

# **BLENREP Risk Evaluation and Mitigation Strategy (REMS)**

## **Education Program for Prescribers**



BLMPPT200025  
0002-0008-13

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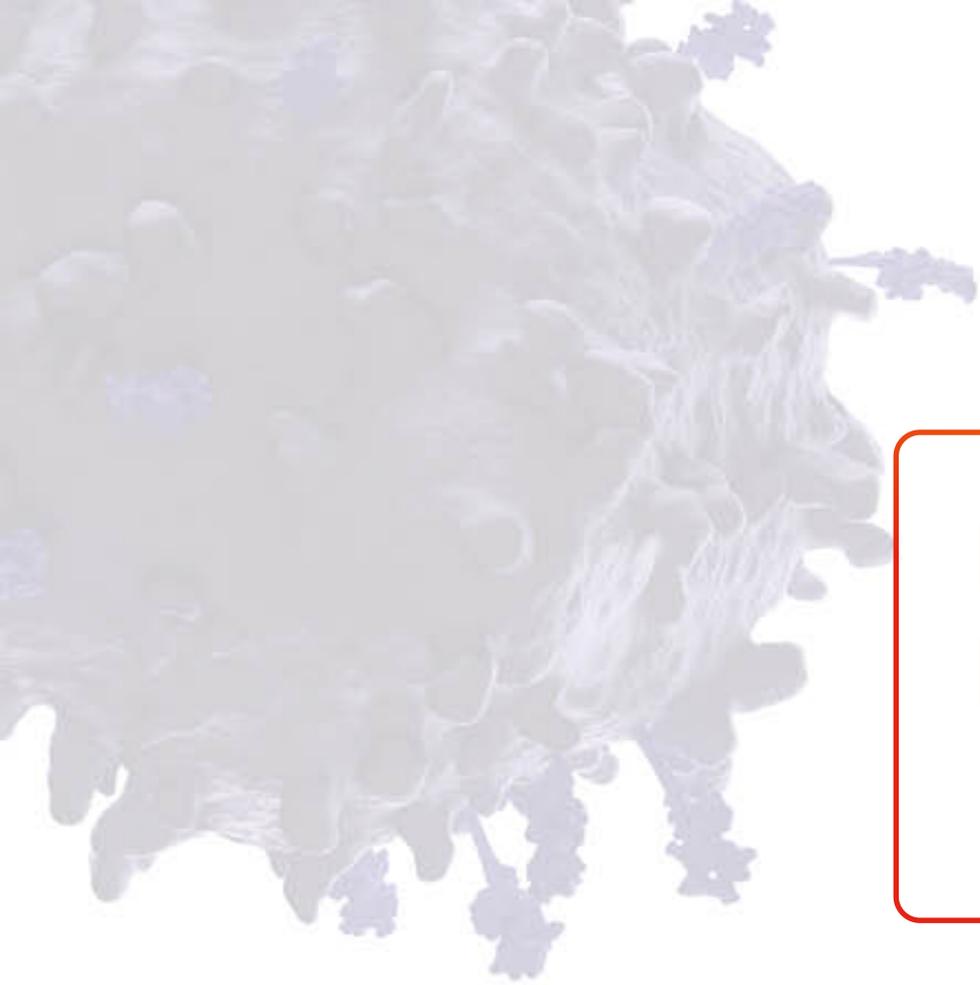
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# **BLENREP: REMS Summary and Key US Prescribing Information**

# BLNREP: Key US Prescribing Information

## Indications and Usage

- BLNREP 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 risk of ocular toxicity, BLENREP is available only through a restricted program called the BLENREP REMS

