I. Administrative Information

Application Number: BLA 761158
Application Holder: GlaxoSmithKline
Initial REMS Approval: [08/2020]

II. REMS Goal

The goal of the BLENREP REMS is to manage the risk of ocular toxicity by:

1. Ensuring that healthcare providers are educated on the risk of ocular toxicity associated with the use of BLENREP
2. Ensuring that healthcare providers are educated and adhere to the following:
   a. submit documentation that ophthalmic exams are being done at baseline and prior to each dose to identify ocular toxicity
   b. counsel patients on the risk of ocular toxicity and the requirement for monitoring via ophthalmic exams at baseline, prior to each dose, and promptly for worsening symptoms as described in the Prescribing Information
3. Ensuring safe use of BLENREP by:
   a. Ensuring that BLENREP is infused in certified healthcare settings only after verification of ophthalmic exams
4. Ensuring that patients are informed about:
   a. the risk of ocular toxicity associated with the use of BLENREP
   b. the requirement for ophthalmic exams at baseline, prior to each dose and promptly for worsening symptoms, as described in the Prescribing Information

III. REMS Requirements

GlaxoSmithKline must ensure that healthcare providers, patients, healthcare settings, and wholesalers-distributors comply with the following requirements:

1. Healthcare Providers who prescribe BLENREP must:

   To become certified to prescribe

   1. Review the drug’s Prescribing Information.
   2. Review the following: Program Overview and Education Program for Prescribers.
   3. Successfully complete the Knowledge Assessment and submit it to the REMS Program.
   4. Enroll in the REMS by completing the Prescriber Enrollment Form and submitting it to the REMS Program.
## Before treatment initiation (first dose)

<table>
<thead>
<tr>
<th>Step</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.</td>
<td>Counsel the patient on the risks associated with BLENREP, including the ocular toxicity and the requirement for monitoring via ophthalmic examinations (e.g., visual acuity and slit lamp) at baseline, prior to each dose, and promptly for worsening symptoms using the Patient Guide.</td>
</tr>
<tr>
<td>6.</td>
<td>Enroll the patient by completing and submitting the Patient Enrollment Form to the REMS Program.</td>
</tr>
<tr>
<td>7.</td>
<td>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.</td>
</tr>
<tr>
<td>8.</td>
<td>Assess the patient’s ophthalmic consult results for appropriateness of initiating treatment. Document and submit to the REMS Program using the Patient Status Form.</td>
</tr>
</tbody>
</table>

## During treatment; before each infusion

<table>
<thead>
<tr>
<th>Step</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>9.</td>
<td>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.</td>
</tr>
<tr>
<td>10.</td>
<td>Assess the patient’s ophthalmic consult results for appropriateness of continuing treatment. Document and submit to the REMS Program using the Patient Status Form.</td>
</tr>
</tbody>
</table>

## 2. Patients who are prescribed BLENREP:

| Before treatment initiation | 1. | Receive counseling from the prescriber 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. |
| During treatment; before each infusion | 4. | Get an eye exam. |
| At all times                | 5. | Inform the prescriber if you have signs or symptoms of worsening eyesight or eye health. |

## 3. Healthcare Settings that dispense BLENREP must:

| To become certified to dispense | 1. | Designate an authorized representative to carry out the certification process and oversee implementation and compliance with the REMS Program on behalf of the healthcare setting. |
|                                | 2. | Have the authorized representative review the Prescribing Information, Program Overview and Education Program for Health. |
### Care Settings.

3. Have the authorized representative enroll in the REMS Program by completing the **Healthcare Setting Enrollment Form** and submitting it to the REMS Program.

4. Train all relevant staff involved in dispensing BLENREP using the **Program Overview** and **Education Program for Health Care Settings**.

5. Establish processes and procedures to verify the **REMS Checklist** is completed and submitted for each patient.

<table>
<thead>
<tr>
<th>Before administering</th>
<th>6. Obtain authorization to dispense each dose by contacting the REMS Program to verify that the prescriber is certified, and the patient is enrolled and authorized to receive the drug.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>7. Complete the <strong>REMS Checklist</strong>.</td>
</tr>
<tr>
<td>After administering, within 5 business days</td>
<td>8. Submit the <strong>REMS Checklist</strong> to the REMS Program.</td>
</tr>
<tr>
<td>To maintain certification to dispense</td>
<td>9. Have a new authorized representative enroll in the REMS Program by completing and submitting the <strong>Healthcare Setting Enrollment Form</strong> to the REMS program.</td>
</tr>
<tr>
<td>At all times</td>
<td>10. Not distribute, transfer, loan, or sell BLENREP.</td>
</tr>
<tr>
<td></td>
<td>11. Maintain records documenting staff’s completion of REMS training.</td>
</tr>
<tr>
<td></td>
<td>12. Maintain records that all processes and procedures are in place and are being followed.</td>
</tr>
<tr>
<td></td>
<td>13. Comply with audits carried out by GlaxoSmithKline or a third party acting on behalf of GlaxoSmithKline to ensure that all processes and procedures are in place and are being followed.</td>
</tr>
</tbody>
</table>

### 4. Wholesalers-distributors that distribute BLENREP must:

<table>
<thead>
<tr>
<th>To be able to distribute</th>
<th>1. Establish processes and procedures to ensure that the drug is distributed only to certified healthcare settings.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2. Train all relevant staff involved in distribution on the REMS requirements.</td>
</tr>
<tr>
<td>At all times</td>
<td>3. Distribute only to certified healthcare settings.</td>
</tr>
<tr>
<td></td>
<td>4. Maintain records of all drug distribution.</td>
</tr>
<tr>
<td></td>
<td>5. Comply with audits carried out by GlaxoSmithKline or a third party acting on behalf of GlaxoSmithKline to ensure that all processes and procedures are in place and are being followed.</td>
</tr>
</tbody>
</table>
GlaxoSmithKline must provide training to healthcare providers who prescribe BLENREP. The training includes the following educational materials: Program Overview, Education Program for Prescribers and Prescriber Knowledge Assessment. The training must be available online and in a hard copy format via mail or fax.

GlaxoSmithKline must provide training to healthcare settings that dispense BLENREP. The training includes the following educational material: Program Overview and Education Program for Healthcare Settings. The training must be available online and in a hard copy format via mail or fax.

To inform healthcare providers about the REMS Program and the risks and safe use of BLENREP, GlaxoSmithKline must disseminate REMS communication materials according to the table below:

<table>
<thead>
<tr>
<th>Target Audience</th>
<th>Communication Materials &amp; Dissemination Plans</th>
</tr>
</thead>
</table>
| Healthcare providers likely to prescribe BLENREP, oncology nurses, and pharmacists | REMS Letter: Healthcare Provider REMS Letter, REMS Letter for Professional Societies with attachment: REMS Factsheet
1. Email within 30 calendar days of the date BLENREP is first commercially distributed and again 12 months later.
   a. Send by mail within 30 calendar days of the date the first email was sent if a healthcare provider’s email address is not available or the email is undeliverable.
   b. Send a second email within 30 calendar days of the date the first email was sent if the first email is marked as unopened.
   c. Send by mail within 30 calendar days of the date the second email was sent if the second email is marked as unopened.
2. Disseminate through field-based sales and medical representatives.
3. Disseminate through the following professional societies and request the letter or content be provided to their members.
   a. American Society of Clinical Oncology (ASCO), American Society of Hematology (ASH), Advanced Practitioner Society for Hematology and Oncology (APSHO), Oncology Nursing Society (ONS), National Comprehensive Cancer Network (NCCN), Society of Hematologic Oncology (SOHO), Hematology Oncology Pharmacy Association (HOPA)
4. Disseminate at Professional Meetings for 12 months from the date BLENREP is first commercially distributed.

Fact Sheet
1. Disseminate through field-based sales and medical representatives during the initial discussion with healthcare providers for 12 months after BLENREP is first commercially distributed. Field-based sales and/or medical representatives will discuss ocular toxicity and associated management messages contained in the REMS Factsheet during the visit with the health care provider.

To support REMS Program operations, GlaxoSmithKline must:
1. Authorize dispensing for each patient based on receipt of the Patient Enrollment Form and Patient Status Form on the following schedule: Authorize the first dispensing upon receipt of the Patient Enrollment Form and Patient Status Form. If a completed Patient Enrollment Form and Patient Status Form are not received, the patient is not authorized to receive the drug. For subsequent dispensing, authorize dispensing based on receipt of the Patient Status Form. The authorization is valid for 14 calendar days from receipt of the Patient Status Form.
2. Establish and maintain a REMS Program website, [www.BLENREPREMS.com](http://www.BLENREPREMS.com). The REMS Program website must include the capability to complete prescriber and healthcare setting certification and enrollment online, the capability to enroll and manage patients online, the capability to review patient enrollment status and prescriber and healthcare facility certification status, the capability to search for a REMS certified prescriber or healthcare facility, and the option to print the Prescribing Information, Medication Guide, and REMS materials. All product websites for consumers and healthcare providers must include prominent REMS-specific links to the REMS Program website. The REMS Program website must not link back to the promotional product website(s).

3. Make the REMS Program website fully operational and all REMS materials available through [www.BLENREPREMS.com](http://www.BLENREPREMS.com) and the REMS Program call center.

4. Establish and maintain a REMS Program call center for REMS participants at [1-855-209-9188].

5. Establish and maintain a validated, secure database of all REMS participants who are enrolled and/or certified in the BLENREP REMS Program.

6. Ensure prescribers and healthcare settings are able to complete the certification process online and by fax.

7. Ensure prescribers are able to use the Eye Care Professional Consult Request Form by fax and to adapt it as a template to use within healthcare information technology system software.

8. Ensure healthcare settings are able to obtain authorization to dispense BLENREP by phone and online.

9. Ensure healthcare settings are able to complete and submit the [REMS Checklist](#) online or by phone/fax.

10. Provide [Prescriber Enrollment Form](#), [Patient Enrollment Form](#), [Healthcare Setting Enrollment Form](#), [Program Overview](#), [Education Program for Prescribers](#), [Eye Care Professional Consult Request Form](#), [Patient Status Form](#), [REMS Checklist](#), [Education Program for Healthcare Settings](#), [Patient Guide](#) and the Prescribing Information to prescribers or healthcare settings who want to prescribe/dispense BLENREP but are not yet certified.

11. Notify prescribers and healthcare settings within 2 business days after they become certified in the REMS Program.

12. Provide certified prescribers access to the database of certified healthcare settings and their enrolled patients.

13. Provide certified healthcare settings access to the database of certified prescribers and enrolled patients.

14. Provide authorized wholesalers-distributors access to the database of certified healthcare settings.

To ensure REMS participants’ compliance with the REMS Program, GlaxoSmithKline must:

15. Verify annually that the designated authorized representative for the healthcare setting is the same. If different, the healthcare setting must re-certify with a new authorized representative.

16. Notify healthcare settings if a completed REMS Checklist has not been received by the REMS.

17. Maintain adequate records to demonstrate that REMS requirements have been met, including, but not limited to records of: drug distribution and administration; certification of prescribers and healthcare settings; enrolled patients; and audits of health care settings and wholesalers-distributors. These records must be readily available for FDA inspections.

18. Establish a plan for addressing noncompliance with REMS Program requirements.

19. Monitor prescribers and healthcare settings on an ongoing basis to ensure the requirements of the REMS are being met. Take corrective action if non-compliance is identified, including de-certification.

20. Audit certified health care settings no later than 180 calendar days after they have dispensed BLENREP, and once every 3 years thereafter to ensure that all REMS processes and procedures are in place, functioning, and support the REMS Program requirements.
21. Audit wholesalers-distributors that have distributed BLENREP no later than 90 calendar days after they become authorized to distribute the drug and annually thereafter to ensure that all REMS processes and procedures are in place, functioning, and support the REMS requirements.

22. Take reasonable steps to improve implementation of and compliance with the requirements in the BLENREP REMS Program based on monitoring and evaluation of the BLENREP REMS Program.

