

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



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REMS-102025

BLNREP REMS Education Program for Prescribers

GSK

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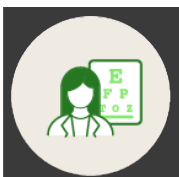
Overview



What is BLENREP?



What is the ocular toxicity seen with BLENREP?



How are patients monitored for ocular toxicity while receiving BLENREP?



How is ocular toxicity managed while receiving BLENREP?



What is the BLENREP REMS?



What are the BLENREP REMS prescriber requirements?

Boxed Warning

▶	What is BLENREP?
	Ocular Toxicity
	Patient Monitoring
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WARNING: OCULAR TOXICITY

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

Overview: About this Education Program



This education program includes information about:



BLENREP (belantamab mafodotin-blmf), in combination with bortezomib and dexamethasone, for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least two prior lines of therapy, including a proteasome inhibitor and an immunomodulatory agent



Ocular toxicity associated with BLENREP, including monitoring and management



Prescriber requirements of the BLENREP REMS

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

Indications and Usage



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

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- ▶ **Ocular Toxicity**
- Patient Monitoring
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Ocular Toxicity (≥10%) in DREAMM-7

Adverse Reaction – Eye Disorders ¹ (≥10%)	All Grades	Grade 3/4
Reduction in BCVA ²	89%	57%
Corneal exam findings ²	86%	72%
Blurred vision	66%	22%
Dry eye ³	51%	7%
Photophobia	47%	2%
Foreign body sensation in eyes ³	44%	3%
Eye irritation	43%	5%
Eye pain ³	33%	0.8%
Cataract ³	24%	8%
Visual Impairment	11%	5%

Prescribing Information for BLENREP

BCVA = best-corrected visual acuity

1: Adverse reactions, except ophthalmic exam findings, were graded according to Common Terminology Criteria for Adverse Events v5.0

2: Based on ophthalmic exam findings

3: Grouped term includes other related terms

Severity of ocular toxicity

- In DREAMM-7, ocular toxicity occurred in 92% of patients
- Ophthalmic Exam Findings:
 - Ocular toxicity based on ophthalmic exam findings¹ was reported as Grade 2 in 9% of patients, Grade 3 in 56% of patients, and Grade 4 in 21% of patients.
 - The median time to onset of the first Grade 2 to 4 ophthalmic exam findings was 43 days (range: 15 to 611 days). The median duration of all Grade 2 to 4 ophthalmic exam findings was 85 days (range: 5 to 813 days).
 - Patients experienced a median of 3 episodes (range: 1 to 11 episodes) of ocular toxicity based on ophthalmic exam findings.
 - Of the patients with Grade 2 to 4 ophthalmic exam findings, 42% had improvement of the last event to Grade 1 or better; 22% had resolution of the last event based on return to baseline or normal ophthalmic exam findings.
- Corneal Exam Findings:
 - The most commonly reported corneal exam findings included superficial punctate keratopathy, microcyst-like deposits, epithelial changes, and haze.
 - Cases of corneal ulcer, including cases with infection, have been reported and should be managed promptly by an eye care professional.

Prescribing Information for BLENREP

1: ophthalmic exam findings include both corneal exam findings and change in best corrected visual acuity (BCVA) as assessed by an eye care professional

Severity of ocular toxicity

- Reduction in BCVA

- A reduction in BCVA to 20/50 or worse in at least one eye occurred in 69% of patients, including 29% who experienced a change in BCVA to 20/100 or worse, and 12% who experienced a change in BCVA to 20/200 or worse.
 - Of the patients with reduced BCVA to 20/50 or worse in at least one eye, 61% had resolution of the last event to baseline or better.
 - Of the patients with reduced BCVA to 20/100 or worse, 57% had resolution of the last event.
 - Of the patients with reduced BCVA to 20/200 or worse, 48% had resolution of the last event.

Ocular toxicity can occur with BLENREP, including corneal exam findings, reduction in best-corrected visual acuity (BCVA), and ocular adverse reactions (1 of 2)

What is BLENREP?

