

Risk Evaluation and Mitigation Strategy (REMS) Document

BLENREP™ (belantamab mafodotin) REMS Program

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)	<ol style="list-style-type: none"> 5. 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. 6. Enroll the patient by completing and submitting the Patient Enrollment Form to the REMS Program. 7. 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. 8. Assess the patient's ophthalmic consult results for appropriateness of initiating treatment. Document and submit to the REMS Program using the Patient Status Form.
During treatment; before each infusion	<ol style="list-style-type: none"> 9. 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 10. Assess the patient's ophthalmic consult results for appropriateness of continuing treatment. Document and submit to the REMS Program using the Patient Status Form.

2. Patients who are prescribed BLENREP:

Before treatment initiation	<ol style="list-style-type: none"> 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	<ol style="list-style-type: none"> 4. Get an eye exam.
At all times	<ol style="list-style-type: none"> 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	<ol style="list-style-type: none"> 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
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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.

Before administering

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.
7. Complete the [REMS Checklist](#).

After administering, within 5 business days

8. Submit the [REMS Checklist](#) to the REMS Program.

To maintain certification to dispense

9. Have a new authorized representative enroll in the REMS Program by completing and submitting the [Healthcare Setting Enrollment Form](#) to the REMS program.

At all times

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

4. Wholesalers-distributors that distribute BLENREP must:

To be able to distribute

1. Establish processes and procedures to ensure that the drug is distributed only to certified healthcare settings.
2. Train all relevant staff involved in distribution on the REMS requirements.

At all times

3. Distribute only to certified healthcare settings.
 4. Maintain records of all drug distribution.
 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.
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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:

Target Audience	Communication Materials-& Dissemination Plans
Healthcare providers likely to prescribe BLENREP, oncology nurses, and pharmacists	<p>REMS Letter: Healthcare Provider REMS Letter, REMS Letter for Professional Societies with attachment: REMS Factsheet</p> <ol style="list-style-type: none">1. Email within 30 calendar days of the date BLENREP is first commercially distributed and again 12 months later.<ol style="list-style-type: none">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.<ol style="list-style-type: none">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. <p>Fact Sheet</p> <ol style="list-style-type: none">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. 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 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](#)

14. [REMS Fact Sheet](#)
15. [REMS Letter for Professional Societies](#)

Other Materials

16. [Program website](#)

BLENREP™ REMS Prescriber Enrollment Form



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			
First Name*:		Middle Initial:	Last Name*:
Credentials*: <input type="checkbox"/> MD <input type="checkbox"/> DO <input type="checkbox"/> NP <input type="checkbox"/> PA <input type="checkbox"/> Other (please specify) _____			
Specialty*: <input type="checkbox"/> Oncology <input type="checkbox"/> Hematology <input type="checkbox"/> Internal Medicine <input type="checkbox"/> Other (please specify) _____			
National Provider Identifier (NPI) #*:		State License #:	
Practice/Facility Name*:			
Address*:			
City*:		State*:	ZIP Code*:
Phone*:	Fax*:		Email*:
Preferred Method of Communication: (please select one) <input type="checkbox"/> Phone <input type="checkbox"/> Fax <input type="checkbox"/> Email			Preferred Time of Contact: <input type="checkbox"/> AM <input type="checkbox"/> 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.			
First Name*		Last Name*:	Email*:
<input type="checkbox"/> Address – Same as Prescriber			
Address:		City:	State: ZIP Code:
Phone:		Fax:	
Alternative Practice/Facility Location			
Address:			
City:		State:	ZIP Code:



BLENREP™ REMS Prescriber Enrollment Form (continued)

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 BLNREP REMS.

Before treatment initiation (first dose), I must:

- Counsel the patient, using the *Patient Guide*, on
 - the risk of ocular toxicity associated with BLNREP 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 BLNREP 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 BLNREP 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 BLNREP REMS using the *Patient Status Form*.

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

I understand the BLNREP 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 BLNREP is only available through the BLNREP REMS and I must comply with the REMS Requirements.

Prescriber Signature*: _____ Date*: _____

Month/Day/Year

Print Name*: _____

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 BLNREP REMS at 1-888-635-1044.

Fields marked with an * are REQUIRED.

Patient Information (Please Print)		
First Name*:	Middle Initial:	Last Name*:
Date of Birth (MM/DD/YYYY)*:	Gender*: <input type="checkbox"/> Female <input type="checkbox"/> Male <input type="checkbox"/> Other	
Address*:		
City*:	State*:	ZIP Code*:
Phone*:	Email:	
Preferred Method of contact*: <input type="checkbox"/> Phone <input type="checkbox"/> 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 <ul style="list-style-type: none">• Receive counseling from my prescriber using the <i>Patient Guide</i>.• Enroll in the BLNREP REMS by completing the <i>Patient Enrollment Form</i> with my prescriber.• Get an eye exam. During my treatment and before each infusion, I must <ul style="list-style-type: none">• Get an eye exam. At all times <ul style="list-style-type: none">• I must inform my prescriber if I have any signs or symptoms of worsening eyesight or eye health including:<ul style="list-style-type: none">- Blurry vision- Dry eyes- Worsening vision• I understand I must tell the BLNREP REMS if I change my BLNREP doctor.• I understand I must tell the BLNREP 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 BLNREP REMS. Information about all patients who get BLNREP 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 BLNREP 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 BLNREP REMS.		
Patient Acknowledgement		
By signing this form, I agree BLNREP is only available through the BLNREP REMS and I must comply with the REMS Requirements.		
Patient/Legal Guardian Signature*:		Date*: _____ <small>Month/Day/Year</small>
PRINT NAME*: _____		
Prescriber Acknowledgement		
I have reviewed and discussed the risks of BLNREP and the requirements of the BLNREP REMS with this patient.		
Prescriber Signature*:		Date*: _____ <small>Month/Day/Year</small>
PRINT NAME*: _____		

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Phone: 1-855-209-9188

www.BLENREPREMS.com

Fax: 1-888-635-1044



BLNREP™ REMS Healthcare Setting Enrollment Form

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BLNREP
belantamab
mafodotin-blmf
for injection 100 mg

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 BLNREP 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*: <input type="checkbox"/> Infusion Center <input type="checkbox"/> Group Practice <input type="checkbox"/> Independent Practice <input type="checkbox"/> Outpatient Clinic <input type="checkbox"/> Hospital <input type="checkbox"/> Other (please specify) _____		
Address*:		
City*:	State*:	ZIP Code*:
Phone*:	Fax*:	
Ship To Information		
Ship To Address <input type="checkbox"/> Same as above	Ship To Contact Name*:	
Address*:		
City*:	State*:	ZIP Code*:
Phone:	Fax:	
Authorized Representative Information		
First Name*:	Last Name*:	
Credentials*: <input type="checkbox"/> DO <input type="checkbox"/> MD <input type="checkbox"/> PharmD <input type="checkbox"/> RN <input type="checkbox"/> NP <input type="checkbox"/> PA <input type="checkbox"/> Other (please specify)		
National Provider Identifier (NPI)*:		
Phone*:	Fax*:	Email*:
Healthcare Setting Agreement:		
<p>As the Authorized Representative:</p> <ul style="list-style-type: none">I have reviewed the drug's Prescribing Information.I have reviewed the <i>Program Overview and Education Program for Healthcare Settings</i>.I must train all relevant staff involved in dispensing and administering BLNREP using the <i>Program Overview and Education Program for Healthcare Settings</i>.I must establish processes and procedures to ensure the <i>REMS Checklist</i> is completed and submitted for each patient. <p>On behalf of the healthcare setting, I must comply with the following REMS requirements:</p> <p>Before administering each dose:</p> <ul style="list-style-type: none">Obtain authorization to dispense each dose by contacting the BLNREP REMS to verify<ul style="list-style-type: none">The prescriber is certified in the BLNREP REMSThe patient is enrolled in the BLNREP REMS and authorized to receive this dose of BLNREPComplete the <i>REMS Checklist</i> <p>After administering BLNREP, within 5 business days:</p> <ul style="list-style-type: none">Submit the <i>REMS Checklist</i> to the BLNREP REMS. <p>At all times:</p> <ul style="list-style-type: none">Not distribute, transfer, loan or sell BLNREP.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 BLNREP is only available through the BLNREP REMS and I must comply with the REMS Requirements.		
Authorized Representative Signature*:		Date*:
PRINT NAME: _____		Month/Day/Year

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

Reference ID: 4652412



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)

Healthcare Setting Information		
Healthcare Setting Name*:		
National Provider Identifier (NPI)*:	HIN:	DEA#:
Site Type*: <input type="checkbox"/> Infusion Center <input type="checkbox"/> Group Practice <input type="checkbox"/> Independent Practice <input type="checkbox"/> Outpatient Clinic <input type="checkbox"/> Hospital <input type="checkbox"/> Other (please specify)_____		
Address*:		
City*:	State*:	ZIP Code*:
Phone*:	Fax*:	
Ship To Information		
Ship To Address <input type="checkbox"/> Same as above	Ship To Contact Name*:	
Address*:		
City*:	State*:	ZIP Code*:
Phone:	Fax:	

Healthcare Setting Information		
Healthcare Setting Name*:		
National Provide Identifier (NPI)*:	HIN:	DEA#:
Site Type*: <input type="checkbox"/> Infusion Center <input type="checkbox"/> Group Practice <input type="checkbox"/> Independent Practice <input type="checkbox"/> Outpatient Clinic <input type="checkbox"/> Hospital <input type="checkbox"/> Other (please specify)_____		
Address*:		
City*:	State*:	ZIP Code*:
Phone*:	Fax*:	
Ship To Information		
Ship To Address <input type="checkbox"/> Same as above	Ship To Contact Name*:	
Address*:		
City*:	State*:	ZIP Code*:
Phone:	Fax:	

Use this section to request portal access for Healthcare Setting staff that are trained and authorized to use the BLNREP 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.

