

- A restricted program designed to mitigate the risk of ocular toxicity.
- Required by the Food and Drug Administration (FDA) to ensure the potential benefits of BLENREP outweigh its risks.

What is the goal of the BLENREP REMS?

- The goal of the BLENREP REMS is to mitigate the risk of ocular toxicity.
- Prescribers monitor patients for ocular toxicity by assessing ophthalmic exam findings at baseline and during treatment as described in the Prescribing Information.

The BLENREP REMS has requirements for prescribers, patients, healthcare settings, and wholesalers-distributors

<p>Prescribers</p>	<ul style="list-style-type: none"> • Must be certified in the BLENREP REMS by enrolling and completing training. • Must counsel patients receiving BLENREP on the risk of ocular toxicity, the need for monitoring via ophthalmic exams before each dose, and provide patients with the Patient Guide. • Must document confirmation they assessed the patient’s ophthalmic exam findings and authorized treatment, and submit to the REMS using the Patient Status Form, at baseline and before each dose.
<p>Patients</p>	<ul style="list-style-type: none"> • Must be enrolled in the BLENREP REMS and adhere to monitoring.
<p>Healthcare Settings</p>	<ul style="list-style-type: none"> • Must be certified in the BLENREP REMS by enrolling and must obtain authorization prior to dispensing.
<p>Wholesalers-distributors</p>	<ul style="list-style-type: none"> • Must distribute BLENREP only to certified healthcare settings.

Healthcare settings must become certified to dispense BLENREP

To become certified to dispense BLENREP, healthcare settings must:

1. Designate an Authorized Representative to carry out the one-time certification process.
2. Have the Authorized Representative review the **Program Overview** and **Education Program for Healthcare Settings** (this presentation).
3. Have the Authorized Representative enroll by completing and submitting the **Healthcare Setting Enrollment Form**.
4. Train all relevant staff involved in dispensing BLENREP using the **Program Overview** and **Education Program for Healthcare Settings** (this presentation).

To enroll in the REMS, submit the Healthcare Setting Enrollment Form

The Authorized Representative will need to provide the following information for enrollment:

1. Healthcare setting name
2. Healthcare setting identifier that is on file with your distributor (NPI, DEA, or HIN – at least 1 is required)
3. Site type (e.g., infusion center, group practice)
4. Facility address (where patients will receive BLENREP infusions) and facility contact information
5. Ship to address (where BLENREP will be shipped to based on NPI, DEA, or HIN on file with your distributor)
6. Authorized Representative name, credentials, and contact information

Note: Use the identifier and ship to address matching your distributor's records. Confirm with your distributor or buyer/purchaser if unsure. Incorrect identifier and/or ship to address could delay BLENREP orders.

The **Healthcare Setting Enrollment Form** can be submitted:

ONLINE AT

SCAN ME



www.BLENPREMS.com

OR BY FAX TO



1-888-635-1044

Additional Healthcare Settings Within the Same Healthcare System

If the Authorized Representative will oversee additional healthcare setting(s) within the same healthcare system (e.g., multiple affiliated infusion centers), the additional healthcare setting(s) can also become certified at this stage or added at a later time.

Note: Every unique location that will infuse patients with BLENREP must become certified in the REMS.

On the **Healthcare Setting Enrollment Form**, the Authorized Representative can add additional healthcare setting location(s) if:

- They will be the Authorized Representative for the additional healthcare setting location(s).
- They may transfer BLENREP inventory within the healthcare system. Please note that BLENREP inventory can only be transferred in the following scenarios:
 1. Recurring transfer of BLENREP from a centralized healthcare system pharmacy location to affiliated REMS-certified infusion centers as part of normal business operations.
 2. Transfer of BLENREP to another REMS-certified healthcare setting / infusion center within their respective healthcare system.

If there are other healthcare setting location(s) within the healthcare system where BLENREP may be transferred, but the Authorized Representatives are different individuals, please contact the REMS Call Center at 1-855-690-9572 to add the additional location(s) to the healthcare system network.

Train Relevant Staff

- Use the **Program Overview** and the **Education Program for Healthcare Settings** (this presentation) to train relevant staff involved in dispensing BLENREP:
 - Relevant staff are those who will have access to the BLENREP REMS online portal, in order to perform **REMS Verification** and obtain **Authorization to Dispense** BLENREP.
 - Maintain records documenting staff's completion of training.
- Note:** If using the online REMS Portal, training is recorded when the Authorized Representative grants staff access, attests to staff training, and enters training date.