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Corneal exam findings are observed on slit lamp exam

- BLENREP causes changes in the corneal epithelium
- Changes to the corneal epithelium are assessed during a corneal exam, called a slit lamp exam
- Corneal exam findings may or may not be accompanied by changes in BCVA or ocular symptoms

Reduction in BCVA

- Reduction in BCVA was observed with BLENREP; reduction to 20/200 or worse was infrequent
- BCVA refers to the best resolution achievable using vision correction. It is measured by an eyecare professional using a technique called refraction
- The BCVA score is expressed as a fraction, such as 20/20, which indicates the distance at which a person can read a line of letters with correction compared to the distance at which a person with normal vision can read the same line
- A lower BCVA score, such as 20/50 or 20/200, means worse vision



20/20



20/50



20/100



20/200

Images are for illustrative purposes only. Vision will differ for each individual. Images created with an Eye Care Professional, using methodology derived from Hunt & Bassie applying defined Gaussian Blur and Pixelation.

Methodology: Vision impairment simulation via Adobe Photoshop through application of a fixed gaussian blur level: 20/20 0.5 pixels; 20/50 4.0 pixels; 20/100 7.5 pixels; 20/200 15 pixels.¹

¹: Hunt LA & Bassi CJ, Am J Occup Ther. 2010;64:105-13.

Corneal exam findings and BCVA are identified during exams from an eyecare professional, such as an ophthalmologist or optometrist

Ocular toxicity can occur with BLENREP, including corneal exam findings, reduction in best-corrected visual acuity (BCVA), and ocular adverse reactions (2 of 2)

What is BLENREP?

► **Ocular Toxicity**

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Ocular Adverse Reactions per CTCAE

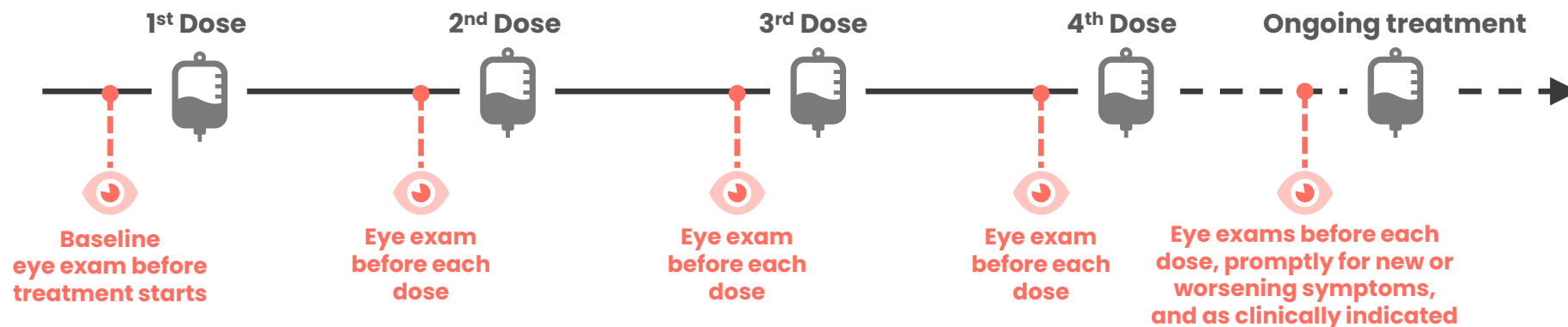
- Ocular adverse reactions refers to any ocular toxicity besides changes in the corneal epithelium and changes in BCVA based on ophthalmic exam (including slit lamp exam).
- Adverse reactions were graded according to CTCAE v5.0.
- The most common ocular adverse reactions (>25%) were blurred vision (66%), dry eye (51%), photophobia (47%), foreign body sensation in eyes (44%), eye irritation (43%), and eye pain (33%).

BCVA = Best Corrected Visual Acuity; CTCAE = National Cancer Institute Common Terminology Criteria for Adverse Events

Ophthalmic exams



- Ophthalmic exams (including slit lamp exam and BCVA assessment) should be conducted by an eye care professional, such as an ophthalmologist or optometrist:
 - At baseline
 - Before each dose of BLENREP
 - Promptly for new or worsening symptoms, and as clinically indicated
- Perform baseline exam within 4 weeks prior to the first dose.
- Perform each follow-up exam within 10 days prior to the next planned dose.
- All effort should be made to schedule the exam as close to BLENREP dosing as possible.



