Support in the Management of Corneal Adverse Reactions for Your Patients Prescribed BLENREP
Adverse reactions (ARs) have been reported with BLENREP (belantamab mafodotin). This guide is intended to provide an overview of the corneal ARs that may occur with BLENREP.

This guide will provide the background information to support the understanding of the corneal ARs observed in the clinical study, how symptoms may present, and anatomy of the cornea that may be affected.

In addition, this guide is intended to provide direction on supportive care and dose modifications related to corneal ARs observed in the DREAMM (Driving Excellence in Approaches to Multiple Myeloma)-2 (Study 205678) clinical study. In this guide, this information is referred to as the 3 Ms of corneal AR management: Monitor, Minimise, and Modify.

Corneal ARs are not the only ARs associated with BLENREP.1

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Overview of BLENREP

**BLENREP, the first BCMA-targeting antibody-drug conjugate for relapsed/refractory multiple myeloma**

BLENREP is indicated as monotherapy for the treatment of multiple myeloma in adult patients, who have received at least four prior therapies and whose disease is refractory to at least one proteasome inhibitor, one immunomodulatory agent, and an anti-CD38 monoclonal antibody, and who have demonstrated disease progression on the last therapy.1

BLENREP specifically binds to B-cell maturation antigen (BCMA), a cell-surface protein expressed on myeloma cells, late-stage B cells, and plasma cells. BLENREP binds to cell surface BCMA and is rapidly internalised. Once inside the tumour cell, free cytotoxic agent (cys-mcMMAF) is released, disrupting the microtubule network, leading to cell cycle arrest and apoptosis.1,3

The antibody enhances recruitment and activation of immune effector cells, killing tumour cells by antibody-dependent cellular cytotoxicity and phagocytosis. Apoptosis induced by BLENREP is accompanied by markers of immunogenic cell death (ICD), which may contribute to an adaptive immune response to tumour cells.1,3

**Multiple mechanisms of action**

- Delivers cytotoxic payload
- Enhances immune-mediated actions
- Induces immunogenic cell death

BLENREP may have an effect on healthy cells.4

**DREAMM-2 study design overview**

DREAMM-2 (Study 205678) was an open-label, 2-arm, phase 2, multicentre study, which evaluated belantamab mafodotin as monotherapy in heavily pretreated patients with multiple myeloma.1

**Study Population**1,5
- Relapsed/refractory multiple myeloma patients, N=97
- ≥3 prior lines of therapy and who were refractory to an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 antibody alone or in combination
- Had undergone autologous HSCT or were considered ineligible
- Patients with pre-existing eye conditions, including mild punctate keratopathy, were not excluded from the study, with the exception of patients with current corneal epithelial disease

**Dosing**1,5
- 2.5 mg/kg BLENREP as a single agent by intravenous infusion
- Administered over at least 30 minutes, every 3 weeks
- Treatment continued until disease progression or unacceptable toxicity
- Dose was modified or discontinued in some cases of ARs

**Primary Endpoint**1,5
- Overall response rate

**Secondary Endpoints**4
- Duration of response
- Time to first response
- Progression-free survival
- Overall survival
- Safety

1The BLENREP indication requires at least 4 prior therapies.1

HSCT=hematopoietic stem cell transplantation.
Efficacy of BLENREP in Patients With Relapsed/Refractory Multiple Myeloma

32% overall response rate in a heavily pretreated patient population

Depth and durability of responses observed in a patient population with a median 7 lines of prior therapy

Overall response rate
32% (31/97; 97.5% CI: 22%, 44%)

Median 13 months of follow-up

58% of responding patients had very good partial response or better

Median duration of response
11 months (95% CI: 4.2, not reached)

• Clinical benefit rate (sCR + CR + VGPR + PR + minimal response) was 36% (95% CI: 26.6, 46.5)

Median time to first response was 1.5 months (95% CI: 1.0, 2.1)

Median time to best response was 2.2 months (95% CI: 1.5, 3.6)

