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

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 dose or more frequently as clinically indicated. If changes in vision or corneal signs are not observed at or before the sixth dose, ophthalmic examination frequency may be reduced to approximately every 3 months, and whenever clinically indicated. 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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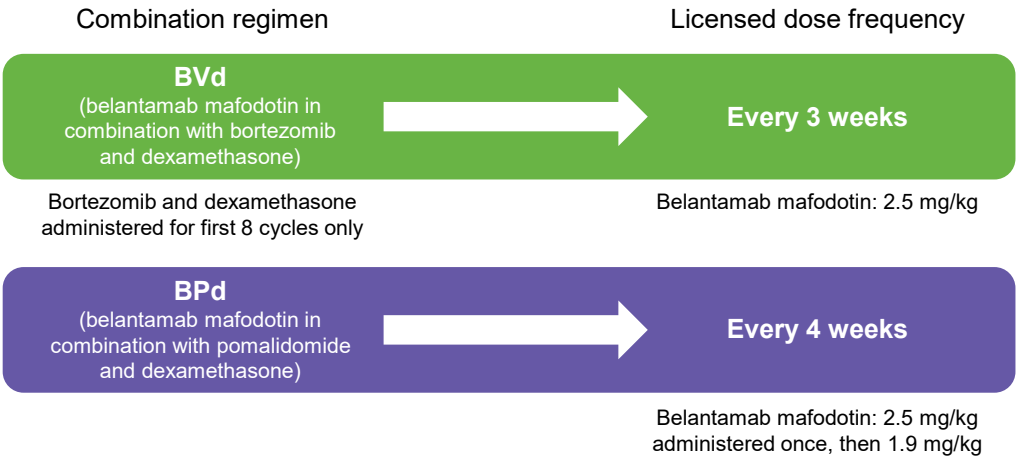
Overview of belantamab mafodotin

Belantamab mafodotin is indicated for the treatment of adults with relapsed or refractory multiple myeloma.

Belantamab mafodotin is a MMAF-containing antibody-drug conjugate (ADC) – a monoclonal antibody linked with a mafodotin payload, which is associated with ocular events.

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.

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



Belantamab mafodotin dose modifications, including reductions and extended dosing schedules (see Page 12), are implemented to manage ocular events.

Please refer to the Blenrep Singapore Package Insert for additional details

Ocular events with belantamab mafodotin

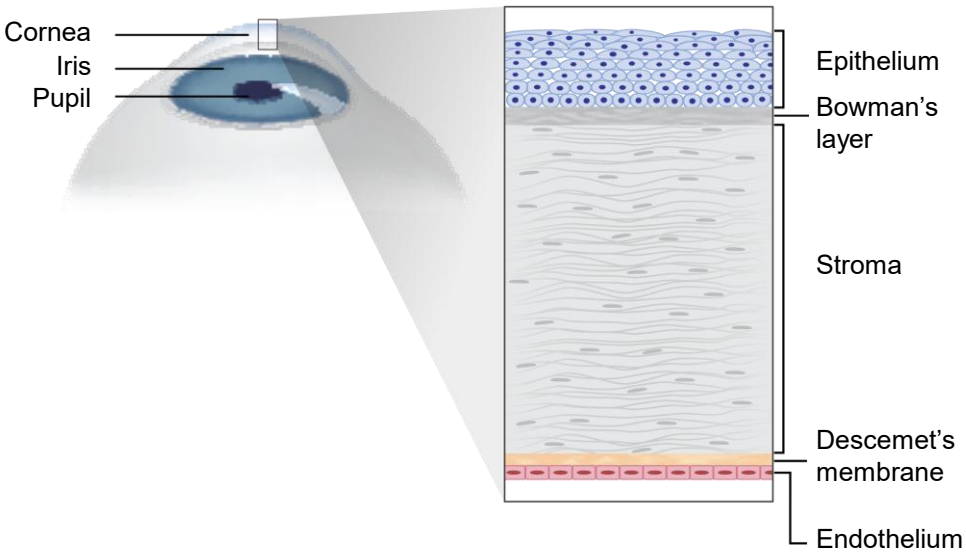
Belantamab mafodotin may have an effect on healthy cells, such as those in the cornea, which may lead to ocular events.

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

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. 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.

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.