Prescribing Information for BLENREP
1: As described in the Prescribing Information

Knowledge Check

While on treatment with BLENREP, patients are at risk of experiencing ocular toxicity, such as:

SELECT THE BEST ANSWER

A Corneal exam findings

B Reduction in best-corrected visual acuity (BCVA)

C Blurred vision

D Dry eye

E All of the above

Knowledge Check

While on treatment with BLENREP, patients are at risk of experiencing ocular toxicity, such as:

SELECT THE BEST ANSWER

Corneal exam findings

Reduction in best-corrected visual acuity (BCVA)

Blurred vision

Dry eye

All of the above

Knowledge Check

Prescribers ensure ophthalmic exams are conducted by an eye care professional, such as an ophthalmologist or optometrist, per the following:

SELECT THE BEST ANSWER

- A** Once annually
- B** Before the first dose of BLENREP and for worsening symptoms
- C** At baseline, before each dose of BLENREP, promptly for new or worsening symptoms, and as clinically indicated
- D** None of the above

Knowledge Check

Prescribers ensure ophthalmic exams are conducted by an eye care professional, such as an ophthalmologist or optometrist, per the following:

SELECT THE BEST ANSWER

- Once annually**
- Before the first dose of BLENREP and for worsening symptoms**
- At baseline, before each dose of BLENREP, promptly for new or worsening symptoms, and as clinically indicated**
- None of the above**

Recommended Starting Dosage for BLENREP

- The recommended dosage for BLENREP is 2.5 mg/kg of actual body weight once every 3 weeks in combination with bortezomib and dexamethasone (BVD) for the first 8 cycles, followed by BLENREP 2.5 mg/kg of actual body weight once every 3 weeks as a single agent until disease progression or unacceptable toxicity.
- BLENREP is administered as an intravenous infusion over approximately 30 minutes.

Dosage modifications for BLENREP-related adverse reactions

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- In the BVd arm of the clinical study, 98% of patients required a dosage modification for any component of treatment for an adverse reaction, including 87% who required a dosage modification of BLENREP.
- Eighty-three percent of patients required a dosage modification of BLENREP for ocular toxicity based on ophthalmic exam findings or other ocular adverse reactions as defined by the Common Terminology Criteria for Adverse Events (CTCAE).
- There were high rates of dosage modifications in early treatment cycles. By Cycle 3, 53% of patients had a dosage interruption or reduction, 7% had discontinued treatment, and only 40% received the planned dose of BLENREP.

Recommended dosage modifications for ocular toxicity and for other adverse reactions, including ocular adverse reactions

What is BLENREP?

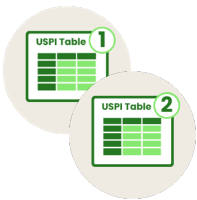
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- The recommended dosage modifications for ocular toxicity based on ophthalmic exam findings are provided in Tables 1 and 2 of the US Prescribing Information.
 - Ophthalmic exam findings include both corneal exam findings and change in BCVA as assessed by an eye care professional.
 - The overall grade of ophthalmic exam findings is based on the worst finding in the worst affected eye, based on either corneal exam finding or a change in BCVA.
 - Corneal exam findings may or may not be accompanied by changes in BCVA or ocular symptoms.



Recommended dosage modifications for ocular toxicity and for other adverse reactions, including ocular adverse reactions

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- Do not re-escalate the dose of BLENREP after a dosage reduction is made for ocular toxicity based on ophthalmic exam findings.
- In the clinical study, 67% of patients required a dosage interruption of BLENREP for ocular toxicity that lasted longer than 3 weeks (time between doses, median: 5.7 weeks [range: 3 to 31 weeks]).



- The recommended dosage modifications for other adverse reactions, including dosage modifications for ocular adverse reactions based on the CTCAE, are provided in Table 3 of the US Prescribing Information.