• Median overall survival was 13.7 months (95% CI: 9.9, not reached)

ARs (Any Grade) Reported in DREAMM-2 (Study 205678); (N=95)

<table>
<thead>
<tr>
<th>System Organ Class</th>
<th>Adverse Reactions</th>
<th>Any Grade (%)</th>
<th>Grade 3/4 (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infections and infestations</td>
<td>Pneumonia(a)</td>
<td>11</td>
<td>7</td>
</tr>
<tr>
<td></td>
<td>Upper respiratory tract infection</td>
<td>9</td>
<td>0</td>
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<tr>
<td>Blood and lymphatic system disorders</td>
<td>Thrombocytopenia(a)</td>
<td>38</td>
<td>22</td>
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<tr>
<td></td>
<td>Anaemia</td>
<td>27</td>
<td>21</td>
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<tr>
<td></td>
<td>Lymphopenia(a)</td>
<td>20</td>
<td>17</td>
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<tr>
<td></td>
<td>Leukopenia(a)</td>
<td>17</td>
<td>6</td>
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<tr>
<td></td>
<td>Neutropenia(a)</td>
<td>15</td>
<td>11</td>
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<tr>
<td>Eye disorders</td>
<td>Keratopathy(a)</td>
<td>71</td>
<td>31</td>
</tr>
<tr>
<td></td>
<td>Blurred vision events(a)</td>
<td>25</td>
<td>4</td>
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<tr>
<td></td>
<td>Dry eye events(a)</td>
<td>15</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Photophobia</td>
<td>4</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Eye irritation</td>
<td>3</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Ulcerative keratitis</td>
<td>11</td>
<td>1</td>
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<tr>
<td></td>
<td>Infective keratitis</td>
<td>1</td>
<td>1</td>
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<tr>
<td>Gastrointestinal disorders</td>
<td>Nausea</td>
<td>25</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Diarrhoea</td>
<td>13</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Vomiting</td>
<td>7</td>
<td>2</td>
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<tr>
<td>General disorders and administration site conditions</td>
<td>Pyrexia</td>
<td>23</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>Fatigue</td>
<td>16</td>
<td>2</td>
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<tr>
<td>Investigations</td>
<td>Increased aspartate aminotransferase</td>
<td>21</td>
<td>2</td>
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<tr>
<td></td>
<td>Increased gamma glutamyltransferase</td>
<td>11</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>Increased creatine phosphokinase</td>
<td>5</td>
<td>2</td>
</tr>
<tr>
<td>Injury, poisoning, and procedural complications</td>
<td>Infusion-related reactions(a)</td>
<td>21</td>
<td>3</td>
</tr>
</tbody>
</table>

\(a\)Adverse reactions coded using MedDRA and graded for severity based on Common Terminology Criteria for Adverse Events (CTCAE v4.03).

\(b\)Includes pneumonia and herpes simplex pneumonia.

\(c\)Includes thrombocytopenia and decreased platelet count.

\(d\)Includes lymphopenia and decreased lymphocyte count.

\(e\)Includes leukopenia and decreased leukocyte count.

\(f\)Includes neutropenia and decreased neutrophil count.

\(g\)Based on eye examination, characterised as corneal epithelium changes with or without symptoms.

\(h\)Includes diplopia, vision blurred, visual acuity reduced, and visual impairment.

\(i\)Includes dry eye, ocular discomfort, and eye pruritus.

\(j\)Includes events determined by investigators to be related to infusion. Infusion reactions may include, but are not limited to, pyrexia, chills, diarrhoea, nausea, asthenia, hypertension, lethargy, and tachycardia.
Keratopathy (or microcyst-like epithelial changes), the most commonly reported AR, was characterised as changes in corneal epithelium (as seen on eye examination) with or without changes in visual acuity, blurred vision, and dry eye symptoms.

