An Overview of BLENREP and Corneal Adverse Reactions for Eye Care Professionals
Patients with relapsed or refractory multiple myeloma prescribed BLENREP (belantamab mafodotin) require an eye exam at baseline, before the subsequent 3 treatment cycles, and as clinically indicated whilst on treatment.¹

Adverse reactions (ARs) have been reported with BLENREP, including corneal events, during clinical trials. Patients may be referred to you by a haematologist/oncologist or may see you directly for their eye exams.

This guide is intended to provide you an overview of why eye exams are required and what corneal ARs could potentially occur with BLENREP.

It is important to communicate these findings to the haematology/oncology care team, as findings of the eye exam(s) may impact the patient’s treatment.

Corneal ARs are not the only risks associated with BLENREP.¹
Understanding a Patient With Relapsed/Refractory Multiple Myeloma

Multiple myeloma is a malignancy of the plasma cells (PCs), resulting in bone marrow (BM) infiltration and monoclonal protein in serum and/or urine²

Multiple myeloma is the third most common haematological malignancy worldwide, with an estimated 159,985 new multiple myeloma cases and 106,105 deaths per year³

Multiple myeloma is most frequently diagnosed in older individuals, with a median age at diagnosis of 72 years⁴

The highest age-standardised death and incidence rates of multiple myeloma have been observed in countries in Australasia, North America, and Western Europe, while Asia, Oceania, and sub-Saharan Africa are regions with the lowest age-standardised incidence of multiple myeloma⁵

Although currently considered incurable, multiple myeloma is treatable⁶

- Due to the relapsing course of multiple myeloma, patients often receive multiple lines of therapy. Most patients receive several courses of therapy that may include: an immunomodulatory agent, a proteasome inhibitor (PI) used in combination with a corticosteroid, or anti-CD38 monoclonal antibodies (mAbs)⁶,⁷
- Advances have been made in the management of multiple myeloma in recent years with the introduction of these novel therapies. Yet the duration of response, time to progression, and survival get shorter with each successive line of therapy⁸-¹⁰
- Most patients will eventually progress to relapsed and refractory disease, highlighting the need for new treatments⁸
- The addition of BLENREP to the therapeutic landscape is an important option for 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 therapy¹,⁶,⁷

The content contained within this section is not specific to product indication and is intended to provide general disease state background on multiple myeloma.
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.\(^1,11,12\)

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.\(^1,11,12\)

Multiple mechanisms of action\(^1\)

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

BLENREP may have an effect on healthy cells.\(^13\)

DREAMM-2 study design overview

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

**Study Population**\(^1,14\)
- 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**\(^1,14\)
- 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**\(^1,14\)
- Overall response rate

**Secondary Endpoints**\(^1,14\)
- Duration of response
- Time to first response
- Progression-free survival
- Overall survival
- Safety

\(^\#\)The 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

• 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: 1.3, 3.6)

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

Adverse reactions (ARs)

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</td>
<td>11</td>
<td>7</td>
</tr>
<tr>
<td>Blood and lymphatic system disorders</td>
<td>Thrombocytopenia</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</td>
<td>20</td>
<td>17</td>
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<td></td>
<td>Leukopenia</td>
<td>17</td>
<td>6</td>
</tr>
<tr>
<td></td>
<td>Neutropenia</td>
<td>15</td>
<td>11</td>
</tr>
<tr>
<td>Eye disorders</td>
<td>Keratopathy</td>
<td>71</td>
<td>31</td>
</tr>
<tr>
<td></td>
<td>Blurred vision events</td>
<td>25</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>Dry eye events</td>
<td>15</td>
<td>1</td>
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<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>Ularcerative keratitis</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Infective keratitis</td>
<td>1</td>
<td>1</td>
</tr>
<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>
</tr>
<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>
</tr>
<tr>
<td>Investigations</td>
<td>Increased aspartate aminotransferase</td>
<td>21</td>
<td>2</td>
</tr>
<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</td>
<td>21</td>
<td>3</td>
</tr>
</tbody>
</table>