Healthcare Setting Name*:	First Name*:	Last Name*:	Credentials*:	Email*:

BLNREP™ REMS Patient Status Form



For Certified Prescriber to Complete

INSTRUCTIONS for Prescriber

- Complete this **BLNREP Patient Status Form** for each patient prior to each dose of BLNREP.
- Submit completed form online at www.BLNREPREMS.com. If online capabilities are not available, this form can be completed and faxed to the BLNREP 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.*			<input type="checkbox"/> Yes <input type="checkbox"/> No
Date of last ophthalmic assessment (MM/DD/YYYY)*:			
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*?			<input type="checkbox"/> Yes <input type="checkbox"/> No
If no, please complete the rest of this form >>			



Patient Status Form

First Name*:

Middle Initial:

Last Name*:

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

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

	Corneal Examination Finding <i>Check One</i>	Change in BCVA from Baseline (per Snellen Visual Acuity) <i>Check One</i>
Right eye (OD)	<input type="checkbox"/> No change from baseline <input type="checkbox"/> Mild superficial keratopathy <input type="checkbox"/> Moderate superficial keratopathy <input type="checkbox"/> Severe superficial keratopathy <input type="checkbox"/> Corneal epithelial defect	<input type="checkbox"/> No change from baseline <input type="checkbox"/> Decline from baseline of 1 line <input type="checkbox"/> Decline from baseline of 2 or 3 lines on Snellen Visual Acuity and not worse than 20/200 <input type="checkbox"/> Decline from baseline by more than 3 lines on Snellen Visual Acuity and not worse than 20/200 <input type="checkbox"/> Snellen Visual Acuity worse than 20/200
	Additional Corneal Examination Finding: _____	

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

	Corneal Examination Finding <i>Check One</i>	Change in BCVA from Baseline (per Snellen Visual Acuity) <i>Check One</i>
Left eye (OS)	<input type="checkbox"/> No change from baseline <input type="checkbox"/> Mild superficial keratopathy <input type="checkbox"/> Moderate superficial keratopathy <input type="checkbox"/> Severe superficial keratopathy <input type="checkbox"/> Corneal epithelial defect	<input type="checkbox"/> No change from baseline <input type="checkbox"/> Decline from baseline of 1 line <input type="checkbox"/> Decline from baseline of 2 or 3 lines on Snellen Visual Acuity and not worse than 20/200 <input type="checkbox"/> Decline from baseline by more than 3 lines on Snellen Visual Acuity and not worse than 20/200 <input type="checkbox"/> Snellen Visual Acuity worse than 20/200
	Additional Corneal Examination Finding: _____	

Patient Status Form

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

	Corneal Examination Finding <i>Check One</i>	Change in BCVA from Baseline (per Snellen Visual Acuity) <i>Check One</i>
Right eye (OD)	<input type="checkbox"/> No change from baseline <input type="checkbox"/> Mild superficial keratopathy <input type="checkbox"/> Moderate superficial keratopathy <input type="checkbox"/> Severe superficial keratopathy <input type="checkbox"/> Corneal epithelial defect	<input type="checkbox"/> No change from baseline <input type="checkbox"/> Decline from baseline of 1 line <input type="checkbox"/> Decline from baseline of 2 or 3 lines on Snellen Visual Acuity and not worse than 20/200 <input type="checkbox"/> Decline from baseline by more than 3 lines on Snellen Visual Acuity and not worse than 20/200 <input type="checkbox"/> Snellen Visual Acuity worse than 20/200
	Additional Corneal Examination Finding: _____	

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

	Corneal Examination Finding <i>Check One</i>	Change in BCVA from Baseline (per Snellen Visual Acuity) <i>Check One</i>
Left eye (OS)	<input type="checkbox"/> No change from baseline <input type="checkbox"/> Mild superficial keratopathy <input type="checkbox"/> Moderate superficial keratopathy <input type="checkbox"/> Severe superficial keratopathy <input type="checkbox"/> Corneal epithelial defect	<input type="checkbox"/> No change from baseline <input type="checkbox"/> Decline from baseline of 1 line <input type="checkbox"/> Decline from baseline of 2 or 3 lines on Snellen Visual Acuity and not worse than 20/200 <input type="checkbox"/> Decline from baseline by more than 3 lines on Snellen Visual Acuity and not worse than 20/200 <input type="checkbox"/> 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

Patient Status Form			
First Name*:	Middle Initial:	Last Name*:	Date of Birth (MM/DD/YYYY)*:

Please submit this completed form to the BLENREP REMS online at www.BLENREPREMS.com or fax at 1-888-635-1044	
Signature*:	Date*:
Print Name*:	Month/Day/Year
Submitted by*: <input type="checkbox"/> Prescriber <input type="checkbox"/> Prescriber Delegate	

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 Scale^a

Corneal Adverse Reaction		Recommended Dosage Modifications
Normal	<i>Corneal examination finding(s):</i> Cornea clear/ No change from baseline <i>Change in BCVA^c:</i> No decline from baseline of 1 line on Snellen Visual Acuity	Continue treatment at current dose.
Grade 1	<i>Corneal examination finding(s):</i> Mild superficial keratopathy ^b <i>Change in BCVA^c:</i> Decline from baseline of 1 line on Snellen Visual Acuity	Continue treatment at current dose.
Grade 2	<i>Corneal examination finding(s):</i> Moderate superficial keratopathy ^d <i>Change in BCVA^c:</i> Decline from baseline of 2 or 3 lines on Snellen Visual Acuity and not worse than 20/200	Withhold BLENREP until improvement in both corneal examination findings and change in BCVA to Grade 1 or better and resume at same dose.
Grade 3	<i>Corneal examination finding(s):</i> Severe superficial keratopathy ^e <i>Change in BCVA^c:</i> Decline from baseline by more than 3 lines on Snellen Visual Acuity and not worse than 20/200	Withhold BLENREP until improvement in both corneal examination findings and change in BCVA to Grade 1 or better and resume at reduced dose.
Grade 4	<i>Corneal examination finding(s):</i> Corneal epithelial defect ^f <i>Change in BCVA^c:</i> Snellen Visual Acuity worse than 20/200	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.

^a Adapted and modified from the Prescribing Information

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

^c Changes in visual acuity due to treatment-related corneal findings.

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

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

^f Corneal epithelial defect such as corneal ulcers.



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)

Patient Information	
First Name*:	Last Name*:
Date of Birth (MM/DD/YYYY):	Patient BLENREP REMS Identification #:
Prescriber Information	
First Name*:	Last Name*:
National Provider Identifier (NPI) #*:	
Healthcare Setting Information	
Healthcare Setting Name*:	
National Provider Identifier (NPI) #*:	
Healthcare Setting BLENREP REMS Identification #:	
Phone*:	
Authorization Code Prior to Dispensing	
Authorization:	
Dosing Information	
Date of infusion(MM/DD/YYYY)*:	Actual dose (mg)*:

FOR HEALTHCARE SETTING USE

Signature of Staff Completing Checklist		
First Name*:	Last Name*:	
Signature*:		
Credentials*: <input type="checkbox"/> DO <input type="checkbox"/> MD <input type="checkbox"/> PharmD <input type="checkbox"/> RN <input type="checkbox"/> NP <input type="checkbox"/> PA <input type="checkbox"/> Other (please specify)		
Phone*:	Fax*:	E-mail*:
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

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

Prescriber Information:

First Name:	Last Name:	
Phone:	Fax:	Email:

Eye Care Professional Information

First Name:	Last Name:	Credentials:
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 ____/____



Eye Care Professional Consult Form

First Name*:

Middle Initial:

Last Name*:

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

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

	Corneal Examination Findings <i>Check One</i>	Changes in BCVA from Baseline (per Snellen Visual Acuity) <i>Check One</i>
Right eye (OD)	<div><input type="checkbox"/> No change from baseline</div> <div><input type="checkbox"/> Mild superficial keratopathy</div> <div><input type="checkbox"/> Moderate superficial keratopathy</div> <div><input type="checkbox"/> Severe superficial keratopathy</div> <div><input type="checkbox"/> Corneal epithelial defect</div>	<div><input type="checkbox"/> No change from baseline</div> <div><input type="checkbox"/> Decline from baseline of 1 line</div> <div><input type="checkbox"/> Decline from baseline of 2 or 3 lines on Snellen Visual Acuity and not worse than 20/200</div> <div><input type="checkbox"/> Decline from baseline by more than 3 lines on Snellen Visual Acuity and not worse than 20/200</div> <div><input type="checkbox"/> Snellen Visual Acuity worse than 20/200</div>
	Additional Corneal Examination Finding:	

Corneal Examination Findings and BCVA Changes from Baseline for Left Eye

	Corneal Examination Findings <i>Check One</i>	Changes in BCVA from Baseline (per Snellen Visual Acuity) <i>Check One</i>
Leftt eye (OS)	<div><input type="checkbox"/> No change from baseline</div> <div><input type="checkbox"/> Mild superficial keratopathy</div> <div><input type="checkbox"/> Moderate superficial keratopathy</div> <div><input type="checkbox"/> Severe superficial keratopathy</div> <div><input type="checkbox"/> Corneal epithelial defect</div>	<div><input type="checkbox"/> No change from baseline</div> <div><input type="checkbox"/> Decline from baseline of 1 line</div> <div><input type="checkbox"/> Decline from baseline of 2 or 3 lines on Snellen Visual Acuity and not worse than 20/200</div> <div><input type="checkbox"/> Decline from baseline by more than 3 lines on Snellen Visual Acuity and not worse than 20/200</div> <div><input type="checkbox"/> Snellen Visual Acuity worse than 20/200</div>
	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^a.

Report the grade for the worst eye by checking the box	Grades	Corneal Adverse Reaction
<input type="checkbox"/>	Normal	<i>Corneal examination finding(s)</i> Cornea clear / No change from baseline <i>Change in BCVA^c:</i> No decline from baseline of 1 line on Snellen Visual Acuity
<input type="checkbox"/>	Grade 1	<i>Corneal examination finding(s)</i> Mild superficial keratopathy ^c <i>Change in BCVA^c:</i> Decline from baseline of 1 line on Snellen Visual Acuity
<input type="checkbox"/>	Grade 2	<i>Corneal examination finding(s):</i> Moderate superficial keratopathy ^d <i>Change in BCVA^c:</i> Decline from baseline of 2 or 3 lines on Snellen Visual Acuity and not worse than 20/200
<input type="checkbox"/>	Grade 3	<i>Corneal examination finding(s):</i> Severe superficial keratopathy ^e <i>Change in BCVA^c:</i> Decline from baseline by more than 3 lines on Snellen Visual Acuity and not worse than 20/200
<input type="checkbox"/>	Grade 4	<i>Corneal examination finding(s):</i> Corneal epithelial defect ^f <i>Change in BCVA^c:</i> Snellen Visual Acuity worse than 20/200

^a Adapted and modified from the Prescribing Information

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

^c Changes in visual acuity due to treatment-related corneal findings.

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

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

^f 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



APPEARS THIS WAY ON ORIGINAL



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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



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

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.

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

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

Before administering

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

To maintain certification to administer

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

Who Can Be An Authorized Representative?