IV. REMS Assessment Timetable

GlaxoSmithKline must submit REMS Assessments at 6 months, 12 months, and annually thereafter from the date of the initial approval of the REMS. To facilitate inclusion of as much information as possible while allowing reasonable time to prepare the submission, the reporting interval covered by each assessment should conclude no earlier than 60 calendar days before the submission date for that assessment. GlaxoSmithKline must submit each assessment so that it will be received by the FDA on or before the due date.

V. REMS Materials

The following materials are part of the BLENREP REMS:

Enrollment Forms
Prescriber:
1. Prescriber Enrollment Form

Patient:
2. Patient Enrollment Form

Healthcare Setting:
3. Healthcare Setting Enrollment Form

Patient Care Forms
4. Patient Status Form
5. REMS Checklist
6. Eye Care Professional Consult Request Form

Training and Educational Materials

Prescriber:
7. Program Overview
8. Education Program for Prescribers
9. Prescriber Knowledge Assessment

Patient:
10. Patient Guide

Healthcare Setting:
11. Program Overview
12. Education Program for Health Care Settings

Communication Materials
13. Healthcare Provider REMS Letter

Reference ID: 4652412
14. REMS Fact Sheet
15. REMS Letter for Professional Societies

Other Materials
16. Program website
To become a certified prescriber in the BLENREP REMS and prescribe BLENREP:
1. Review the BLENREP Prescribing Information
2. Review the REMS Program Overview and Education Program for Prescribers
3. Successfully complete and submit the Knowledge Assessment to the BLENREP REMS
4. Enroll in the BLENREP REMS by completing and submitting this Prescriber Enrollment Form

Submit the completed Prescriber Enrollment Form:
- Go to www.BLENREPREMS.com to login and complete this form online. If online capabilities are not available this form can be completed and faxed to the BLENREP REMS at 1-888-635-1044.

(Fields marked with an * are REQUIRED)

### Prescriber Information

<table>
<thead>
<tr>
<th>Field</th>
<th>Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>First Name*</td>
<td>Middle Initial</td>
</tr>
<tr>
<td>Credentials*</td>
<td>MD</td>
</tr>
<tr>
<td>Specialty*</td>
<td>Oncology</td>
</tr>
<tr>
<td>National Provider Identifier (NPI) #*</td>
<td>State License #</td>
</tr>
</tbody>
</table>

### Address Information

<table>
<thead>
<tr>
<th>Field</th>
<th>Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Practice/Facility Name*</td>
<td></td>
</tr>
<tr>
<td>Address*</td>
<td></td>
</tr>
<tr>
<td>City*</td>
<td>State*</td>
</tr>
<tr>
<td>Phone*</td>
<td>Fax*</td>
</tr>
</tbody>
</table>

#### Preferred Method of Communication:
- [ ] Phone
- [ ] Fax
- [ ] Email

#### Preferred Time of Contact:
- [ ] AM
- [ ] PM

### Prescriber Delegate Information

Note: If you want to add a delegate, the first name, last name and email are required fields. If you have any questions, please reach out to the BLENREP REMS at 1-855-209-9188.

<table>
<thead>
<tr>
<th>Field</th>
<th>Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>First Name*</td>
<td>Last Name*</td>
</tr>
<tr>
<td>Email*</td>
<td></td>
</tr>
<tr>
<td>Address - Same as Prescriber</td>
<td></td>
</tr>
<tr>
<td>Address:</td>
<td>City:</td>
</tr>
<tr>
<td>Phone:</td>
<td>Fax:</td>
</tr>
</tbody>
</table>

### Alternative Practice/Facility Location

<table>
<thead>
<tr>
<th>Field</th>
<th>Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Address:</td>
<td></td>
</tr>
<tr>
<td>City:</td>
<td>State:</td>
</tr>
<tr>
<td>Phone:</td>
<td>Fax:</td>
</tr>
</tbody>
</table>
Prescriber Responsibilities

I have:
- Reviewed the drug's Prescribing Information.
- Reviewed the Program Overview and Education Program for Prescribers.
- Successfully completed the Knowledge Assessment and submitted it to the BLENREP REMS.

Before treatment initiation (first dose), I must:
- Counsel the patient, using the Patient Guide, on
  - the risk of ocular toxicity associated with BLENREP and
  - requirement for monitoring via ophthalmic examinations (e.g., visual acuity and slit lamp) at
    - baseline,
    - prior to each dose, and
    - promptly for worsening symptoms
- Enroll the patient by completing and submitting the Patient Enrollment Form to the BLENREP REMS.
- Assess the patient's ocular health by consulting an eye care professional to complete the visual acuity and slit lamp examinations using the Eye Care Professional Consult Request Form or equivalent.
- Assess the patient's ophthalmic consult results for appropriateness of initiating treatment. Document and submit to the BLENREP REMS using the Patient Status Form.

Before each infusion, I must
- 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.
- Assess the patient's ophthalmic consult results for appropriateness of continuing treatment. Document and submit to the BLENREP REMS using the Patient Status Form.

I understand that if I do not maintain compliance with the requirements of the BLENREP REMS, I will no longer be able to prescribe BLENREP.

I understand the BLENREP REMS may contact me via phone, mail, or email to discuss and/or to survey me on the effectiveness of the REMS requirements.

By signing this form, I agree BLENREP is only available through the BLENREP REMS and I must comply with the REMS Requirements.

Prescriber Signature*: ___________________________________________ Date*: __________________________

Print Name*: __________________________________________________

Month/Day/Year
BLENREP™ REMS Patient Enrollment Form

This form must be completed before you can receive BLENREP.

Your prescriber will submit the completed Form:
- Go to www.BLENREPREMS.com to login and complete this form online. If online capabilities are not available, this form can be completed and faxed to the BLENREP REMS at 1-888-635-1044.

Fields marked with an * are REQUIRED.

**Patient Information (Please Print)**

<table>
<thead>
<tr>
<th>First Name*</th>
<th>Middle Initial</th>
<th>Last Name*</th>
</tr>
</thead>
</table>

Date of Birth (MM/DD/YYYY)*: Gender: □ Female □ Male □ Other

Address*:

City*: State*: ZIP Code*:

Phone*: Email:

Preferred Method of contact*: □ Phone □ Email

Secondary Contact:

Phone for secondary contact:

**Prescriber Information: Please PRINT your name, National Provider Identifier (NPI) and phone number here.**

First Name*: Last Name*:

Prescriber National Provider Identifier (NPI)#*: Phone*:

**Patient Agreement:**

Before I start treatment, I must
- Receive counseling from my prescriber using the Patient Guide.
- Enroll in the BLENREP REMS by completing the Patient Enrollment Form with my prescriber.
- Get an eye exam.

During my treatment and before each infusion, I must
- Get an eye exam.

At all times
- I must inform my prescriber if I have any signs or symptoms of worsening eyesight or eye health including:
  - Blurry vision
  - Dry eyes
  - Worsening vision
- I understand I must tell the BLENREP REMS if I change my BLENREP doctor.
- I understand I must tell the BLENREP REMS if my contact information changes.
- I understand GlaxoSmithKline and its agents may use and share my personal information to enroll me into and manage the BLENREP REMS. Information about all patients who get BLENREP will be stored in a private and secure database. My health information may be shared with the U.S. Food and Drug Administration (FDA) to evaluate the BLENREP REMS. However, my name will not be shared.
- I give permission for GlaxoSmithKline and its agents to contact me or my prescriber by phone, mail, or email to manage the BLENREP REMS.

**Patient Acknowledgement**

By signing this form, I agree BLENREP is only available through the BLENREP REMS and I must comply with the REMS Requirements.

Patient/Legal Guardian Signature*: ______________________ Date*: _________ Month/Day/Year

PRINT NAME*: ______________________

**Prescriber Acknowledgement**

I have reviewed and discussed the risks of BLENREP and the requirements of the BLENREP REMS with this patient.

Prescriber Signature*: ______________________ Date*: _________ Month/Day/Year

PRINT NAME*: ______________________
Submit the completed Form:

- Go to www.BLENREPREMS.com to login and complete this form online. If online capabilities are not available this form can be completed and faxed to the BLENREP REMS at 1-888-635-1044.

(Fields marked with an * are REQUIRED)

Healthcare Setting Information

Healthcare Setting Name*:
National Provider Identifier (NPI)#*:
HIN:
DEA#:
Site Type*:
- Infusion Center
- Group Practice
- Independent Practice
- Outpatient Clinic
- Hospital
- Other (please specify)
Address*:
City*:
State*:
ZIP Code*:
Phone*:
Fax*:

Ship To Information

Ship To Address
- Same as above
Ship To Contact Name*:
Address*:
City*:
State*:
ZIP Code*:
Phone:
Fax:

Authorized Representative Information

First Name*:
Last Name*:
Credentials*:
- DO
- MD
- PharmD
- RN
- NP
- PA
- Other (please specify)
National Provider Identifier (NPI)#:
Phone*:
Fax*:
Email*:

Healthcare Setting Agreement:

As the Authorized Representative:
- I have reviewed the drug’s Prescribing Information.
- I have reviewed the Program Overview and Education Program for Healthcare Settings.
- I must train all relevant staff involved in dispensing and administering BLENREP using the Program Overview and Education Program for Healthcare Settings.
- I must establish processes and procedures to ensure the REMS Checklist is completed and submitted for each patient.

On behalf of the healthcare setting, I must comply with the following REMS requirements:

Before administering each dose:
- Obtain authorization to dispense each dose by contacting the BLENREP REMS to verify
  - The prescriber is certified in the BLENREP REMS
  - The patient is enrolled in the BLENREP REMS and authorized to receive this dose of BLENREP
- Complete the REMS Checklist

After administering BLENREP, within 5 business days:
- Submit the REMS Checklist to the BLENREP REMS.

At all times:
- Not distribute, transfer, loan or sell BLENREP.
- Maintain records documenting staff completion of REMS training.
- Maintain records that all processes and procedures are in place and are being followed.
- Comply with audits carried out by GlaxoSmithKline or third party acting on GlaxoSmithKline’s behalf to ensure that all processes and procedures are in place and are being followed.

By signing this form, I agree BLENREP is only available through the BLENREP REMS and I must comply with the REMS Requirements.

Authorized Representative Signature*:
Authorized Representative Signature*:
Date*:
Month/Day/Year

PRINT NAME:

GSK Final (08/2020)

Phone: 1-855-209-9188 www.BLENREPREMS.com Fax: 1-888-635-1044
Use this section to add each additional Healthcare Setting location for which the same Authorized Representative will be responsible.

(Fields marked with an * are REQUIRED)

<table>
<thead>
<tr>
<th>Healthcare Setting Information</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Healthcare Setting Name</strong>*:</td>
</tr>
<tr>
<td><strong>National Provider Identifier (NPI)#</strong>*:</td>
</tr>
<tr>
<td><strong>Site Type</strong>*:</td>
</tr>
<tr>
<td><strong>Address</strong>*:</td>
</tr>
<tr>
<td><strong>City</strong>*:</td>
</tr>
<tr>
<td><strong>Phone</strong>*:</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Ship To Information</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Ship To Address</strong>*:</td>
</tr>
<tr>
<td><strong>Address</strong>*:</td>
</tr>
<tr>
<td><strong>City</strong>*:</td>
</tr>
<tr>
<td><strong>Phone</strong>*:</td>
</tr>
</tbody>
</table>
# BLENREP™ REMS Healthcare Setting Enrollment Form

Use this section to request portal access for Healthcare Setting staff that are trained and authorized to use the BLENREP REMS portal to generate authorization codes prior to dispensing and submit REMS Checklists.

(Fields marked with an * are REQUIRED)

User Access Form. Please Print clearly.

<table>
<thead>
<tr>
<th>Healthcare Setting Name*</th>
<th>First Name*</th>
<th>Last Name*</th>
<th>Credentials*</th>
<th>Email*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
**BLENREP™ REMS Patient Status Form**

*For Certified Prescriber to Complete*

**INSTRUCTIONS for Prescriber**
- Complete this **BLENREP Patient Status Form** for each patient prior to each dose of BLENREP.
- Submit completed form online at www.BLENREPREMS.com. If online capabilities are not available, this form can be completed and faxed to the BLENREP REMS at 1-888-635-1044.