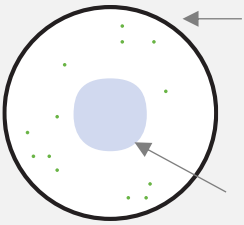
Ocular ARs refer to patient-reported symptoms such as dry eyes and blurred vision, graded per CTCAE.



For illustrative purposes only.

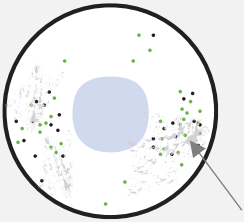
Corneal examination findings

Frequency of events*



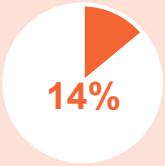
Grade 1

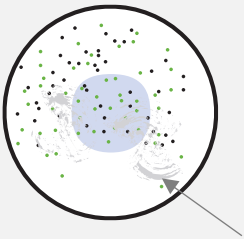
Mild superficial punctate keratopathy with worsening from baseline, with or without symptoms.



Grade 2

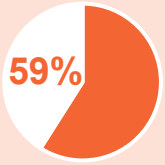
Moderate superficial punctate keratopathy, patchy microcyst-like deposits, peripheral sub-epithelial haze, or a new peripheral stromal opacity.





Grade 3

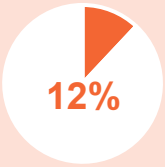
Severe superficial punctate keratopathy, diffuse microcyst-like deposits involving the central cornea, central sub-epithelial haze, or a new central stromal opacity.



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.

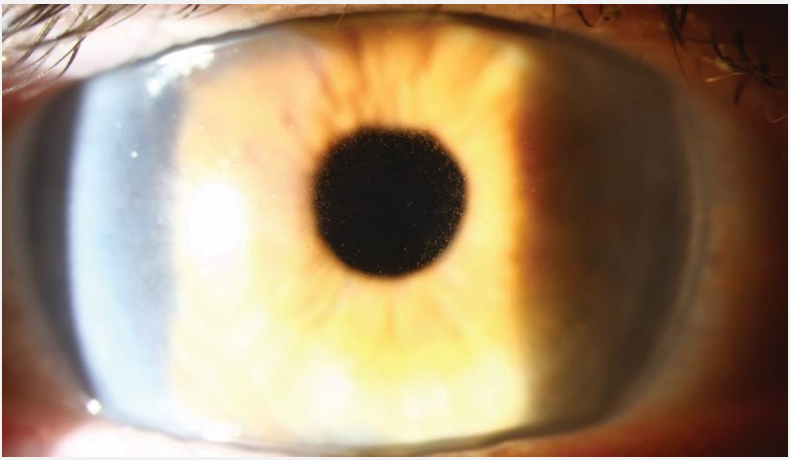


green dot = superficial punctate keratopathy
black dot = microcyst-like deposits
Images above are for illustrative purpose only.

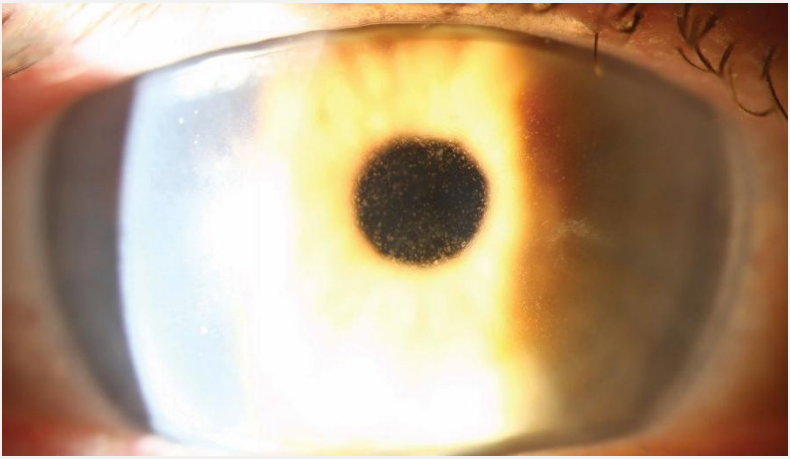
*Pooled data from 3 clinical trials of belantamab mafodotin in combination with other therapies, n=516.

