



# BLENREP Risk Evaluation and Mitigation Strategy (REMS) Program Overview

If you have any questions regarding the BLENREP REMS, please visit [www.BLENREPREMS.com](http://www.BLENREPREMS.com) or call 1-855-209-9188.

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Please see BLENREP™ Prescribing Information, including BOXED WARNING for ocular toxicity, for additional Important Safety Information



## Table of Contents

What is the BLENREP REMS (Risk Evaluation and Mitigation Strategy).....	3
Indication.....	3
Risks of BLENREP.....	3
What are the Requirements of the BLENREP REMS?.....	4
Prescriber Instructions .....	5
Healthcare Setting Instructions.....	6
Who Can be an Authorized Representative? .....	6
Patient Instructions.....	7
Wholesalers-Distributors Instructions .....	7
How to Enroll in the BLENREP REMS.....	8
BLENREP REMS Portal Overview .....	8
BLENREP REMS Resources .....	9



**This overview describes the requirements of the BLENREP™ (belantamab mafodotin-blmf) REMS and responsibilities of prescribers and Healthcare Settings.**

**What is the BLENREP REMS (Risk Evaluation and Mitigation Strategy)?**

The BLENREP REMS is a safety program that manages the risk of ocular toxicity from BLENREP. The BLENREP REMS is required by the Food and Drug Administration (FDA) to ensure the potential benefits of BLENREP outweigh its risks. The BLENREP REMS is a restricted distribution program.

**Indication**

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.

**Risks of BLENREP**

**Boxed Warning for 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.

**What are the Requirements of the BLENREP REMS?**

In order to receive BLENREP, prescribers, Healthcare Settings, and patients must comply with the requirements of the BLENREP REMS.

 <b>Prescribers</b>	 <b>Healthcare Settings</b>	 <b>Patients</b>	 <b>Wholesalers-Distributors</b>
<p><b>To prescribe BLENREP:</b></p> <ol style="list-style-type: none"> <li><b>Become certified</b> by completing a one-time certification process</li> <li>As you start patients on BLENREP, <b>counsel and enroll</b> them into the BLENREP REMS and <b>complete Patient Status Forms</b> prior to each dose</li> </ol>	<p><b>To dispense BLENREP:</b></p> <ol style="list-style-type: none"> <li><b>Designate an authorized representative</b> and <b>become certified</b> by completing a one-time certification process</li> <li><b>Train</b> staff and <b>comply</b> with REMS requirements</li> <li><b>Obtain authorization</b> to dispense each dose by contacting the BLENREP REMS to verify that the prescriber is certified, the patient is enrolled and authorized to receive the drug. <b>Complete and Submit the REMS Checklist</b></li> </ol>	<p><b>To receive BLENREP:</b></p> <ol style="list-style-type: none"> <li><b>Understand the eye problems</b> associated with BLENREP</li> <li><b>Understand the need to get an eye exam</b> at baseline, prior to each dose, and promptly for worsening symptoms</li> <li><b>Enroll</b> in the BLENREP REMS by completing the <i>Patient Enrollment Form</i> with your healthcare provider</li> <li><b>Inform</b> your healthcare provider if you have signs or symptoms of worsening eyesight or eye health</li> </ol>	<p><b>To be able to distribute BLENREP:</b></p> <ol style="list-style-type: none"> <li><b>Establish</b> processes and procedures to ensure that BLENREP is distributed <b>only</b> to certified Healthcare Settings</li> <li><b>Train</b> all relevant staff involved in distribution of the REMS requirements</li> </ol>

## Prescriber Instructions:



### Become Certified

#### (One-time)

#### Before prescribing BLENREP

1. **Review** the following educational materials on BLENREP to understand the risk of ocular toxicity and the need for the BLENREP REMS:
  - *Prescribing Information*
  - *Program Overview* (this document)
  - *Education Program for Prescribers*
2. **Complete and submit** using the submission details at the end of this document:
  - *Prescriber Knowledge Assessment*
  - *Prescriber Enrollment Form*
3. Once completed, the BLENREP REMS will notify you that you are certified to prescribe BLENREP via email provided in the Enrollment Form (automated and sent immediately from the online portal) or within 2 business days (if enrollment by fax)