Prescribing Information for BLENREP

USPI Table 1: Recommended Dosage Reductions of BLENREP for Adverse Reactions

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	BLENREP
Reduced Dosage Level 1	1.9 mg/kg every 3 weeks
Reduced Dosage Level 2¹	1.9 mg/kg every 8 weeks

Prescribing Information for BLENREP

1: Reduced Dosage Level 2 is specific to dosage reductions due to ocular toxicity based on ophthalmic exam findings.

USPI Table 2: Recommended Dosage Modifications for Ocular Toxicity Based on Ophthalmic Exam Findings¹

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Severity	Ophthalmic Exam Findings	Recommended Dosage Modification
Grade 1	<p><i>Corneal Exam Findings:</i> Mild superficial punctate keratopathy² and/or <i>Change in BCVA:</i> Decline from baseline of 1 line on Snellen Equivalent BCVA</p>	Continue treatment at current dosage
Grade 2	<p><i>Corneal Exam Findings:</i> Moderate superficial punctate keratopathy, patchy microcyst-like deposits³, peripheral sub-epithelial haze, or a new peripheral stromal opacity and/or <i>Change in BCVA:</i> Decline from baseline of 2 lines on Snellen Equivalent BCVA and not worse than 20/200</p>	<p>Withhold BLENREP until improvement in both corneal exam findings and change in BCVA to Grade 1 or less. Resume treatment at Reduced Dosage Level 1 as per Table 1. If recurrent Grade 2 or 3 ocular toxicity is experienced, resume treatment at Reduced Dosage Level 2.</p>
Grade 3	<p><i>Corneal Exam Findings:</i> Severe superficial punctate keratopathy, diffuse microcyst-like deposits³ involving the central cornea, central sub-epithelial haze, or a new central stromal opacity and/or <i>Change in BCVA:</i> Decline from baseline of 3 or more lines on Snellen Equivalent BCVA and not worse than 20/200</p>	<p>Consider permanent discontinuation of BLENREP. If continuing treatment, withhold BLENREP until improvement in both corneal exam findings and change in BCVA to Grade 1 or less. For patients previously on 2.5 mg/kg every 3 weeks, resume treatment at Reduced Dosage Level 1 as per Table 1. For patients previously on 1.9 mg/kg every 3 weeks, resume treatment at Reduced Dosage Level 2. If recurrent Grade 4 ocular toxicity is experienced, permanently discontinue BLENREP.</p>
Grade 4	<p><i>Corneal Exam Findings:</i> Corneal epithelial defect or corneal ulcer, with or without infection and/or <i>Change in BCVA:</i> Decline to Snellen Equivalent BCVA of worse than 20/200</p>	<p>Consider permanent discontinuation of BLENREP. If continuing treatment, withhold BLENREP until improvement in both corneal exam findings and change in BCVA to Grade 1 or less. For patients previously on 2.5 mg/kg every 3 weeks, resume treatment at Reduced Dosage Level 1 as per Table 1. For patients previously on 1.9 mg/kg every 3 weeks, resume treatment at Reduced Dosage Level 2. If recurrent Grade 4 ocular toxicity is experienced, permanently discontinue BLENREP.</p>

Prescribing Information for BLENREP
BCVA = best-corrected visual acuity

1: Refer to Table 3 of the US Prescribing Information for recommended dosage modifications for other ocular adverse reactions.

2: Mild superficial keratopathy (documented worsening from baseline). Refer to Table 3 for recommended dosage modifications for other ocular adverse reactions.

3: Microcyst like deposits are considered at least a Grade 2 finding. Withhold BLENREP if any microcyst like deposits are observed.

Knowledge Check

Eighty-three percent of patients required a dosage modification of BLENREP for ocular toxicity based on ophthalmic exam findings or other ocular adverse reactions as defined by the Common Terminology Criteria for Adverse Events (CTCAE).

SELECT THE BEST ANSWER

A True

B False

Knowledge Check

Eighty-three percent of patients required a dosage modification of BLENREP for ocular toxicity based on ophthalmic exam findings or other ocular adverse reactions as defined by the Common Terminology Criteria for Adverse Events (CTCAE).