An authorized representative at the Healthcare Setting can be a:

- Pharmacist
- Physician
- Nurse
- Nurse Practitioner
- Director of Healthcare Setting
- Physician'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

At all times

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

During Treatment; before each dose

1. Get an eye exam

Wholesalers-Distributors Instructions:

To be able to distribute

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

At all times

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

How to Enroll in the BLENREP REMS

The completed forms should be submitted to the BLENREP REMS online, using the BLENREP REMS Portal at www.BLENREPREMS.com. 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.

BLNREP REMS Resources

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

Visit 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.

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.

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BLNREP 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.**

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BLNREP: Overview and Clinical Data



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Patient Counseling and Monitoring

BLNREP REMS Goals and Operations



REMS Process Overview and Goals



Reminders



BLNREP: REMS Summary and Key US Prescribing Information

BLENREP: Key US Prescribing Information

Indications and Usage

- 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.

BLNREP: Key US Prescribing Information

WARNING: OCULAR TOXICITY

- BLNREP caused changes in the corneal epithelium resulting in changes in vision, including severe vision loss and corneal ulcer, and symptoms, such as blurred vision and dry eyes.
- Conduct ophthalmic exams at baseline, prior to each dose, and promptly for worsening symptoms. Withhold BLNREP until improvement and resume, or permanently discontinue, based on severity.
- Because of the risk of ocular toxicity, BLNREP is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the BLNREP REMS.

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.



BLNREP: Overview and Clinical Data

Overview of BLENREP: What it is and how it works

The Target

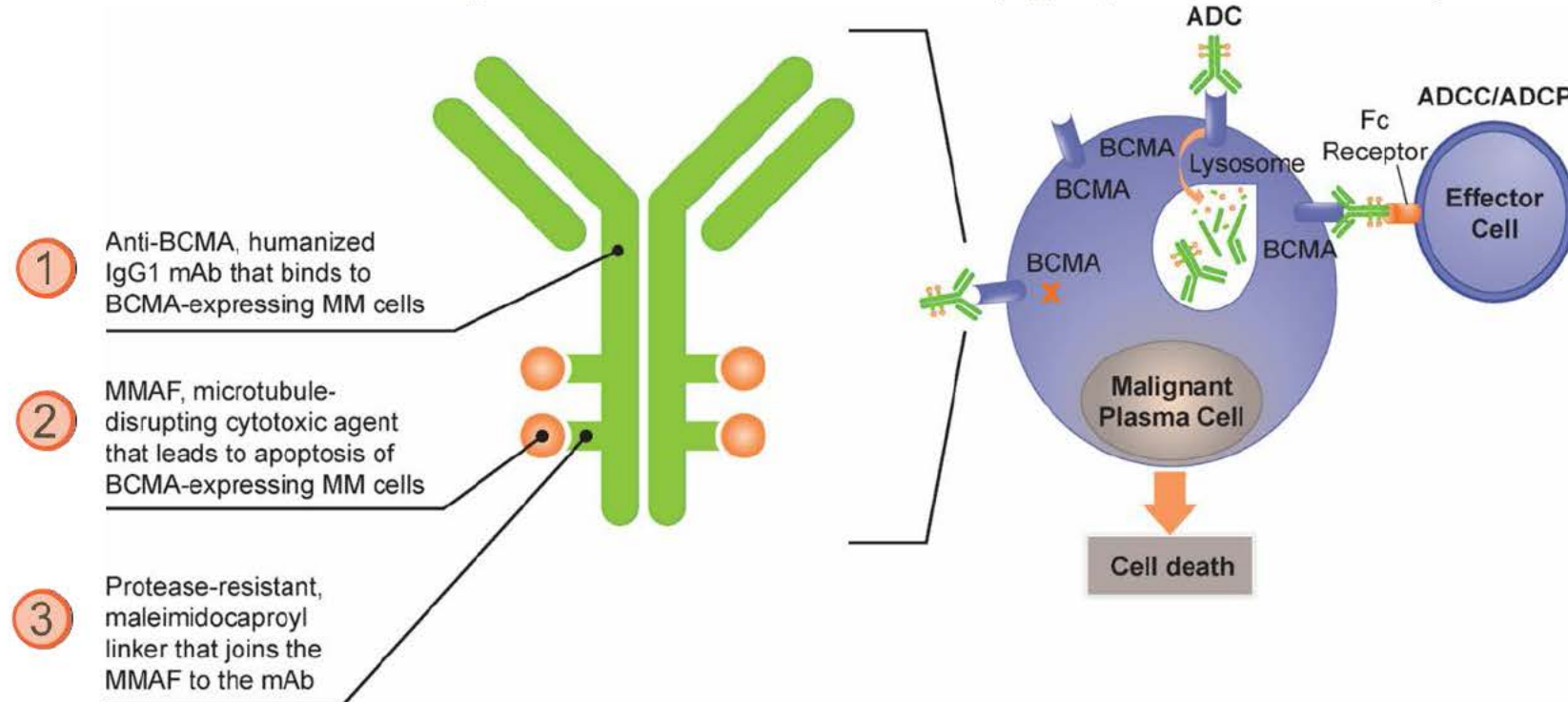


B-cell maturation antigen (BCMA) is a protein expressed on normal B lymphocytes and multiple myeloma cells that promotes cellular proliferation and survival^{1,2}

The agent and mechanism of action



BLENREP is a BCMA-directed antibody and microtubule inhibitor conjugate, composed of 3 components³



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

1. O'Connor BP et al. *J Exp Med.* 2004;199(1):91–8; 2. Lee L et al. *Br J Haematol.* 2016;174(6):911–22; 3. Tai Y-T et al. *Blood.* 2014;123(20):3128–38. Figure from Farooq et al. manuscript under review

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.

Prescribing Information for BLENREP

Ocular Adverse Reactions Observed in the 2.5mg/kg Cohort of DREAMM-2

Adverse Reactions (≥10%) in Patients Who Received BLENREP in DREAMM-2	BLENREP 2.5 mg/kg dosing; N = 95	
	All Grades (%)	Grade 3-4 (%)

Eye Disorders		
Keratopathy ^a	71	44
Decreased Visual Acuity ^b	53	28
Blurred Vision ^c	22	4
Dry Eyes ^d	14	1

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

- 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%)

^aKeratopathy was based on slit lamp eye examination, characterized as corneal epithelium changes with or without symptoms

^bVisual acuity changes were determined upon eye examination

^cBlurred vision included diplopia, vision blurred, visual acuity reduced, and visual impairment

^dDry eyes included dry eye, ocular discomfort, and eye pruritus

Prescribing Information for BLENREP

Warnings and Precautions: Ocular Toxicity

Ocular Adverse Reactions	BLENREP 2.5 mg/kg dosing N = 95
Keratopathy^a	71% (n=67)
With Ocular Symptoms ^b	43% (n=29)
With decline of 2 or more lines on Snellen Visual Acuity in any eye	66% (n=44)
With both Ocular Symptoms and decline of 2 or more lines on Snellen Visual Acuity in any eye	30% (n=20)
Visual Acuity Changes^c	53% (n=50)
Blurred Vision^d	22% (n=21)
Dry Eye^e	14% (n=13)

^aKeratopathy was based on slit lamp eye examination, characterized as corneal epithelium changes with or without symptoms

^bOcular symptoms included visual acuity changes, blurred vision, or dry eye

^cVisual acuity changes included all grade BCVA change per KVA scale

^dBlurred vision included diplopia, vision blurred, visual acuity reduced, and visual impairment

^eDry eyes included dry eye, ocular discomfort, and eye pruritus.

DREAMM-2 Data on file.

Warnings and Precautions: Keratopathy^a

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

Grade per KVA Scale	Patients with Keratopathy BLENREP 2.5 mg/kg dosing; N = 95
All Grades	71%
Grade 1	8%
Grade 2	18%
Grade 3	44%
Grade 4	0%

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

^aKeratopathy 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^a; Median follow up: 6.3 months

	Patients with Keratopathy (Grade ≥ 2)
	BLNREP 2.5 mg/kg dosing, N = 59
Recovered to Grade 1 or lower, %	41%
Median time to resolution, days (range)	62 (11, 193)
Had ongoing keratopathy, %	59%
Still on treatment	29%
In follow-up	7%
Follow-up ended due to death, study withdrawal, or lost to follow up	24%

^aKeratopathy was based on slit lamp eye examination, characterized as corneal epithelium changes with or without symptoms

DREAMM-2 Data on file.

	BLNREP 2.5 mg/kg dosing N = 95	
	Visual Acuity in Better-seeing Eye Worse than 20/40	Visual Acuity in Better-seeing Eye 20/200 or Worse
Patients, %	17%	1%
Resolved, %	94%	100%
Median duration, days (range)	22 (7-64 days)	22 (22-22 days)

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 and Dosage Modifications for Adverse Reactions

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

Dosage Modifications for Corneal Adverse Reactions per the KVA Scale		
Category	Corneal Adverse Reaction	Recommended Dosage Modifications
Grade 1	<i>Corneal examination finding(s):</i> Mild superficial keratopathy ^a <i>Change in BCVA^b:</i> Decline from baseline of 1 line on Snellen Visual Acuity	Continue treatment at current dose.
Grade 2	<i>Corneal examination finding(s):</i> Moderate superficial keratopathy ^c <i>Change in BCVA^b:</i> Decline from baseline of 2 or 3 lines on Snellen Visual Acuity and not worse than 20/200	Withhold BLENREP until improvement in both corneal examination findings and changes in BCVA to Grade 1 or better and resume at same dose.
Grade 3	<i>Corneal examination finding(s):</i> Severe superficial keratopathy ^d <i>Change in BCVA^b:</i> Decline from baseline by more than 3 lines on Snellen Visual Acuity and not worse than 20/200	Withhold BLENREP until improvement in both corneal examination findings and changes in BCVA to Grade 1 or better and resume at reduced dose.
Grade 4	<i>Corneal examination finding(s):</i> Corneal epithelial defect ^e <i>Change in BCVA^b:</i> Snellen Visual Acuity worse than 20/200	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.

Reference Prescribing Information for BLENREP for management of other adverse reactions

^aMild superficial keratopathy (documented worsening from baseline), with or without symptoms; ^bChanges in visual acuity due to treatment-related corneal findings; ^cModerate superficial keratopathy with or without patchy microcyst-like deposits, sub-epithelial haze (peripheral), or a new peripheral stromal opacity; ^dSevere superficial keratopathy with or without diffuse microcyst-like deposits, sub-epithelial haze (central), or a new central stromal opacity; ^eCorneal epithelial defect such as corneal ulcers.