Before Dispensing Every Dose of BLENREP: Perform REMS Verification & Generate Authorization Code

What is BLENREP?
BLENREP REMS
Healthcare Setting Certification
► Authorization to Dispense
REMS Portal Functions

Before dispensing each dose, perform REMS Verification

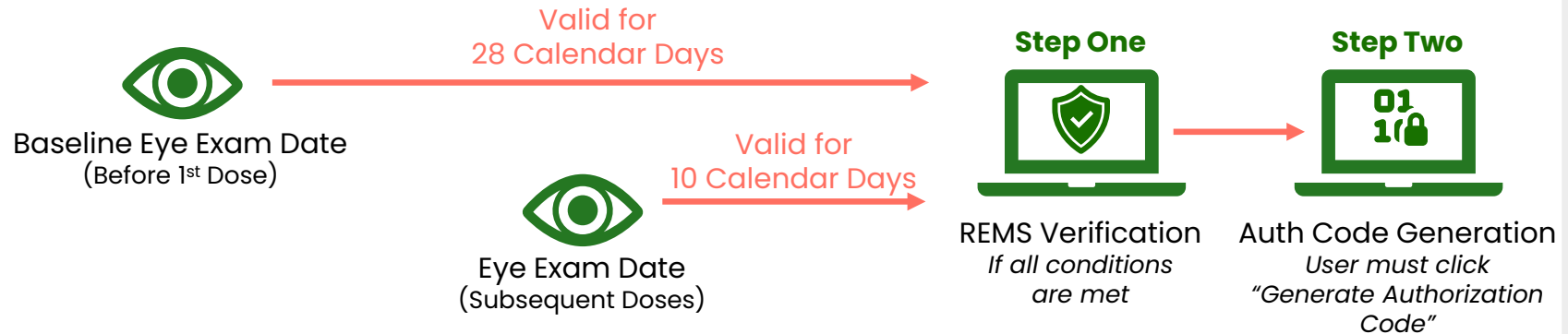
The Authorized Representative or healthcare setting staff must perform REMS Verification to verify the:

- Prescriber is certified;
- Healthcare setting is certified; and
- Patient is enrolled and authorized to receive BLENREP

Information needed to perform REMS Verification

- Prescriber NPI or name
- Patient name and date of birth
- Number of BLENREP vials to be dispensed
- Date of BLENREP infusion
- Dosage to be administered (mg/kg)

REMS Verification & Authorization Code generation must be performed within the validity window



Authorization Code Instructions



- Healthcare setting staff can login to the online portal accessible at www.BLENREPREMS.com or call the BLENREP REMS at 1-855-690-9572 to obtain authorization to dispense.



- If the REMS requirements are not met, an Authorization Code is not able to be generated and the reason(s) why an Authorization Code cannot be provided will be presented.



- If an Authorization Code is generated but the patient is not or will not be infused, cancel the Authorization Code:
 - Within 60 days of the original authorization date: directly in the REMS portal, or contact the BLENREP REMS at 1-855-690-9572
 - After more than 60 days of the original authorization date: contact the BLENREP REMS at 1-855-690-9572

Additional Functions of the BLENREP REMS Portal for Healthcare Settings

Authorized Representative and Healthcare Setting Staff:

1. Patient Dashboard: View existing patients for your healthcare setting and initiate common tasks, such as performing **REMS Verification** and generating **Authorization Codes**.
2. Healthcare System Network: View other BLENREP REMS-certified healthcare settings that have been associated with your healthcare system or health network.

Authorized Representative Only:

1. Healthcare Setting Management:
 - Add/remove BLENREP REMS portal access for healthcare setting staff. It is recommended to perform periodic reviews of staff access and update as needed.
 - Record training of each staff member at the time access is granted to the online REMS portal. The Authorized Representative will attest their staff member(s) have been trained and enter the training date.
 - Add additional healthcare setting(s) where they will also serve as the Authorized Representative.
2. View audit status information.

BLNREP REMS: Key points to remember

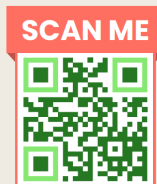
- ✔ Follow requirements for healthcare settings outlined in the **Program Overview** and this **Education Program for Healthcare Settings**.
- ✔ Any new Authorized Representative must enroll by completing and submitting the **Healthcare Setting Enrollment Form** to the REMS (select 'Change in Authorized Representative' option).
- ✔ Do not distribute, transfer, loan, or sell BLNREP, except to REMS-certified healthcare settings.
- ✔ Maintain records documenting staff's completion of training.
- ✔ Maintain records that all processes and procedures are in place and being followed.
- ✔ Comply with audits carried out by GlaxoSmithKline LLC or a third party acting on behalf of GlaxoSmithKline LLC to ensure that all training, processes and procedures are in place and are being followed.

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

FOR MORE INFORMATION



Call 1-855-690-9572 (Monday – Friday,
8:00 am - 8:00 pm Eastern Time)



Visit www.BLENREPREMS.com