(All fields marked with an * are REQUIRED)

### Patient Information
- **First Name**: 
- **Middle Initial**: 
- **Last Name**: 
- **Date of Birth (MM/DD/YYYY)**: 
- **Phone**: 

### Prescriber Information
- **First Name**: 
- **Last Name**: 
- **National Provider Identifier (NPI)#**: 
- **Phone**: 
- **Fax**: 

### Eye Care Professional Information
- **First Name**: 
- **Last Name**: 
- **Phone**: 
- **Email**: 
- **Fax**: 
- **National Provider Identifier (NPI)#**: 
- **Practice/Facility Name**: 
- **Address**: 
- **City**: 
- **State**: 
- **ZIP Code**: 

### Prescriber Attestation
- I confirm that I have reviewed the ophthalmic exam for this patient and authorize treatment. 

### Assessment:
1. What are the current best corrected Snellen visual acuity results? 
   - Right eye (OD) /  Left eye (OS) / 

2. Is this the patient’s 1st dose? 

If no, please complete the rest of this form >>
Patient Status Form

<table>
<thead>
<tr>
<th>First Name*</th>
<th>Middle Initial</th>
<th>Last Name*</th>
<th>Date of Birth (MM/DD/YYYY)*</th>
</tr>
</thead>
</table>

3. Are you recommending dose modifications due to a corneal adverse event based on this ophthalmic assessment?  
☐ Yes  ☐ No

Please refer to Table 1 for information on relevant corneal examination findings for BLENREP.

If Y, please check affected eyes:
☐ Right eye (OD)  ☐ Left eye (OS)

If yes, please complete the following:

### Corneal Examination Findings and Change in BCVA from Baseline for Right Eye

<table>
<thead>
<tr>
<th>Corneal Examination Finding</th>
<th>Change in BCVA from Baseline (per Snellen Visual Acuity)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Check One</td>
<td>Check One</td>
</tr>
<tr>
<td>☐ No change from baseline</td>
<td>☐ No change from baseline</td>
</tr>
<tr>
<td>☐ Mild superficial keratopathy</td>
<td>☐ Decline from baseline of 1 line</td>
</tr>
<tr>
<td>☐ Moderate superficial keratopathy</td>
<td>☐ Decline from baseline of 2 or 3 lines on Snellen Visual Acuity and not worse than 20/200</td>
</tr>
<tr>
<td>☐ Severe superficial keratopathy</td>
<td>☐ Decline from baseline by more than 3 lines on Snellen Visual Acuity and not worse than 20/200</td>
</tr>
<tr>
<td>☐ Corneal epithelial defect</td>
<td>☐ Snellen Visual Acuity worse than 20/200</td>
</tr>
</tbody>
</table>

Additional Corneal Examination Finding:

---

### Corneal Examination Findings and Change in BCVA from Baseline for Left Eye

<table>
<thead>
<tr>
<th>Corneal Examination Finding</th>
<th>Change in BCVA from Baseline (per Snellen Visual Acuity)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Check One</td>
<td>Check One</td>
</tr>
<tr>
<td>☐ No change from baseline</td>
<td>☐ No change from baseline</td>
</tr>
<tr>
<td>☐ Mild superficial keratopathy</td>
<td>☐ Decline from baseline of 1 line</td>
</tr>
<tr>
<td>☐ Moderate superficial keratopathy</td>
<td>☐ Decline from baseline of 2 or 3 lines on Snellen Visual Acuity and not worse than 20/200</td>
</tr>
<tr>
<td>☐ Severe superficial keratopathy</td>
<td>☐ Decline from baseline by more than 3 lines on Snellen Visual Acuity and not worse than 20/200</td>
</tr>
<tr>
<td>☐ Corneal epithelial defect</td>
<td>☐ Snellen Visual Acuity worse than 20/200</td>
</tr>
</tbody>
</table>

Additional Corneal Examination Finding:

---
### Patient Status Form

First Name*:  | Middle Initial: | Last Name*: | Date of Birth (MM/DD/YYYY)*: |
---|---|---|---|

4. Was the last cycle held due to a corneal adverse reaction*?

- [ ] Yes  - [ ] No

Please refer to Table 1 for information on relevant corneal examination findings for BLENREP.

*If Y, please check affected eyes:*

- [ ] Right eye (OD)
- [ ] Left eye (OS)

*If yes, please complete the following*:

| Corneal Examination Findings and Change in BCVA from Baseline for Right Eye |
|---|---|---|---|
| **Right eye (OD)** | **Corneal Examination Finding** | **Check One** | **Change in BCVA from Baseline (per Snellen Visual Acuity)** | **Check One** |
| | **No change from baseline** | [ ] | **No change from baseline** | [ ] |
| | **Mild superficial keratopathy** | [ ] | **Decline from baseline of 1 line** | [ ] |
| | **Moderate superficial keratopathy** | [ ] | **Decline from baseline of 2 or 3 lines on Snellen Visual Acuity and not worse than 20/200** | [ ] |
| | **Severe superficial keratopathy** | [ ] | **Decline from baseline by more than 3 lines on Snellen Visual Acuity and not worse than 20/200** | [ ] |
| | **Corneal epithelial defect** | [ ] | **Snellen Visual Acuity worse than 20/200** | [ ] |

Additional Corneal Examination Finding:

---

5. What is the current grading from the examinations finding(s) and BCVA?

(Report the grade for the worst eye based on Keratopathy and Visual Acuity (KVA) scale) *Check one*

- [ ] Normal  - [ ] Grade 1  - [ ] Grade 2  - [ ] Grade 3  - [ ] Grade 4

---

GSK Final (08/2020)
Please submit this completed form to the BLENREP REMS online at www.BLENREPREMS.com or fax at 1-888-635-1044

<table>
<thead>
<tr>
<th>Signature*</th>
<th>Date*</th>
<th>Month/Day/Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Print Name*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Submitted by:</td>
<td>Prescriber</td>
<td>Prescriber Delegate</td>
</tr>
</tbody>
</table>

Please Note: A BLENREP REMS certified prescriber or prescriber delegate may complete and submit this form on behalf of the certified prescriber of record. The certified prescriber of record is responsible for compliance with the REMS requirements, including monitoring, evaluation, and management of each patient under his/her care.

**Dosage Modifications for Corneal Adverse Reactions per the KVA Scale.**

Determine the recommended dosage modification of BLENREP based on the worst finding in the worst affected eye. Worst finding should be based on either a corneal examination finding or a change in visual acuity per the Keratopathy and Visual Acuity (KVA) scale.

| Table 1. Dosage Modifications for Corneal Adverse Reactions per the KVA Scalea |
|---------------------------------|---------------------------------|
| **Corneal Adverse Reaction**    | **Recommended Dosage Modifications** |
| Normal                          | Continue treatment at current dose. |
| Change in BCVA<:                | No change from baseline. |
| Normal                          | Continue treatment at current dose. |
| Change in BCVA<:                | No decline from baseline of 1 line on Snellen Visual Acuity. |
| Grade 1                         | Withhold BLENREP until improvement in both corneal examination findings and change in BCVA to Grade 1 or better and resume at same dose. |
| Change in BCVA<:                | No decline from baseline of 2 or 3 lines on Snellen Visual Acuity and not worse than 20/200. |
| Grade 2                         | Withhold BLENREP until improvement in both corneal examination findings and change in BCVA to Grade 1 or better and resume at reduced dose. |
| Change in BCVA<:                | Decline from baseline by more than 3 lines on Snellen Visual Acuity and not worse than 20/200. |
| Grade 3                         | Consider permanent discontinuation of BLENREP. If continuing treatment, withhold BLENREP until improvement in both corneal examination findings and change in BCVA to Grade 1 or better and resume at reduced dose. |
| Change in BCVA<:                | Snellen Visual Acuity worse than 20/200. |

* Adapted and modified from the Prescribing Information:

• Severe superficial keratopathy with or without diffuse microcyst-like deposits, sub-epithelial haze (central), or a new central stromal opacity.

• Corneal epithelial defect such as corneal ulcers.
REMS Checklist

For Healthcare Setting Use

As a condition of your authorization to infuse BLENREP, this checklist must be completed online or faxed to 1-888-635-1044.

Verify patient eligibility by obtaining an authorization code prior to dispensing BLENREP online at www.BLENREPREMS.com.

1. Log into the BLENREP REMS online portal at www.BLENREPREMS.com
2. Select the REMS Verification tab in the online portal to verify patient eligibility (i.e. prescriber is certified, patient is enrolled and authorized to receive the dose)
   a. If the patient is eligible you must generate an authorization code prior to dispensing BLENREP
   b. If the patient is not eligible call the BLENREP REMS at 1-855-209-9188
3. Select the REMS Checklist Tab (online portal referenced above) to provide the dosing information and submit within 5 days of the infusion.

If you complete this information online, you do not need to fax a paper copy to the BLENREP REMS.

If online capabilities are not available, you have the option to call the BLENREP REMS at 1-855-209-9188 to verify patient eligibility and obtain an authorization code prior to dispensing BLENREP.

(Fields marked with an * are REQUIRED)

<table>
<thead>
<tr>
<th>Patient Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>First Name*:</td>
</tr>
<tr>
<td>Last Name*:</td>
</tr>
<tr>
<td>Date of Birth (MM/DD/YYYY):</td>
</tr>
<tr>
<td>Patient BLENREP REMS Identification #:</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Prescriber Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>First Name*:</td>
</tr>
<tr>
<td>Last Name*:</td>
</tr>
<tr>
<td>National Provider Identifier (NPI) #:</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Healthcare Setting Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Healthcare Setting Name*:</td>
</tr>
<tr>
<td>National Provider Identifier (NPI) #:</td>
</tr>
<tr>
<td>Healthcare Setting BLENREP REMS Identification #:</td>
</tr>
<tr>
<td>Phone*:</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Authorization Code Prior to Dispensing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Authorization:</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Dosing Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date of infusion (MM/DD/YYYY)*:</td>
</tr>
<tr>
<td>Actual dose (mg)*:</td>
</tr>
</tbody>
</table>
**Signature of Staff Completing Checklist**

<table>
<thead>
<tr>
<th>First Name*</th>
<th>Last Name*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Signature*

<table>
<thead>
<tr>
<th>Credentials*</th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th>Other (please specify)</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ DO</td>
<td>☐ MD</td>
<td>☐ PharmD</td>
<td>☐ RN</td>
<td>☐ NP</td>
<td>☐ PA</td>
<td>☐ Other (please specify)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Phone*</th>
<th>Fax*</th>
<th>E-mail*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Send infusion information to the BLENREP REMS**

Fax to the BLENREP REMS at 1-888-635-1044 within 5 business days of infusion. You will receive a confirmation of receipt via e-mail.
BLENREP™ REMS Eye Care Professional Consult Form

This patient is being treated with BLENREP (belantamab-mafodotin-blmf). BLENREP can cause 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 examinations (visual acuity and slit lamp) at baseline, prior to each dose, and promptly for worsening symptoms.

The information that is requested in this form is vital for the prescriber of BLENREP to make treatment and dose modification decisions.

INSTRUCTIONS
• Please complete this form and provide to the prescriber. This form may be faxed, carried by the patient or adapted into healthcare technology.

(All fields marked with an * are REQUIRED)

Patient Information
<table>
<thead>
<tr>
<th>First Name:</th>
<th>Middle Initial:</th>
<th>Last Name:</th>
</tr>
</thead>
</table>

Date of Birth (MM/DD/YYYY)*: Phone:

Prescriber Information:
<table>
<thead>
<tr>
<th>First Name:</th>
<th>Last Name:</th>
</tr>
</thead>
</table>

Phone: Fax: Email:

Eye Care Professional Information
<table>
<thead>
<tr>
<th>First Name:</th>
<th>Last Name:</th>
<th>Credentials:</th>
</tr>
</thead>
</table>

Phone: Fax: Email:

Information for Eye Care Professional:
The prescriber will determine the recommended dosage modification of BLENREP based on the worst finding in the worst affected eye.