SELECT THE BEST ANSWER

- True
- False

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

What is BLENREP?
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What is the BLENREP REMS?

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

What is the goal of the BLENREP REMS?

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

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

Prescribers

- Must be certified in the BLENREP REMS by enrolling and completing training.
- Must counsel patients receiving BLENREP on the risk of ocular toxicity, the need for monitoring via ophthalmic exams before each dose, and provide patients with the **Patient Guide**.
- Must document confirmation they assessed the patient’s ophthalmic exam findings and authorized treatment, and submit to the REMS using the **Patient Status Form**, at baseline and before each dose.

Patients

- Must be enrolled in the BLENREP REMS and adhere to monitoring.

Healthcare Settings

- Must be certified in the BLENREP REMS by enrolling and must obtain authorization prior to dispensing.

Wholesalers–distributors

- Must distribute BLENREP only to certified healthcare settings.

Patient counseling



- Counsel patients
 - On the risk of ocular toxicity and that eye problems may occur during treatment using the **Patient Guide**. Provide patients with the **Patient Guide**.
 - To **tell their healthcare provider right away** if they notice any new or worsening eye symptoms or vision changes during treatment with BLENREP.
 - That they will be referred to an eye care specialist (such as an ophthalmologist or optometrist) to check their eyes before they start treatment, before they receive each dose of BLENREP, and as needed for any new or worsening eye problems.
 - To use preservative-free artificial tears at least 4 times per day starting with the first infusion and continuing until the end of treatment with BLENREP.
 - To avoid wearing contact lenses during treatment with BLENREP unless directed by their eye care specialist.
 - To use caution when driving or operating machinery as BLENREP may cause changes to their vision.

Certify in the REMS before initiating treatment with BLENREP

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► **Prescriber Requirements**

Prior to prescribing BLENREP, the prescriber must become certified by:

1

Reviewing the Prescribing Information, **Program Overview**, and **Education Program for Prescribers**

2

Successfully completing the **Knowledge Assessment** and submitting it to the REMS

3

Enrolling by completing and submitting the **Prescriber Enrollment Form** to the REMS

The **Knowledge Assessment** and **Prescriber Enrollment Form** can be completed

ONLINE AT

SCAN ME



www.BLENREPREMS.com

OR BY FAX TO



1-888-635-1044

The healthcare setting where BLENREP will be administered needs to enroll and certify in the REMS

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► **Prescriber Requirements**



If BLENREP will be administered within your practice, your practice must enroll and certify as a healthcare setting.



If BLENREP will not be administered within your practice, contact the healthcare setting to inform them they need to enroll and certify in the REMS.

In order for patients to receive BLENREP, prescribers must do the following:

Before treatment initiation (first dose):

- **Counsel** the patient on the risk of ocular toxicity.
- **Counsel** the patient on the need for monitoring via ophthalmic exams:
 - at baseline,
 - before each dose of BLENREP,
 - promptly for new or worsening symptoms,
 - and as clinically indicated using the **Patient Guide**.
- **Provide** the patient with the **Patient Guide**.
- **Enroll** the patient by completing and submitting the **Patient Enrollment Form** to the REMS.
- **Assess** the patient's ocular health by consulting an eye care professional to conduct a baseline ophthalmic exam using the **Eye Care Professional Exam Form**.
- **Assess** the patient's baseline ophthalmic exam findings for appropriateness of initiating treatment. Document and submit to the REMS using the **Patient Status Form**.

During treatment; before each dose:

- **Assess** the patient's ocular health by consulting an eye care professional to conduct ophthalmic exams using the **Eye Care Professional Exam Form**.
- **Assess** the patient's ophthalmic exam findings for appropriateness of continuing treatment. Document and submit to the REMS using the **Patient Status Form***.

At all times:

- **Assess** the patient for new or worsening ophthalmic symptoms and consult an eye care professional as clinically indicated.

*Certified prescribers may utilize designees to initiate patient enrollment and fill out **Patient Status Forms** for prescriber signature.

