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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BLENREP: REMS Summary and Key US Prescribing Information
BLENREP is a B-cell maturation antigen (BCMA)-directed antibody and microtubule inhibitor conjugate indicated for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least 4 prior therapies including an anti-CD38 monoclonal antibody, a proteasome inhibitor, and an immunomodulatory agent.

This indication is approved under accelerated approval based on response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.
WARNING: OCULAR TOXICITY

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

- Conduct ophthalmic exams at baseline, prior to each dose, and promptly for worsening symptoms. Withhold BLENREP until improvement and resume, or permanently discontinue, based on severity.

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

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

What are the BLENREP REMS requirements?

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

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

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

**Wholesalers and distributors** must only distribute BLENREP to certified healthcare facilities.
BLENREP: Overview and Clinical Data
Overview of BLENREP: What it is and how it works

The Target

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

The agent and mechanism of action

BLENREP is a **BCMA-directed antibody and microtubule inhibitor conjugate**, composed of 3 components.3

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

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

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

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

<table>
<thead>
<tr>
<th>Eye Disorders</th>
<th>All Grades (%)</th>
<th>Grade 3-4 (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Keratopathy(a)</td>
<td>71</td>
<td>44</td>
</tr>
<tr>
<td>Decreased Visual Acuity(b)</td>
<td>53</td>
<td>28</td>
</tr>
<tr>
<td>Blurred Vision(c)</td>
<td>22</td>
<td>4</td>
</tr>
<tr>
<td>Dry Eyes(d)</td>
<td>14</td>
<td>1</td>
</tr>
</tbody>
</table>

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

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

\(b\)Visual acuity changes were determined upon eye examination

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

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

Prescribing Information for BLENREP

- 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%)
## Warnings and Precautions: Ocular Toxicity

### Ocular Adverse Reactions

<table>
<thead>
<tr>
<th></th>
<th>BLENREP 2.5 mg/kg dosing</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>N = 95</td>
</tr>
</tbody>
</table>

| 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)              |         |

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

\(^b\) Ocular symptoms refer to adverse events graded per CTCAE criteria, such as blurred vision, dry eye, or eye pain

\(^c\) Visual acuity changes included all grade BCVA change per KVA scale

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

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

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

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

<table>
<thead>
<tr>
<th>Grade per KVA Scale</th>
<th>Patients with Keratopathy</th>
</tr>
</thead>
<tbody>
<tr>
<td>All Grades</td>
<td>71%</td>
</tr>
<tr>
<td>Grade 1</td>
<td>8%</td>
</tr>
<tr>
<td>Grade 2</td>
<td>18%</td>
</tr>
<tr>
<td>Grade 3</td>
<td>44%</td>
</tr>
<tr>
<td>Grade 4</td>
<td>0%</td>
</tr>
</tbody>
</table>

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

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

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

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

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

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

<table>
<thead>
<tr>
<th></th>
<th>BLENREP 2.5 mg/kg dosing</th>
<th>N = 95</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Visual Acuity in Better-seeing Eye Worse than 20/40</td>
<td>17%</td>
</tr>
<tr>
<td></td>
<td>Visual Acuity in Better-seeing Eye 20/200 or Worse</td>
<td>1%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Patients, %</th>
<th>17%</th>
<th>1%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Resolved, %</td>
<td>94%</td>
<td>100%</td>
</tr>
<tr>
<td>Median duration, days (range)</td>
<td>22 (7-64 days)</td>
<td>22 (22-22 days)</td>
</tr>
</tbody>
</table>

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

• Conduct ophthalmic examinations (visual acuity and slit lamp) at baseline, prior to each dose, and promptly for worsening symptoms.
  