## What is the BLENREP REMS?



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

## What are the BLENREP REMS requirements?



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



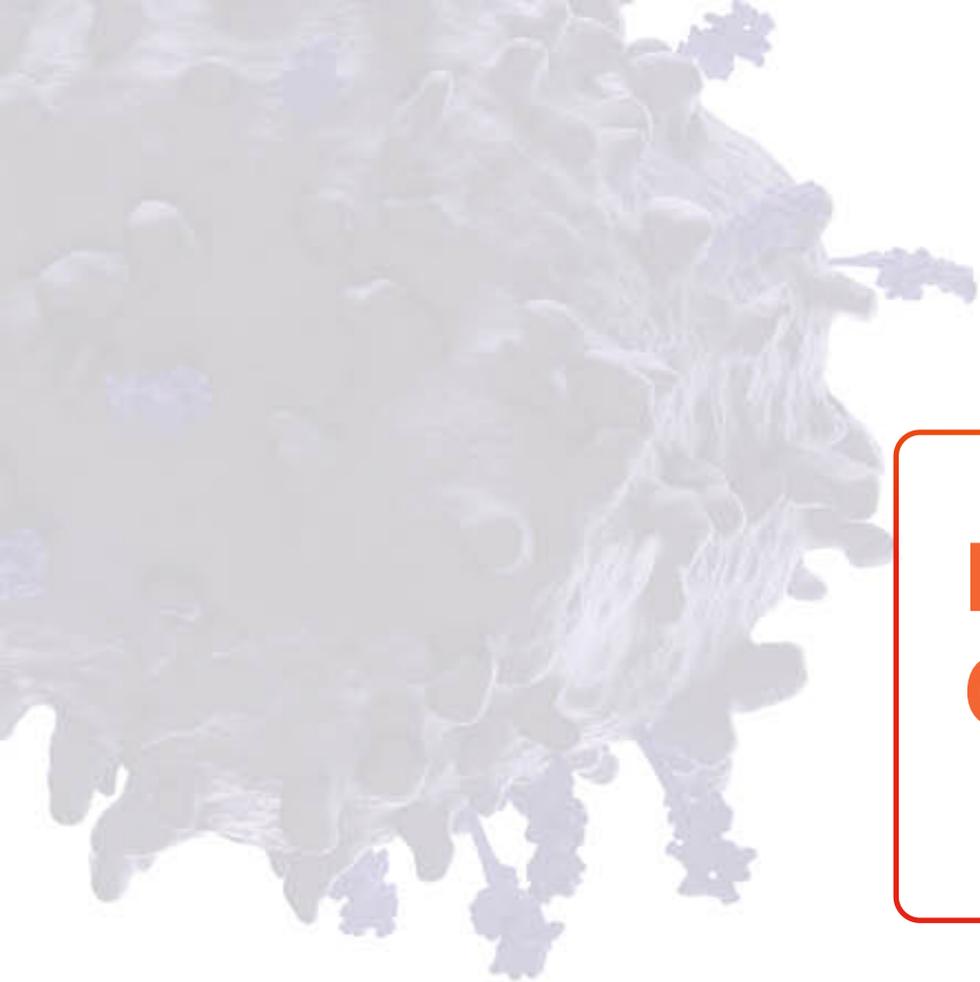
**Patients** must be enrolled in the BLENREP REMS and comply with monitoring.



