Intended for healthcare professionals registered in Ireland.

Guide for healthcare professionals: Management of ocular events in patients receiving Blenrep▼ (belantamab mafodotin)

▼ These medicinal products are subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance: Website: www.hpra.ie. Adverse reactions should also be reported to GlaxoSmithKline on 1800 244 255.

The contents of this document have been approved by the HPRA.
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Introduction

Ocular events are **anticipated** with belantamab mafodotin.

Therefore, a close working relationship between the **prescriber** and an **eye care professional** is encouraged when a patient is receiving belantamab mafodotin.

Ocular events can be **managed** with **appropriate dose modifications and follow-up**. Some ocular events can occur without symptoms and are only detected through ophthalmic examination.

Ophthalmic examinations should be performed by an eye care professional before each of the **first 4 doses** and as clinically indicated thereafter. Examination findings should be **promptly reported** to the prescriber enabling informed decision-making regarding the management of these findings, as described in this guide.

It is important for prescribers and eye care professionals to **educate patients** on how to **identify symptoms** and to **reassure patients** that ocular events can be managed with appropriate dose modifications and follow-up.

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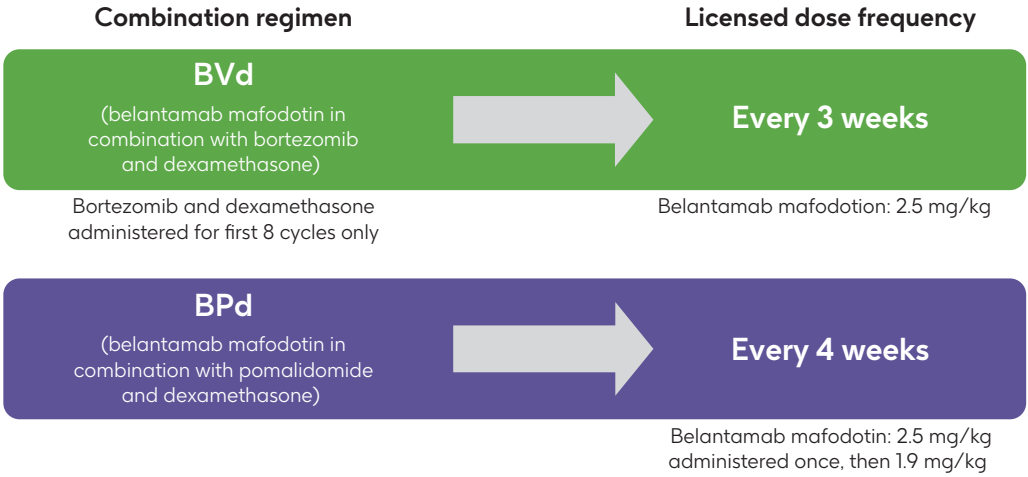
Overview of belantamab mafodotin

Belantamab mafodotin is indicated for the treatment of adults with multiple myeloma.[1]

Belantamab mafodotin is a MMAF-containing ADC – a monoclonal antibody linked with a mafodotin payload, which is associated with ocular events.[1–5]

Belantamab mafodotin binds to BCMA, a cell surface protein expressed on myeloma cells, late-stage B cells, and plasma cells. Upon binding, belantamab mafodotin is rapidly internalised.[1–3]

Depending on the combination regimen, belantamab mafodotin is administered in either 3-week cycles or 4-week cycles until disease progression or unacceptable toxicity.[1]



Belantamab mafodotin dose modifications, including reductions and extended dosing schedules (see Page 11), are implemented for nearly all patients to manage ocular events[1,6–8]

Please refer to the SmPC before prescribing on **www.medicines.ie**.