Prescribing Information for BLENREP

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

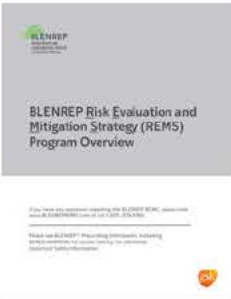
➔	Review Training Materials
	Access Knowledge Assessment
	Complete Enrollment Form
	Enroll Patients
	Manage Enrolled Patients
	Complete Patient Status Form
	Report Adverse Event



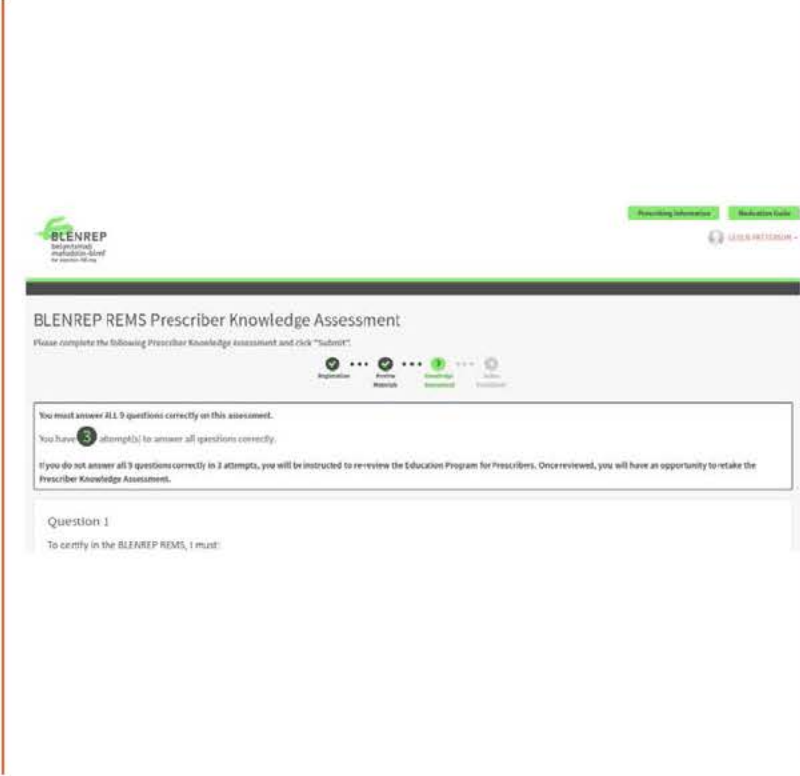
Education Program for Healthcare Settings (this presentation)



US Prescribing Information



REMS Program Overview



PRESCRIBER INFORMATION

*National Provider Identifier (NPI) #:

*State License #:

*First Name: Middle Initial: Last Name:

*Credentials:
☐ MD ☐ DO ☐ NP ☐ PA
☐ Other (please specify):

*Practice/Facility Name:

*Address Line 1: Address Line 2:


*City: *State: *ZIP Code:

*Phone: *Fax: *Email:

Access and Complete Knowledge Assessment following review of Training Materials

➔


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



BLENREP
belantamab
mafodotin-blmf
for injection 100 mg


Prescribing Information


Medication Guide


 LESLIE PATTERSON


BLENREP REMS Prescriber Knowledge Assessment

Please complete the following Prescriber Knowledge Assessment and click "Submit".

 Registration

 Review Materials

 Knowledge Assessment

 Online Enrollment

You must answer ALL 9 questions correctly on this assessment.

You have **3** attempt(s) to answer all questions correctly.

Answer nine multiple choice and/or true/false questions



COMPLETE ONLINE ENROLLMENT




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

Question 1 ✖

While on treatment with BLENREP



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



REVIEW MATERIALS



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

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

PRESCRIBER INFORMATION		
*National Provider Identifier (NPI) #:	State License #:	
<input type="text" value="1234567890"/>	<input type="text"/>	
*First Name	Middle Initial	*Last Name
<input type="text"/>	<input type="text"/>	<input type="text"/>
*Credentials	*Specialty	
<input type="checkbox"/> MD <input type="checkbox"/> DO <input type="checkbox"/> NP <input type="checkbox"/> PA <input type="checkbox"/> Other (please specify)	<input type="checkbox"/> Oncology <input type="checkbox"/> Hematology <input type="checkbox"/> Internal Medicine <input type="checkbox"/> Other (please specify)	
*Practice/Facility Name		
<input type="text"/>		
*Address Line 1	Address Line 2	
<input type="text"/>	<input type="text"/>	
*City	*State	*ZIP Code
<input type="text"/>	<input type="text" value="-- Please Select --"/>	<input type="text"/>
*Phone	*Fax	*Email
<input type="text"/>	<input type="text"/>	<input type="text"/>
Preferred Method of Communication	Preferred Time of Contact	
<input type="radio"/> Phone <input type="radio"/> Fax <input type="radio"/> Email	<input type="checkbox"/> AM <input type="checkbox"/> PM	

You may designate a delegate who will be copied on your automatic e-mail notifications; you may also designate a second practice location

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

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 1-885-209-9188.

*First Name

John

*Last Name

*Email

☐ Address - Same as Prescriber Address

Address Line 1

Address Line 2

City

State

-- Please Select --

ZIP Code

Phone

Fax

ALTERNATIVE PRACTICE/FACILITY LOCATION

Address Line 1

Address Line 2

City

State

-- Please Select --

ZIP Code

- 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

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



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 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.

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

RESET

SUBMIT

Click "Prescriber Signature" and then "Submit" to complete enrollment




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



For support, call 1-855-209-9188

To enroll patients, the prescriber will login to **BLNPREPREMS.com**, access “My Patients” and select “Enroll Patient”


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



BLENREP
belantamab
mafodotin-blmf
for injection 100 mg

Prescribing Information

Medication Guide

 Jones, Mark ▾

MY PATIENTS


My Patients

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

Download the list to spreadsheet format by clicking the Excel icon just above the column headers

Search/Filter the list by entering information in the textbox below any column header

Sort the list by clicking on any column header




REMS ID	First Name	Last Name	Zip	Date of Birth (MM/DD/YYYY)	Prescriber Signature Status	Patient Signature Status	Patient Status	Status Form Completed Date (MM/DD/YYYY)	Action

You currently have no patients enrolled

ENROLL PATIENT

REPORT CORNEAL ADVERSE EVENT

SUBMIT PATIENT STATUS FORM

 **ENROLL PATIENT**

Please begin the enrollment process by entering patient information and clicking on "Continue".

Note: Fields marked with an * are required.

*First Name

*Last Name

*Date of Birth (MM/DD/YYYY)

CANCEL

CONTINUE

Enter Name and Date of Birth

Click “Enroll Patient” to begin Patient Enrollment;
each Patient must be enrolled prior to receiving BLENREP

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

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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

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

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 Attestation**

☐ Patient Attestation ☐ Legal Guardian Attestation

***Print Name**

***Is patient or parent/guardian currently available to complete patient signature during online enrollment?**

☐ Yes ☐ No

☐ Would you like to receive text messages from the BLENREP REMS in order to sign your BLENREP REMS enrollment form? Message and data rates may apply. By clicking this check box, you are confirming that the patient has verbally agreed to receive text messages.

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

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

Welcome

Agree to Terms

Sign

Done

A new document from BLENREP REMS is available for you to sign. You will be given the opportunity to:

- Preview the document
- Send feedback or questions to BLENREP REMS
- Decline signing and send feedback to BLENREP REMS
- Sign the document electronically using AssureSign

UserName: abc@abc.com

Note - Please check your text message/email for the password.

Password*

Powered by AssureSign

Welcome

Agree to Terms

Sign

Done

Review the terms and conditions below and check the checkbox indicating your agreement to receive and sign this document electronically. Click **Start Signing** when you are ready to sign.

By checking the box below, I agree that the electronic, digitized signatures I apply on the following document are representations of my signature and are legally valid and binding as if I had signed the document with ink on paper in accordance with the Uniform Electronic Transactions Act (UETA) and the Electronic Signatures in Global and National Commerce Act (E-SIGN) of 2000.

AssureSign complies with requirements and standards of the Electronic Signatures in Global and National Commerce Act (E-SIGN Act) effective October 1, 2000, the UETA, and the Government Paperwork Elimination Act (GPEA).

☐ I have read and agree to the terms and conditions

Preview Document

Powered by AssureSign



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

Patient will enter the verification code received via email or text

Patient will read and agree to the terms and conditions

Adopt a Signature

Provide your name by drawing with touch, mouse, or stylus.

Signature

By clicking "Adopt Signature", I agree that the signature and initials above will be the electronic representation of my signature and initials for all purposes when I use them to sign documents. Applying them to a document is legally equivalent to signing with a pen on paper.

Adopt Signature

Patient will draw signature and click "adopt signature"

The Prescriber assesses the Patient's ocular health prior to each dose by consulting an Eye Care Professional

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



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

Date of Assessment: _____

Section 1: For Baseline Examination Only

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

Eye Care Professional Consult Form

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

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

	Corneal Examination Findings Check One	Changes in BCVA from Baseline (per Snellen Visual Acuity) Check One
Right eye (OD)	<input type="checkbox"/> No change from baseline <input type="checkbox"/> Mild superficial keratopathy <input type="checkbox"/> Moderate superficial keratopathy <input type="checkbox"/> Severe superficial keratopathy <input type="checkbox"/> Corneal epithelial defect	<input type="checkbox"/> No change from baseline <input type="checkbox"/> Decline from baseline of 1 line <input type="checkbox"/> Decline from baseline of 2 or 3 lines on Snellen Visual Acuity and not worse than 20/200 <input type="checkbox"/> Decline from baseline by more than 3 lines on Snellen Visual Acuity and not worse than 20/200 <input type="checkbox"/> 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	Changes in BCVA from Baseline (per Snellen Visual Acuity) Check One
Left eye (OS)	<input type="checkbox"/> No change from baseline <input type="checkbox"/> Mild superficial keratopathy <input type="checkbox"/> Moderate superficial keratopathy <input type="checkbox"/> Severe superficial keratopathy <input type="checkbox"/> Corneal epithelial defect	<input type="checkbox"/> No change from baseline <input type="checkbox"/> Decline from baseline of 1 line <input type="checkbox"/> Decline from baseline of 2 or 3 lines on Snellen Visual Acuity and not worse than 20/200 <input type="checkbox"/> Decline from baseline by more than 3 lines on Snellen Visual Acuity and not worse than 20/200 <input type="checkbox"/> 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 **BLNPREPREMS.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



Prescribing Information

Medication Guide

Jones, Mark

MY PATIENTS

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/Filter the list by entering information in the textbox below any column header

Sort the list by clicking on any column header

REPORT CORNEAL ADVERSE EVENT

SUBMIT PATIENT STATUS FORM (PSF)

REMS ID	First Name	Last Name	Zip	Date of Birth (MM/DD/YYYY)	Prescriber Signature Status	Patient Signature Status	Patient Status	Status Form Completed Date (MM/DD/YYYY)	Action
1234	Peggy	Sue	19542	3/2/2000			ENROLLED - PENDING PATIENT STATUS FORM		<div>Submit PSF</div>
5876	Martin	Berry	34534	8/31/1995		<div>Sign</div>	PENDING		

<<<>>>

Page 1 of 11 | Total Records: 55

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



Prescribing Information

Medication Guide

Jones, Mark

MY PATIENTS

My Patients

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

ENROLL PATIENT

REPORT CORNEAL ADVERSE EVENT

SUBMIT PATIENT STATUS FORM (PSF)

Download the list to spreadsheet format by clicking the Excel icon just above the column headers.

