Medical Policy

Utilization Management and Clinical Medical Policy

Policy Name:	Policy Number:	Scope:	Origination Date:	Effective Date:
Belantamab mafodotin-blmf (Blenrep®)	**MP-RX-FP-192-26**	☒ **MMM MA** ☒ **MMM MultiHealth**	**10/21/2026** **Last Review Date:** **10/21/2026**	**10/21/2026** **Frequently Revision:** **Annual**

Service Category:

- ☐ Anesthesia
- ☐ Surgery
- ☐ Radiology Procedures
- ☐ Pathology and Laboratory Procedures
- ☐ Medicine Services and Procedures
- ☐ Evaluation and Management Services
- ☐ DME/Prosthetics or Supplies
- ☒ Other: Part B Drugs

Service Description:

This document addresses the use of *Belantamab mafodotin-blmf (Blenrep®),* a drug approved by the Food and Drug Administration (FDA) for the treatment of adult patients with relapsed or refractory multiple myeloma.

Background Information:

Blenrep (belantamab mafodotin-blmf), a B-cell maturation antigen (BCMA)-directed antibody and microtubule inhibitor conjugate, is FDA 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.

FDA approval was supported by DREAMM-7, an open-label, randomized, multicenter study comparing Blenrep in combination with bortezomib and dexamethasone (BVd) versus daratumumab, bortezomib, and dexamethasone (DVd) in adult patients with relapsed or refractory multiple myeloma. The efficacy population included patients who had received at least two prior lines of therapy, including a proteasome inhibitor and an immunomodulatory agent. In this population, median progression-free survival was 31.3 months with BVd compared with 10.4 months with DVd (HR 0.31; 95% CI, 0.21–0.47). Overall response rate was 81.5% with BVd compared with 56.9% with DVd.

The National Comprehensive Cancer Network® (NCCN) provides additional recommendations with a category 2A level of evidence for the use of Blenrep as therapy for previously treated multiple myeloma for relapsed/refractory disease in patients who have received at least three prior lines of therapy (useful in certain circumstances). NCCN also provides a category 1 level of evidence for the use of Blenrep as therapy for previously treated multiple myeloma for relapsed/refractory disease in combination with dexamethasone and bortezomib in patients who have received at least two prior therapies including a proteasome inhibitor and an immunomodulatory agent.

Blenrep has a Boxed Warning for ocular toxicity. Blenrep causes changes in the corneal epithelium resulting in changes in vision, including severe visual impairment, and symptoms such as blurred vision and dry eyes. Corneal ulcers, including cases with infection, have also occurred. Ophthalmic exams, including slit lamp exam and assessment of best-corrected visual acuity (BCVA), should be conducted at baseline, before each dose, promptly for new or worsening symptoms, and as clinically indicated. Because of the risk of ocular toxicity, Blenrep is available only through a restricted program under the Blenrep Risk Evaluation and Mitigation Strategy (REMS).

Definitions and Measures

- Line of Therapy:
  - First-line therapy: The first or primary treatment for the diagnosis, which may include surgery, chemotherapy, radiation therapy or a combination of these therapies.

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- Second-line therapy: Treatment given when initial treatment (first-line therapy) is not effective or there is disease progression.
- Third-line therapy: Treatment given when both initial (first-line therapy) and subsequent treatment (secondline therapy) are not effective or there is disease progression.

- Multiple myeloma: A type of cancer that begins in plasma cells (white blood cells that produce antibodies).
- Proteasome inhibitors: A class of drugs used to treat multiple myeloma that work by blocking the action of proteasomes which are cellular complexes that break down proteins. Examples include bortezomib, carfilzomib and ixazomib.
- Refractory Disease: Illness or disease that does not respond to treatment.
- Relapse or recurrence: After a period of improvement, during which time a disease (for example, cancer) could not be detected, the return of signs and symptoms of illness or disease. For cancer, it may come back to the same place as the original (primary) tumor or to another place in the body

Approved Indications

A. 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.

Other Uses

A. NCCN also provides guidance for use of Blenrep in the treatment of Polyneuropathy, Organomegaly, Endocrinopathy, Monoclonal protein, Skin changes (POEMS) (useful in certain circumstances), Monoclonal Immunoglobulin Deposition Disease (MIDD), and plasma cell-related Monoclonal Gammopathy of Renal Significance (MGRS).