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



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



# **BLENREP: Overview and Clinical Data**

# Overview of BLENREP: What it is and how it works

## The Target

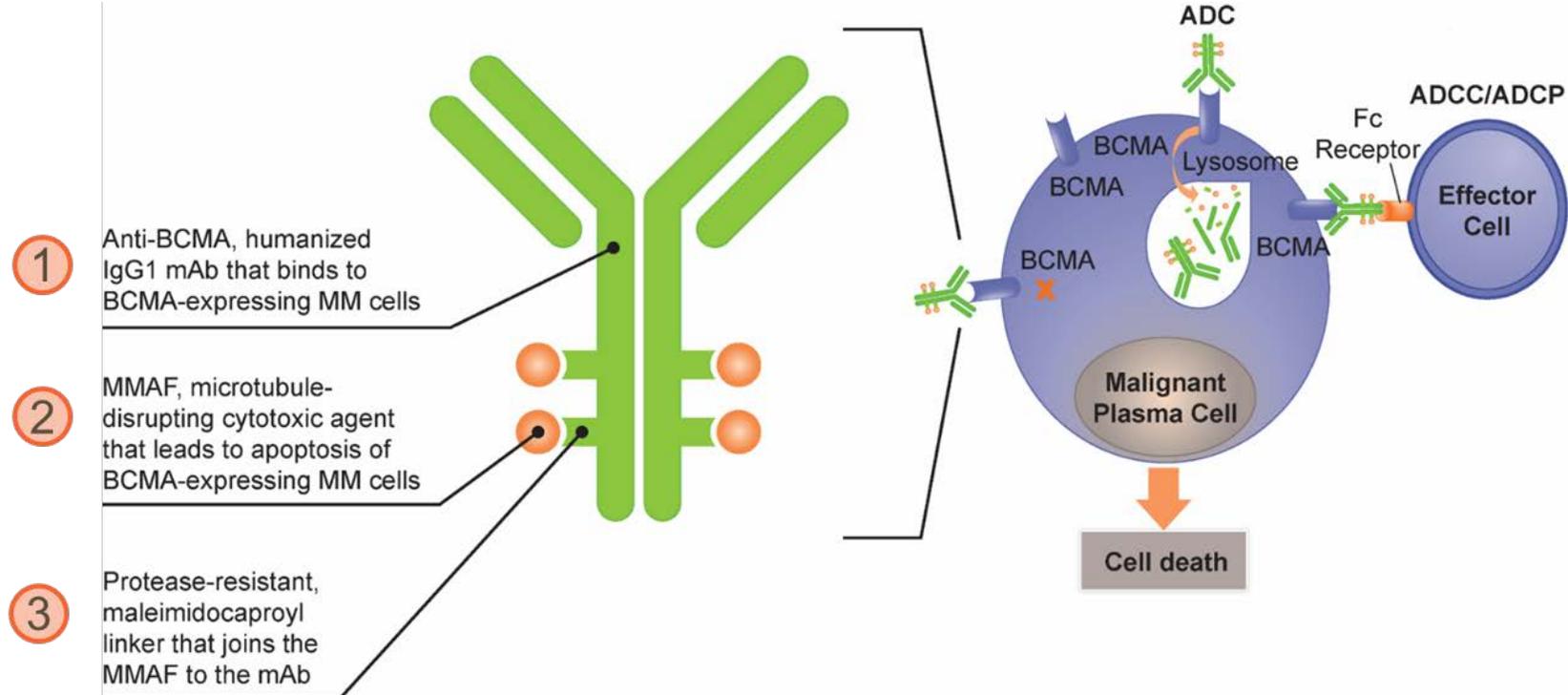


**B-cell maturation antigen (BCMA)** is a protein expressed on normal B lymphocytes and multiple myeloma cells that promotes cellular proliferation and survival<sup>1,2</sup>

## The agent and mechanism of action



**BLENREP is a BCMA-directed antibody and microtubule inhibitor conjugate**, composed of 3 components<sup>3</sup>



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 2.5 mg/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	All Grades (%)	Grade 3-4 (%)
Keratopathy <sup>a</sup>	71	44
Decreased Visual Acuity <sup>b</sup>	53	28
Blurred Vision <sup>c</sup>	22	4
Dry Eyes <sup>d</sup>	14	1

- The most common ocular adverse reactions (≥20%) were keratopathy, decreased visual acuity, and blurred vision
- The most frequent adverse reaction resulting in permanent discontinuation was keratopathy (2.1%)
- Ocular adverse reactions which required a dosage interruption in >3% of patients included keratopathy (47%), blurred vision (5%) and dry eye (3.2%)
- Ocular adverse reactions which required a dose reduction in >3% of patients included keratopathy (23%)

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

<sup>a</sup>Keratopathy was based on slit lamp eye examination, characterized as corneal epithelium changes with or without symptoms  
<sup>b</sup>Visual acuity changes were determined upon eye examination  
<sup>c</sup>Blurred vision included diplopia, vision blurred, visual acuity reduced, and visual impairment  
<sup>d</sup>Dry eyes included dry eye, ocular discomfort, and eye pruritus

Prescribing Information for BLENREP

# Warnings and Precautions: Ocular Toxicity

Ocular Adverse Reactions	BLNREP 2.5 mg/kg dosing N = 95
<b>Keratopathy<sup>a</sup></b>	<b>71% (n=67)</b>
With Ocular Symptoms <sup>b</sup>	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)
<b>Visual Acuity Changes<sup>c</sup></b>	<b>53% (n=50)</b>
<b>Blurred Vision<sup>d</sup></b>	<b>22% (n=21)</b>
<b>Dry Eye<sup>e</sup></b>	<b>14% (n=13)</b>

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

<sup>b</sup>Ocular symptoms refer to adverse events graded per CTCAE criteria, such as blurred vision, dry eye, or eye pain

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

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

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

DREAMM-2 Data on file.

# Warnings and Precautions: Keratopathy<sup>a</sup>

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

Grade per KVA Scale	Patients with Keratopathy BLNREP 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).

<sup>a</sup>Keratopathy was based on slit lamp eye examination, characterized as corneal epithelium changes with or without symptoms  
Based on 21JUN2019 data cut-off. 1 patient experienced a grade 4 event (corneal ulcer / infective keratitis) per KVA at the 9-month safety update DREAMM-2 Data on file.