### At all times

#### During treatment, before each infusion

1. **Assess** the patient's ocular health by consulting an eye care professional to complete visual acuity and slit lamp examinations using the *Eye Care Professional Consult Request Form* or equivalent
2. **Assess** the patient's ophthalmic consult results for corneal adverse reactions, which are based on both corneal examination findings and changes in best-corrected visual acuity (BCVA)
3. **Manage** corneal adverse reactions per **Table 1. Dosage Modifications for Corneal Adverse Reactions per the Keratopathy and Visual Acuity (KVA) Scale** in the *Prescribing Information* with dose reductions or withhold BLENREP until improvement or permanently discontinue based on severity
4. If continuation of therapy is appropriate, **document and submit** the *Patient Status Form* to the BLENREP REMS
5. Notify the BLENREP REMS if an enrolled patient who has received BLENREP is no longer under your care or has discontinued treatment

The BLENREP REMS will send confirmation of your enrollment in the BLENREP REMS, including your assigned BLENREP REMS identification number, to the email provided in your Enrollment Form. You will not be able to prescribe BLENREP without completing your certification in the BLENREP REMS. If you fail to comply with the BLENREP REMS requirements, you will no longer be able to participate in the BLENREP REMS.

The Healthcare Setting where BLENREP will be administered to the patient also needs to be enrolled in the REMS. If this is at your clinic, please refer to the Healthcare Setting Instructions within this Program Overview. If this is not at your clinic, then reach out to the Healthcare Setting to inform them that they need to enroll in the REMS.

### Enroll Your Patients

#### Before starting each patient on BLENREP

1. **Counsel** your patient using the *Patient Guide* about
  - 1) the risk of ocular toxicity and
  - 2) the requirement for monitoring via ophthalmic exams (visual acuity and slit lamp)
    - at baseline,
    - prior to each dose and
    - promptly for worsening symptoms
2. **Complete and submit** using the submission details at the end of this document:
  - *Patient Enrollment Form*
3. Once completed, the BLENREP REMS will provide confirmation of patient enrollment via email provided in the Enrollment Form (automated and sent immediately from the online portal) or within 2 business days (if enrollment by fax)
4. **Assess** the patient's ocular health by consulting an eye care professional to complete visual acuity and slit lamp examinations using the *Eye Care Professional Consult Request Form* or equivalent
5. **Assess** the patient's ophthalmic consult results for appropriateness of initiating treatment. **Document and submit** to the REMS Program using the:
  - *Patient Status Form*

## Healthcare Settings Instructions:



### To Become Certified

1. **Review** the following educational materials on BLENREP to understand the risk of ocular toxicity and the need for the BLENREP REMS:
  - *Prescribing Information*
  - *Program Overview* (this document)
  - *Education Program for Healthcare Settings*
2. **Complete and submit** using the submission details at the end of this document:
  - *Healthcare Setting Enrollment Form*
3. Once completed, the BLENREP REMS will notify you that you are certified to dispense BLENREP via email provided in the Enrollment Form (automated and sent immediately from the online portal) or within 2 business days (if enrollment by fax)

### At all times

1. Do not distribute, transfer, loan, or sell BLENREP
2. Maintain records documenting staff's completion of REMS training
3. Maintain records to demonstrate all processes and procedures are in place and being followed
4. Comply with 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

The BLENREP REMS will send confirmation of your Healthcare Setting's enrollment in the BLENREP REMS, including your Healthcare Setting's assigned BLENREP REMS identification number, to the email provided in the Enrollment Form. Your Healthcare Setting will not be able to order or dispense BLENREP without completing certification in the BLENREP REMS. If your Healthcare Setting fails to comply with the BLENREP REMS requirements, the Healthcare Setting will no longer be able to participate in the BLENREP REMS.

\* Alternatively, you may contact the BLENREP REMS Coordinating Center at 1-855-209-9188 to verify this information and obtain the authorization to dispense BLENREP.

† If online capabilities are not available, you have the option to fax the *REMS Checklist* to the BLENREP REMS at 1-888-635-1044.

### Before administering

1. **Train** all relevant staff involved in dispensing and administering BLENREP using:
  - *Program Overview* (this document)
  - *Education Program for Healthcare Settings*
2. **Establish processes and procedures** to verify the *REMS Checklist* is completed and submitted for each patient
3. **Obtain authorization** to dispense each dose by logging into the BLENREP REMS portal at [www.BLENREPREMS.com](http://www.BLENREPREMS.com)\* to verify:
  - 1) prescriber is certified
  - 2) patient is enrolled and authorized to receive BLENREP
4. **Capture** the dose and date of infusion in the online *REMS Checklist* and submit it to the REMS program within 5 business days of the infusion†

### To maintain certification to administer

1. Have a new authorized representative enroll in the BLENREP REMS by completing the *Healthcare Setting Enrollment Form* and submitting it to the REMS program if the authorized representative changes

## Who Can Be An Authorized Representative?

An authorized representative at the Healthcare Setting can be a:

- Pharmacist
- Physician
- Nurse
- Nurse Practitioner
- Director of Healthcare Setting
- Physician Assistant
- Or any responsible individual in the Healthcare Setting

Please check with your manager to ensure the appropriate person represents the Healthcare Setting and attests to the enrollment requirements as stated on the BLENREP REMS *Healthcare Setting Enrollment Form*.