Search/Filter the list by entering information in the textbox below any column header

Sort the list by clicking on any column header

REMS ID

First Name

Last Name

Zip

Date of Birth (MM/DD/YYYY)

Prescriber Signature Status

Patient Signature Status

Patient Status

Status Form Completed Date (MM/DD/YYYY)

Action

1234	Peggy	Sue	19542	3/2/2000			ENROLLED - PENDING PATIENT STATUS FORM	<div>Submit PSF</div>
5876	Martin	Berry	34534	8/31/1995		<div>Sign</div>	PENDING	

Page 1 of 11 | Total Records: 55

The Prescriber will enter the Eye Care Professional's Information, Ophthalmic Assessment, and attest to having reviewed the ophthalmic exam

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

EYE CARE PROFESSIONAL INFORMATION

* First Name:

* Last Name:

* Phone:

Email:

Fax:

National Provider Identifier (NPI) #:

Practice/Facility Name:

Address Line 1:

Address Line 2:

City:

State:

-- Please Select --

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 finding(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

CANCEL

SUBMIT

Additional detail will be requested if you select "no"; see next slide

Reference ID: 4652412

BLMPPT200025
0002-0008-13

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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

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

* 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 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

- ☐ No change from baseline
- ☐ Mild superficial keratopathy
- ☐ Moderate superficial keratopathy
- ☐ Severe superficial keratopathy
- ☐ Corneal epithelial defect

*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

Additional Corneal Examination Finding

Specify

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

☐ Yes ☒ No

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

*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)

☐ Normal ☐ Grade 1 ☐ Grade 2 ☐ Grade 3 ☐ Grade 4

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”


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



BLENREP
belantamab-
bimol
for injection 100 mg

Prescribing Information

Medication Guide

 Jonas, Mark

MY PATIENTS

My Patients

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

ENROLL PATIENT

REPORT CORNEAL ADVERSE EVENT

SUBMIT PATIENT STATUS FORM (PSF)

Patient Listing

Download the list to spreadsheet format by clicking the Excel icon just above the column headers

Search/Filter the list by entering information in the textbox below any column header

Sort the list by clicking on any column header

REMS ID	First Name	Last Name	Zip	Date of Birth (MM/DD/YYYY)	Prescriber Signature Status	Patient Signature Status	Patient Status	Status Form Completed Date (MM/DD/YYYY)	Action
1234	Peggy	Sue	19542	3/2/2000			ENROLLED - PENDING PATIENT STATUS FORM		<div>Submit PSF</div>
9876	Martin	Berry	34534	8/31/1995		<div>Sign</div>	PENDING		

Page 1 of 13 | Total Records: 55

Patient Adverse Event Form

SELECT PATIENT

Please click on the row to select the patient

First Name	Last Name	Date of Birth
Peggy	Sue	2/2/2000
Martin	Berry	7/8/1999

CANCEL

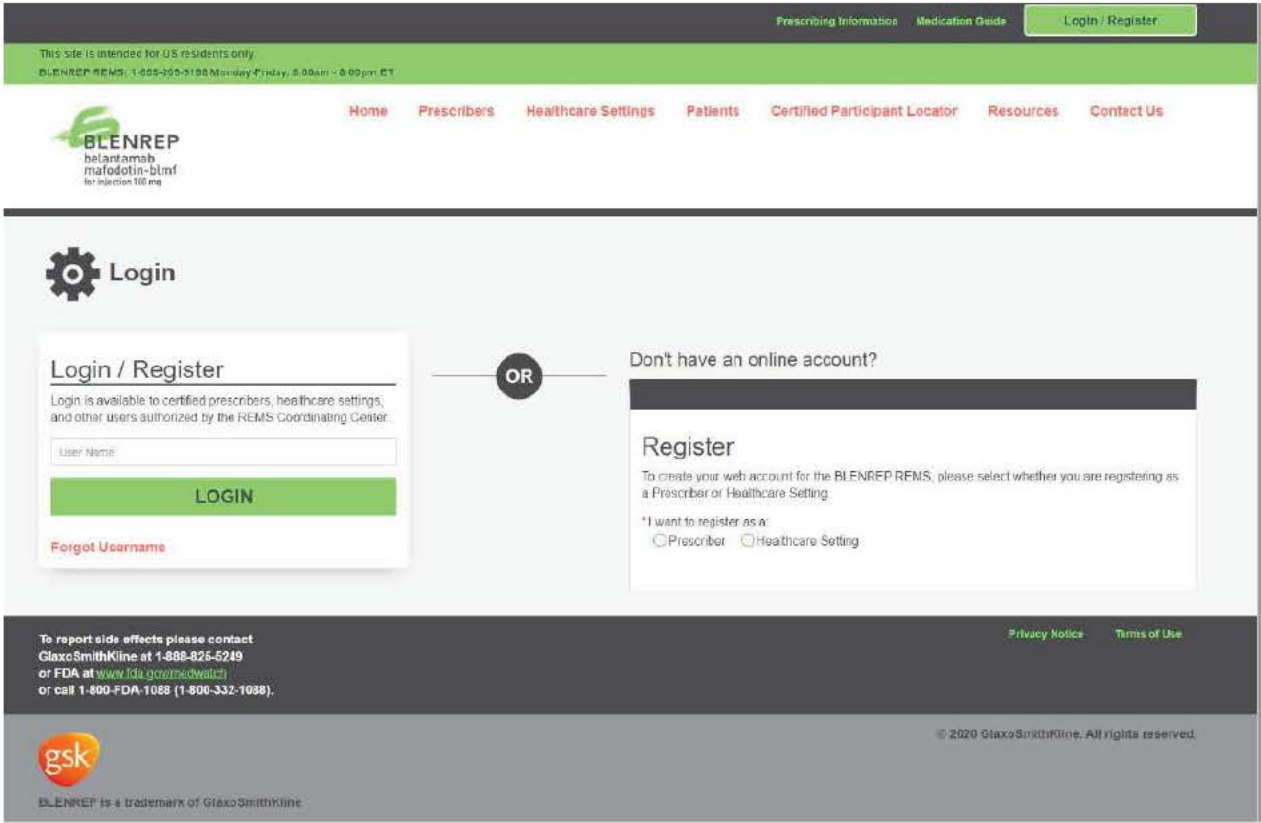
CONTINUE

Select the Correct Patient

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



Key Features of BLNPREMS.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.BLNPREMS.com

BLENREP™ REMS Prescriber Knowledge Assessment



BLENREP
belantamab
mafodotin-blmf
for injection 100 mg

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 exam 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)

First Name*:

Last Name*:

National Provider Identifier (NPI) *:

Phone:

Email*:

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

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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

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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 **R**isk **E**valuation and **M**itigation **S**trategy (**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)

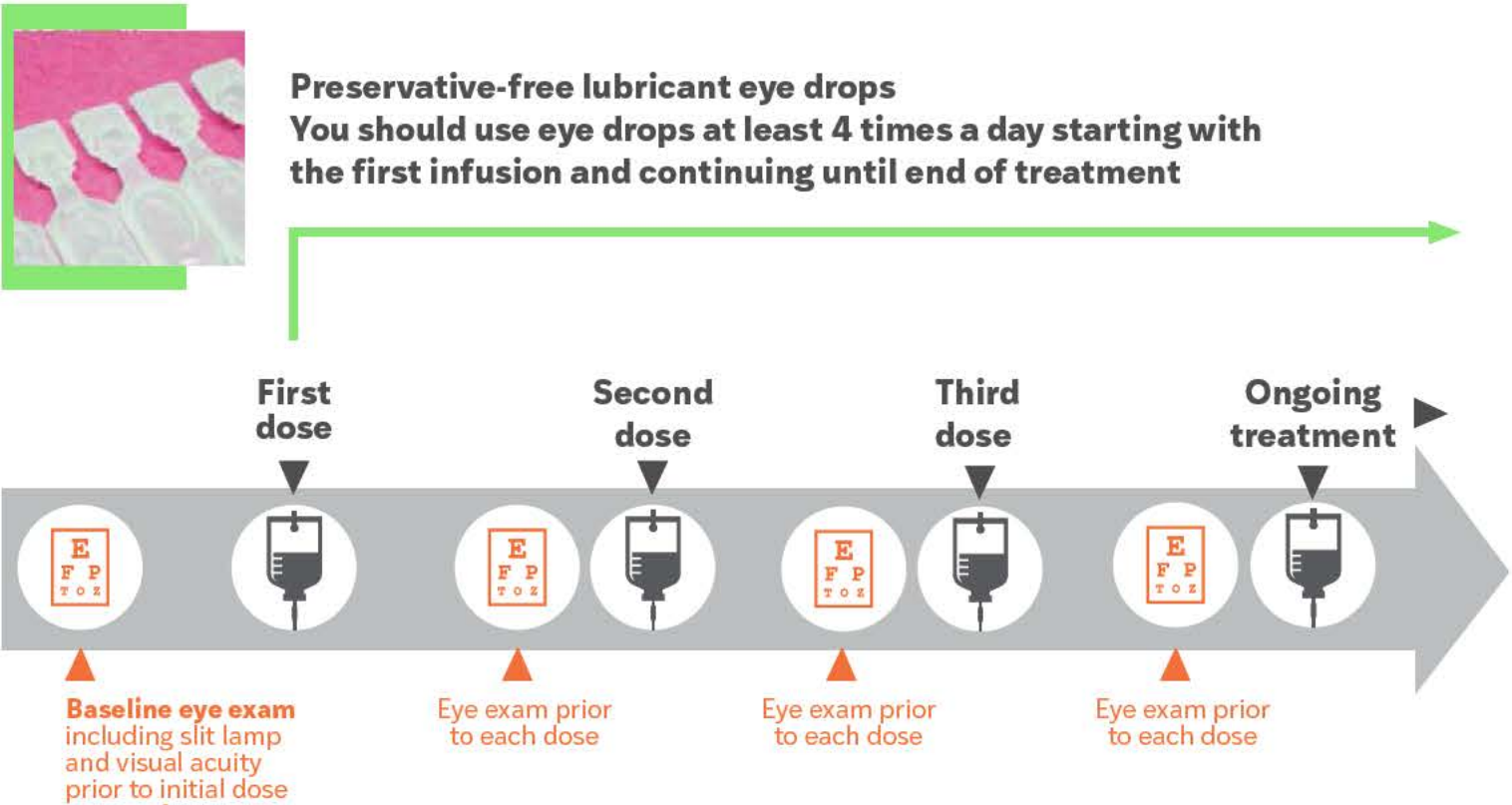
2 Your healthcare provider will help you complete and sign the Patient Enrollment Form to enroll you in the BLENREP REMS.