# Resolution of Grade 2-4 Keratopathy<sup>a</sup>; Median follow up: 6.3 months

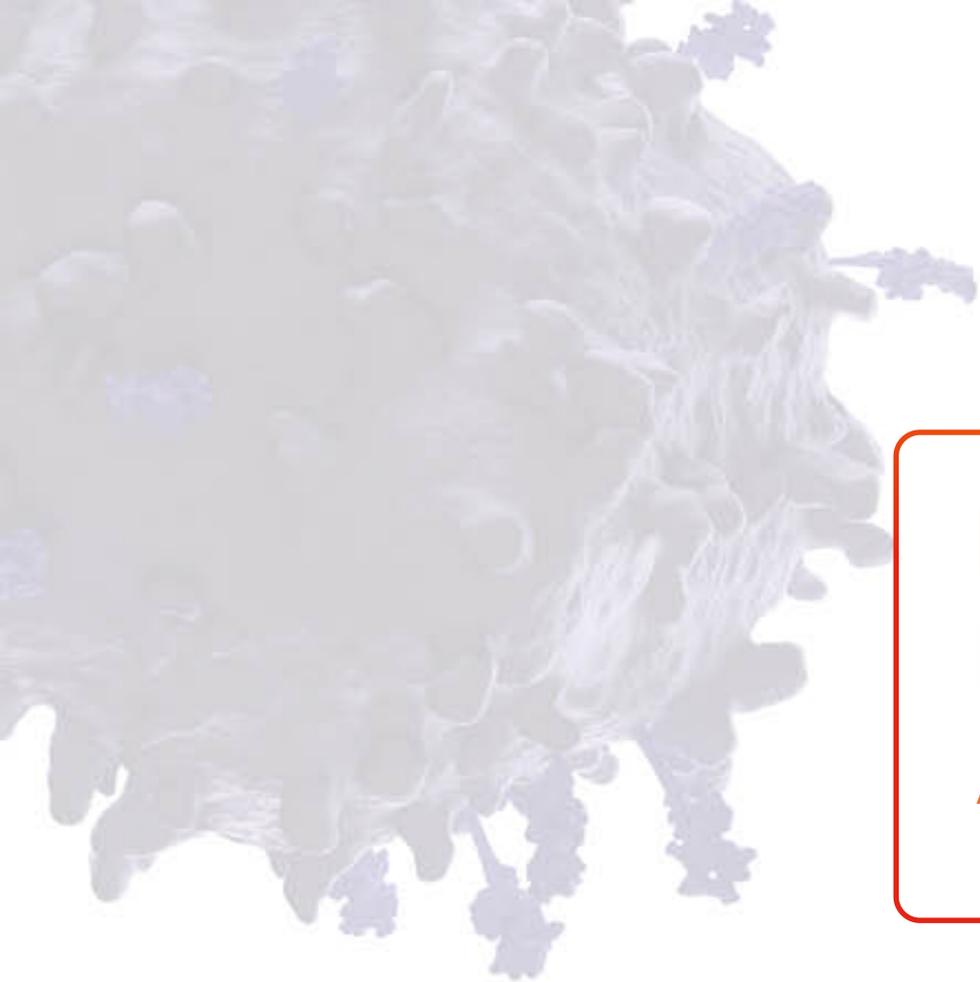
	Patients with Keratopathy (Grade ≥ 2) BLENREP 2.5 mg/kg dosing, N = 59
Recovered to Grade 1 or lower, %	41%
Median time to resolution, days (range)	62 (11, 193)
Had ongoing keratopathy, %	59%
Still on treatment	29%
In follow-up	7%
Follow-up ended due to death, study withdrawal, or lost to follow up	24%

<sup>a</sup>Keratopathy was based on slit lamp eye examination, characterized as corneal epithelium changes with or without symptoms  
DREAMM-2 Data on file.

# Visual Acuity Changes

	BLENREP 2.5 mg/kg dosing 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 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	<p><i>Corneal examination finding(s):</i> Mild superficial keratopathy<sup>a</sup></p> <p><i>Change in BCVA<sup>b</sup>:</i> Decline from baseline of 1 line on Snellen Visual Acuity</p>	Continue treatment at current dose.
Grade 2	<p><i>Corneal examination finding(s):</i> Moderate superficial keratopathy<sup>c</sup></p> <p><i>Change in BCVA<sup>b</sup>:</i> Decline from baseline of 2 or 3 lines on Snellen Visual Acuity and not worse than 20/200</p>	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	<p><i>Corneal examination finding(s):</i> Severe superficial keratopathy<sup>d</sup></p> <p><i>Change in BCVA<sup>b</sup>:</i> Decline from baseline by more than 3 lines on Snellen Visual Acuity and not worse than 20/200</p>	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	<p><i>Corneal examination finding(s):</i> Corneal epithelial defect<sup>e</sup></p> <p><i>Change in BCVA<sup>b</sup>:</i> Snellen Visual Acuity worse than 20/200</p>	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

