

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 >>			



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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

Right eye (OD)	Corneal Examination Findings <i>Check One</i>	Change in BCVA from Baseline (per Snellen Visual Acuity) <i>Check One</i>
	<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 Change in BCVA from Baseline for Left Eye

Left eye (OS)	Corneal Examination Findings <i>Check One</i>	Change in BCVA from Baseline (per Snellen Visual Acuity) <i>Check One</i>
	<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: _____ _____		

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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 Findings <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 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 Change in BCVA from Baseline for Left Eye

	Corneal Examination Findings <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 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: _____ _____	

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

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First Name*:	Middle Initial:	Last Name*:	Date of Birth (MM/DD/YYYY)*:
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 Keratopathy and Visual Acuity (KVA) Scale

Determine the recommended dosage modification of BLENREP based on the worst findings in the worst affected eye. Worst finding should be based on either a corneal examination finding or a change in visual acuity per the 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^b:</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 ^c <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 ^d <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 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^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 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^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.

^a Adapted and modified from the Prescribing Information

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

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

^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.