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.

BLENREP Treatment Overview



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.

- 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.

Notes

This image shows a single sheet of white paper with horizontal ruling lines. The lines are evenly spaced and run across the width of the page. There are no margins, text, or other markings on the paper.



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0002-0008-16
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BLNREP Risk Evaluation and Mitigation Strategy (REMS)

Healthcare Setting Training



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: Key US Prescribing Information

Indications and Usage

- 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.

BLNREP: Key US Prescribing Information

WARNING: OCULAR TOXICITY

- BLNREP caused changes in the corneal epithelium resulting in changes in vision, including severe vision loss and corneal ulcer, and symptoms, such as blurred vision and dry eyes.
- Conduct ophthalmic exams at baseline, prior to each dose, and promptly for worsening symptoms. Withhold BLNREP until improvement and resume, or permanently discontinue, based on severity.
- Because of the risk of ocular toxicity, BLNREP is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the BLNREP REMS.



BLENREP: REMS Overview

Due to the risks of ocular toxicity, BLENREP is available only through a restricted program called the BLENREP REMS

What is the BLENREP REMS?



- A Risk Evaluation and Mitigation Strategy, or REMS, is a strategy to manage known or potential risks associated with a product. It is required by the Food and Drug Administration (FDA) to ensure the benefits of the drug outweigh its risks.
- Because of the risk of ocular toxicity, BLENREP is available only through a restricted program called the BLENREP REMS.

What are the BLENREP REMS requirements?



Prescribers must be certified with the program by enrolling and completing training in the BLENREP REMS, and they must counsel patients receiving BLENREP about the risk of ocular toxicity and the need for ophthalmic examinations prior to each dose.



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



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



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

Prior to first patient infusion, the Healthcare Setting will designate an authorized representative to review training, enroll in the REMS, establish REMS processes and train staff



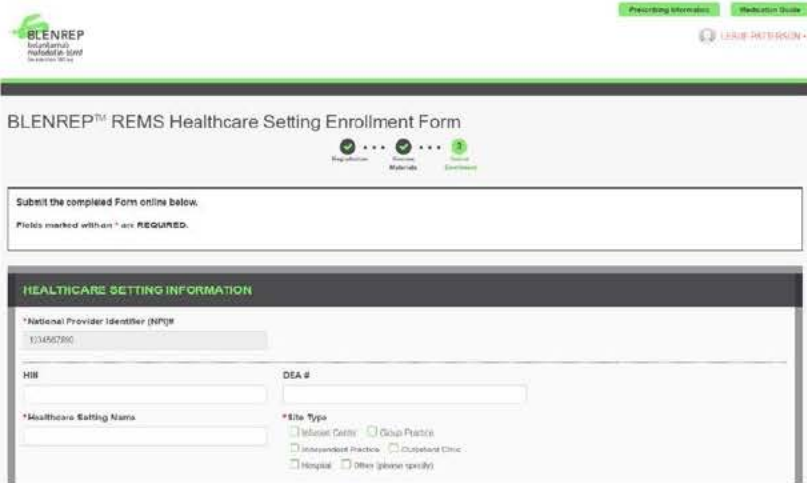
Education Program for Healthcare Settings (this presentation)



US Prescribing Information




REMS Program Overview



The screenshot shows the 'BLENREP™ REMS Healthcare Setting Enrollment Form'. It includes a progress bar with three steps: 'Registration', 'Review Materials', and 'Enrollment', with the third step being active. Below the progress bar, it says 'Submit the completed Form online below.' and 'Fields marked with an * are REQUIRED.' The form fields include: 'National Provider Identifier (NPI)*' (with value 1234567890), 'HIN', 'DEA #', 'Healthcare Setting Name', and 'Site Type'. The 'Site Type' section has checkboxes for 'Infusion Center', 'Outpatient Clinic', 'Independent Practice', 'Hospital', and 'Other (please specify)'.




After reviewing training materials, the Healthcare Setting Authorized Representative will enroll in the BLENREP REMS via the online portal



Prescribing Information

Medication Guide

 LESLIE PATTERSON

BLENREP™ REMS Healthcare Setting Enrollment Form

1

Registration

2

Review Materials

3

Online Enrollment

Submit the completed Form online below.

Fields marked with an * are REQUIRED.

HEALTHCARE SETTING INFORMATION

* National Provider Identifier (NPI)*

1234567890

HIN

* Healthcare Setting Name

DEA #

* Site Type

☐ Infusion Center

☐ Group Practice

☐ Independent Practice

☐ Outpatient Clinic

☐ Hospital

☐ Other (please specify)

You will need to provide:

- Healthcare Setting NPI
- Healthcare Setting Name and Type
- Healthcare Setting Address
- Authorized Representative contact information

During enrollment, you may designate one Authorized Representative for multiple healthcare settings (e.g. multiple affiliated infusion centers), if relevant

Paper form available for fax submission



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

REMS VERIFICATION HEALTHCARE SETTING MANAGEMENT REMS CHECKLIST

Delegate/User Management

Below is a list of your associated Delegates/Users who require access to the BLENREP REMS portal.

Healthcare Settings

HCS 1
123 Main Street
City, State Zip
NPI #: 1234567890

DELEGATES **ADD/ASSOCIATE DELEGATE**

Loretta Maybly
lmaybly@hcs1.com
REMOVE ASSOCIATION

Steve Mason
smason@hcs1.com
REMOVE ASSOCIATION



Prior to Patient Infusion: obtain authorization to dispense;
Following infusion: complete the REMS Checklist



BLINREP
bupivacaine
hydrochloride
injection, 0.5%
10 mg/mL

Prescribing information | Medication guide

REMS VERIFICATION | HEALTHCARE SETTING MANAGEMENT | REMS CHECKLIST

REMS Verification

Please enter the information below to verify enrollment.
Fields marked with * are required.

HEALTHCARE SETTING INFORMATION

You may enter the Healthcare Setting NPI#, Name or Address/City/State/Zip, then select the healthcare setting.

*Healthcare Setting

PRESCRIBER INFORMATION

You may enter the Prescriber NPI#, First Name or Last Name, then select the prescriber.

*Prescriber

PATIENT INFORMATION

*First Name *Last Name *Date of Birth

CLEAR SUBMIT



BLINREP
bupivacaine
hydrochloride
injection, 0.5%
10 mg/mL

Prescribing information | Medication guide

REMS VERIFICATION | HEALTHCARE SETTING MANAGEMENT | REMS CHECKLIST

REMS Checklist

Submit the completed form online below.

As a condition of your authorization to dispense BLINREP this checklist must be completed for each patient within 5 business days of infusion. You will receive a confirmation of receipt via an automatic email notification after submission of this checklist. Keep a copy of the notification in the patient's medical record.

Fields marked with an * are REQUIRED.

PATIENT INFORMATION

First Name: Proxy Last Name: Doe Date of Birth (MM/DD/YYYY): 3/24/2001
Patient BLINREP REMS Identification #: 12345

PRESCRIBER INFORMATION

First Name: Adams Last Name: Bob National Provider Identifier (NPI) #: 123456789


HEALTHCARE SETTING INFORMATION

Healthcare Setting Name: Mockland Associated HCS Healthcare Setting BLINREP REMS Identification #: 12345
National Provider Identifier (NPI) #: 234567891 Phone: 555.555.3454

SUBMIT

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:



BLENREP
belantamab mafodotin-blmf
for injection 100 mg

Prescribing information

Medication Guide

 Jones, Mark

REMS VERIFICATION

HEALTHCARE SETTING MANAGEMENT

REMS CHECKLIST

REMS Verification

Please enter the information below to verify enrollment.

Fields marked with * are required.

HEALTHCARE SETTING INFORMATION

You may enter the Healthcare Setting NPI#, Name or Address/City/State/Zip, then select the healthcare setting

*Healthcare Setting

PRESCRIBER INFORMATION

You may enter the Prescriber NPI#, First Name or Last Name, then select the prescriber.

*Prescriber

PATIENT INFORMATION

*First Name	*Last Name	*Date of Birth
<input type="text"/>	<input type="text"/>	<input type="text"/>

CLEAR

SUBMIT

The REMS Coordinating Center
(1-855-209-9188) can also provide
authorization information

REMS Verification will indicate if it is okay to infuse the patient or not


If patient is eligible, you will receive the “OK TO INFUSE” message noted below; select **“Generate Authorization Code”** and note the code for the REMS Checklist:

Verification Results

You must generate an authorization code to complete this verification.

GENERATE AUTHORIZATION CODE

REMS Authorization Code:
32327

 **OK TO INFUSE**
REMS verification successful.
Authorization Code needed

Prescriber	✓ Susan Gold Prescriber REMS ID: 12345	Certified
Patient	✓ Janet Bowers Patient REMS ID: 987374	Enrolled - Cleared for Infusion



If patient is not eligible, **do not proceed; contact the REMS Coordinating Center (1-855-209-9188)**

Verification Results

PLEASE CALL FOR ASSISTANCE
1-855-209-9188

 **DO NOT INFUSE**
REMS verification failed.

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



Complete the REMS Checklist within 5 business days of infusion by entering the date of administration, actual dose, and by electronically signing the checklist (1/2)



Prescribing Information Medication Guide

MAURA BARR

REMS VERIFICATION HEALTHCARE SETTING MANAGEMENT REMS CHECKLIST

REMS Checklist

Submit the completed form online below.