- Eye disorders (any grade) reported in ≥3% of patients in the clinical trial were keratopathy (71%), blurred vision events (25%), dry eye events (15%), photophobia (4%), and eye irritation (3%)
- Patients with a history of dry eyes were more prone to develop changes in the corneal epithelium
- Decreased vision (Snellen Visual Acuity worse than 20/50) in the better eye was reported in 18% of patients and severe vision loss (20/200 or worse) in the better seeing eye was reported in 1% of patients
- The median time to onset of moderate to severe corneal findings (best corrected visual acuity [BCVA] or slit lamp examination) was 36 days (range: 19 to 143 days), and the median time to resolution of these corneal findings was 91 days (range: 21 to 201 days)
- Corneal findings led to dose delays in 47% of patients and dose reductions in 27% of patients. 3% of patients discontinued treatment due to ocular ARs
- Cases of corneal ulcer (ulcerative and infective keratitis) have been reported. These should be managed promptly and as clinically indicated by an eye care professional. Treatment with BLENREP should be interrupted until the corneal ulcer has healed

BLENREP is an antibody-drug conjugate linking a monoclonal antibody with mafodotin, a toxic payload with known corneal ARs

In nonclinical studies, BLENREP was taken up into cells throughout the body, including human corneal epithelial cells, by a mechanism unrelated to BCMA receptor expression on the cell membrane.

Corneal ARs were anticipated and monitored in the clinical trial.

To help manage corneal ARs associated with BLENREP, remember the 3 Ms, detailed on pages 12-13:

- Monitor
- Minimise
- Modify
Understanding the Anatomy and Physiology of the Eye

An overview of the eye helps provide an understanding of ARs.

The eye is a complex organ comprised of many structures that work together to enable vision.

- The cornea, covering the iris and the pupil, is responsible for focusing most of the light that enters the eye.
- The pupil at the center of the iris allows light to strike the retina.
- The iris, which forms the colored portion of the eye, controls the size of the pupil, which, in turn, controls the amount of light that enters the eye.
- The lens is a transparent structure in the eye that, in concert with the cornea, helps refract light and focus it on the retina.
- The retina is the innermost layer of the eye that contains light-responsive cells, which transmit electrochemical signals to the brain via the optic nerve.
- The optic nerve consists of nerve fibers that carry visual information from the retina to the brain.

Corneal ARs have been associated with the use of BLENREP.

Cornea

There are 5 layers of the cornea—epithelium, Bowman’s layer, stroma, Descemet’s membrane, and endothelium.

The cellular layers of the corneal epithelium regenerate, allowing for repair after trauma, typically without scarring.

Keratopathy (or microcyst-like epithelial changes), the most common AR reported with BLENREP, was characterised as changes in the corneal epithelium (as seen on eye examination) with or without changes in visual acuity, blurred vision, and dry eyes.
In order to provide optimal care for your patients being treated with BLENREP, follow these 3 management approaches: Monitor their vision, looking for changes in the cornea. Minimise any ARs they may have. Modify treatment when necessary with dose adjustments.

The recommended dose of BLENREP is 2.5 mg/kg administered as an intravenous infusion once every 3 WEEKS until disease progression or unacceptable toxicity¹.

Advise patients to:
- Avoid contact lenses until the end of treatment
- Use caution when driving or operating machines
- Continue monitoring for corneal adverse reactions after treatment and contact haematologist/oncologist if any symptoms occur. Dose modifications may be necessary, including discontinuation of therapy (see dose modifications on page 21).

Visual acuity and slit lamp exams should be performed by an eye care professional.

Ophthalmic exams and observation of potential ophthalmic symptoms.

Treatment every 3 WEEKS until disease progression or unacceptable toxicity.

Ophthalmic exams and observation of potential ophthalmic symptoms.

For patients with dry eye symptoms, additional therapies may be considered as recommended by their eye care professional.

Advise patients to:
- Administer preservative-free artificial tear drops at least 4 times a day beginning on the first day of infusion and continuing until completion of treatment, as this may reduce corneal symptoms.
- For patients with dry eye symptoms, additional therapies may be considered as recommended by their eye care professional.