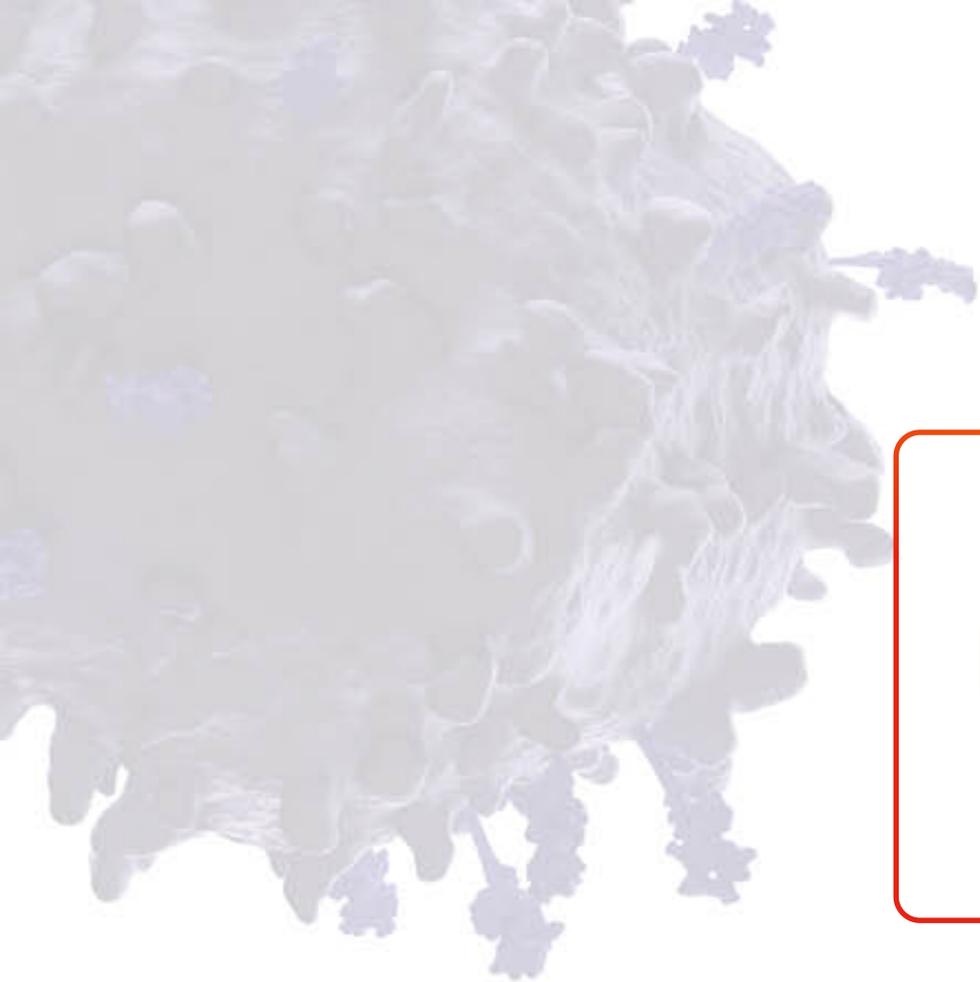
<sup>a</sup>Mild superficial keratopathy (documented worsening from baseline), with or without symptoms; <sup>b</sup>Changes in visual acuity due to treatment-related corneal findings; <sup>c</sup>Moderate superficial keratopathy with or without patchy microcyst-like deposits, sub-epithelial haze (peripheral),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