System Organ Class Adverse Reactions Any Grade (%) Grade 3/4 (%)

| Infections and infestations | Pneumonia | 11 | 7 |
| Blood and lymphatic system disorders | Thrombocytopenia | 38 | 22 |
| | Anaemia | 27 | 21 |
| | Lymphopenia | 20 | 17 |
| | Leukopenia | 17 | 6 |
| | Neutropenia | 15 | 11 |
| Eye disorders | Keratopathy | 71 | 31 |
| | Blurred vision events | 25 | 4 |
| | Dry eye events | 15 | 1 |
| | Photophobia | 4 | 0 |
| | Eye irritation | 3 | 0 |
| | Ularcerative keratitis | 1 | 1 |
| | Infective keratitis | 1 | 1 |
| Gastrointestinal disorders | Nausea | 25 | 0 |
| | Diarrhoea | 13 | 1 |
| | Vomiting | 7 | 2 |
| General disorders and administration site conditions | Pyrexia | 23 | 4 |
| | Fatigue | 16 | 2 |
| Investigations | Increased aspartate aminotransferase | 21 | 2 |
| | Increased gamma glutamyltransferase | 11 | 3 |
| | Increased creatine phosphokinase | 5 | 2 |
| Injury, poisoning, and procedural complications | Infusion-related reactions | 21 | 3 |

- Adverse reactions coded using MedDRA and graded for severity based on Common Terminology Criteria for Adverse Events (CTCAE v4.03).
- Includes pneumonia and herpes simplex pneumonia.
- Includes thrombocytopenia and decreased platelet count.
- Includes lymphopenia and decreased lymphocyte count.
- Includes neutropenia and decreased neutrophil count.
- Based on eye examination, characterised as corneal epithelium changes with or without symptoms.

These are not all the possible ARs of BLENREP.

If your patient experiences any ARs while taking BLENREP, please tell your patient to contact the haematologist/oncologist.
Corneal ARs Observed in the DREAMM-2 (Study 205678) Clinical Trial

Keratopathy or microcyst-like epithelial changes were the most common ARs

- Keratopathy or microcyst-like epithelial changes (MECs) were 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 (keratopathy) 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 corneal epithelial cells, by a mechanism unrelated to BCMA receptor expression on the cell membrane.

To help the haematology/oncology clinical care team manage corneal ARs associated with BLENREP, remember the 3 Ms, detailed on pages 12-13:

- Monitor
- Minimise
- Modify
MONITOR, MINIMISE, MODIFY:
The 3 Ms of Corneal AR Management

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. Consult with the haematology/oncology clinical care team, who may need to **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:**
- 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.
- 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 19).

**Ophthalmic Exam**
- Before 1st Treatment,
- before the subsequent 3 treatment cycles,
- and as clinically indicated whilst on treatment.
- Treatment every 3 WEEKS until disease progression or unacceptable toxicity.
- Ophthalmic exams and observation of potential ophthalmic symptoms.

**Visual acuity and slit lamp exams should be performed by an eye care professional.**
You can evaluate possible patient-reported corneal ARs with questions targeting the signs and symptoms of corneal ARs, such as:

- 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 excessive watering of your eyes?
- Have the changes with your vision or eyes reported 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?

**Clinician-patient interactions**

Assessment of possible corneal ARs before initiating and during treatment with BLENREP can help identify patients who need additional monitoring and/or management by an eye care professional.

- Visual acuity and slit lamp examination should be performed at baseline, before the subsequent 3 treatment cycles, and as clinically indicated whilst on treatment.
- Advise patients to administer preservative-free artificial tears at least 4 times a day beginning on the first day of infusion and continuing until completion of treatment.
- Questions to help identify symptoms are included on page 15.

**Patient-identified symptoms** reported to you should be conveyed to the haematology/oncology clinical care team immediately.

**Patient-reported symptom communications**

Educating patients on possible symptoms associated with the corneal ARs observed in the clinical study will help monitor, identify, and report potential symptoms that may occur outside the clinical setting.

You can evaluate possible patient-reported corneal ARs with questions targeting the signs and symptoms of corneal ARs, such as:

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- 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 excessive watering of your eyes?
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- Have you been using preservative-free artificial tears eye drops as directed?

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- Do you ever feel that your vision is blurred?
- Are you experiencing any pain in your eyes?
- Have you noticed excessive watering of your eyes?
- Have the changes with your vision or eyes reported 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 and caregivers should receive education on potential corneal ARs, and patients should complete initial ophthalmological exams prior to initiating the first infusion with BLENREP. During the treatment and in subsequent follow-ups with the clinician, patients may report signs and symptoms indicative of corneal ARs:

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

**Supportive care**

Advise patients that corneal ARs may occur during treatment with BLENREP and that they will have ophthalmic exams performed at baseline, before the subsequent 3 treatment cycles, and as clinically indicated whilst on treatment.