Eye Care Professional Exam Form

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What is the purpose of the Eye Care Professional Exam Form?

- To facilitate referral of patients to an eye care professional to conduct ophthalmic exams, and communication of exam results
- To assist with completing the **Patient Status Form**

When should the Eye Care Professional Exam Form be completed?

- With every ophthalmic exam
- Before treatment initiation (first dose) and during treatment, before each dose

Who can complete the Eye Care Professional Exam Form?

- An eye care professional, such as an ophthalmologist or optometrist, or their designated staff

How will ophthalmic exam results be provided?

- The eye care professional office may provide the completed form via fax, e-fax, the patient, or adapt it into healthcare technology.
- A new form must be completed at each visit to the eye care professional

Where can I find the Eye Care Professional Exam form?

- Online at www.BLENREPREMS.com

BLENREP REMS Eye Care Professional Exam Form (continued)

For the Eye Care Professional to Complete

CLINICAL CONTEXT

This patient is being treated with BLENREP (belantamab mafodotin-bimf).
 BLENREP may cause adverse effects in the cornea, epithelium, retina, or choroid, including severe vision loss.
 • BLENREP may cause adverse effects in the cornea, epithelium, retina, or choroid, including severe vision loss.
 • BLENREP may cause adverse effects in the cornea, epithelium, retina, or choroid, including severe vision loss.

Assessment

Please complete Tables B & C to provide the overall grade in Table A for the prescriber.
What is the current overall grade for ophthalmic exam findings? (SELECT ONE)
Table A. Overall Grade of Ophthalmic Exam Findings*

Current Grade / 5	Ophthalmic Exam Findings	Recommended Dosage Modification	
		Right	Left
<input type="checkbox"/> Non			
<input type="checkbox"/> Gro			
<input type="checkbox"/> Gro			
<input type="checkbox"/> Gro			

Table B. Corneal Exam Findings^a

	Eye	
	Right	Left
Normal Cornea clear/No change from baseline	<input type="checkbox"/>	<input type="checkbox"/>
Grade 1 Mild superficial punctate keratopathy ^b	<input type="checkbox"/>	<input type="checkbox"/>
Grade 2 Moderate superficial punctate keratopathy, patchy microcyst-like deposits ^c , peripheral sub-epithelial haze, or a new peripheral stromal opacity	<input type="checkbox"/>	<input type="checkbox"/>
Grade 3 Severe superficial punctate keratopathy, diffuse microcyst-like deposits involving the central cornea, central sub-epithelial haze, or a new stromal opacity	<input type="checkbox"/>	<input type="checkbox"/>
Grade 4 Corneal epithelial defect or corneal ulcer, with or without infection	<input type="checkbox"/>	<input type="checkbox"/>

a. Adapted and modified from the US Prescribing Information.
 b. Mild superficial keratopathy (documented decreasing from baseline). Refer to Table 3 in the US Prescribing Information for recommended dosage modifications for other ocular adverse reactions.
 c. Microcyst-like deposits are considered at least a Grade 2 finding. WITHOUT BLENREP if any microcyst-like deposits are observed.

Table C. Change in BCVA^a

	Eye	
	Right	Left
Baseline BCVA (Pre-treatment)	20/____	20/____
Current BCVA	20/____	20/____
BCVA Change From Baseline	Right	Left
Normal No decline from baseline of 1 line on Snellen Equivalent BCVA	<input type="checkbox"/>	<input type="checkbox"/>
Grade 2 Decline from baseline of 2 lines on Snellen Equivalent BCVA	<input type="checkbox"/>	<input type="checkbox"/>
Grade 1 Decline from baseline of 1 line on Snellen Equivalent BCVA and not worse than 20/200	<input type="checkbox"/>	<input type="checkbox"/>
Grade 3 Decline from baseline of 3 or more lines on Snellen Equivalent BCVA and not worse than 20/200	<input type="checkbox"/>	<input type="checkbox"/>
Grade 4 Decline to Snellen Equivalent BCVA of worse than 20/200	<input type="checkbox"/>	<input type="checkbox"/>

a. Adapted and modified from the US Prescribing Information.