### Prescribing Information for BLENREP

# Patient counseling can support management and identification of corneal adverse reactions

## Prior to starting treatment with BLENREP, advise Patients:

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



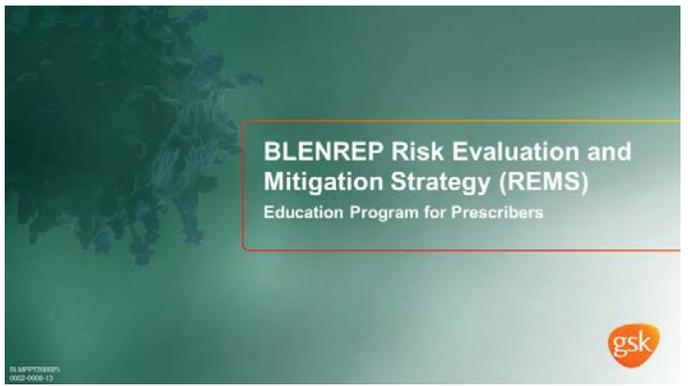
# REMS Goals and Operations

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

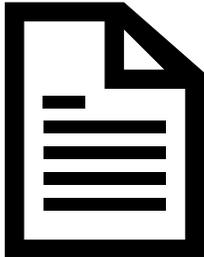
1. Ensuring that healthcare providers are educated on the risk of ocular toxicity associated with the use of BLENREP
2. Ensuring that healthcare providers are educated and adhere to the following:
  - a. submit documentation that ophthalmic exams are being done at baseline and prior to each dose to identify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

# Prior to prescribing BLENREP, the Prescriber will review training materials, complete a Knowledge Assessment, and enroll in the REMS

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



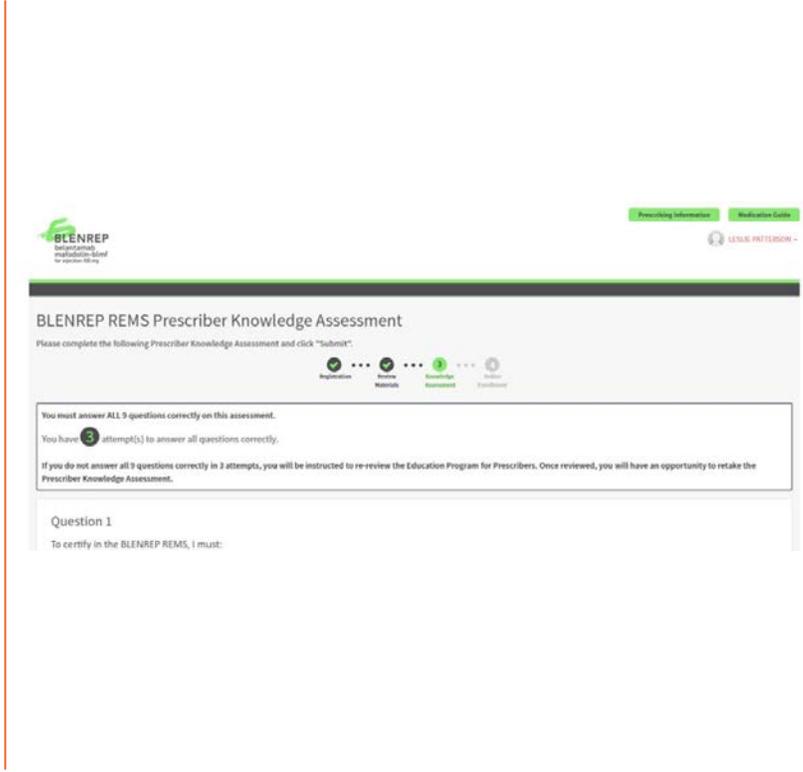
Education Program for Healthcare Settings (this presentation)



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

 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

# After completing the Knowledge Assessment, fill out and submit the Prescriber Enrollment Form to complete enrollment

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

**PRESCRIBER INFORMATION**

**\* National Provider Identifier (NPI) #:**  **State License #:**

**\* First Name**  **Middle Initial**  **\* Last Name**

**\* Credentials**  MD  DO  NP  PA  Other (please specify) **\* Specialty**  Oncology  Hematology  Internal Medicine  Other (please specify)

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**\* Practice/Facility Name**

**\* Address Line 1**  **Address Line 2**

**\* City**  **\* State**  **\* ZIP Code**

**\* Phone**  **\* Fax**  **\* Email**

**Preferred Method of Communication**  Phone  Fax  Email **Preferred Time of Contact**  AM  PM

Provide requested personal and practice contact information

# 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
<b>Complete Enrollment Form</b>
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 1-855-209-9188.

<b>*First Name</b>	<b>*Last Name</b>	<b>*Email</b>
<input type="text" value="John"/>	<input type="text"/>	<input type="text"/>
<input type="checkbox"/> Address - Same as Prescriber		
<b>Address Line 1</b>	<b>Address Line 2</b>	
<input type="text"/>	<input type="text"/>	
<b>City</b>	<b>State</b>	<b>ZIP Code</b>
<input type="text"/>	<input type="text" value="-- Please Select --"/>	<input type="text"/>
<b>Phone</b>	<b>Fax</b>	
<input type="text"/>	<input type="text"/>	

## ALTERNATIVE PRACTICE/FACILITY LOCATION

<b>Address Line 1</b>	<b>Address Line 2</b>	
<input type="text"/>	<input type="text"/>	
<b>City</b>	<b>State</b>	<b>ZIP Code</b>
<input type="text"/>	<input type="text" value="-- Please Select --"/>	<input type="text"/>

- 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
<b>Complete Enrollment Form</b>
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 examinations using the *Eye Care Professional Consult Request Form* or equivalent.
- Assess the patient's ophthalmic consult results for appropriateness of continuing treatment. Document and submit to the BLENREP REMS using the *Patient Status Form*.