Moderate and severe microcyst-like deposits as observed via slit lamp examination

Moderate



Severe



Images courtesy of the Flaum Eye Institute, Rochester, NY.

Changes in visual acuity (DREAMM-7)

- A decline in BCVA to 20/50 or worse in 34% of patients
  - Median time to onset: 73.5 days
- After the first occurrence of this decline, BCVA subsequently improved in 98% of patients and resolution of visual acuity* in 94% patients at the last follow up was reported.
  - Median time to resolution: 64 days

- A decline in BCVA to 20/200 or worse in 2% of patients
  - Median time to onset: 105 days
- After the first occurrence of this decline, BCVA subsequently improved in 100% of patients and resolution of visual acuity* in 80% of patients at the last follow up was reported.
  - Median time to resolution: 86.5 days

Please refer to the Blenrep Singapore Package Insert for additional details

*Resolution of visual acuity was defined as 20/25 or better in at least one eye;

Images are for illustrative purposes only; vision will differ for each individual. Vision impairment simulated via Adobe Photoshop through application of a fixed gaussian blur level: 20/20, 0.5 pixels; 20/50, 4.0 pixels; 20/100, 7.5 pixels; 20/200, 15 pixels.

Changes in visual acuity (DREAMM-8)

- A decline in BCVA to 20/50 or worse in 34% of patients
  - Median time to onset: 112 days
- After the first occurrence of this decline, BCVA subsequently improved in 92% of patients and resolution of visual acuity* in 84% patients at the last follow up was reported.
  - Median time to resolution: 57 days

- A decline in BCVA to 20/200 or worse in 1% of patients
  - Median time to onset: Not Applicable^
- After the first occurrence of this decline, BCVA subsequently improved in 100% of patients and resolution of visual acuity* in 50% of patients at the last follow up was reported.
  - Median time to resolution: Not Applicable^

Please refer to the Blenrep Singapore Package Insert for additional details

*Resolution of visual acuity was defined as 20/25 or better in at least one eye;

^In patients with 20/200 or worse, two patients were reported. Time to first onset was 29 and 673 days. Both events improved to better than bilateral 20/200 by the data cut-off, of which 1 event resolved after 57 days;

Images are for illustrative purposes only; vision will differ for each individual. Vision impairment simulated via Adobe Photoshop through application of a fixed gaussian blur level: 20/20, 0.5 pixels; 20/50, 4.0 pixels; 20/100, 7.5 pixels; 20/200, 15 pixels.

Ocular events observed in clinical trials

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**.

Pooled data from these trials (516 patients) reported:

	Incidence (% of 516 patients*)	
Adverse reactions	**Any grade**	**Grade 3/4**
Corneal examination findings (including keratopathy)†‡	89	71
Visual acuity reduced†	90	59
Vision blurred	62	17
Dry eye	44	6
Foreign body sensation in eyes	40	3
Photophobia	37	2
Eye irritation	35	4
Eye pain	27	<1

*Includes 516 patients from the DREAMM-6, DREAMM-7, and DREAMM-8 studies; †Based on ophthalmic examination findings; ‡Includes superficial punctate keratopathy, microcyst-like epithelial changes, sub-epithelial haze, corneal epithelial defects, and stromal opacity with or without changes in visual acuity.

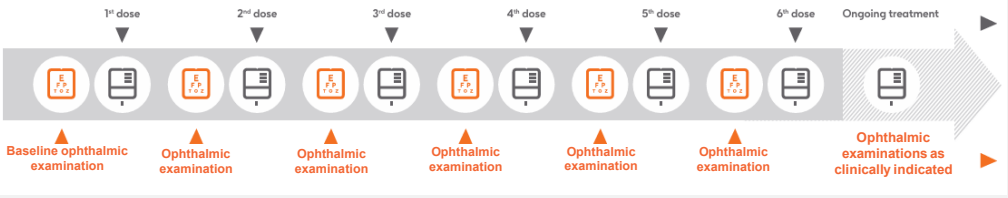
Optimising patient care delivery

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.

Dose modifications should be implemented to manage ocular events when necessary.

Ophthalmic examinations should be performed prior to each dose or more frequently as clinically indicated. If changes in vision or corneal signs are not observed at or before the sixth dose, ophthalmic examination frequency may be reduced to approximately every 3 months, and whenever clinically indicated.