During the ophthalmic exam, the eye care professional should:
• Assess the patient for corneal examination finding(s) and decline of best corrected visual acuity (BCVA).
• Determine the most severely affected eye as both eyes may not be affected to the same degree.
• Report the grade for the worst eye for examination finding(s) and BCVA to the treating physician by using Table 1 Corneal Adverse Reactions for KVA Scale, which was used in the clinical trial.

Corneal Examination Findings and Best Corrected Visual Acuity
Please refer to Table 1 for information on relevant examination findings for BLENREP

Date of Assessment: __________________________

Section 1: For Baseline Examination Only
• What are the current best corrected Snellen visual acuity results?
  OD ____/____ OS ____/____
**Section 2: For Follow Up Examinations**

- What are the current best corrected Snellen visual acuity results?
  - OD __/___ OS __/___

- Were there findings upon corneal examination and/or visual acuity assessment?  
  - Yes  
  - No

  If Y, please check affected eyes:
  - OD
  - OS
  - OU

---

### Corneal Examination Findings and Change in BCVA from Baseline for Right Eye

<table>
<thead>
<tr>
<th>Corneal Examination Findings</th>
<th>Changes in BCVA from Baseline (per Snellen Visual Acuity)</th>
<th>Check One</th>
</tr>
</thead>
<tbody>
<tr>
<td>No change from baseline</td>
<td>No change from baseline</td>
<td></td>
</tr>
<tr>
<td>Mild superficial keratopathy</td>
<td>Decline from baseline of 1 line</td>
<td></td>
</tr>
<tr>
<td>Moderate superficial keratopathy</td>
<td>Decline from baseline of 2 or 3 lines on Snellen Visual Acuity and not worse than 20/200</td>
<td></td>
</tr>
<tr>
<td>Severe superficial keratopathy</td>
<td>Decline from baseline by more than 3 lines on Snellen Visual Acuity and not worse than 20/200</td>
<td></td>
</tr>
<tr>
<td>Corneal epithelial defect</td>
<td>Snellen Visual Acuity worse than 20/200</td>
<td></td>
</tr>
</tbody>
</table>

**Additional Corneal Examination Finding:**

---

### Corneal Examination Findings and BCVA Changes from Baseline for Left Eye

<table>
<thead>
<tr>
<th>Corneal Examination Findings</th>
<th>Changes in BCVA from Baseline (per Snellen Visual Acuity)</th>
<th>Check One</th>
</tr>
</thead>
<tbody>
<tr>
<td>No change from baseline</td>
<td>No change from baseline</td>
<td></td>
</tr>
<tr>
<td>Mild superficial keratopathy</td>
<td>Decline from baseline of 1 line</td>
<td></td>
</tr>
<tr>
<td>Moderate superficial keratopathy</td>
<td>Decline from baseline of 2 or 3 lines on Snellen Visual Acuity and not worse than 20/200</td>
<td></td>
</tr>
<tr>
<td>Severe superficial keratopathy</td>
<td>Decline from baseline by more than 3 lines on Snellen Visual Acuity and not worse than 20/200</td>
<td></td>
</tr>
<tr>
<td>Corneal epithelial defect</td>
<td>Snellen Visual Acuity worse than 20/200</td>
<td></td>
</tr>
</tbody>
</table>

**Additional Corneal Examination Finding:**

---

**Section 3: What is the current grading from the examination finding(s) and BCVA?** (Report the grade for the worst eye by checking the box)

**Table 1. Corneal Adverse Reactions per the for KVA Scale.**

<table>
<thead>
<tr>
<th>Corneal Adverse Reaction</th>
<th>Checks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Corneal examination finding(s)</td>
<td>Grade 1</td>
</tr>
<tr>
<td>Decline from baseline of 1 line on Snellen Visual Acuity</td>
<td></td>
</tr>
<tr>
<td>Change in BCVA: Decline from baseline of 1 line on Snellen Visual Acuity</td>
<td></td>
</tr>
<tr>
<td>Grade 2</td>
<td></td>
</tr>
<tr>
<td>Corneal examination finding(s): Mild superficial keratopathy</td>
<td></td>
</tr>
<tr>
<td>Change in BCVA: Decline from baseline of 2 or 3 lines on Snellen Visual Acuity and not worse than 20/200</td>
<td></td>
</tr>
<tr>
<td>Grade 3</td>
<td></td>
</tr>
<tr>
<td>Corneal examination finding(s): Severe superficial keratopathy</td>
<td></td>
</tr>
<tr>
<td>Change in BCVA: Decline from baseline by more than 3 lines on Snellen Visual Acuity and not worse than 20/200</td>
<td></td>
</tr>
<tr>
<td>Grade 4</td>
<td></td>
</tr>
<tr>
<td>Corneal epithelial defect</td>
<td></td>
</tr>
<tr>
<td>Change in BCVA: Snellen Visual Acuity worse than 20/200</td>
<td></td>
</tr>
</tbody>
</table>

*Adapted and modified from the Prescribing Information

- Mild superficial keratopathy (documented worsening from baseline), with or without symptoms.

- Change in visual acuity due to treatment-related corneal findings.

- Moderate superficial keratopathy with or without patchy microcyst-like deposits, sub-epithelial haze (peripheral), or a new peripheral stromal opacity.

- Severe superficial keratopathy with or without diffuse microcyst-like deposits, sub-epithelial haze (central), or a new central stromal opacity.

- Corneal epithelial defect such as corneal ulcers.
BLENREP Risk Evaluation and Mitigation Strategy (REMS) Program Overview

If you have any questions regarding the BLENREP REMS, please visit www.BLENREPREMS.com or call 1-855-209-9188.

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.

**Prescribers**

**To prescribe BLENREP:**
1. **Become certified** by completing a one-time certification process.
2. As you start patients on BLENREP, **counsel and enroll** them into the BLENREP REMS and **complete Patient Status Forms** prior to each dose.

**Healthcare Settings**

**To dispense BLENREP:**
1. **Designate an authorized representative and become certified** by completing a one-time certification process.
2. **Train** staff and **comply** with REMS requirements.
3. **Obtain authorization** 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. **Complete and Submit the REMS Checklist.**

**Patients**

**To receive BLENREP:**
1. **Understand the eye problems** associated with BLENREP.
2. **Understand the need to get an eye exam at baseline, prior to each dose, and promptly for worsening symptoms.**
3. **Enroll** in the BLENREP REMS by completing the **Patient Enrollment Form** with your healthcare provider.
4. **Inform** your healthcare provider if you have signs or symptoms of worsening eyesight or eye health.

**Wholesalers-Distributors**

**To be able to distribute BLENREP:**
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.

Phone: 1-855-209-9188  www.BLENREPREMS.com  Fax: 1-888-635-1044
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)

Enroll Your Patients

Before starting each patient on BLENREP

1. **Counsel** your patient using the Patient Guide about the
   1) the risk of ocular toxicity and
   2) the requirements 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 within 2 business days (if enrollment of initiating treatment.

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.
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.

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’s 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

During Treatment; before each dose
1. Get an eye exam

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

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. 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

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

<table>
<thead>
<tr>
<th>Before Prescribing/Dispensing</th>
<th>Before treatment initiation (first dose)</th>
<th>During treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Prescribers</strong></td>
<td><strong>Healthcare Settings</strong></td>
<td><strong>Patients</strong></td>
</tr>
<tr>
<td>• Prescribing Information</td>
<td>• Prescribing Information</td>
<td>• Patient Guide</td>
</tr>
<tr>
<td>• Program Overview</td>
<td>• Program Overview</td>
<td>• Patient Enrollment Form</td>
</tr>
<tr>
<td>• Education Program for Prescribers</td>
<td>• Education Program for Healthcare Settings</td>
<td></td>
</tr>
<tr>
<td>• Prescriber Knowledge Assessment</td>
<td>• Healthcare Setting Enrollment Form</td>
<td></td>
</tr>
<tr>
<td>• Prescriber Enrollment Form</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Eye Care Professional Consult Request Form or equivalent</td>
<td>• Eye Care Professional Consult Request Form or equivalent (Before each infusion)</td>
<td>• REMS Checklist (within 5 business days of infusion)</td>
</tr>
<tr>
<td>• Patient Status Form</td>
<td>• Patient Status Form (Before each infusion)</td>
<td></td>
</tr>
</tbody>
</table>

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 Risk Evaluation and Mitigation Strategy (REMS)
Education Program for Prescribers
Important information

• This educational module contains information on BLENREP (belantamab mafodotin-blmf) associated ocular adverse events observed in DREAMM-2 (Study 205678) in patients with relapsed or refractory multiple myeloma.

• Because of the risks of ocular toxicity, BLENREP is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the BLENREP REMS.

• This education module is not intended to be a comprehensive description of risks associated with the use of BLENREP.

• Please see full Prescribing Information, including Boxed WARNING, WARNINGS AND PRECAUTIONS, and ADVERSE REACTIONS, for further information regarding the use of BLENREP.
# Table of Contents

**BLENREP REMS Summary and Key US Prescribing Information**

**BLENREP: Overview and Clinical Data**
- Mechanism of Action
- DREAMM-2 Study Data
- Safety Data

**BLENREP: Management of Ocular Adverse Reactions**
- Corneal Adverse Reactions and Dose Modifications
- Patient Counseling and Monitoring

**BLENREP REMS Goals and Operations**
- REMS Process Overview and Goals
- Reminders
BLENREP:
REMS Summary and
Key US Prescribing Information
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.
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.
BLENREP: Overview and Clinical Data
Overview of BLENREP: What it is and how it works

The Target

**B-cell maturation antigen (BCMA)** is a protein expressed on normal B lymphocytes and multiple myeloma cells that promotes cellular proliferation and survival.\(^1\)\(^,\)\(^2\)

The agent and mechanism of action

BLENREP is a BCMA-directed antibody and microtubule inhibitor conjugate, composed of 3 components.\(^3\)

1. **Anti-BCMA**, humanized IgG1 mAb that binds to BCMA-expressing MM cells
2. **MMAF**, microtubule-disrupting cytotoxic agent that leads to apoptosis of BCMA-expressing MM cells
3. **Protease-resistant, maleimido-caproyl linker** that joins the MMAF to the mAb

ADC = antibody-drug conjugate; ADCC = antibody-dependent cellular cytotoxicity; ADCP = antibody-dependent cellular phagocytosis; BCMA = B-cell maturation antigen; Fc = fragment crystallizable; IgG1 = immunoglobulin G1; mAb = monoclonal antibody; MM = multiple myeloma; MMAF = monomethyl auristatin F

The safety and efficacy of BLENREP as a single agent were evaluated in the DREAMM-2 study.

- DREAMM-2 was an open-label, multicenter study.
- Eligible patients had:
  - relapsed or refractory multiple myeloma
  - previously received 3 or more prior therapies, including an anti-CD38 monoclonal antibody
  - were refractory to an immunomodulatory agent and a proteasome inhibitor
- Patients with corneal epithelial disease, except mild punctate keratopathy, at baseline were excluded from the study.
- Patients had measurable disease by International Myeloma Working Group (IMWG) criteria.
- Patients received either BLENREP 2.5 mg/kg or 3.4 mg/kg intravenously once every 3 weeks until disease progression or unacceptable toxicity.
  - Only the efficacy results of the recommended dosage of 2.5 mg/kg are described in the Prescribing Information.
- The major efficacy outcome measure was overall response rate as evaluated by an Independent Review Committee (IRC) based on the IMWG Uniform Response Criteria for Multiple Myeloma.
Ocular Adverse Reactions Observed in the 2.5mg/kg Cohort of DREAMM-2

<table>
<thead>
<tr>
<th>Adverse Reactions (≥10%) in Patients Who Received BLENREP in DREAMM-2</th>
<th>BLENREP 2.5 mg/kg dosing; N = 95</th>
</tr>
</thead>
<tbody>
<tr>
<td>All Grades (%)</td>
<td>Grade 3-4 (%)</td>
</tr>
<tr>
<td>Keratopathy(^a)</td>
<td>71</td>
</tr>
<tr>
<td>Decreased Visual Acuity(^b)</td>
<td>53</td>
</tr>
<tr>
<td>Blurred Vision(^c)</td>
<td>22</td>
</tr>
<tr>
<td>Dry Eyes(^d)</td>
<td>14</td>
</tr>
</tbody>
</table>

The most common ocular adverse reactions (≥20%) were keratopathy, decreased visual acuity, and blurred vision.