Ocular events with belantamab mafodotin

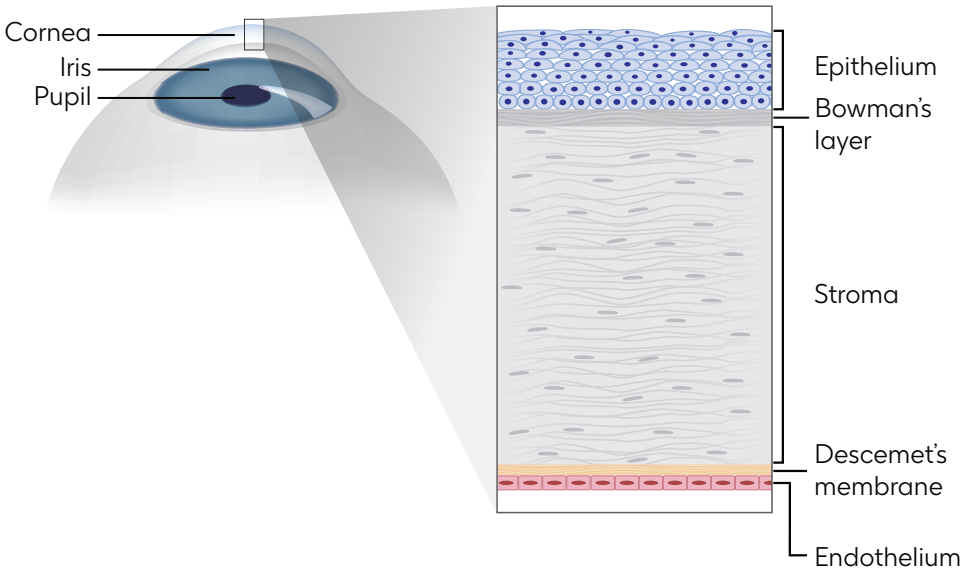
Belantamab mafodotin may have an effect on healthy cells, such as those in the cornea, which may lead to ocular events.[5]

In this guide, **ocular events** refer to **corneal examination findings**, reductions in **best corrected visual acuity (BCVA)**, and **ocular ARs**. Ocular events occur within the corneal epithelium and are proposed as an off-target effect of belantamab mafodotin and other similar ADCs.[7] Some ocular events can occur without symptoms and are only detected through ophthalmic examinations.[5]

Corneal examination findings (keratopathies such as superficial punctate keratopathy and microcyst-like deposits) may occur as a result of corneal epithelial cell apoptosis, following internalisation of belantamab mafodotin and can be observed via **slit-lamp examination**.[5] The migration of early apoptotic corneal epithelial cells to the visual axis may result in **changes in visual acuity** and **symptoms** such as dry eye and blurred vision. The corneal epithelium has the ability to **repair and regenerate** (in a minimum of 14 days). This may aid in the **resolution** of ocular events.[5,9]

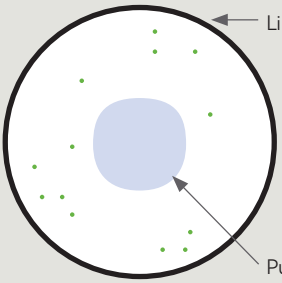
BCVA is a measure of the sharpest vision achievable with corrective lenses. BCVA is typically reported as a fraction (e.g., 20/20). It can be assessed using methods such as refraction or the **Snellen Visual Acuity test**.

Ocular ARs refer to patient-reported **symptoms** such as dry eyes and blurred vision, graded per CTCAE.



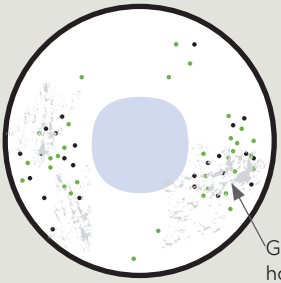
For illustrative purposes only.

Corneal examination findings



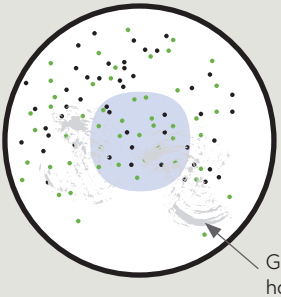
Grade 1

Mild superficial punctate keratopathy with worsening from baseline, with or without symptoms.



Grade 2

Moderate superficial punctate keratopathy, patchy **microcyst-like deposits**, peripheral sub-epithelial haze, or a new peripheral stromal opacity.



Grade 3

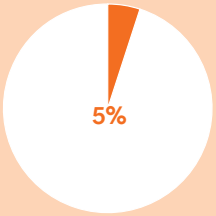
Severe superficial punctate keratopathy, diffuse **microcyst-like deposits** involving the central cornea, central sub-epithelial haze, or a new central stromal opacity.