Assessment of ocular events

Ophthalmic examinations should be performed before each dose or more frequently as clinically indicated. If changes in vision or corneal signs are not observed at or before the sixth dose, ophthalmic examination frequency may be reduced to approximately every 3 months, and whenever clinically indicated.

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 (see example below) and reported to the prescribing doctor promptly.

Since both eyes may not be affected to the same degree, the worst severity should be reported for the more 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 in BVCA 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 more 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 examination 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 worse eye: ☐ No change ☐ Grade 1 ☑ Grade 2 ☐ Grade 3 ☐ Grade 4

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

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.

	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 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 or 3 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 by more than 3 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. 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 Blenrep Singapore Package Insert.

*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.

Patient education on managing ocular events

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

Attend scheduled appointments for eye examinations before the first 6 doses as well as any additional examinations assessed to be necessary by the prescriber. This is to facilitate prompt detection of any 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.

References

1. Blenrep Singapore Package Insert

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

Reporting of side effects

Healthcare professionals are encouraged to report any suspected adverse reactions to HSA online at www.hsa.gov.sg/adverse-events, or to GSK via sg.drugsafety@gsk.com.

Ophthalmic examination findings form (Sample)

Ask your GSK Representatives for more copies of the form if you need them.

Patient information

Patient name:

For baseline examination only

Date of assessment: Current BCVA results (Snellen visual acuity):OS / OD /

Any pre-existing eye conditions the prescriber should be aware of:

Ophthalmic examination before 2nd dose

Date of assessment:

BCVA changes and corneal examination 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 worse eye: ☐ No change ☐ Grade 1 ☐ Grade 2 ☐ Grade 3 ☐ Grade 4

Ophthalmic examination before 3rd dose

Date of assessment:

BCVA changes and corneal examination 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 worse eye: ☐ No change ☐ Grade 1 ☐ Grade 2 ☐ Grade 3 ☐ Grade 4

Ophthalmic examination before 4th dose

Date of assessment:

BCVA changes and corneal examination 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 worse eye: ☐ No change ☐ Grade 1 ☐ Grade 2 ☐ Grade 3 ☐ Grade 4

Ophthalmic examination before 5th dose

Date of assessment:

BCVA changes and corneal examination 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 worse eye: ☐ No change ☐ Grade 1 ☐ Grade 2 ☐ Grade 3 ☐ Grade 4

Ophthalmic examination before 6th dose

Date of assessment:

BCVA changes and corneal examination 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 worse eye: ☐ No change ☐ Grade 1 ☐ Grade 2 ☐ Grade 3 ☐ Grade 4

Ask your GSK Representatives for more copies of the form if you need them.

Ophthalmic examination before __th dose

Date of assessment:

BCVA changes and corneal examination 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 worse eye: ☐ No change ☐ Grade 1 ☐ Grade 2 ☐ Grade 3 ☐ Grade 4

Ophthalmic examination before __th dose

Date of assessment:

BCVA changes and corneal examination 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 worse eye: ☐ No change ☐ Grade 1 ☐ Grade 2 ☐ Grade 3 ☐ Grade 4

Ophthalmic examination before __th dose

Date of assessment:

BCVA changes and corneal examination 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 worse eye: ☐ No change ☐ Grade 1 ☐ Grade 2 ☐ Grade 3 ☐ Grade 4

Prescriber

- Complete your preferred contact information to receive ophthalmic examination results from your patient's eye care professional
- Review this form for important information relating to ophthalmic examination for patients taking belantamab mafodotin
- Provide this form to your patient's eye care professional ahead of each ophthalmic examination visit
- Determine the dose of belantamab mafodotin, based on ophthalmic examination findings and recommended dose modifications on pages 12 and 13
- Consult an eye care professional if ocular events occur

Eye care professional

- Complete your preferred contact information so that the prescriber can contact you if necessary
- Review this form for important information relating to eye examination for patients taking belantamab mafodotin
- Return results to the prescriber to help them make informed decisions on potential dose modifications or discontinuation in consultation with an ophthalmologist (see grading scale on page 13)
- Fill out new sections for each follow-up examination, as ocular events may reoccur following readministration of belantamab mafodotin

Contact Information

Name:

Phone:

Fax:

Email:

Contact Information

Name:

Phone:

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