  – Perform baseline examinations within 3 weeks prior to the first dose.
  – Perform each follow-up examination at least 1 week after the previous dose and within 2 weeks prior to the next dose

• Withhold BLENREP until improvement and resume at same or reduced dose, or consider permanently discontinuing, based on severity (see Dosage and Admin (2.3), US Prescribing Information)
Recommended Dosage

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

Dosage Modifications for Adverse Reactions

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

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

<table>
<thead>
<tr>
<th>Category</th>
<th>Corneal Adverse Reaction</th>
<th>Recommended Dosage Modifications</th>
</tr>
</thead>
</table>
| Grade 1  | Corneal examination finding(s): Mild superficial keratopathy<sup>a</sup>  
  *Change in BCVA<sup>b</sup>*: Decline from baseline of 1 line on Snellen Visual Acuity | Continue treatment at current dose. |
| Grade 2  | Corneal examination finding(s): Moderate superficial keratopathy<sup>c</sup>  
  *Change in BCVA<sup>b</sup>*: 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  | Corneal examination finding(s): Severe superficial keratopathy<sup>d</sup>  
  *Change in BCVA<sup>b</sup>*: 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  | Corneal examination finding(s): Corneal epithelial defect<sup>e</sup>  
  *Change in BCVA<sup>b</sup>*: 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. |

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

Reference Prescribing Information for BLENREP for management of other adverse reactions.

Prescribing Information for BLENREP
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

Patient counseling can support management and identification of corneal adverse reactions
REMS Goals and Operations
The goal of the BLENREP REMS is to manage the risk of ocular toxicity by:

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

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

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

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

1. Review Training Materials
2. Complete Knowledge Assessment
3. Enroll in the REMS

For support with BLENREPREMS.com call 1-855-209-9188
Access and Complete Knowledge Assessment following review of Training Materials

Answer nine multiple choice and/or true/false questions

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

Provide requested personal and practice contact information

<table>
<thead>
<tr>
<th>PRESCRIBER INFORMATION</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>*National Provider Identifier (NPI) #: 1234567890</td>
<td></td>
</tr>
<tr>
<td>*First Name</td>
<td>Middle Initial</td>
</tr>
<tr>
<td>*Credentials</td>
<td></td>
</tr>
<tr>
<td>☐ MD ☐ DO ☐ NP ☐ PA ☐ Other (please specify)</td>
<td>☐ Oncology ☐ Hematology ☐ Internal Medicine ☐ Other (please specify)</td>
</tr>
<tr>
<td>*Practice/Facility Name</td>
<td></td>
</tr>
<tr>
<td>*Address Line 1</td>
<td>Address Line 2</td>
</tr>
<tr>
<td>*City</td>
<td>*State</td>
</tr>
<tr>
<td>☐ Please Select --</td>
<td></td>
</tr>
<tr>
<td>*Phone</td>
<td>*Fax</td>
</tr>
<tr>
<td>Preferred Method of Communication</td>
<td></td>
</tr>
<tr>
<td>☐ Phone ☐ Fax ☐ Email</td>
<td>Preferred Time of Contact</td>
</tr>
<tr>
<td>☐ AM ☐ PM</td>
<td></td>
</tr>
<tr>
<td>*ZIP Code</td>
<td>*Email</td>
</tr>
</tbody>
</table>
At enrollment, prescribers may designate a delegate who will be able to support initiation of the Patient Enrollment Form, completion of the Patient Status Form and Adverse Event Forms, and who will be copied on relevant automatic e-mail notifications; Prescribers may also designate a second practice location.
Review and agree to Prescriber Responsibilities to complete enrollment

**PRESCRIBER RESPONSIBILITIES**

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

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

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
You may add or remove an unlimited number of delegates after initial REMS enrollment by logging in and selecting “Delegate Management”.

Click “Add Delegate” to add a delegate, or “Remove” to remove a delegate.

If you have multiple delegates to add or remove, you may download and complete the editable User Access Form and fax it to the BLENREP REMS Coordinating Center at 1-888-635-1044.
To enroll Patients, the Prescriber or Delegate will login to BLENREPREMS.com, access “My Patients” and select “Enroll Patient”.

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

If you enter the name and date of birth of a patient already enrolled in the BLENREP REMS, you will be directed to contact the BLENREP REMS Coordinating Center at 1-855-209-9188 for further support.
Patients will provide their contact information

<table>
<thead>
<tr>
<th>PATIENT INFORMATION</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>First Name</strong></td>
<td>Mary</td>
</tr>
<tr>
<td><strong>Date of Birth</strong></td>
<td>01/01/2000</td>
</tr>
<tr>
<td><strong>Gender</strong></td>
<td>Female</td>
</tr>
<tr>
<td><strong>Address Line 1</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Address Line 2</strong></td>
<td></td>
</tr>
<tr>
<td><strong>City</strong></td>
<td></td>
</tr>
<tr>
<td><strong>State</strong></td>
<td>- Please Select -</td>
</tr>
<tr>
<td><strong>Phone</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Email</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Secondary Contact</strong></td>
<td></td>
</tr>
<tr>
<td><strong>ZIP Code</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Preferred Method of Contact</strong></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>PRESCRIBER INFORMATION</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>First Name: Lovile</td>
<td></td>
</tr>
<tr>
<td>Last Name: Patterson</td>
<td></td>
</tr>
</tbody>
</table>