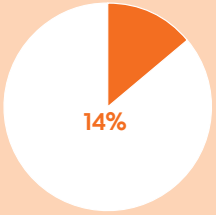
Grade 4

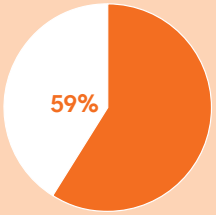
Corneal epithelial defect

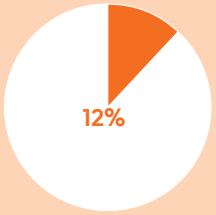
Note: a corneal defect may lead to corneal ulcers. These should be managed promptly and as clinically indicated by an eye care professional.

Frequency of events[1,*]









green dot = superficial punctate keratopathy
black dot = microcyst-like deposits
Images above are for illustrative purpose only.

*Pooled data from 3 clinical trials of belantamab mafodotin in combination with other therapies, n=516.

Changes in visual acuity observed with belantamab mafodotin[1]

Belantamab mafodotin, in combination with other therapies, has been evaluated in 3 clinical trials, including DREAMM-6 (a Phase 1/2, open-label dose exploration study), and the open-label, Phase 3 studies, **DREAMM-7** and **DREAMM-8**.[1]

The presence of ocular conditions at baseline was not found to increase the incidence of ocular events in patients treated with BPd or BVd[10]

Pooled data from these trials (516 patients) reported:[1]

- A decline in BCVA to 20/50 or worse in 31% of patients
  - Median time to onset: **85 days**
- After the first occurrence of this decline, BCVA subsequently improved in 96% of patients and returned to baseline* in 90% patients at the last follow up†
  - Median time to resolution: **57 days**

- A decline in BCVA to 20/200 or worse in 2% of patients
  - Median time to onset: **99 days**
- After the first occurrence of this decline, BCVA subsequently improved in 100% of patients and returned to baseline in 75% of patients at the last follow up†
  - Median time to resolution: **86.5 days**

Please refer to the SmPC before prescribing on **www.medicines.ie**.

*Baseline defined as 20/25 or better in at least one eye[1]; †Ocular occurrences that had not resolved at data cut off were mainly in patients who were still on treatment or in follow up, or in those who died or withdrew consent before resolution could be documented.[11]

Ocular ARs observed with belantamab mafodotin[1]

Adverse reactions	Incidence (% of 828 patients*)	
	Any grade	Grade 3/4
Corneal examination findings (including keratopathy)†‡	84	62
Visual acuity reduced†	81	50
Vision blurred	52	13
Dry eye	36	5
Foreign body sensation in eyes	32	2
Photophobia	30	1
Eye irritation	28	3
Eye pain	21	<1
Cataract	13	4
Visual impairment	8	5
Lacrimation increased	5	<1
Diplopia	3	<1
Eye pruritus	2	<1
Ocular discomfort	1	<1
Corneal ulcer§	1	<1
Corneal hypoesthesia	0	0

*Includes 516 patients from the DREAMM-6, DREAMM-7, and DREAMM-8 studies and 312 patients who received belantamab mafodotin monotherapy in the DREAMM-2 and DREAMM-3 studies; †Based on ophthalmic examination findings; ‡Includes superficial punctate keratopathy, microcyst-like epithelial changes, stippled vortex staining pattern, sub-epithelial haze, corneal epithelial defects, and stromal opacity with or without changes in visual acuity; §Includes infective keratitis and ulcerative keratitis.

To manage ocular events:

- **67%** of patients had extended dosing schedules
- **39%** of patients had dose reductions
- **7%** of patients discontinued treatment

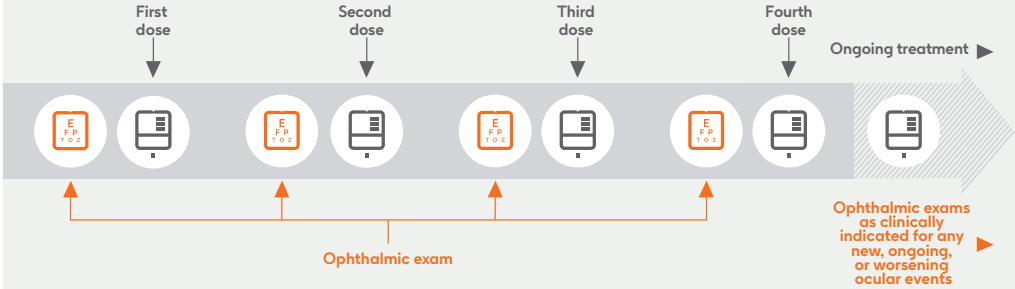
Treatment with belantamab mafodotin

Patient care should be **coordinated between the prescriber and an eye care professional** before beginning treatment with belantamab mafodotin.