Advise patients to administer 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.

Advise patients to avoid contact lenses until the end of treatment.

Advise patients to use caution when driving or operating machines as BLENREP may affect their vision.

For patients with dry eye symptoms, you may recommend additional therapies.
## Dose Modifications for Corneal ARs

The recommended dose modifications for corneal ARs are summarised in the table below.

### Modification of BLENREP dosing may be necessary to manage corneal ARs

**Ophthalmic Exams**

<table>
<thead>
<tr>
<th>Category</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>• Continue treatment at current dose</td>
</tr>
<tr>
<td></td>
<td>Mild superficial keratopathy</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Change in BCVA</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Decline from baseline of 1 line on Snellen Visual Acuity</td>
<td></td>
</tr>
<tr>
<td>Moderate</td>
<td>Corneal examination finding(s)</td>
<td>• Withhold treatment until improvement in examination findings and BCVA to mild severity or better</td>
</tr>
<tr>
<td></td>
<td>Moderate superficial keratopathy</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Change in BCVA</td>
<td></td>
</tr>
<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>Severe</td>
<td>Corneal examination finding(s)</td>
<td>• Withhold until improvement in examination findings and BCVA to mild severity or better</td>
</tr>
<tr>
<td></td>
<td>Severe superficial keratopathy</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Corneal epithelial defect</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Change in BCVA</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Decline from baseline of more than 3 lines</td>
<td></td>
</tr>
</tbody>
</table>

Note: This guide does not cover all potential ARs and recommended dose modifications.

The severity category is defined by the most severely affected eye, as both eyes may not be affected to the same degree. During the ophthalmic examination, assess:

- The corneal examination finding(s) and the decline in 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 the treating physician

If corneal ARs occur, dose modification or discontinuation (based on AR severity) may be applied by the haematology/oncology care team.

Corneal adverse reactions may include findings upon eye examination and/or changes in visual acuity. The treating physician 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, assess:

- The corneal examination finding(s) and the decline in 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 the treating physician

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a Note: This guide does not cover all potential ARs and recommended dose modifications.

b The severity category is defined by the most severely affected eye, as both eyes may not be affected to the same degree.

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

d Moderate superficial keratopathy—with or without patchy microcyst-like deposits, subepithelial haze (peripheral), or a new peripheral stromal opacity.

e Severe superficial keratopathy with or without diffuse microcyst-like deposits involving the central cornea, subepithelial haze (central), or a new central stromal opacity.

f A 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: Are there materials to document symptoms of corneal events?
A: Patients will be provided with an "Eye Care Evaluation Guide" that provides key contact information to facilitate communication for you and the haematologist/oncologist regarding corneal ARs. Patients will also be provided with a “Symptom and Activity Tracker" to document if they have symptoms affecting their eyes and if they are having difficulty seeing during daily activities.

Q: What type of eye exams will patients 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: 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.14

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 were 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 were 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 been reported.1

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: Whom should patients contact if symptoms occur?
A: Patients and eye care professionals should consult the haematologist/oncologist if corneal ARs occur.1

Q: Can patients use contact lenses during treatment with BLENREP?
A: Advise patients to avoid contact lenses unless directed by an eye care professional.1

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.1

Q: Why does BLENREP affect the eyes?
A: In nonclinical studies, BLENREP was taken up into cells throughout the body, including corneal epithelial cells, by a mechanism unrelated to BCMA receptor expression on the cell membrane.1
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.1

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.1

Modification of BLENREP dosing by the haematologist/oncologist, including discontinuation, may be necessary to manage corneal ARs.1

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

References
1. BLNREP (belantamab mafodotin) Summary of Product Characteristics.
An Overview of BLENREP and Corneal Adverse Reactions (ARs) for Eye Care Professionals

- Efficacy and safety of BLENREP as demonstrated in the DREAMM-2 (Study 205678) clinical trial
- Potential corneal ARs with BLENREP
- The 3 Ms of corneal AR management: Monitor, Minimise, and Modify
- Frequently asked questions