To be able to sign the form electronically, patients must have an email address and access to their email. If patients do not have email access, the paper enrollment form may be completed and faxed to the BLENREP REMS Coordinating Center at 1-888-635-1044.
Patients or Legal Guardians with e-mail access can electronically agree to the Patient Acknowledgement; if the Patient/Legal Guardian is unable to sign, complete the “Patient Verbal Attestation” section.

**Two online options** for Patients/Legal Guardians to complete enrollment:

- **Electronic Signature (Patient e-mail required):** If Patient/Legal Guardian has an email address, access to their email, and can sign the form electronically.

  - **PATIENT ACKNOWLEDGEMENT** (If Patient/Legal Guardian is able to sign)
    - By signing this form, I agree BLENREP is only available through the BLENREP REMS.
    - *Patient Attestation*
      - Patient Attestation
      - Legal Guardian Attestation
    - *Patient Name*
      - [Input field]
    - *Is patient or parent/guardian currently available to complete patient signature during enrollment?*
      - [Radio buttons: Yes, No]
    - *Would you like to receive text messages from the BLENREP REMS in order to sign the informed consent?*
      - [Radio buttons: Yes, No]

- **Patient Verbal Attestation (Patient e-mail not required):** If Patient/Legal Guardian is unable to sign the form electronically or via signature on the paper form.

  - **PATIENT VERBAL ATTESTATION** (If Patient/Legal Guardian is unable to sign)
    - If the Patient/Legal Guardian is unable to sign this form, a verbal acknowledgment may be provided. Patient/Legal Guardian has provided verbal attestation.
    - *Date of Verbal Attestation*
      - [Input field]

**Options for Patients/Legal Guardians to complete enrollment:**
- Review Training Materials
- Access Knowledge Assessment
- Complete Enrollment Form
- Manage Delegates
- Enroll Patients
- Manage Patient Sharing
- View & Manage Enrolled Patients
- Pt. Status Form & REMS Checklist
- Report Adverse Event

**Record:**
- Electronic Signature
- Verbal acknowledgement
- Paper enrollment form available for patients who can sign but do not have email access.
- Verbal acknowledgement may be provided to the Prescriber or Prescriber Delegate; patient e-mail is not required.
If patients electronically sign, patients will enter the password received via text message or e-mail, agree to the terms and conditions, and adopt a signature.

- 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”
Certified Prescribers may set preferences to share care of their enrolled patients with other certified prescribers by clicking “My Profile”, then “Share Your Patients”.

To adjust sharing with multiple certified prescribers, prescribers may download and complete the editable User Access Form and fax it to the BLENREP REMS Coordinating Center at 1-888-635-1044.

Selecting “Stop Sharing” will end the ability of the selected certified prescriber to share patient care.

Selecting “Share Your Patients” allows prescribers to share patient care with other certified prescribers.
To manage enrolled Patients, the Prescriber or Delegate will login to BLENREPREMS.com and access “My Patients”.

A list of enrolled Patients may be downloaded, or search enrolled Patients using the fields provided.

Prescriber Delegates can only view and manage online patients enrolled by a Prescriber they are associated with (not patients shared by another Prescriber).
After selecting a patient, you may view the patient’s specific treatment details by selecting Patient Treatment History, Patient Status Form History or Adverse Event Form History (highlighted below)

Select here if the patient is no longer under your care; reason will be requested
The Prescriber assesses the Patient’s ocular health prior to each dose by consulting an Eye Care Professional.
The Prescriber will review information provided by the Eye Care Professional; if the Prescriber plans to dose the Patient with BLENREP, the Prescriber or Delegate will input this information to a Patient Status Form by selecting “Submit PSF”

**REMS Prescriber Portal**

### My Patients

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

#### Patient Listing

- Download the list in spreadsheet format by clicking the Excel icon just above the column headers
- Search/filter the list by entering information in the text box below any column header
- Sort the list by clicking on any column header