I understand that if I do not maintain compliance with the requirements of the BLENREP REMS, I will no longer be able to prescribe BLENREP.  
I understand the BLENREP REMS may contact me via phone, mail, or email to discuss and/or to survey me on the effectiveness of the REMS requirements.

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

\*Prescriber Signature

**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](http://www.BLENREPREMS.com)) to 1-888-635-1044



For support, call 1-855-209-9188

# To enroll Patients, the Prescriber will login to BLENREPREMS.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

Enter Name and Date of Birth

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

# Patients will provide their contact information

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



**PATIENT INFORMATION**

**\*First Name**  **Middle Initial**  **\*Last Name**

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

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**\*Address Line 1**  **Address Line 2**

**\*City**  **\*State**  **\*ZIP Code**

**\*Phone**  **\*Email**  **\*Preferred Method of contact**  Phone  Email

**Secondary Contact**  **Phone for secondary contact**

**PRESCRIBER INFORMATION**

**First Name:** Leslie **Prescriber National Provider Identifier (NPI)#:** 1234567890  
**Last Name:** Patterson **Phone:** 555 555-1212

# To allow Patients or Legal Guardians to electronically sign and agree to the terms, Patients will receive a password via email or text message

Review Training Materials
Access Knowledge Assessment
Complete Enrollment Form
<b>Enroll Patients</b>
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 password (based on the contact information provided); if not checked, Patients will only receive the password at their email address

# Patients will enter the password 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
<b>Enroll Patients</b>
Manage Enrolled Patients
Complete Patient Status Form
Report Adverse Event

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

Patient will enter the password received via email or text

Patient will read and agree to the terms and conditions

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

**BLENREP™ REMS Eye Care Professional Consult Request Form**

**INSTRUCTIONS**

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

**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(s) 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 \_\_\_/\_\_\_

**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 Request 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)	<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 on Snellen Visual Acuity <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 Findings:		

**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>
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 on Snellen Visual Acuity <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 Findings:		

The Eye Care Professional Consult Request Form may be faxed or adapted as a template to use within electronic medical record systems

# To manage enrolled Patients, the Prescriber will login to **BLENREPREMS.com** and access “My Patients”

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



Prescribing information Medication Guide  
Jones, Mark

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**MY PATIENTS**

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## My Patients

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



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### 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		Submit PSF
9876	Martin	Berry	34534	8/31/1995	✓	Sign	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

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MY PATIENTS

## My Patients

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



### Patient Listing

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-  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		<span style="border: 2px solid orange; padding: 2px;">Submit PSF</span>
9876	Martin	Berry	34534	8/31/1995	✓	<span style="background-color: #4CAF50; color: white; padding: 2px;">Sign</span>	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:  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 1<sup>st</sup> 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



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

**For the second and later doses, the Prescriber will enter (if applicable) dose modifications, dose holds, and ophthalmic adverse event findings and BCVA gradings from the Eye Care Professional**

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

\* Is this the patient's 1<sup>st</sup> 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 <input type="radio"/> No change from baseline <input type="radio"/> Mild superficial keratopathy <input type="radio"/> Moderate superficial keratopathy <input type="radio"/> Severe superficial keratopathy <input type="radio"/> Corneal epithelial defect	*Change in BCVA from Baseline (per Snellen Visual Acuity) <input type="radio"/> No change from... baseline <input type="radio"/> Decline from baseline of 1 line <input type="radio"/> Decline from baseline of 2 or 3 lines on Snellen Visual Acuity and not worse than 20/200 <input type="radio"/> Decline from baseline by more than 3 lines on Snellen Visual Acuity and not worse than 20/200 <input type="radio"/> Snellen Visual Acuity worse than 20/200	Additional Corneal Examination Finding <input type="text" value="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

Repeated for Left eye (not pictured)

You may also fax a completed paper patient status form (available at [www.BLENREPREMS.com](http://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**

**MY PATIENTS**

### My Patients

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

**ENROLL PATIENT**

#### Patient Listing

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- Sort the list by clicking on any column header

