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<b>Section:</b>	Prescription Drugs	<b>Effective Date:</b>	January 1, 2024
<b>Subsection:</b>	Antineoplastic Agents	<b>Original Policy Date:</b>	September 4, 2020
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**Last Review Date:** December 8, 2023

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## Blenrep

### Description

Blenrep (belantamab mafodotin-blmf)

#### Background

Blenrep (belantamab mafodotin-blmf) is an antibody-drug conjugate (ADC). The antibody component is an afucosylated IgG1 directed against B-cell maturation antigen (BCMA), a protein expressed on normal B lymphocytes and multiple myeloma cells. The small molecule component is MMAF, a microtubule inhibitor. Upon binding to BCMA, Blenrep is internalized followed by release of MMAF via proteolytic cleavage. The released MMAF intracellularly disrupts the microtubule network, leading to cell cycle arrest and apoptosis. Blenrep has antitumor activity in multiple myeloma cells and mediated killing of tumor cells through MMAF-induced apoptosis, as well as by tumor cell lysis through antibody-dependent cellular cytotoxicity (ADCC) and antibody-dependent cellular phagocytosis (ADCP) (1).

#### Regulatory Status

FDA-approved indication: Blenrep is a B-cell maturation antigen (BCMA)-directed antibody and microtubule inhibitor conjugate indicated for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least 4 prior therapies including an anti-CD38 monoclonal antibody, a proteasome inhibitor, and an immunomodulatory agent (1).

Blenrep has a boxed warning regarding ocular toxicity. Blenrep can cause changes in the corneal epithelium resulting in changes in vision, including severe vision loss and corneal ulcer, and symptoms, such as blurred vision and dry eyes. Ophthalmic exams should be conducted at baseline, prior to each dose, and promptly for worsening symptoms. Blenrep is only available

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through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS), called the Blenrep REMS (1).

Blenrep may cause thrombocytopenia. Complete blood cell counts (CBC) should be completed at baseline and during treatment as clinically indicated (1).

Blenrep can cause fetal harm when administered to a pregnant woman because it contains a genotoxic compound and it targets actively dividing cells. Pregnant women should be advised of the potential risk to a fetus. Females of reproductive potential should be advised to use effective contraception during treatment with Blenrep and for 4 months after the last dose. Males with female partners of reproductive potential should be advised to use effective contraception during treatment with Blenrep and for 6 months after the last dose (1).

The safety and effectiveness of Blenrep in pediatric patients have not been established (1).

### Related Policies

Elrexio, Talvey, Tecvayli

#### Policy

*This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.*

Blenrep may be considered **medically necessary** if the conditions indicated below are met.

Blenrep may be considered **investigational** for all other indications.

### Prior-Approval Requirements

**Age** 18 years of age or older

#### Diagnosis

Patient must have the following:

Relapsed or refractory multiple myeloma (MM)

**AND ALL** of the following:

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- a. Patient has received at least 4 prior therapies, including **ALL** of the following:
  - i. Anti-CD38 monoclonal antibody
  - ii. Proteasome inhibitor
  - iii. Immunomodulatory agent
- b. Patient and prescriber are enrolled in the Blenrep REMS program
- c. Patient will have ophthalmic exams completed at baseline and prior to each dose and will be monitored for ocular toxicity
- d. Prescriber agrees to monitor complete blood cell counts (CBC) for thrombocytopenia
- e. Female patients of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Blenrep and for 4 months after the last dose
- f. Males with female partners of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Blenrep and for 6 months after the last dose

## Prior – Approval *Renewal* Requirements

**Age** 18 years of age or older

### Diagnosis

Patient must have the following:

Relapsed or refractory multiple myeloma (MM)

**AND ALL** of the following:

- a. **NO** disease progression or unacceptable toxicity
- b. Patient will have ophthalmic exams completed prior to each dose and will be monitored for ocular toxicity
- c. Prescriber agrees to monitor complete blood cell counts (CBC) for thrombocytopenia
- d. Female patients of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Blenrep and for 4 months after the last dose

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- e. Males with female partners of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Blenrep and for 6 months after the last dose

#### Policy Guidelines

#### Pre - PA Allowance

None

#### Prior - Approval Limits

**Duration** 12 months

#### Prior – Approval *Renewal* Limits

Same as above

#### Rationale

#### Summary

Blenrep (belantamab mafodotin-blmf) is an antibody-drug conjugate (ADC). The antibody component is an afucosylated IgG1 directed against B-cell maturation antigen (BCMA), a protein expressed on normal B lymphocytes and multiple myeloma cells. The small molecule component is MMAF, a microtubule inhibitor. Upon binding to BCMA, Blenrep is internalized followed by release of MMAF via proteolytic cleavage. The released MMAF intracellularly disrupts the microtubule network, leading to cell cycle arrest and apoptosis. Blenrep has antitumor activity in multiple myeloma cells and mediated killing of tumor cells through MMAF-induced apoptosis, as well as by tumor cell lysis through antibody-dependent cellular cytotoxicity (ADCC) and antibody-dependent cellular phagocytosis (ADCP). The safety and effectiveness of Blenrep in pediatric patients have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate and cost-effective use of Blenrep while maintaining optimal therapeutic outcomes.

#### References

1. Blenrep [package insert]. Research Triangle Park, NC: GlaxoSmithKline; February 2022.
2. NCCN Drugs & Biologics Compendium<sup>®</sup> Belantamab mafodotin-blmf 2023. National Comprehensive Cancer Network, Inc. Accessed on October 3, 2023.

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Policy History	
Date	Action
September 2020	Addition to PA
December 2020	Annual review
March 2021	Annual editorial review
March 2022	Annual review and reference update
June 2022	Annual review and reference update
March 2023	Annual review and reference update
December 2023	Annual review and reference update
Keywords	

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 8, 2023 and is effective on January 1, 2024.