#### REMS ID

<table>
<thead>
<tr>
<th>REMS ID</th>
<th>Shared Patient</th>
<th>First Name</th>
<th>Last Name</th>
<th>Zip</th>
<th>Date of Birth (MM/DD/YYYY)</th>
<th>Prescriber Signature Status</th>
<th>Patient Signature Status</th>
<th>Patient Status</th>
<th>PSF Completed Date (MM/DD/YYYY)</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>1234</td>
<td>Y</td>
<td>Peggy</td>
<td>Sue</td>
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<td>Dee</td>
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<td>N</td>
<td>Martin</td>
<td>Barry</td>
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<td></td>
<td>E001-001</td>
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- **Submit PSF**

**Reminder:** The Patient Status Form only needs to be submitted if the Prescriber is planning to dose the Patient with BLENREP; if the Patient’s dose will be held, do not submit the Patient Status Form

- A BLENREP REMS certified prescriber or prescriber delegate may complete and submit this form on behalf of the certified prescriber of record.
- PSF will not be routed to the certified prescriber for signature if the delegate completed PSF on their behalf.
- 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.
The Prescriber or Delegate will enter the Eye Care Professional’s information, Ophthalmic Assessment, and attest to Prescriber review of the ophthalmic exam.

Additional detail will be requested if you select “no”; see next slide.
For the second and later doses, the Prescriber or Delegate will enter (if applicable) dose modifications, dose holds, and ophthalmic examination findings and overall grading from the Eye Care Professional.

If the Prescriber answers “yes” to these questions: information about Affected Eyes, Corneal Exam Findings, and Change in BCVA will be requested.

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.
An authorization code must be generated prior to the infusion; within 21 calendar days of the baseline ocular exam or within 14 calendar days of follow-up exams.
If an Authorization Code has not been generated, you may cancel a PSF by selecting “Cancel PSF”.

If an Authorization Code has already been generated, the “Cancel PSF” button will not be available; contact the BLENREP REMS Coordinating Center at 1-855-209-9188.
REMS Checklists are submitted by the Healthcare Setting within 5 business days of infusion; to view REMS Checklists submitted for your patients, click “REMS Checklist”

### REMS Checklist

**Below is a list of REMS Checklist(s) for all patients.**

#### REMS Checklist History

1. Download the list to spreadsheet format by clicking the Excel icon just above the column headers
2. Search/Filter the list by entering information in the text box below any column header
3. Sort the list by clicking on any column header

<table>
<thead>
<tr>
<th>Healthcare Setting Name</th>
<th>Patient First Name</th>
<th>Patient Last Name</th>
<th>Prescriber First Name</th>
<th>Prescriber Last Name</th>
<th>Verification Authorization Code</th>
<th>Infusion Date</th>
<th>Dose (mg)</th>
<th>Checklist Submitted Date</th>
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<tbody>
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<td>Brandon</td>
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<td>12345</td>
<td>05/09/2020</td>
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<td>06/09/2020</td>
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![REMS Prescriber Portal](image)
To report a Corneal Adverse Event, access “My Patients” and select “Report Corneal Adverse Event”
BLENREP REMS: Key points to remember

• **Ensure you enroll** in the BLENREP REMS

• **Enroll each patient** in the BLENREP REMS

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

• **Assess** the patient’s ocular health by consulting an eye care professional to complete visual acuity and slit lamp examinations using the *Eye Care Professional Consult Request Form*

• **Manage** corneal adverse reactions per the *Prescribing Information* with dose reductions or withhold BLENREP 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 BLENREP. For complete safety information, please see the full Prescribing Information, including Boxed Warning, available at www.BLENREPREMS.com
BLENREPREMS.com provides rapid support for the BLENREP REMS program, with additional support available via the REMS Coordinating Center.

Key Features of BLENREPREMS.com:
- real-time enrollment certification
- real-time Patient Status Form entry
- automatic email notifications for REMS enrollment and Patient Status Form submission
- visibility to patient treatment history
- sharing of patient care with other certified prescribers based on user preferences
- management of prescriber delegates

For More Information:
Call 1-855-209-9188 (8am-8pm Eastern Time)
Visit www.BLENREPREMS.com