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Section:	Prescription Drugs	**Effective Date:**	April 1, 2021
Subsection:	Antineoplastic Agents	**Original Policy Date:**	September 4, 2020
Subject:	Blenrep	**Page:**	1 of 4

Last Review Date: March 12, 2021

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. Opthalmic exams should be conducted at baseline, prior to each dose, and promptly for worsening symptoms. 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 administerd 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

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** in patients 18 years of age or older for the treatment of relapsed or refractory multiple myeloma and if the conditions indicated below are met.

Blenrep may be considered **investigational** in patients less than 18 years of age and 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 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

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; August 2020.

Policy History
Date Action

September 2020	Addition to PA
December 2020	Annual review
March 2021	Annual editorial review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 12, 2021 and is effective on April 1, 2021.