Signature _____ **Date (MM/DD/YYYY)** _____

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► **Prescriber Requirements**

Patient Status Form (PSF)

When should the PSF be completed?

- Before each dose of BLENREP **only if you intend to infuse the patient**
- Do not submit to the REMS if you do not intend to infuse the patient

Who can complete and submit the PSF?

- Prescriber or Prescriber Designee may fill out the **Patient Status Form**
- **Only the Prescriber may sign and submit the Patient Status Form to the REMS prior to treatment**
 - *Note: Any certified Prescriber can complete and submit the PSF (not just the original enrolling Prescriber)*

What is the Prescriber Agreement?

- Agreement that the ophthalmic exam findings were assessed and treatment authorized. Prescriber must sign this agreement.

How long is the Prescriber Authorization valid?

- The prescriber treatment authorization will be valid for:
 - 28 calendar days from the baseline ophthalmic exam
 - 10 calendar days from follow-up ophthalmic exams
- Inform the healthcare setting where BLENREP will be infused that they must perform REMS verification and authorization code generation within these timeframes.

How can I complete and submit the PSF?

- Online at www.BLENREPREMS.com
- By fax to 1-888-635-1044

BLENREP REMS Patient Status Form

INSTRUCTIONS

- Prescriber or Prescriber Designee must fill out this Patient Status Form for each patient before each dose of BLENREP.
- Only the Prescriber may sign and submit the Patient Status Form to the REMS prior to treatment:
 - This form should not be submitted to the REMS if the patient is not going to be infused.
 - The prescriber treatment authorization in this Patient Status Form will be valid for 28 calendar days from the baseline ophthalmic exam, and 10 calendar days from follow-up ophthalmic exams. Inform the healthcare setting where BLENREP will be infused that they must perform REMS verification and authorization code generation within these timeframes.
- Submit this form online at www.BLENREPREMS.com or fax the completed form to 1-888-635-1044.

(Fields marked with an * are REQUIRED)

Patient Information

*First Name _____

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

Prescriber Information

*First Name _____

*National Provider Identifier (NPI) # _____

Assessment

Ophthalmic exam findings include acuity (BCVA) as determined by _____

The overall grade of ophthalmic exam based on either corneal exam (if accompanied by changes in BCVA) _____

Is this the patient's 1st dose?

Yes No

***Date of most recent ophthalmic exam** _____

BLENREP REMS Patient Status Form (continued)

1. *What is the current overall grade for ophthalmic exam findings (SELECT ONE)?

Current Grade/Severity	Ophthalmic Exam Findings	Recommended Dosage Modification
<input type="checkbox"/> Normal	Corneal Exam Findings: Cornea clear/no change from baseline and/or Change in BCVA: No decline from baseline of 1 line or Snellen Visual Acuity	Continue treatment at current dosage
<input type="checkbox"/> Grade 1	Corneal Exam Findings: Mild superficial punctate keratopathy and/or Change in BCVA: Decline from baseline of 1 line on Snellen Equivalent BCVA	Continue treatment at current dosage
<input type="checkbox"/> Grade 2	Corneal Exam Findings: Moderate superficial punctate keratopathy, patchy microcyst-like deposits, peripheral sub-epithelial haze, or a new peripheral stromal opacity and/or Change in BCVA: Decline from baseline of 2 lines on Snellen Equivalent BCVA and not worse than 20/200	Withhold BLENREP until improvement in both corneal exam findings and change in BCVA to Grade 1 or less.
<input type="checkbox"/> Grade 3	Corneal Exam Findings: Severe superficial punctate keratopathy, diffuse microcyst-like deposits involving the central cornea, central sub-epithelial haze, or a new central stromal opacity and/or Change in BCVA: Decline from baseline of 3 or more lines on Snellen Equivalent BCVA and not worse than 20/200	Resume treatment at Reduced Dosage Level 1 as per Table 1 in the US Prescribing Information. If recurrent Grade 2 or 3 ocular toxicity is experienced, resume treatment at Reduced Dosage Level 2.
<input type="checkbox"/> Grade 4	Corneal Exam Findings: Corneal epithelial defect or corneal ulcer with or without infection and/or Change in BCVA: Decline to Snellen Equivalent BCVA of worse than 20/200	Consider permanent discontinuation of BLENREP. If continuing treatment, withhold BLENREP until improvement in both corneal exam findings and change in BCVA to Grade 1 or less. For patients previously on 2.5 mg/kg every 3 weeks, resume treatment at Reduced Dosage Level 1 as per Table 1 in the US Prescribing Information. For patients previously on 1.5 mg/kg every 3 weeks, resume treatment at Reduced Dosage Level 2. If recurrent Grade 4 ocular toxicity is experienced, permanently discontinue BLENREP.

