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Section:	Prescription Drugs	**Effective Date:**	June 26, 2026
Subsection:	Antineoplastic Agents	**Original Policy Date:**	September 4, 2020
Subject:	Blenrep	**Page:**	1 of 5

Last Review Date: June 13, 2024

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 mcMMAF, a microtubule inhibitor. Upon binding to BCMA, Blenrep is internalized followed by release of the cytotoxic agent (cys-mcMMAF) via proteolytic cleavage. The released cys-mcMMAF intracellularly disrupts the microtubule network, leading to cell cycle arrest and apoptosis. Blenrep had antitumor activity in multiple myeloma cells and mediated killing of tumor cells through cys-mcMMAF-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, a B-cell maturation antigen (BCMA)-directed antibody and microtubule inhibitor conjugate, is indicated in combination with bortezomib and dexamethasone for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least two prior lines of therapy, including 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 visual impairment, and symptoms such as blurred vision and dry eyes. Ophthalmic exams should be conducted at

baseline, before each dose, promptly for new or worsening symptoms, and as clinically indicated. Blenrep is only available 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
Elrexfio, 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:

a. Patient has received at least two prior lines of therapy, including **BOTH** of the following:
   i. Proteasome inhibitor
   ii. Immunomodulatory agent
b. Used in combination with Velcade (bortezomib) and dexamethasone
c. Patient and prescriber are enrolled in the Blenrep REMS program
d. Patient will have ophthalmic exams completed at baseline and prior to each dose and will be monitored for ocular toxicity
e. Prescriber agrees to monitor complete blood cell counts (CBC) for thrombocytopenia
f. 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
g. 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. Used in combination with Velcade (bortezomib) and dexamethasone
c. Patient will have ophthalmic exams completed 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

Policy Guidelines

Pre - PA Allowance
None

Prior - Approval Limits
Duration 12 months

Prior – Approval *Renewal* Limits
Same as above

Rationale

Summary
Blenrep is a B-cell maturation antigen (BCMA)-directed antibody and microtubule inhibitor conjugate indicated in combination with bortezomib and dexamethasone for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least two prior lines of therapy, including a proteasome inhibitor and an immunomodulatory agent. Blenrep has a boxed warning regarding ocular toxicity and is only available through the Blenrep REMS program. 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]. Durham, NC: GlaxoSmithKline; October 2025.
2. NCCN Drugs & Biologics Compendium® Belantamab mafodotin-blmf 2026. National Comprehensive Cancer Network, Inc. Accessed on June 2, 2026.

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
March 2024	Annual review and reference update
June 2024	Annual review and reference update
March 2025	Removed from PA due to drug withdrawn from market
June 2026	Reinstated policy per FEP

Keywords

This policy was effective with interim approval on June 26, 2026 and will be reviewed by the FEP® Pharmacy and Medical Policy Committee on September 17, 2026.