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Medical Necessity Guidelines:

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

Belantamab mafodotin-blmf (Blenrep®)

A. Criteria For Initial Approval (*Provider must submit documentation [such as office chart notes, lab results, pathology reports, imaging studies, and any other pertinent clinical information] supporting the patient's diagnosis for the drug and confirming that the patient has met **all** approval criteria.)*

Requests for Blenrep (belantamab mafodotin-blmf) may be approved if the following criteria are met:

i. Individual has a diagnosis of relapsed or refractory multiple myeloma (Label, NCCN 1, 2A); **AND**

ii. Individual is using in one of the following ways:

A. Individual is using in combination with bortezomib and dexamethasone (Label, NCCN 1); **AND**

B. Individual has received at least two prior lines of therapy, including a proteasome inhibitor (e.g. bortezomib, ixazomib, or carfilzomib) and an immunomodulatory agent (e.g. lenalidomide or pomalidomide);

OR

C. Individual is using as a single agent (NCCN 2A); **AND**

D. Individual has received at least three prior lines of therapy.

B. Criteria For Continuation of Therapy

i. MMM considers continuation of Belantamab mafodotin-blmf (Blenrep®) therapy medically necessary in members requesting reauthorization for an indication listed in Section A above (Criteria for Initial Approval) when there is no evidence of unacceptable toxicity or disease progression while on the current regimen, and the recommended duration of therapy has not been exceeded. The following information should be submitted for reauthorization:

A. A current oncology note documenting the patient's response to treatment showing no progression of disease.

B. Current imaging studies and other objective measures, as appropriate, showing no progression of disease when compared with previous results (every six months).

C. Documentation that ophthalmic monitoring has been completed before each dose and as clinically indicated, in accordance with Blenrep REMS requirements.

D. Documentation that the individual has no treatment-limiting ocular toxicity or other unacceptable toxicity attributable to Blenrep.

C. Authorization Duration

i. Initial Approval Duration: Up to 6 months

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ii. Reauthorization Approval Duration: Up to 6 months

D. Conditions Not Covered

Any other use is considered experimental, investigational, or unproven, including the following (this list may not be all inclusive):

Blenrep (belantamab mafodotin-blmf) may not be approved when the above criteria are not met and for all other indications.

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Limits or Restrictions:

A. Therapeutic Alternatives

The list below includes preferred alternative therapies recommended in the approval criteria and may be subject to prior authorization.

i. N/A

B. Quantity Limitations

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines. The chart below includes dosing recommendations as per the FDA-approved prescribing information.

Drug	Recommended Dosing Schedule	Treatment Duration
Blenrep (belantamab mafodotin-blmf) inj. 70 mg single dose vial	• **In combination with bortezomib and dexamethasone:** 2.5 mg/kg based on actual body weight IV every 3 weeks (21-day cycles) for 8 cycles, followed by 2.5 mg/kg every 3 weeks as a single agent. • **As a single agent (NCCN 2A):** 2.5 mg/kg based on actual body weight IV once every 3 weeks.	• Until disease progression or unacceptable toxicity.
Exceptions		
• For dosage reductions, interruptions, and discontinuation recommendations for adverse reactions, see the Prescribing Information.		

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Codes Information:

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

ICD-10 Diagnostic Codes:

Codes	Description
C90.00-C90.32	Multiple myeloma and malignant plasma cell neoplasms
Z85.79	Personal history of other malignant neoplasms of lymphoid, hematopoietic and related tissues.

HCPCS Codes:

Codes	Description
J9053	Injection, belantamab mafodotin-blmf, 0.1 mg [Blenrep]

Reference Information:

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: November 3, 2025
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. GlaxoSmithKline. Blenrep® (belantamab mafodotin-blmf) for injection, for intravenous use: Prescribing Information and Medication Guide. Revised October 2025. Accessed August 11, 2026. https://gskpro.com/content/dam/global/hcpportal/en_US/Prescribing_Information/Blenrep/pdf/BLENREP-PI-MG.PDF
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc. Updated periodically.
5. NCCN Clinical Practice Guidelines in Oncology™. © 2026 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Accessed on August 11, 2026.
    a. Multiple Myeloma. V5.2026. Revised January 9, 2026.

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.

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Policy History:

Type of Review	Summary of Changes	P&T Approval Date	UM/CMPC Approval Date
Policy Inception	Elevance Health's Medical Policy adoption.	10/15/2026	10/21/2026