As a condition of your authorization to dispense BLENREP, this checklist must be completed for each patient within 5 business days of infusion. You will receive a confirmation of receipt via an automatic email notification after submission of this checklist. Keep a copy of the notification in the patient's medical record.

Fields marked with an * are REQUIRED.

> PATIENT INFORMATION

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

> PRESCRIBER INFORMATION

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

> HEALTHCARE SETTING INFORMATION

Healthcare Setting Name: Professional Associates, HCS Healthcare Setting BLENREP REMS Identification #: 12345
National Provider Identifier (NPI) #: 2345678901 Phone: 555 555-3434

Complete the REMS Checklist within 5 business days of infusion by entering the date of administration, actual dose, and by electronically signing the checklist (2/2)

AUTHORIZATION CODE PRIOR TO DISPENSING

Authorization: 32327

Dosing Information

*Date of infusion: (MM/DD/YYYY)

*Actual dose (mg)

SIGNATURE OF STAFF COMPLETING CHECKLIST

☐ *Signature

*First Name

Peggy

*Last Name

Sue

*Credentials

☒ DO

☐ MD

☐ PharmD

☐ RN

☐ NP

☐ PA

☐ Other (please specify)

*Phone

*Fax

*Email

a@abc.com

SEND INFUSION INFORMATION TO THE BLENREP REMS

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

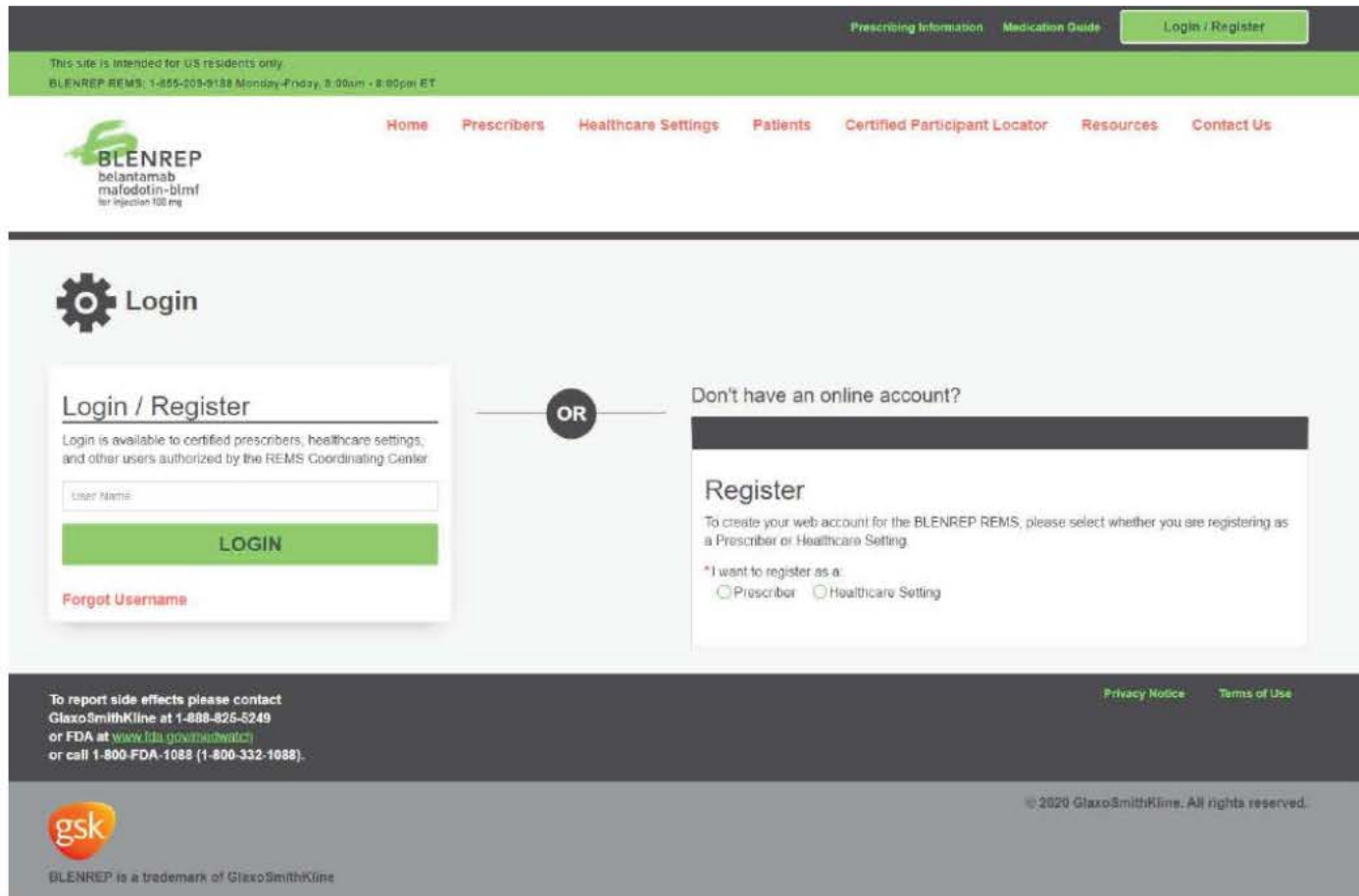
CANCEL

SUBMIT

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



The screenshot displays the BLNPREMS.com website. At the top, there is a navigation bar with links for 'Prescribing Information', 'Medication Guide', and 'Login / Register'. Below this, a green banner states: 'This site is intended for US residents only. BLNPREM REMS: 1-855-209-9188 Monday-Friday, 8:00am - 8:00pm ET'. The main header includes the BLNPREM logo (belantamab mafodotin-blmf for injection 100 mg) and a navigation menu with links: 'Home', 'Prescribers', 'Healthcare Settings', 'Patients', 'Certified Participant Locator', 'Resources', and 'Contact Us'. The central area features a 'Login' section with a gear icon and a 'Login / Register' form. The form has a 'User Name' input field, a green 'LOGIN' button, and a 'Forgot Username' link. To the right of the login form is an 'OR' separator and a 'Don't have an online account?' section with a 'Register' form. The register form includes a text box for the user's name, a 'Register' button, and a section for selecting the user type: 'I want to register as a:' with radio buttons for 'Prescriber' and 'Healthcare Setting'. At the bottom of the page, there is a footer with contact information for reporting side effects, links for 'Privacy Notice' and 'Terms of Use', the GSK logo, and a copyright notice: '© 2020 GlaxoSmithKline. All rights reserved.'.

Key Features of BLNPREMS.com

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

For More Information



Call 1-855-209-9188



Visit www.BLNPREMS.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

From: PDR Drug Alerts <do-not-reply@email.pdr.net>
Sent: <Day>, <Month> <Date>, <Year> <Time>
To: <Last Name, First Name> <XX@XXXX.com>
SUBJECT: BLENREP Healthcare Provider Risk Evaluation and Mitigation Strategy (REMS) Letter
ATTACHMENT: Factsheet

Having trouble reading this email? [View it in your browser.](#)

For additional important information, including the complete Prescribing Information, please visit: <http://www.pdr.net/pdr-drug-communications/drug-alert/?id=XXXXXXX>.



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.
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- Dosage modifications or discontinuation of treatment may be needed to mitigate the risk of ocular toxicity.

REMS Requirements

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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.

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

BLM-LTR-200007
0002-0008-18
GSK Final (08/2020)

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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

MORE INFORMATION >>



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.

For More Information and to enroll in the BLENREP REMS Program call 1-855-209-9188 go to www.BLENREPREMS.com

BLM-LTR-200009
0002-0008-20

Reference ID: A652412

BLENREP
belantamab
mafodotin-blmf
for injection 100 mg





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

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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.

LEARN MORE

HEALTHCARE SETTINGS

Healthcare settings must become certified in the BLENREP REMS to order and dispense BLENREP.

LEARN ABOUT HEALTHCARE SETTING CERTIFICATION.

LEARN MORE

PATIENTS

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](#).

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).



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LEARN MORE

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

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Prescribers

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

To Become Certified in the BLNREP 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 BLNREP REMS

 - Online
 - By fax at 1-888-635-1044
- 4

The Healthcare Setting where BLNREP 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 BLNREP REMS will send confirmation of a prescriber's enrollment within 2 business days, including the prescriber's assigned BLNREP REMS identification number. You will not be able to prescribe BLNREP without completing your certification in the BLNREP REMS. If you fail to comply with the BLNREP REMS requirements, you will no longer be able to participate in the BLNREP REMS.

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

- 1

Counsel your patient using the *Patient Guide* about:

 - the risk of ocular toxicity and
 - 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 BLNREP REMS will send confirmation of a patient's enrollment within 2 business days, including the patient's assigned BLNREP REMS identification number. Patients who are prescribed BLNREP must be enrolled in the BLNREP 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 BLNREP 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 withhold BLNREP until improvement or permanently discontinue based on severity
- If continuation of therapy is appropriate, document and submit the *Patient Status Form* to the BLNREP REMS
 - Online
 - By fax at 1-888-635-1044

Notify the BLNREP REMS if an enrolled patient who has received BLNREP is no longer under your care or has discontinued treatment.

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).

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Healthcare Settings

BLNREP is only available through the BLNREP REMS. In order for a Healthcare Setting to order and dispense BLNREP, they must become certified. Certified Healthcare Settings may access BLNREP through BLNREP-authorized Specialty Distributors contracted with GlaxoSmithKline.

To Become Certified in the BLNREP 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 1-888-635-1044

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

Instructions for Healthcare Settings:

Before administering:

- 1

Train all relevant staff involved in dispensing and administering BLNREP using:
 - [Program Overview](#)
 - [Education Program for Healthcare Settings](#)
- 2

Establish processes and procedures to verify the REMS Checklist is completed and submitted for each patient.
- 3

Obtain authorization to administer each dose by logging into the BLNREP REMS portal to verify*:
 - prescriber is certified
 - patient is enrolled and authorized to receive BLNREP

After administering, within 5 business days:

- 1

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 1-888-635-1044

To maintain certification to administer:

- 1

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:

- 1

Do not distribute, transfer, loan, or sell BLNREP.
- 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 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 BLNREP REMS Coordinating Center at 1-855-209-9188 to verify this information and obtain the authorization to dispense BLNREP.

Who Can Be an Authorized Representative?

An Authorized Representative at the Healthcare Setting can be a:

- Pharmacist
 - Physician
 - Director of Healthcare Setting
 - Nurse
 - Nurse Practioner
 - 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 *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.



A **R**isk **E**valuation and **M**itigation **S**trategy (**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.