The most frequent adverse reaction resulting in permanent discontinuation was keratopathy (2.1%).

Ocular adverse reactions which required a dosage interruption in >3% of patients included keratopathy (47%), blurred vision (5%) and dry eye (3.2%).

Ocular adverse reactions which required a dose reduction in >3% of patients included keratopathy (23%).

Clinically relevant adverse reactions in <10% of patients included the following eye disorders: Photophobia, eye irritation, infective keratitis, ulcerative keratitis.

\(^a\)Keratopathy was based on slit lamp eye examination, characterized as corneal epithelium changes with or without symptoms.

\(^b\)Decreased visual acuity changes were determined upon eye examination.

\(^c\)Blurred vision included diplopia, vision blurred, visual acuity reduced, and visual impairment.

\(^d\)Dry eyes included dry eye, ocular discomfort, and eye pruritus.

Prescribing Information for BLENREP.
### Warnings and Precautions: Ocular Toxicity

<table>
<thead>
<tr>
<th>Ocular Adverse Reactions</th>
<th>BLENREP 2.5 mg/kg dosing</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N = 95</td>
</tr>
<tr>
<td><strong>Keratopathy</strong>&lt;sup&gt;a&lt;/sup&gt;</td>
<td>71% (n=67)</td>
</tr>
<tr>
<td>With Ocular Symptoms&lt;sup&gt;b&lt;/sup&gt;</td>
<td>43% (n=29)</td>
</tr>
<tr>
<td>With decline of 2 or more lines on Snellen Visual Acuity in any eye</td>
<td>66% (n=44)</td>
</tr>
<tr>
<td>With both Ocular Symptoms and decline of 2 or more lines on Snellen Visual Acuity in any eye</td>
<td>30% (n=20)</td>
</tr>
<tr>
<td><strong>Visual Acuity Changes</strong>&lt;sup&gt;c&lt;/sup&gt;</td>
<td>53% (n=50)</td>
</tr>
<tr>
<td><strong>Blurred Vision</strong>&lt;sup&gt;d&lt;/sup&gt;</td>
<td>22% (n=21)</td>
</tr>
<tr>
<td><strong>Dry Eye</strong>&lt;sup&gt;e&lt;/sup&gt;</td>
<td>14% (n=13)</td>
</tr>
</tbody>
</table>

<sup>a</sup>Keratopathy was based on slit lamp eye examination, characterized as corneal epithelium changes with or without symptoms

<sup>b</sup>Ocular symptoms included visual acuity changes, blurred vision, or dry eye

<sup>c</sup>Visual acuity changes included all grade BCVA change per KVA scale

<sup>d</sup>Blurred vision included diplopia, vision blurred, visual acuity reduced, and visual impairment

<sup>e</sup>Dry eyes included dry eye, ocular discomfort, and eye pruritus.

DREAMM-2 Data on file.
Warnings and Precautions: Keratopathy

• Keratopathy was reported in 67 of 95 patients as (per the KVA scale):

<table>
<thead>
<tr>
<th>Grade per KVA Scale</th>
<th>Patients with Keratopathy</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>BLENREP 2.5 mg/kg dosing; N = 95</td>
</tr>
<tr>
<td>All Grades</td>
<td>71%</td>
</tr>
<tr>
<td>Grade 1</td>
<td>8%</td>
</tr>
<tr>
<td>Grade 2</td>
<td>18%</td>
</tr>
<tr>
<td>Grade 3</td>
<td>44%</td>
</tr>
<tr>
<td>Grade 4</td>
<td>0%</td>
</tr>
</tbody>
</table>

• Most keratopathy events developed within the first 2 treatment cycles (cumulative incidence of 54% by Cycle 2).

*Keratopathy was based on slit lamp eye examination, characterized as corneal epithelium changes with or without symptoms
Based on 21JUN2019 data cut-off. 1 patient experienced a grade 4 event (corneal ulcer / infective keratitis) per KVA at the 9-month safety update
DREAMM-2 Data on file.
Resolution of Grade 2-4 Keratopathy\textsuperscript{a}; Median follow up: 6.3 months

<table>
<thead>
<tr>
<th>Patients with Keratopathy (Grade ≥ 2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>BLENREP 2.5 mg/kg dosing, N = 59</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Recovered to Grade 1 or lower, %</th>
<th>41%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Median time to resolution, days (range)</td>
<td>62 (11, 193)</td>
</tr>
<tr>
<td>Had ongoing keratopathy, %</td>
<td>59%</td>
</tr>
<tr>
<td>Still on treatment</td>
<td>29%</td>
</tr>
<tr>
<td>In follow-up</td>
<td>7%</td>
</tr>
<tr>
<td>Follow-up ended due to death, study withdrawal, or lost to follow up</td>
<td>24%</td>
</tr>
</tbody>
</table>

\textsuperscript{a}Keratopathy was based on slit lamp eye examination, characterized as corneal epithelium changes with or without symptoms

DREAMM-2 Data on file.
## Visual Acuity Changes

### BLENREP 2.5 mg/kg dosing

<table>
<thead>
<tr>
<th>Visual Acuity in Better-seeing Eye Worse than 20/40</th>
<th>Visual Acuity in Better-seeing Eye 20/200 or Worse</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients, %</td>
<td>17%</td>
</tr>
<tr>
<td>Resolved, %</td>
<td>94%</td>
</tr>
<tr>
<td>Median duration, days (range)</td>
<td>22 (7-64 days)</td>
</tr>
<tr>
<td></td>
<td>22 (22-22 days)</td>
</tr>
</tbody>
</table>

N = 95

DREAMM-2 Data on file.
BLENREP: Management of Ocular Adverse Reactions
Monitoring and Required Ophthalmic Exams

- Conduct ophthalmic examinations (visual acuity and slit lamp) at baseline, prior to each dose, and promptly for worsening symptoms.
  - Perform baseline examinations within 3 weeks prior to the first dose.
  - Perform each follow-up examination at least 1 week after the previous dose and within 2 weeks prior to the next dose.
- Withhold BLENREP until improvement and resume at same or reduced dose, or consider permanently discontinuing, based on severity (see Dosage and Admin (2.3), US Prescribing Information)
Recommended Dosage

The recommended dosage of BLENREP is 2.5 mg/kg of actual body weight given as an intravenous infusion over approximately 30 minutes once every 3 weeks until disease progression or unacceptable toxicity.

Dosage Modifications for Adverse Reactions

The recommended dose reduction for adverse reactions is:
- BLENREP 1.9 mg/kg intravenously once every 3 weeks.
- Discontinue BLENREP in patients who are unable to tolerate a dose of 1.9 mg/kg.

Corneal Adverse Reaction
- The recommended dosage modifications for corneal adverse reactions, based on both corneal examination findings and changes in best-corrected visual acuity (BCVA), are provided in on the following slide
- Determine the recommended dosage modification of BLENREP based on the worst finding in the worst affected eye.
- Worst finding should be based on either a corneal examination finding or a change in visual acuity per the Keratopathy and Visual Acuity (KVA) scale.
## Dosage Modifications for Corneal Adverse Reactions per the KVA Scale

<table>
<thead>
<tr>
<th>Category</th>
<th>Corneal Adverse Reaction</th>
<th>Recommended Dosage Modifications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grade 1</td>
<td>Corneal examination finding(s): Mild superficial keratopathy&lt;sup&gt;a&lt;/sup&gt; Change in BCVA&lt;sup&gt;b&lt;/sup&gt;: Decline from baseline of 1 line on Snellen Visual Acuity</td>
<td>Continue treatment at current dose.</td>
</tr>
<tr>
<td>Grade 2</td>
<td>Corneal examination finding(s): Moderate superficial keratopathy&lt;sup&gt;c&lt;/sup&gt; Change in BCVA&lt;sup&gt;b&lt;/sup&gt;: Decline from baseline of 2 or 3 lines on Snellen Visual Acuity and not worse than 20/200</td>
<td>Withhold BLENREP until improvement in both corneal examination findings and changes in BCVA to Grade 1 or better and resume at same dose.</td>
</tr>
<tr>
<td>Grade 3</td>
<td>Corneal examination finding(s): Severe superficial keratopathy&lt;sup&gt;d&lt;/sup&gt; Change in BCVA&lt;sup&gt;b&lt;/sup&gt;: Decline from baseline by more than 3 lines on Snellen Visual Acuity and not worse than 20/200</td>
<td>Withhold BLENREP until improvement in both corneal examination findings and changes in BCVA to Grade 1 or better and resume at reduced dose.</td>
</tr>
<tr>
<td>Grade 4</td>
<td>Corneal examination finding(s): Corneal epithelial defect&lt;sup&gt;e&lt;/sup&gt; Change in BCVA&lt;sup&gt;b&lt;/sup&gt;: Snellen Visual Acuity worse than 20/200</td>
<td>Consider permanent discontinuation of BLENREP. If continuing treatment, withhold BLENREP until improvement in both corneal examination findings and change in BCVA to Grade 1 or better and resume at reduced dose.</td>
</tr>
</tbody>
</table>

<sup>a</sup>Mild superficial keratopathy (documented worsening from baseline), with or without symptoms;  
<sup>b</sup>Changes in visual acuity due to treatment-related corneal findings;  
<sup>c</sup>Moderate superficial keratopathy with or without patchy microcyst-like deposits, sub-epithelial haze (peripheral), or a new peripheral stromal opacity;  
<sup>d</sup>Severe superficial keratopathy with or without diffuse microcyst-like deposits, sub-epithelial haze (central), or a new central stromal opacity;  
<sup>e</sup>Corneal epithelial defect such as corneal ulcers.

Reference Prescribing Information for BLENREP for management of other adverse reactions

Prescribing Information for BLENREP
Patient counseling can support management and identification of corneal adverse reactions

Prior to starting treatment with BLENREP, advise patients:

- That ocular toxicity may occur during treatment with BLENREP
- To use preservative-free lubricant eye drops at least 4 times a day starting with the first infusion and continuing until end of treatment.
- To avoid wearing contact lenses during treatment unless directed by an ophthalmologist
- That changes in visual acuity may be associated with difficulty for driving and reading. Advise patients to use caution when driving or operating machinery.
- Tell your healthcare provider if you notice any changes with your eyes, such as dry eyes, blurred vision, worsening vision
- Your healthcare provider will send you to see an eye specialist
- During treatment, even if your vision seems fine, it is important that you get your eyes checked prior to each dose because some changes can happen without symptoms
REMS Goals and Operations
The goal of the BLENREP REMS is to manage the risk of ocular toxicity by:

1. Ensuring that healthcare providers are educated on the risk of ocular toxicity associated with the use of BLENREP

2. Ensuring that healthcare providers are educated and adhere to the following:
   a. submit documentation that ophthalmic exams are being done at baseline and prior to each dose to identify ocular toxicity
   b. counsel patients on the risk of ocular toxicity and the requirement for monitoring via ophthalmic exams at baseline, prior to each dose, and promptly for worsening symptoms as described in the Prescribing Information

3. Ensuring safe use of BLENREP by:
   a. Ensuring that BLENREP is infused in certified healthcare settings only after verification of ophthalmic exams

4. Ensuring that patients are informed about:
   a. the risk of ocular toxicity associated with the use of BLENREP
   b. the requirement for ophthalmic exams at baseline, prior to each dose and promptly for worsening symptoms, as described in the Prescribing Information
Prior to prescribing BLENREP, the Prescriber will review training materials, complete a Knowledge Assessment, and enroll in the REMS.