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1234	Peggy	Sue	19542	3/2/2000	✓	✓	ENROLLED - PENDING PATIENT STATUS FORM		Submit PSF
9876	Martin	Berry	34534	8/31/1995	✓	Sign	PENDING		

Page 1 of 11 | 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**

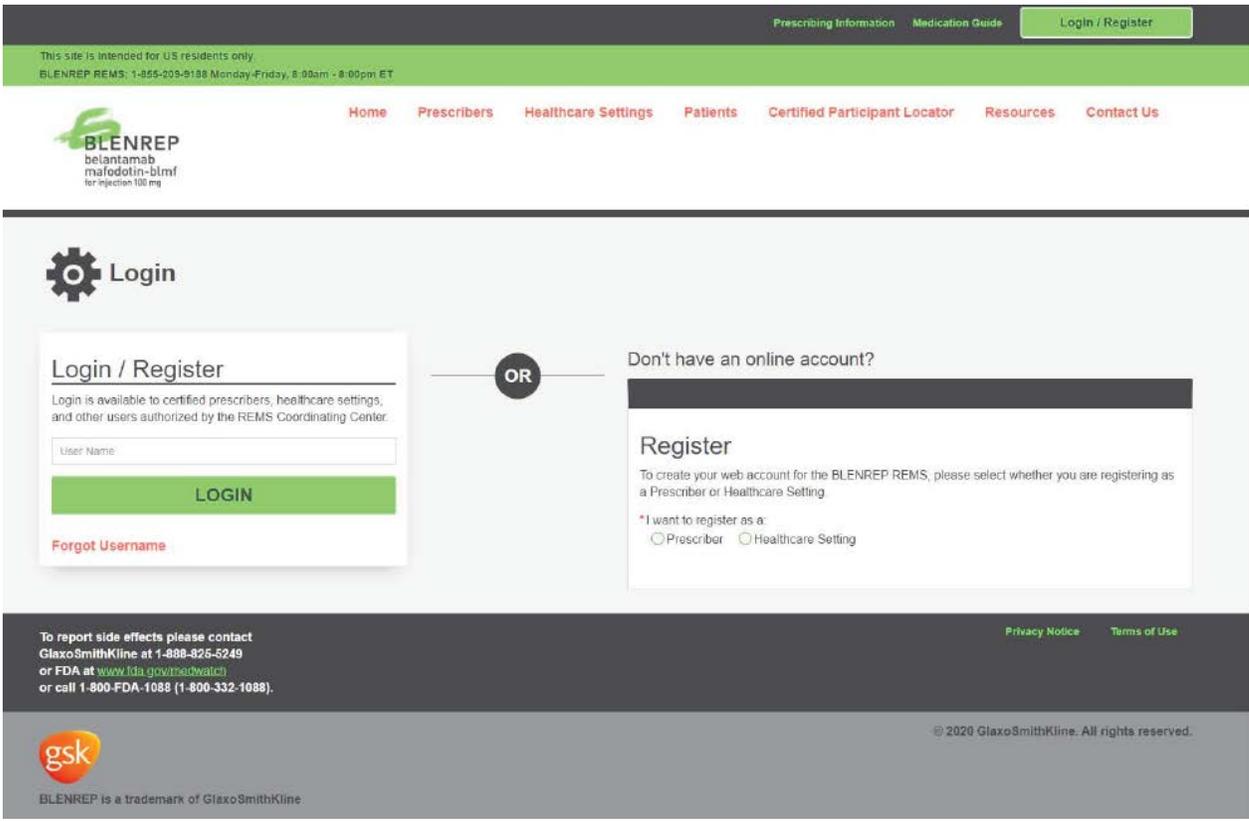
Select the Correct Patient

# BLNREP REMS: Key points to remember

- **Ensure you enroll** in the BLNREP REMS
- **Enroll each patient** in the BLNREP 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* or equivalent
- **Manage** corneal adverse reactions per the *Prescribing Information* with dose reductions or withhold BLNREP until improvement and resume, or permanently discontinue, 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 BLNREP. For complete safety information, please see the full Prescribing Information, including Boxed Warning, available at [www.BLNREPREMS.com](http://www.BLNREPREMS.com)

# BLNREPREMS.com provides rapid support for the BLNREP REMS program, with additional support available via the REMS Coordinating Center



## Key Features of BLNREPREMS.com

- ✓ real-time enrollment certification
- ✓ real-time patient status form entry
- ✓ automatic email notifications for REMS enrollment and patient status form submission

## For More Information



Call 1-855-209-9188



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