A **multidisciplinary** approach involving close collaboration between eye care professionals and prescribers is critical to providing optimal care for individuals receiving belantamab mafodotin.[5]

Dose **modifications** should be implemented to **manage ocular events** when necessary.[1]

Ophthalmic exams are **required** before the **first 4 treatments and as clinically indicated thereafter**



Treatment with belantamab mafodotin (cont.)

It is important to advise patients that:

Ocular events are expected with belantamab mafodotin and may reoccur following readministration.[1]

They will have **eye exams** performed before the first 4 doses, and as clinically indicated for any new, ongoing, or worsening ocular events. Patients should report any ocular symptoms that may indicate additional eye exams are needed.[1]

It is common for prescribers to **adjust treatment** with belantamab mafodotin to manage ocular events.[1]

Ocular events can be managed with **appropriate dose modifications** and **follow-up**.[12,13]

It is important to **communicate in full** to patients about **ocular events that can occur** with belantamab mafodotin treatment.[14]

- Using **simple, non-technical language** and visual aids should facilitate understanding
- Full communication about ocular events should include onset, severity, duration, and management steps
- Open conversations support understanding and empower patients to **participate in shared decision-making**

Assessment of ocular events

Ophthalmic examinations should be performed before the **first 4 doses** and as clinically indicated for any new or worsening ocular events.[1]

The ophthalmic examination should include:

- Slit-lamp examination (corneal examination)
- Snellen Visual Acuity test (change in BCVA)

The severity of the corneal examination findings and change in BCVA should be determined for each eye.

Since both eyes may not be affected to the same degree, the **worst severity** should be reported for the **most severely affected eye**.

Example: If a patient has mild superficial punctate keratopathy with worsening from baseline in the left eye, but no decline in BCVA, the grading for the left eye would be Grade 1 (Mild). If the same patient has a decline from baseline of 1 line in the right eye, along with moderate superficial punctate keratopathy and peripheral sub-epithelial haze, the grading for the right eye would be Grade 2 (Moderate).

In this case, the most severely affected eye is the right eye with a worst severity of Grade 2. Therefore, Grade 2 should be reported as the overall severity (see below).

Assessment table sample:

Date of assessment: _____

BCVA changes and corneal exam findings

	No change	Grade 1	Grade 2	Grade 3	Grade 4
Corneal findings		Mild	Moderate	Severe	Corneal epithelial defect
Check the box that corresponds to the more severely affected eye		☐	☑	☐	☐
BCVA change from baseline		Mild	Moderate	Severe	20/200 or worse
Check the box that corresponds to the more severely affected eye		☑	☐	☐	☐

Highest severity in worst eye: ☐ No change ☐ Grade 1 ☑ Grade 2 ☐ Grade 3 ☐ Grade 4

Assessment of ocular events (cont.)

Encourage patients to inform you of any ocular events they may have, and ask questions regarding signs and symptoms, such as:

Is it taking longer for your eyes to **adjust to light**?

Have you noticed any **redness, dryness, itching, burning sensation**, or a **sandy/gritty** sensation in your eyes?

Are you experiencing any **changes in your vision**?

Do you ever feel that your vision is **blurred**?

Do you feel any **pain** in your eyes?

Are you currently taking any additional **medications**?

Have you noticed if your eyes are **watery** or **irritated**?

Have you been using **preservative-free artificial tears eye drops** as directed?

Have you noticed if your **vision has changed at all** (e.g., got worse or better) since your last checkup, or has it stayed the same?

Dose modifications for ocular events[1]

The **findings** of the ophthalmic examination should be used to **guide the modification** of the belantamab mafodotin dose and/or schedule, using the dose modification tables provided in this guide.

The dose of belantamab mafodotin **should not be re-escalated** after a dose reduction due to ocular events.

Extended dosing intervals were reported during the clinical trials.