1. Review Training Materials
2. Complete Knowledge Assessment
3. Enroll in the REMS
Access and Complete Knowledge Assessment following review of Training Materials

Answer nine multiple choice and/or true/false questions

If you answer all questions correctly, you will proceed to finalize enrollment

If you do not answer all questions correctly, you will have 2 more opportunities to complete the Assessment. Incorrect answers will be indicated with a red X

If you do not answer all questions correctly after 3 attempts, you must review educational materials prior to attempting the test again

Question 1 ×
While on treatment with BLENREP
After completing the Knowledge Assessment, fill out and submit the Prescriber Enrollment Form to complete enrollment.
You may designate a delegate who will be copied on your automatic e-mail notifications; you may also designate a second practice location. Delegates added by Prescribers will be able to enter Patient Status Forms on their behalf starting in late 2020. The Certified Prescriber of Record is responsible for compliance with the REMS Requirements, including monitoring, evaluation, and management of each patient under his or her care.
Review and agree to Prescriber Responsibilities to complete enrollment

**Prescriber Responsibilities**

I have:
- Reviewed the drug’s Prescribing Information.
- Reviewed the Program Overview and Education Program for Prescribers.
- Successfully completed the Knowledge Assessment and submitted it to the BLENREP REMS.

Before treatment initiation (first dose), I must:
- Counsel the patient, using the Patient Guide on:
  - the risk of ocular toxicity associated with BLENREP and
  - requirement for monitoring via ophthalmic examinations (e.g., visual acuity and slit lamp) at:
    - baseline,
    - prior to each dose, and
    - promptly for worsening symptoms
- Enroll the patient by completing and submitting the Patient Enrollment Form to the BLENREP REMS.
- 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.
- Assess the patient’s ophthalmic consult results for appropriateness of initiating treatment. Document and submit to the BLENREP REMS using the Patient Status Form.

Before each infusion, I must:
- Assess the patient’s ocular health by consulting an eye care professional to complete visual acuity and slit lamp using the Eye Care Professional Consult Request Form or equivalent.
- Assess the patient’s ophthalmic consult results for appropriateness of continuing treatment. Document and submit to the REMS Program using the Patient Status Form.

I understand that if I do not maintain compliance with the requirements of the BLENREP REMS, I will no longer be able to prescribe BLENREP.

By signing this form, I agree BLENREP is only available through the BLENREP REMS and I must comply with the REMS Requirements.

Click “Prescriber Signature” and then “Submit” to complete enrollment.
To enroll patients, the prescriber will login to BLENREPREMS.com, access “My Patients” and select “Enroll Patient”.

Enter Name and Date of Birth

Click “Enroll Patient” to begin Patient Enrollment; each Patient must be enrolled prior to receiving BLENREP.
Patients will provide their contact information
To allow Patients or Legal Guardians to electronically sign and agree to the terms, patients will receive a verification code via email or text message.

If this box is checked, patients will receive both an email and text message with a verification code (based on the contact information provided); if not checked, patients will only receive the verification code at their email address.
Patients will enter the verification code received via text message or e-mail, agree to the terms and conditions, and adopt a signature.

You may also fax a completed paper enrollment form (available at www.BLENREPREMS.com) to 1-888-635-1044.
The Prescriber assesses the Patient’s ocular health prior to each dose by consulting an Eye Care Professional.

**Corneal Examination Findings and Best Corrected Visual Acuity**

Please refer to Table 1 for information on relevant examination findings for BLNREP.

**Section 1:** For Baseline Examination Only
- What are the current best corrected Snellen visual acuity results?
  - OD __/____ OS __/____
- Were there findings upon corneal examination and/or visual acuity assessment?  
  - Yes  
  - No
- If yes, please check affected eyes:  
  - OD  
  - OS  
  - OU

**Section 2:** For Follow Up Examinations
- What are the current best corrected Snellen visual acuity results?
  - OD __/____ OS __/____
- Were there findings upon corneal examination and/or visual acuity assessment?  
  - Yes  
  - No
- If yes, please check affected eyes:  
  - OD  
  - OS  
  - OU

**Corneal Examination Findings and Change in BCVA from Baseline for Right Eye**

- **Corneal Examination Findings**
  - Check One
  - **No change from baseline**
  - **Mild superficial keratopathy**
  - **Moderate superficial keratopathy**
  - **Severe superficial keratopathy**
  - **Corneal epithelial defect**

- **Changes in BCVA from Baseline (per Snellen Visual Acuity)**
  - Check One
  - **No change from baseline**
  - **Decline from baseline of 1 line**
  - **Decline from baseline of 2 or 3 lines on Snellen Visual Acuity and not worse than 20/200**
  - **Decline from baseline by more than 3 lines on Snellen Visual Acuity and not worse than 20/200**
  - **Snellen Visual Acuity worse than 20/200**

**Additional Corneal Examination Finding:**

**Corneal Examination Findings and BCVA Changes from Baseline for Left Eye**

- **Corneal Examination Findings**
  - Check One
  - **No change from baseline**
  - **Mild superficial keratopathy**
  - **Moderate superficial keratopathy**
  - **Severe superficial keratopathy**
  - **Corneal epithelial defect**

- **Changes in BCVA from Baseline (per Snellen Visual Acuity)**
  - Check One
  - **No change from baseline**
  - **Decline from baseline of 1 line**
  - **Decline from baseline of 2 or 3 lines on Snellen Visual Acuity and not worse than 20/200**
  - **Decline from baseline by more than 3 lines on Snellen Visual Acuity and not worse than 20/200**
  - **Snellen Visual Acuity worse than 20/200**

**Additional Corneal Examination Finding:**

The Eye Care Professional Consult Form may be faxed or adapted as a template to use within healthcare information technology system software.
To manage enrolled patients, the prescriber will login to BLENREPREMS.com and access “My Patients”.

- Review Training Materials
- Access Knowledge Assessment
- Complete Enrollment Form
- Enroll Patients
- Manage Enrolled Patients
- Complete Patient Status Form
- Report Adverse Event

**My Patients**

Below is a list of your patients. Click “Enroll Patient” to add a new patient.

**Patient Listing**

- Download the list to spreadsheet format by clicking the Excel icon just above the column headers.
- Search the list by entering information in the textbox below any column header.
- Sort the list by clicking on any column header.

<table>
<thead>
<tr>
<th>REMS ID</th>
<th>First Name</th>
<th>Last Name</th>
<th>Zip</th>
<th>Date of Birth (MM/DD/YYYY)</th>
<th>Prescriber Signature Status</th>
<th>Patient Signature Status</th>
<th>Patient Status</th>
<th>Status Form Completed Date (MM/DD/YYYY)</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>1234</td>
<td>John</td>
<td>Smith</td>
<td>1234</td>
<td>01/01/1990</td>
<td>-</td>
<td>-</td>
<td>PENDING</td>
<td>01/01/2020</td>
<td>PENDING</td>
</tr>
<tr>
<td>5678</td>
<td>Jane</td>
<td>Doe</td>
<td>5678</td>
<td>02/02/1991</td>
<td>-</td>
<td>-</td>
<td>ENROLLED - PENDING</td>
<td>02/02/2021</td>
<td>Submitt PSP</td>
</tr>
</tbody>
</table>

A list of enrolled patients may be downloaded, or search enrolled patients using the fields provided.
The Prescriber will review information provided by the Eye Care Professional and input it to a Patient Status Form by selecting “Submit PSF.”

- Review Training Materials
- Access Knowledge Assessment
- Complete Enrollment Form
- Enroll Patients
- Manage Enrolled Patients
- Complete Patient Status Form
- Report Adverse Event
The Prescriber will enter the Eye Care Professional's Information, Ophthalmic Assessment, and attest to having reviewed the ophthalmic exam.

**EYE CARE PROFESSIONAL INFORMATION**
- **First Name:**
- **Last Name:**
- **Phone:**
- **Email:**
- **National Provider Identifier (NPI):**
- **Practice/Facility Name:**
- **Address Line 1:**
- **Address Line 2:**
- **City:**
- **State:**
- **ZIP Code:**

**PRESCRIBER ATTESTATION**
- I confirm that I have reviewed the ophthalmic exam for this patient and authorize treatment.
  - [ ] Yes
  - [ ] No
- **Date of last ophthalmic assessment (MM/DD/YYYY):**

**ASSESSMENT**
- What are the current best corrected Snellen visual acuity results?
  - **Right eye (OD):**
  - **Left eye (OS):**
- Is this the patient's 1st dose?
  - [ ] Yes
  - [ ] No
- What is the current grading from the examinations findings(s) and BCVA? (Report the grade for the worst eye based on Keratopathy and Visual Acuity (KVA) scale)
  - [ ] Normal
  - [ ] Grade 1
  - [ ] Grade 2
  - [ ] Grade 3
  - [ ] Grade 4

**PRESCRIBER SIGNATURE**
- [ ] Prescriber Signature

Additional detail will be requested if you select “no”, see next slide.
For the second and later doses, the Prescriber will enter (if applicable) dose modifications, dose holds, and ophthalmic adverse event findings and BCVA gradings from the Eye Care Professional.

Is this the patient's 1st dose?
- Yes
- No

Are you recommending dose modifications due to a corneal adverse reaction based on this ophthalmic assessment?
- Yes
- No

Please refer to Table 1 for information on relevant corneal adverse reactions for BLENREP.

If yes, please check affected eyes:
- Right eye (OD)
- Left eye (OS)

If yes, please complete the following:

CORNEAL EXAMINATION FINDINGS AND CHANGE IN BCVA FROM BASELINE FOR RIGHT EYE

- Corneal Examination Finding
  - No change from baseline
  - Mild superficial keratopathy
  - Moderate superficial keratopathy
  - Severe superficial keratopathy
  - Corneal opacities

*Change in BCVA from Baseline (per Snellen Visual Acuity)
- No change from baseline
- Decline from baseline of 1 line
- Decline from baseline of 2 or 3 lines on Snellen Visual Acuity and not worse than 20/200
- Decline from baseline by more than 3 lines on Snellen Visual Acuity and not worse than 20/200
- Snellen Visual Acuity worse than 20/200

*Was the last cycle held due to a corneal adverse reaction?
- Yes
- No

Consult the Dosage Modifications for Corneal Adverse Reactions per the KVA Scale Table in the Prescribing Information to Support Dose Modification or Dose Hold Decisions.

You may also fax a completed paper patient status form (available at www.BLENREPREMS.com) to 1-888-635-1044.

For support, call 1-855-209-9188.

If the Prescriber answers “yes” to these questions: information about Affected Eyes, Corneal Exam Findings, and Change in BCVA will be requested.
To report a Corneal Adverse Event, access “My Patients” and select “Report Corneal Adverse Event”
BLENREP REMS: Key points to remember

• Ensure you enroll in the BLENREP REMS

• Enroll each patient in the BLENREP REMS

• Counsel patients on the risk of corneal adverse reactions and the requirement for monitoring via ophthalmic examinations at baseline, prior to each dose and promptly for worsening symptoms

• 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 Template

• Manage corneal adverse reactions per the Prescribing Information with dose reductions or withhold BLENREP until improvement based on severity.

• Document ophthalmic exam findings using the Patient Status Form prior to each dose in the REMS

This educational module for Prescribers 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 certification
- real-time patient status form entry
- automatic email notifications for REMS enrollment and patient status form submission

For More Information

Call 1-855-209-9188

Visit www.BLENREPREMS.com
To become a certified prescriber in the BLENREP (belantamab mafodotin-blmf) Risk Evaluation and Mitigation Strategy (REMS), you must review the Prescribing Information, Program Overview, and Education Program for Prescribers and complete this Prescriber Knowledge Assessment and the Prescriber Enrollment Form. You must answer ALL 9 questions correctly on this assessment.

- Go to www.BLENREPREMS.com to register and complete the Prescriber Knowledge Assessment and Prescriber Enrollment Form online. If online capabilities are not available, you may also fax the completed forms to the BLENREP REMS at 1-888-635-1044.
- You will receive correspondence from the BLENREP REMS within two business days via email or fax confirming your certification in the BLENREP REMS or providing instructions on how to retake your Knowledge Assessment, if necessary.