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

How Do I Enroll in the BLNREP 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 BLNREP.
 - The risk of eye problems while you are on treatment with BLNREP, 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 BLNREP
 - prior to each dose of BLNREP
 - 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 BLNREP 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 BLNREP as instructed by your healthcare provider.
 - You should use caution when driving or operating machinery as BLNREP may affect your vision.
 - Avoid wearing contact lenses during treatment with BLNREP 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 BLNREP REMS.

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).

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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

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or FDA at www.fda.gov/medwatch
or call 1-800-FDA-1088 (1-800-332-1088).

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Certified Participant Locator

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CERTIFIED PRESCRIBERS

CERTIFIED HEALTHCARE SETTINGS

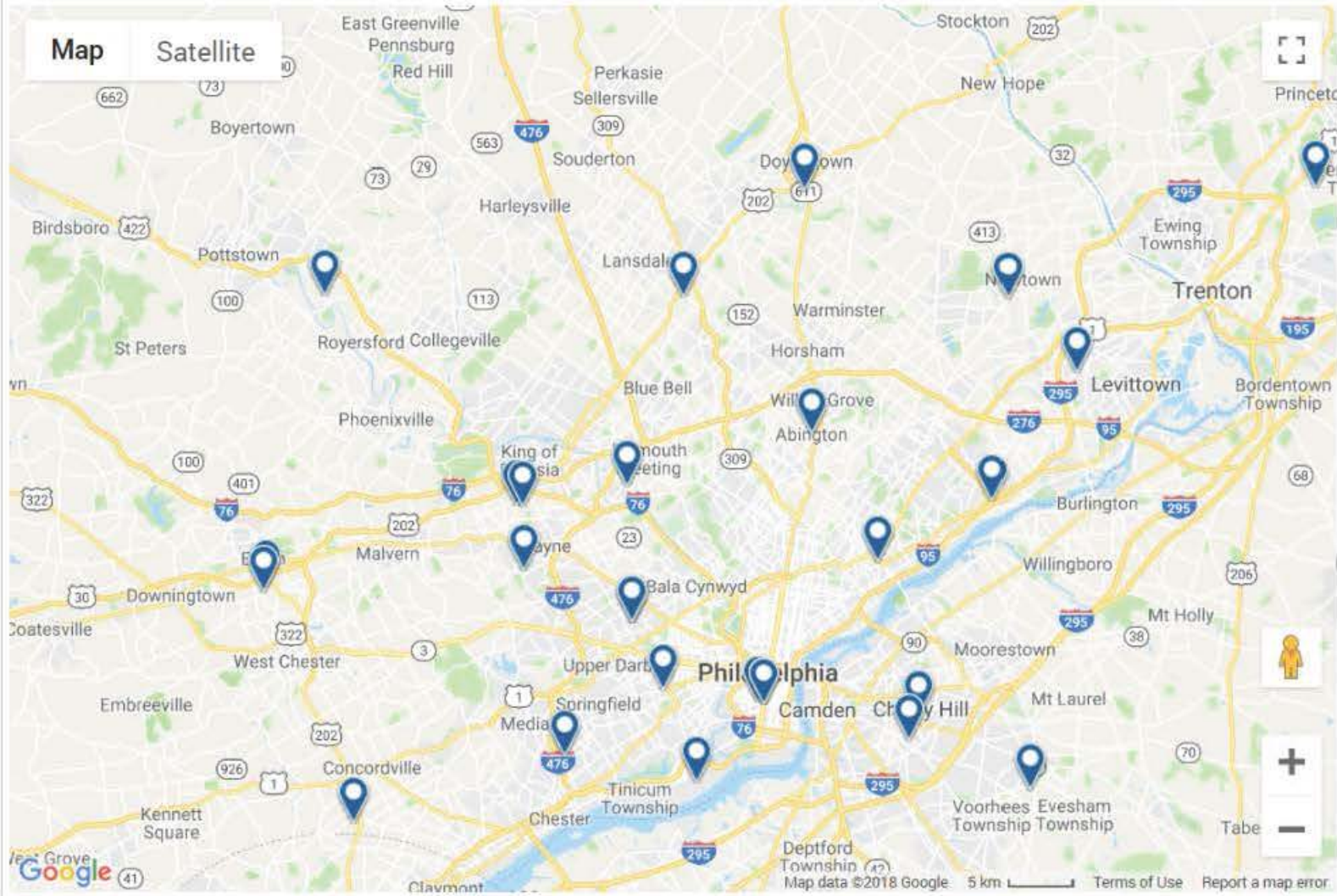
*Find a Certified Participant near:







12345

*Search Radius:

Within 25 miles

SEARCH



	PRESCRIBER NAME 100 Main St Blue Bell, PA 19422 555 555-1212	75.1 miles	DIRECTIONS
	PRESCRIBER NAME 100 Main St Blue Bell, PA 19422 555 555-1212	75.6 miles	DIRECTIONS
	PRESCRIBER NAME 100 Main St Blue Bell, PA 19422 555 555-1212	75.6 miles	DIRECTIONS
	PRESCRIBER NAME 100 Main St Blue Bell, PA 19422 555 555-1212	75.6 miles	DIRECTIONS
	PRESCRIBER NAME 100 Main St Blue Bell, PA 19422 555 555-1212	76.2 miles	DIRECTIONS
	PRESCRIBER NAME 100 Main St Blue Bell, PA 19422 555 555-1212	76.6 miles	DIRECTIONS

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



Certified Participant Locator

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

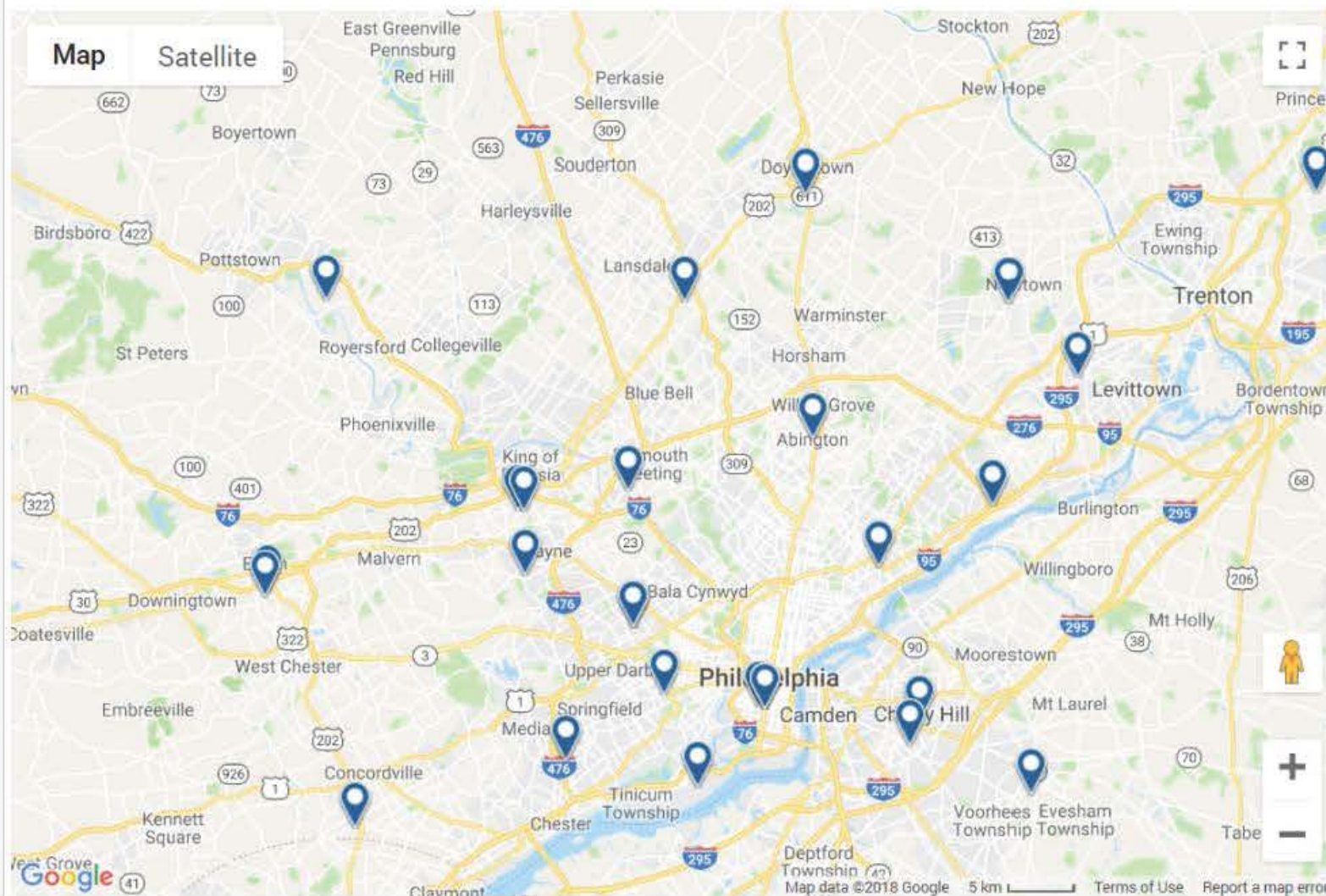
CERTIFIED HEALTHCARE SETTINGS

* Search Radius:

12345

Within 25 miles

SEARCH



75.1 miles

100 Main St
Blue Bell, PA 19422
555 555-1212

DIRECTIONS

75.6 miles

100 Main St
Blue Bell, PA 19422
555 555-1212

DIRECTIONS

75.6 miles

100 Main St
Blue Bell, PA 19422
555 555-1212

DIRECTIONS

75.6 miles

100 Main St
Blue Bell, PA 19422
555 555-1212

DIRECTIONS

76.2 miles

100 Main St
Blue Bell, PA 19422
555 555-1212

DIRECTIONS

76.6 miles

100 Main St
St. Paul, MN 55102

DIRECTIONS

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[Resources](#)

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Resources

PRESCRIBERS

[Program Overview](#)

[Education Program for Prescribers](#)

[Knowledge Assessment](#)

[Prescriber Enrollment Form](#)

[Patient Status Form](#)

[Eye Care Professional Consult Request Form](#)

[Healthcare Provider Letter](#)

[Professional Society Letter](#)

[BLNREP REMS Fact Sheet](#)

HEALTHCARE SETTINGS

[Program Overview](#)

[Education Program for Healthcare Settings](#)

[Healthcare Setting Enrollment Form](#)

[REMS Checklist](#)

PATIENTS

[Medication Guide](#)

[Patient Guide](#)

[Patient Enrollment Form](#)

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or FDA at www.fda.gov/medwatch
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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

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