One representative needs to enroll per Healthcare Setting (the "authorized representative"). One authorized representative can manage more than one Healthcare Setting and has the ability to add additional users to the online portal.

## Patient Instructions:



### Before treatment initiation

1. Receive counseling from the prescriber on the eye problems associated with BLENREP using the *Patient Guide*
2. Enroll in the REMS Program by completing the *Patient Enrollment Form* with the prescriber. Enrollment information will be provided to the REMS Program
3. Get an eye exam

### At all times

1. **Inform** the prescriber if you have signs or symptoms of worsening eyesight or eye health

### During Treatment; before each dose

1. Get an eye exam

## Wholesalers-Distributors Instructions:



### To be able to distribute

1. **Establish** processes and procedures to ensure that BLENREP is distributed only to certified Healthcare Settings
2. **Train** all relevant staff involved in distribution of the REMS requirements

### At all times

1. **Distribute only** to certified Healthcare Settings
2. **Maintain** records of all drug distribution
3. **Comply** with audits carried out by GSK or a third party acting on behalf of GSK to ensure that all processes and procedures are in place and are being followed

## How to Enroll in the BLENREP REMS

The completed forms should be submitted to the BLENREP REMS online, using the BLENREP REMS Portal at [www.BLENREPREMS.com](http://www.BLENREPREMS.com). If online capabilities are not available, you have the option to fax to the BLENREP REMS at 1-888-635-1044.

## BLENREP REMS Portal Overview

[www.BLENREPREMS.com](http://www.BLENREPREMS.com)

The BLENREP REMS Portal is a web-based tool designed to:

- Provide real-time access to BLENREP REMS patient, prescriber, and Healthcare Setting information
- Maintain compliance with the BLENREP REMS

The BLENREP REMS Portal allows prescribers to:

- Certify and enroll in the BLENREP REMS
- Enroll and manage patients
- Complete the required *Patient Status Forms*
- Report corneal adverse reactions

The BLENREP REMS Portal allows Healthcare Settings to:

- Certify and enroll in the BLENREP REMS
- Obtain the authorization to dispense BLENREP
- Complete and submit the *REMS Checklist*

The BLENREP REMS portal contains all of the BLENREP REMS resources.

# BLENREP REMS Resources

	<u>Before Prescribing/ Dispensing</u>	<u>Before treatment initiation (first dose)</u>	<u>During treatment</u>
 <p><b>Prescribers</b></p>	<ul style="list-style-type: none"> <li>• Prescribing Information</li> <li>• Program Overview</li> <li>• Education Program for Prescribers</li> <li>• Prescriber Knowledge Assessment</li> <li>• Prescriber Enrollment Form</li> </ul>	<ul style="list-style-type: none"> <li>• Eye Care Professional Consult Request Form or equivalent</li> <li>• Patient Status Form</li> </ul>	<ul style="list-style-type: none"> <li>• Eye Care Professional Consult Request Form or equivalent (Before each infusion)</li> <li>• Patient Status Form (Before each infusion)</li> </ul>
 <p><b>Healthcare Settings</b></p>	<ul style="list-style-type: none"> <li>• Prescribing Information</li> <li>• Program Overview</li> <li>• Education Program for Healthcare Settings</li> <li>• Healthcare Setting Enrollment Form</li> </ul>		<ul style="list-style-type: none"> <li>• REMS Checklist (within 5 business days of infusion)</li> </ul>
 <p><b>Patients</b></p>		<ul style="list-style-type: none"> <li>• Patient Guide</li> <li>• Patient Enrollment Form</li> </ul>	

Visit [www.BLENREPREMS.com](http://www.BLENREPREMS.com) to begin enrollment and for additional information.

You may also contact the BLENREP REMS at 1-855-209-9188.

You are encouraged to report adverse reactions of BLENREP to GSK at 1-888-825-5249 and/or FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).

**This is not a comprehensive description of the risks associated with the use of BLENREP. Please see the full Prescribing Information, including Boxed WARNING, WARNINGS AND PRECAUTIONS, and ADVERSE REACTIONS, for further information regarding the use of BLENREP.**



**BLENREP**  
belantamab  
mafodotin-blmf  
for injection 100 mg



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