2. *Was the last dose held due to a Grade 2 or 3 ophthalmic exam finding?

Yes No

Prescriber Agreement

By checking this box, I confirm that I have assessed the ophthalmic exam findings for this patient and authorized treatment.

*** Prescriber Signature** _____ ***Date (MM/DD/YYYY)** _____

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Knowledge Check

While treating patients with BLENREP, I should counsel patients:

SELECT THE BEST ANSWER

- A** They may experience loss of sense of smell
- B** To use preservative-free artificial tears at least 4 times a day starting with the first infusion and continuing until the end of treatment, and to avoid wearing contact lenses for the duration of therapy
- C** To not eat grapefruit while taking BLENREP
- D** BLENREP is for home administration

Knowledge Check

While treating patients with BLENREP, I should counsel patients:

SELECT THE BEST ANSWER

- X They may experience loss of sense of smell**
- To use preservative-free artificial tears at least 4 times a day starting with the first infusion and continuing until the end of treatment, and to avoid wearing contact lenses for the duration of therapy**
- X To not eat grapefruit while taking BLENREP**
- X BLENREP is for home administration**

Knowledge Check

Before starting a patient on BLENREP, I must counsel patients on the following:

SELECT THE BEST ANSWER

- A** The risk of ocular toxicity
- B** The need for monitoring via ophthalmic exams
- C** To inform their healthcare provider of any ocular symptoms
- D** All of the above

Knowledge Check

Before starting a patient on BLENREP, I must counsel patients on the following:

SELECT THE BEST ANSWER

- The risk of ocular toxicity**
- The need for monitoring via ophthalmic exams**
- To inform their healthcare provider of any ocular symptoms**
- All of the above**

Knowledge Check

Before initiating treatment with BLENREP, I must enroll my patients in the REMS.

SELECT THE BEST ANSWER

A True

B False

Knowledge Check

Before initiating treatment with BLENREP, I must enroll my patients in the REMS.

SELECT THE BEST ANSWER

- True
- False

Knowledge Check

How can the eye care professional provide prescribers the completed **Eye Care Professional Exam Form** before each dose?

SELECT THE BEST ANSWER

- A** Fax/e-Fax
- B** Patient
- C** Adapted into healthcare technology
- D** All of the above

Knowledge Check

How can the eye care professional provide prescribers the completed **Eye Care Professional Exam Form** before each dose?

SELECT THE BEST ANSWER

- Fax/e-Fax
- Patient
- Adapted into healthcare technology
- All of the above

Knowledge Check

Before each dose, I must submit the **Patient Status Form** to the REMS, confirming I assessed the patient's ophthalmic exam findings and authorized treatment.

SELECT THE BEST ANSWER

A True

B False

Knowledge Check

Before each dose, I must submit the **Patient Status Form** to the REMS, confirming I assessed the patient's ophthalmic exam findings and authorized treatment.

SELECT THE BEST ANSWER

- True
- False

BLENREP REMS: Key points to remember

- ✓ Become certified by completing a one-time certification process.
- ✓ As you start your patient on BLENREP, counsel and enroll them in the BLENREP REMS.
- ✓ Refer patients to an eye care professional to conduct ophthalmic exams using the **Eye Care Professional Exam Form**.
- ✓ Before each dose, document confirmation you assessed the patient's ophthalmic exam findings and authorized treatment, and submit to the REMS using the **Patient Status Form**.

This **Education Program 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.

FOR MORE INFORMATION



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

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