1st Dose BLENREP 3 WEEKS 2nd Dose BLENREP 3 WEEKS 3rd Dose BLENREP 3 WEEKS 4th Dose BLENREP

Ophthalmic Exam Before 1st Treatment, before the subsequent 3 treatment cycles, and as clinically indicated whilst on treatment.

Ophthalmic Exam Before 2nd Dose

Ophthalmic Exam Before 3rd Dose

Ophthalmic Exam Before 4th Dose

12 13
Changes in visual acuity as indicated in the grading scale on page 21 can determine if dose modifications are clinically warranted during treatment with BLENREP.

**Visual acuity assessment**

Visual acuity, a “vital sign” of ocular function, provides a measure of the ability of the visual system to discern fine distinctions in the visual environment. BCVA refers to the visual acuity achieved with correction (such as glasses), as measured on the standard Snellen eye chart.

*What is measured?*

- A patient’s visual function is measured by assessing their ability to distinguish fine details with and without corrective lenses, monocularly and binocularly.

*How is it measured?*

- Patient reads the smallest letters that they can identify on a chart (typically a Snellen eye chart) located 20 feet away, or if the chart cannot be set at 20 feet, the height of the letters is calibrated to the appropriate size.

*What do the measurements mean?*

- “Normal” vision, a visual acuity score of 20/20 or better, indicates proper refraction, clarity of ocular media, proper functioning of the retina, and generally unimpaired optic nerve and visual cortex.
- A visual acuity score lower than 20/20 may need to be corrected with new or updated prescription glasses, or it may indicate the presence of an eye condition, such as eye infection, injury, or disorder.

**Slit lamp exam**

Slit lamp exams provide detailed information on the anatomical structures in the eye. They can help detect a range of conditions, including dry eye events. Examination of the surface of the eye is assessed using the slit lamp and can help identify superficial punctate epithelial erosions or superficially damaged cells.
Advise patients that corneal ARs may occur during treatment with BLENREP.1

Advise patients that they will have ophthalmic examinations performed at baseline, before the subsequent 3 treatment cycles, and as clinically indicated whilst on treatment.1

Clinician-patient interactions

Assessment of possible corneal ARs before initiation and during treatment with BLENREP can help identify patients who need additional monitoring and/or management by an eye care professional.1 Questions to help identify symptoms are included on page 17.1

Patients and caregivers should receive education on potential corneal ARs.

Corneal ARs can be assessed with questions targeting signs and symptoms, such as1:

- Are you experiencing any changes with your vision?
- Do you have a history of eye problems?
- Have you noticed any redness, dryness, itching, burning sensation, or sandy or gritty sensation in your eyes?
- Do you feel any sensitivity to light?
- Do you ever feel that your vision is blurred?
- Are you experiencing any pain in your eyes?
- Have you noticed any excessive watering of your eyes?
- Have the changes with your vision or eyes after initiating treatment with BLENREP (improved, persisted, or worsened since your last check-in)?
- Have you been using preservative-free artificial tears eye drops as directed?
Patients who report corneal symptoms should be referred to an eye care professional.

My eyes feel dry and itchy.
My eyes hurt.
I feel that my vision is blurred.
My eyes are watery and feel irritated.
I cannot see very clearly.
I feel more sensitive to light and am always squinting or shielding my eyes.

Counsel patients on the importance of using preservative-free artificial tears at least 4 times a day beginning on the first day of infusion and continuing until completion of treatment, as this may reduce corneal symptoms.

Patients should be advised to avoid contact lenses until the end of treatment.

Patients should also be advised to use caution when driving or operating machines, as BLENREP may affect their vision.

Patients need to be reminded to contact their haematologist/oncologist immediately if they experience any vision/eye symptoms.

For patients with dry eye symptoms, additional therapies may be considered as recommended by their eye care professional.

Support materials are available for patients and caregivers, such as visual acuity images, as well as ways to describe symptoms of these ARs. Call [1-800-XXX-XXXX] or visit BLENREPHCP.com to obtain these resources.