**ASSESSMENT QUESTIONS**

1. While on treatment with BLENREP patients are at risk of experiencing ocular adverse reaction, such as:
   - Keratopathy
   - Blurred vision/Changes in visual acuity
   - Dry eyes
   - All of the above

2. BLENREP can cause corneal adverse reactions that may or may not be symptomatic:
   - True
   - False

3. Before starting a patient on BLENREP, I need to do the following:
   - Enroll the patient in the BLENREP REMS using the Patient Enrollment Form
   - Assist the patient in finding an eye care professional if they are not already under an eye care professionals care
   - Ensure the Healthcare Setting or infusion center where administration of BLENREP will take place for the patient is enrolled in the BLENREP REMS (even if it is at the same location as my practice)
   - Complete the Patient Status Form attesting that I have reviewed the ophthalmic examination for the patient
   - All of the above

4. While treating patients with BLENREP, I should advise patients:
   - That they may experience loss of sense of smell
   - To administer preservative-free lubricant eye drops at least four times a day during treatment, starting with the first infusion, as it may help reduce corneal symptoms
   - That they should not eat grapefruit while taking BLENREP
   - That BLENREP is for at home administration

5. As a part of patient counseling, I should inform patients starting on BLENREP of the following:
   - They will need to visit an eye care professional before initiating treatment with BLENREP and before each subsequent dose
   - It is important they get their eyes checked because some changes can happen without symptoms
   - They should use preservative-free lubricating eye drops at least four times a day during treatment with BLENREP to help reduce corneal symptoms
   - They should use caution when driving or operating machinery as BLENREP may adversely affect their vision
   - All of the above

6. Throughout a patient’s treatment with BLENREP I must complete a Patient Status Form attesting that I have reviewed the ophthalmic examination prior to each dose:
   - True
   - False

7. If a patient experiences a Grade 3 corneal adverse reaction per the KVA Scale in the Prescribing Information (Table 1), I should withhold BLENREP until improvement in both corneal examination findings and change in BCVA to Grade 1 or better and resume at reduced dose:
   - True
   - False

8. Which of the following statements is FALSE:
   - Ophthalmic exams need to include an assessment of visual acuity and a slit lamp exam
   - The Healthcare Setting where BLENREP will be administered (infused) also needs to enroll in the BLENREP REMS
   - Ophthalmic exams should only be performed when a patient is experiencing symptoms
   - Each patient being started on BLENREP needs to have an ophthalmic exam before initiating therapy

9. I should complete and submit the Patient Status Form to the BLENREP REMS:
   - Once annually
   - After every dose of BLENREP
   - Before every dose of BLENREP
   - None of the above

Please provide your name and NPI number so we can associate your progress with your stakeholder record. You can provide this information below:

* indicates REQUIRED field

**Prescriber Information (please print)**

<table>
<thead>
<tr>
<th>First Name*:</th>
<th>Last Name*:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>National Provider Identifier (NPI)*:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Phone:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Email*:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

Access this form and enroll online at www.BLENREPREMS.com. To submit this form via fax, please complete all required fields above and fax to the BLENREP REMS at 1-888-635-1044.
BLENREP Risk Evaluation and Mitigation Strategy (REMS) Patient Guide

Patients: Your healthcare provider will go over this Patient Guide with you. It is important to ask your healthcare provider any questions you might have during treatment with BLENREP.

Healthcare Providers: Review this Patient Guide with your patient prior to initiating treatment with BLENREP.
Why am I receiving this Patient Guide?

Before you receive BLENREP, you must read and agree to all the instructions in the BLENREP Risk Evaluation and Mitigation Strategy (REMS). Before prescribing BLENREP, your healthcare provider will explain the BLENREP REMS to you and ask you to sign the Patient Enrollment Form.

Table of Contents

Why am I receiving this Patient Guide? .................................. 1
What is BLENREP?............................................................... 2
What is the BLENREP REMS? ........................................... 2
Why does BLENREP have a REMS? .................................... 2
What is the most important information I should know about the eye problems with BLENREP? ........................................... 3
How is BLENREP given? ..................................................... 4
Information about the preservative-free lubricant eye drops ............ 4
How do I enroll in the BLENREP REMS and what is required of me? 5
Where can I Get More Information on BLENREP? ..................... 6
BLENREP Treatment Overview ............................................ 7
What is BLENREP?

BLENREP is a prescription medicine used to treat adults with multiple myeloma who:

- have received at least 4 prior medicines to treat multiple myeloma, and
- their cancer has come back or did not respond to prior treatment.

It is not known if BLENREP is safe and effective in children.

What is the BLENREP REMS?

A Risk Evaluation and Mitigation Strategy (REMS) is a drug safety program that the U.S. Food and Drug Administration (FDA) can require for certain medicines with serious safety concerns. Drug companies and healthcare providers must take extra steps to make sure the benefits of using the drug are more than the risks. FDA must approve these steps as part of a REMS.

Why does BLENREP have a REMS?

BLENREP has a REMS because of the risk of eye problems. The BLENREP REMS educates patients and doctors about the risks associated with BLENREP. You must be enrolled in the BLENREP REMS to get BLENREP.

What is the most important information I should know about the eye problems with BLENREP?

- Eye problems are common with BLENREP.
- BLENREP can cause changes to the surface of your eye that can lead to:
  - dry eyes
  - blurred vision
  - worsening vision
  - severe vision loss
  - open sores on the cornea (corneal ulcer)
- Tell your healthcare provider if you have any vision changes or eye problems during treatment with BLENREP.
- Your healthcare provider will send you to see an eye specialist to check your eyes:
  - before starting treatment
  - prior to each dose of BLENREP
  - if you have worsening symptoms of eye problems
- Tell your healthcare provider if you have a history of vision or eye problems.
- Even if your vision seems fine, it is important that you get your eyes checked during treatment with BLENREP because some changes can happen without symptoms and may only be seen on an eye exam.
- Tell your healthcare provider if you notice any changes with your eyes.

- You should use preservative-free lubricant eye drops at least 4 times per day during treatment with BLENREP as instructed by your healthcare provider.
- You should use caution when driving or operating machinery as BLENREP may affect your vision.
- Avoid wearing contact lenses during treatment with BLENREP unless directed by your eye specialist.

Eye problems are not the only side effect you should be aware of while on treatment with BLENREP. For more information please see the Medication Guide for BLENREP or talk to your healthcare provider.
How is BLENREP given?

BLENREP will be given to you by your healthcare provider by intravenous infusion into your vein over approximately 30 minutes.

BLENREP is usually given every 3 weeks.

Your healthcare provider will decide how many treatments you need.

Your healthcare provider may decrease your dose, temporarily stop or completely stop treatment with BLENREP if you have serious side effects.

If you miss any appointments, call your healthcare provider as soon as possible to reschedule your appointment.

Information about the preservative-free lubricant eye drops

Preservative-free lubricant eye drops are an over-the-counter medicine that should be used at least 4 times per day during treatment with BLENREP as instructed by your healthcare provider.

If your infusion is scheduled before you get preservative-free lubricant eyes drops, please discuss with your healthcare provider on how to obtain them. If you need to purchase preservative-free lubricant eyes drops over-the-counter, please ensure that the label on the eye drops says “preservative-free”.

How do I enroll in the BLENREP REMS and what is required of me?

1. Your healthcare provider will go over this Patient Guide with you to ensure you understand:
   - The risk of eye problems while you are on treatment with BLENREP, which can cause changes to the surface of your eye that can lead to dry eyes, blurred vision, worsening vision, severe vision loss, and corneal ulcer.
   - The need to see an eye specialist to check your eyes:
     - before starting treatment with BLENREP
     - prior to each dose of BLENREP
     - if you have worsening symptoms of eye problems
   - The eye exam performed by the eye specialist will include a slit lamp exam and a visual acuity exam.

   Slit lamp exam
   The surface of the eye is examined to identify damaged cells or any changes to the surface of the eye.

   Visual acuity exam
   A chart is placed a distance from you, and you are asked to read the letters. A visual acuity score of 20/20 is considered normal vision.

   - Your healthcare provider will discuss the importance of using preservative-free lubricant eye drops (Page 5 in this document)

2. Your healthcare provider will help you complete and sign the Patient Enrollment Form to enroll you in the BLENREP REMS.
Where can I Get More Information on BLENREP?

Your healthcare provider will give you a BLENREP Medication Guide at the beginning of your treatment course. You can ask your pharmacist or healthcare provider for information about BLENREP that is written for healthcare professionals. You can also find additional information at www.BLENREPREMS.com or call the BLENREP REMS at 1-855-209-9188.

You are encouraged to report side effects of prescription drugs to the FDA. Visit MedWatch online at www.fda.gov/medwatch, or call 1-800-FDA-1088.

Preservative-free lubricant eye drops
You should use eye drops at least 4 times a day starting with the first infusion and continuing until end of treatment.

**Baseline eye exam**
Including slit lamp and visual acuity prior to initial dose.

**Eye exam prior to each dose**

- *Eye exams are required for treatment with BLENREP. Your doctor will use your eye exam results to make sure that you are receiving the correct dose.*
- *If you experience eye problems during treatment with BLENREP you may need to see your eye care specialist more often.*

**Slit lamp exam**
The surface of the eye is examined to identify damaged cells or any changes to the surface of the eye.

**Visual acuity exam**
A chart is placed a distance from you, and you are asked to read the letters. A visual acuity score of 20/20 is considered normal vision.
BLENREP Risk Evaluation and Mitigation Strategy (REMS)
Healthcare Setting Training
Table of Contents

BLENREP REMS Summary

BLENREP REMS Program

- REMS Overview
- Healthcare Setting Training, Enrollment, and Setup
- Authorization and REMS Checklist
- Important Reminders and the REMS Portal
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.

Prescribing Information for BLENREP
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.

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:

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.
- 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)
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.

Call 1-855-209-9188  Visit www.BLENREPREMS.com
FDA-REQUIRED REMS* SAFETY INFORMATION

Subject:
• Risk of Ocular Toxicity with BLENREP Treatment
• FDA Required BLENREP REMS

Dear Healthcare Provider:

This letter is to inform you about the risk of ocular toxicity associated with BLENREP and the BLENREP REMS. BLENREP is 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.

The U.S. Food and Drug Administration (FDA) has determined a Risk Evaluation and Mitigation Strategy (REMS) is necessary to manage the risk of ocular toxicity. BLENREP is only available through a restricted program; the BLENREP REMS.

Risks of BLENREP:
• BLENREP can cause 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.
• Ophthalmic exams must be performed at baseline, prior to each dose, and promptly for worsening symptoms.
• Dosage modifications or discontinuation of treatment may be needed to mitigate the risk of ocular toxicity.

REMS Requirements
• Prescribers of BLENREP must be certified in the BLENREP REMS in order to prescribe BLENREP.
• Additional details about the requirements of the BLENREP REMS are included in the Factsheet that is included with this letter.
• To enroll in the BLENREP REMS, visit www.BLENREPREMS.com.

For additional details about the REMS, visit www.BLENREPREMS.com or contact the BLENREP REMS at 1-888-209-9188.

The information in this letter is not intended as a complete description of the benefits and risks associated with the use of BLENREP. Please see accompanying Prescribing Information including Medication Guide.

Adverse Event Reporting
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.

Sincerely,
GlaxoSmithKline
FDA-REQUIRED REMS* SAFETY INFORMATION

Subject:
- Risk of Ocular Toxicity with BLENREP Treatment
- FDA Required BLENREP REMS

Dear Healthcare Provider:

This letter is to inform you about the risk of ocular toxicity associated with BLENREP and the BLENREP REMS. BLENREP is 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.

The U.S. Food and Drug Administration (FDA) has determined a Risk Evaluation and Mitigation Strategy (REMS) is necessary to manage the risk of ocular toxicity. BLENREP is only available through a restricted program; the BLENREP REMS.

Risks of BLENREP:

- BLENREP can cause 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.
- Ophthalmic exams must be performed at baseline, prior to each dose, and promptly for worsening symptoms.
- Dosage modifications or discontinuation of treatment may be needed to mitigate the risk of ocular toxicity.

REMS Requirements

- Prescribers of BLENREP must be certified in the BLENREP REMS in order to prescribe BLENREP.
- Additional details about the requirements of the BLENREP REMS are included in the Factsheet that is included with this letter.
- To enroll in the BLENREP REMS, visit www.BLENREPREMS.com.