	Combination with bortezomib and dexamethasone* (Cycle length = 3 weeks)	**Combination with pomalidomide and dexamethasone*** (Cycle length = 4 weeks)
Standard schedule	2.5 mg/kg every 3 weeks	Cycle 1: 2.5 mg/kg administered once Cycle 2 onwards: 1.9 mg/kg every 4 weeks
Reduced dose level 1	1.9 mg/kg every 3 weeks	1.9 mg/kg every 8 weeks
Reduced dose level 2	Not applicable	1.4 mg/kg every 8 weeks

***Extended dosing intervals were observed frequently during the clinical trials.**

	Eye examination findings	Recommended dose modifications
Grade 1 (Mild)	**Corneal examination finding(s)** Mild superficial punctate keratopathy with worsening from baseline, with or without symptoms **Change in BCVA** Decline from baseline of 1 line on Snellen Equivalent Visual Acuity	Continue treatment at current dose
Grade 2 (Moderate)	**Corneal examination finding(s)** Moderate superficial punctate keratopathy, patchy microcyst-like deposits, peripheral subepithelial haze, or a new peripheral stromal opacity **Change in BCVA** Decline from baseline of 2 lines (and Snellen Equivalent Visual Acuity not worse than 20/200)	Withhold treatment until improvement in both corneal examination findings and BCVA to mild severity or better Resume treatment at reduced dose level 1* • **With Vd:** 1.9 mg/kg every 3 weeks; belantamab mafodotin is administered from Cycle 1 until completion of treatment, Vd is administered for the first 8 cycles • **With Pd:** 1.9 mg/kg every 8 weeks
Grade 3 (Severe)	**Corneal examination finding(s)** Severe superficial punctate keratopathy, diffuse microcyst-like deposits involving the central cornea, central sub-epithelial haze, or a new central stromal opacity **Change in BCVA** Decline from baseline of 3 or more lines (and Snellen Equivalent Visual Acuity not worse than 20/200)	
Grade 4	**Corneal examination finding(s)** Corneal epithelial defect† **Change in BCVA** Decline to Snellen Equivalent Visual Acuity of worse than 20/200	Withhold until improvement in both corneal examination findings and BCVA to mild severity or better Resume treatment at reduced dose level 1 for BVd and reduced dose level 2 for BPd, if applicable: • **With Vd:** 1.9 mg/kg every 3 weeks • **With Pd:** 1.4 mg/kg every 8 weeks For worsening symptoms that are unresponsive to appropriate management, consider permanent discontinuation

Note: This guide does not cover all potential ocular events and recommended dose modifications. For a full list of ARs, please refer to the belantamab mafodotin Summary of Product Characteristics. 2024.[1]
*If toxicity is identified prior to dosing Cycle 2 for combination with pomalidomide and dexamethasone, dose at 1.9 mg/kg every 4 weeks; †A corneal defect may lead to corneal ulcers. These should be managed promptly and as clinically indicated by an eye care professional.

Management of ocular events

Advise patients on the following strategies to minimise the impact of ocular events:

Administer **preservative-free artificial tears** at least 4 times a day, beginning on the first day of infusion and continuing until completion of treatment. This may reduce ocular symptoms.

For patients with dry eye symptoms, additional therapies may be recommended by eye care professionals.

Do not use contact lenses until the end of treatment. Bandage contact lenses may be used under the direction of an eye care professional.

Use caution when driving or operating machinery and avoid these activities if vision is affected. Discuss with eye care professional if unsure.

Contact their care team promptly if they experience any ocular events.

A **Guide for Patients** is available to help educate patients and caregivers on potential ocular events.

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Abbreviations

ADC	antibody-drug conjugate
AR	adverse reaction
BCMA	B-cell maturation antigen
BCVA	best corrected visual acuity
BPd	belantamab mafodotin with pomalidomide and dexamethasone
BVd	belantamab mafodotin with bortezomib and dexamethasone
CTCAE	Common Terminology Criteria for Adverse Events
MMAF	monomethyl auristatin
SmPC	summary of product characteristics

Reporting of adverse events

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information.
Adverse events should be reported directly to the Health Products Regulatory Authority (HPRA) on their website: www.hpra.ie. Adverse events should also be reported to GlaxoSmithKline on 1800 244 255 or via online form https://gsk.public.reportum.com.

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