At every doctor visit, patients should be encouraged to share what medications they are taking as well as contact information for their haematologist/oncologist, eye care professional, primary healthcare provider, and any other specialty healthcare provider.
The recommended dose modifications for corneal ARs are summarised in the table on the next page.

Modification of BLENREP dosing may be necessary to manage corneal ARs

Corneal adverse reactions may include findings upon eye examination and/or changes in visual acuity. You and your team should review the patient's ophthalmic examination report before dosing and should determine the dose of BLENREP based on the highest category from the report in the most severely affected eye, as both eyes may not be affected to the same degree.

During the ophthalmic examination, the eye care professional should assess the following:

- The corneal examination finding(s) and the decline in best corrected visual acuity (BCVA)
- If there is a decline in BCVA, the relationship of corneal examination findings to BLENREP should be determined
- The highest category grading for these examination findings and BCVA should be reported to you, as the treating physician

<table>
<thead>
<tr>
<th>AR#b</th>
<th>Eye examination findings</th>
<th>Recommended dose modifications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mild</td>
<td>Corneal examination finding(s)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Mild superficial keratopathy\c</td>
<td></td>
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<tr>
<td></td>
<td>Change in BCVA</td>
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<tr>
<td></td>
<td>Decline from baseline of 1 line on Snellen Visual Acuity</td>
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</tr>
<tr>
<td></td>
<td>• Continue treatment at current dose</td>
<td></td>
</tr>
<tr>
<td>Moderate</td>
<td>Corneal examination finding(s)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Moderate superficial keratopathy\d</td>
<td></td>
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<tr>
<td></td>
<td>Change in BCVA</td>
<td></td>
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<tr>
<td></td>
<td>Decline from baseline of 2 or 3 lines (and Snellen Visual Acuity not worse than 20/200)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Withhold treatment until improvement in examination findings and BCVA to mild severity or better</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Consider resuming treatment at a reduced dose of 1.9 mg/kg</td>
<td></td>
</tr>
<tr>
<td>Severe</td>
<td>Corneal examination finding(s)</td>
<td></td>
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<tr>
<td></td>
<td>Severe superficial keratopathy\e</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Corneal epithelial defect\f</td>
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<td></td>
<td>Change in BCVA</td>
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</tr>
<tr>
<td></td>
<td>Decline from baseline of more than 3 lines</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Withhold until improvement in examination findings and BCVA to mild severity or better</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• For worsening symptoms that are unresponsive to appropriate management, consider discontinuation</td>
<td></td>
</tr>
</tbody>
</table>

\aNote: This guide does not cover all potential ARs and recommended dose modifications.
\bThe severity category is defined by the most severely affected eye, as both eyes may not be affected to the same degree.
\cMild superficial keratopathy (documented worsening from baseline), with or without symptoms.
\dModerate superficial keratopathy—with or without patchy microcyst-like deposits, subepithelial haze (peripheral), or a new peripheral stromal opacity.
\eSevere superficial keratopathy with or without diffuse microcyst-like deposits involving the central cornea, subepithelial haze (central), or a new central stromal opacity.
\fA corneal defect may lead to corneal ulcers. These should be managed promptly and as clinically indicated by an eye care professional.
Frequently Asked Questions

Q: What type of eye exams will my patient need before starting BLENREP, and when will these exams be conducted?
A: Ophthalmic examination, including visual acuity and slit lamp exam, should be performed by an eye care professional at baseline, before the subsequent 3 treatment cycles, and as clinically indicated whilst on treatment.1

Q: What type of eye drops should my patient use?
A: Preservative-free artificial tears, available over the counter, should be used at least 4 times a day beginning on the first day of infusion and continuing until completion of treatment with BLENREP to help reduce corneal symptoms. For patients with dry eye symptoms, additional therapies may be considered as recommended by their eye care professional.1