For additional details about the REMS, visit www.BLENREPREMS.com or contact the BLENREP REMS at 1-888-209-9188.

The information in this letter is not intended as a complete description of the benefits and risks associated with the use of BLENREP. Please see the Prescribing Information including Medication Guide.

Reference ID: 4652412
Adverse Event Reporting

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.

Sincerely,

GlaxoSmithKline
BLENREP REMS Fact Sheet

BLENREP REMS Overview

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 that the benefits of the drug outweigh its risks. The BLENREP REMS is a restricted distribution program.

Prescribers must be certified with the program by enrolling and completing training in the BLENREP REMS.

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

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

Wholesalers and distributors must only distribute BLENREP to certified Healthcare Settings.

What is the Risk?

- BLENREP caused changes in the corneal epithelium resulting in:
  - Changes in vision, including severe vision loss and corneal ulcer
  - Symptoms such as blurred vision and dry eyes

How can Prescribers Manage the Risk?

- Counsel patients receiving BLENREP about the risk of ocular toxicity and on the need for ophthalmic examinations (visual acuity and slit lamp) at baseline, prior to each dose, and promptly for worsening symptoms.
- 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.
- Assess the ophthalmic exam results for corneal adverse reactions, which are based on both corneal examination findings and changes in best-corrected visual acuity (BCVA). Document these findings using the Patient Status Form prior to each dose in the REMS.
- Manage corneal adverse reactions per the Prescribing Information with dose reductions or withhold BLENREP until improvement and resume, or permanently discontinue, based on severity.

To enroll in the BLENREP REMS Program

- call 1-855-209-9188
- go to www.BLENREPREMS.com

Reference ID: 4652412
What are the key requirements of the BLENREP REMS?

Prescribers

- Review the training: BLENREP Prescribing Information, Program Overview, and Education Program for Prescribers
- Complete the Knowledge Assessment and Prescriber Enrollment Form
- Submit the completed and signed Knowledge Assessment and Prescriber Enrollment Form at www.BLENREPREMS.com, or fax to 1-888-635-1044
- You will not be able to prescribe BLENREP without completing your certification in the BLENREP REMS

Healthcare Settings

- Designate an authorized representative to review the following: BLENREP Prescribing Information, Program Overview and Education Program for Healthcare Settings
- Complete the Healthcare Setting Enrollment Form
- Implement staff training and procedures to comply with the BLENREP REMS
- You will not be able to order BLENREP without completing your certification in the BLENREP REMS

Patient Responsibilities

- Prescribers: Using the Patient Guide, counsel patient on ocular adverse reaction risk and ophthalmic exam requirements
- Complete the Patient Enrollment Form and submit a copy online or via fax

Wholesalers-Distributors

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

Reporting Adverse Events

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.

This Fact Sheet does not contain the complete safety information for BLENREP. For complete safety information, please see the full Prescribing Information, including Boxed Warning, available at www.BLENREPREMS.com.
FDA-REQUIRED REMS* SAFETY INFORMATION

Subject:
- Risk of Ocular Toxicity with BLENREP Treatment
- FDA Required BLENREP REMS

Dear Professional Society:

We request that you share the following with your members.

This letter is to inform you about the risk of ocular toxicity associated with BLENREP and the BLENREP REMS. BLENREP is 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.

The U.S. Food and Drug Administration (FDA) has determined a Risk Evaluation and Mitigation Strategy (REMS) is necessary to manage the risk of ocular toxicity. BLENREP is only available through a restricted program; the BLENREP REMS.

Risks of BLENREP:
- BLENREP can cause 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.
- Ophthalmic exams must be performed at baseline, prior to each dose, and promptly for worsening symptoms.
- Dose modifications or discontinuation of treatment of BLENREP may be necessary to mitigate the risk of ocular toxicity

REMS Requirements
- Prescribers of BLENREP must be certified in the BLENREP REMS in order to prescribe BLENREP.
- See the Factsheet that is included with this letter for more information about the requirements of the BLENREP REMS.
- To enroll in the BLENREP REMS, visit www.BLENREPREMS.com.

For additional details about the REMS, visit www.BLENREPREMS.com or contact the BLENREP REMS at 1-888-209-9188.

Sincerely,
GlaxoSmithKline
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. BLENREP is only available through the BLENREP REMS, a restricted distribution program.

Prescribers must become certified in the BLENREP REMS to prescribe BLENREP. LEARN ABOUT PRESCRIBER CERTIFICATION. LEARN MORE

Healthcare settings must become certified in the BLENREP REMS to order and dispense BLENREP. LEARN ABOUT HEALTHCARE SETTING CERTIFICATION. LEARN MORE

Patients who are prescribed BLENREP must be enrolled in the BLENREP REMS. LEARN ABOUT PATIENT ENROLLMENT. LEARN MORE

To learn more about the risks associated with BLENREP please refer to the Prescribing Information, including Boxed Warning, and the Medication Guide.
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. BLENREP is only available through the BLENREP REMS, a restricted distribution program.

Prescribers

Prescribers must become certified in the BLENREP REMS to prescribe BLENREP. Learn about Prescriber Certification.

Healthcare settings

Healthcare settings must become certified in the BLENREP REMS to order and dispense BLENREP. Learn about Healthcare Setting Certification.

Patients

Patients who are prescribed BLENREP must be enrolled in the BLENREP REMS. Learn about Patient Enrollment.

To learn more about the risks associated with BLENREP please refer to the Prescribing Information, including Boxed Warning, and the Medication Guide.
Prescribing Information Medication Guide

This site is intended for US residents only.

BLENREP REMS: 1-855-209-9188 Monday-Friday, 8:00am - 8:00pm ET

BLENREP is only available through the BLENREP REMS. In order for a prescriber to prescribe BLENREP, they must become certified.

To Become Certified in the BLENREP REMS, Prescribers Must:

1. Complete the training program, which includes reviewing the following educational materials:
   - Prescribing Information
   - Program Overview
   - Education Program for Prescribers

2. Successfully complete and submit the Knowledge Assessment:
   - Online
   - By fax at 1-888-635-1044

3. Enroll in the program by completing the Prescriber Enrollment Form and submitting it to the BLENREP REMS:
   - Online
   - By fax at 1-888-635-1044

4. 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 the 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.

The BLENREP REMS will send confirmation of a prescriber’s enrollment within 2 business days, including the prescriber’s assigned BLENREP REMS identification number. 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.

How Do I Enroll a Patient in the BLENREP REMS Program?

1. Counsel your patient using the Patient Guide about:
   - the risk of ocular toxicity
   - the requirements 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 the Patient Enrollment Form:
   - Online
   - By fax at 1-888-635-1044

The BLENREP REMS will send confirmation of a patient’s enrollment within 2 business days, including the patient’s assigned BLENREP REMS identification number. Patients who are prescribed BLENREP must be enrolled in the BLENREP REMS.

Patient Management:

Before Treatment:
- 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.
- Assess the patient’s ophthalmic consult results for appropriateness of initiating treatment. Document and submit to the BLENREP REMS using the Patient Status Form.

During Treatment:
- 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.
- 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).
- 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 withholding BLENREP until improvement or permanently discontinue based on severity.
- If continuation of therapy is appropriate, document and submit the Patient Status Form to the BLENREP REMS.
  - Online
  - By fax at 1-888-635-1044

Notify the BLENREP REMS if an enrolled patient who has received BLENREP is no longer under your care or has discontinued treatment.
To Become Certified in the BLENREP REMS, Healthcare Settings Must:

1. Designate an Authorized Representative.

2. Review the Prescribing Information, Program Overview and the Education Program for Healthcare Settings.

3. Complete and submit the Healthcare Setting Enrollment Form.
   - Online
   - By fax at 1-866-635-1044

The BLENREP REMS will send confirmation of a healthcare setting's enrollment within 2 business days, including the healthcare setting's assigned BLENREP REMS identification number. The Healthcare Setting will not be able to order or dispense BLENREP without complying certification in the BLENREP REMS. If the Healthcare Setting fails to comply with the BLENREP REMS requirements, the healthcare setting will no longer be able to participate in the BLENREP REMS.

Before administering:
- Train all relevant staff in dispensing and administering BLENREP using:
  - Program Overview
  - Education Program for Healthcare Setting

- Establish processes and procedures to verify the REMS Checklist is completed and submitted for each patient.

- Obtain authorization to administer each dose by logging in to the BLENREP REMS portal to verify:
  - Prescriber is certified
  - patient is enrolled and authorized to receive BLENREP

After administering, within 5 business days:
- Capture the dose and date of infusion in the online REMS Checklist and submit it to the REMS within 5 business days of the infusion.
  - Online
  - By fax at 1-866-635-1044

To maintain certification to administer:
- Have a new authorized representative enroll in the REMS Program by completing the Healthcare Setting Enrollment Form and submitting it to the REMS program if the authorized representative changes.

At all times:
- Do not distribute, transfer, loan, or sell BLENREP.
- Maintain records documenting staff's completion of REMS training.
- Maintain records to demonstrate all processes and procedures are in place and being followed.
- Comply with audits carried out by GlaxoSmithKline or third parties acting on behalf of GlaxoSmithKline to ensure all processes and procedures are in place and are being followed.

*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.

An Authorized Representative at the Healthcare Setting can be a:
- Pharmacist
- Physician
- Director of Healthcare Setting
- Nurse
- Nurse Practitioner
- Physician's Assistant
- Or any responsible individual in the Healthcare Setting
A Risk Evaluation and Mitigation Strategy (REMS) is a drug safety program that the U.S. Food and Drug Administration (FDA) can require for certain medicines with serious safety concerns. Drug companies and healthcare providers must take extra steps to make sure the benefits of using the drug are more than the risks. FDA must approve these steps as part of a REMS.

BLENREP has a REMS because of the risk of eye problems. The BLENREP REMS educates patients and doctors about the risks associated with BLENREP. You must be enrolled in the BLENREP REMS to get BLENREP.

How Do I Enroll in the BLENREP REMS and What Is Required of Me?

1. Your healthcare provider will go over this Patient Guide with you to ensure that you understand:
   - Eye problems are common with BLENREP.
   - The risk of eye problems while you are on treatment with BLENREP, which can cause changes to the surface of your eye that can lead to dry eyes, blurred vision, worsening vision, severe vision loss, and corneal ulcer.
   - The need to see an eye specialist to check your eyes:
     - before starting treatment with BLENREP
     - prior to each dose of BLENREP
     - if you have worsening symptoms of eye problems
   - Even if your vision seems fine, it is important that you get your eyes checked during treatment with BLENREP because some changes can happen without symptoms and may only be seen on an eye exam.
   - You should use preservative-free lubricant eye drops at least 4 times per day during treatment with BLENREP as instructed by your healthcare provider.
   - You should use caution when driving or operating machinery as BLENREP may affect your vision.
   - Avoid wearing contact lenses during treatment with BLENREP unless directed by your eye specialist.

2. Your healthcare provider will help you complete and sign the Patient Enrollment Form to enroll you in the BLENREP REMS.
Certified Participant Locator

This may not be an all-inclusive list. Please discuss with your Healthcare Provider.

Please enter a street address, city, state, or ZIP Code you would like to search for.

Find a Certified Participant near:

Search Radius:

Within 25 miles.

Search
Certified Participant Locator

This may not be an all-inclusive list. Please discuss with your Healthcare Provider.

Please enter a street address, city, state, or ZIP Code you would like to search for.

CERTIFIED PRESCRIBERS  CERTIFIED HEALTHCARE SETTINGS

Find a Certified Participant near:

12345

Search Radius:

Within 25 miles

SEARCH

Map Satellite

To report side effects please contact GlaxoSmithKline at 1-888-825-5249 or FDA at www.fda.gov/medwatch or call 1-800-FDA-1088 (1-800-332-1088).
Contact Us

PHONE
1-855-209-9188

FAX
1-888-635-1044

HOURS OF OPERATION
Monday - Friday
8:00 AM - 8:00 PM
Eastern Time
This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

MARC R THEORET
08/05/2020 06:52:09 PM