Q: What types of effects on the eyes may occur during and after treatment with BLENREP?
A: Corneal ARs have been reported with the use of BLENREP. Eye disorders (any grade) reported in ≥3% of patients in the clinical trial were keratopathy (71%), blurred vision events (25%), dry eye events (15%), photophobia (4%), and eye irritation (3%). Keratopathy (or microcyst-like epithelial changes) was characterised as changes in corneal epithelium (as seen on eye examination) with or without changes in visual acuity, blurred vision, and dry eye symptoms. Patients with a history of dry eyes were more prone to develop changes in the corneal epithelium. Decreased vision (Snellen Visual Acuity worse than 20/50) in the better eye was reported in 18% of patients and severe vision loss (20/200 or worse) in the better-seeing eye was reported in 1% of patients. Cases of corneal ulcer (ulcerative and infective keratitis) have also been reported.1

Q: Were patients in DREAMM-2 (Study 205678) eligible to participate in the study if they had pre-existing eye conditions?
A: Patients with pre-existing eye conditions, including mild punctate keratopathy, were not excluded from the study, with the exception of patients with current corneal epithelial disease.5

Q: When did corneal symptoms begin in patients treated with BLENREP?
A: In the DREAMM-2 study (Study 205678), the median time to onset of moderate to severe corneal findings (BCVA or corneal examination) was 36 days (range: 19 to 143 days).1

Q: How long did corneal symptoms last in patients treated with BLENREP?
A: In the DREAMM-2 study (Study 205678), the median time to resolution of these corneal findings was 91 days (range: 21 to 201 days).1

Q: Did all patients experience eye-related ARs with BLENREP?
A: Keratopathy was reported in 71% of the patients in the DREAMM-2 study (Study 205678). Corneal exam findings did not always correspond to symptoms reported by patients. Permanent vision loss was not reported in the DREAMM-2 trial (Study 205678).1,5

Q: Can patients use contact lenses during treatment with BLENREP?
A: Advise patients to avoid contact lenses until the end of treatment.1

Q: What is keratopathy or microcyst-like epithelial changes?
A: Keratopathy or microcyst-like epithelial changes was characterised as changes in corneal epithelium (as seen on eye examination) with or without changes in visual acuity, blurred vision, and dry eyes.1
Frequently Asked Questions (continued)

Q: Are there any restrictions on certain daily activities involving vision after initiating treatment with BLENREP?
A: Advise patients to use caution when driving or operating machines as BLENREP may affect their vision.

Q: Why does BLENREP affect the eyes?
A: In nonclinical studies, BLENREP was taken up into cells, including corneal epithelial cells, by a mechanism unrelated to BCMA receptor expression on the cell membrane.

Q: How can the ARs be managed?
A: Remember the 3 Ms: Monitor, Minimise, and Modify.

- To monitor corneal ARs, ophthalmic examination, including visual acuity and slit lamp exam, should be performed by an eye care professional at baseline, before the subsequent 3 treatment cycles, and as clinically indicated whilst on treatment.

- To minimise corneal symptoms, preservative-free artificial tears need to be administered at least 4 times a day beginning on the first day of infusion and continuing until completion of treatment. For patients with dry eye symptoms, additional therapies may be considered as recommended by their eye care professional.

- Modification of BLENREP dosing, including discontinuation, may be necessary to manage corneal ARs. Please see recommended dose modifications on page 21.

Q: Whom should patients contact if the symptoms occur?
A: Patients should consult their haematologist/oncologist as well as their eye care professional if corneal ARs occur.

References
1. BLENREP (belantamab mafodotin) Summary of Product Characteristics.
Support in the Management of Corneal Adverse Reactions (ARs) for Your Patients Prescribed BLENREP

An overview of the corneal ARs that may occur with BLENREP, including:

- Corneal ARs observed in the DREAMM-2 (Study 205678) clinical trial
- How symptoms may present
- Anatomy of the cornea that may be affected
- The 3 Ms of corneal AR management: Monitor, Minimise, and Modify
- Frequently asked questions

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