

Coverage of any drug intervention discussed in the plans prior authorization guideline is subject to the limitations and exclusions outlined in the member's benefit certificate or policy and to applicable state and/or federal laws.

Blenrep[®] (belantamab mafodotin-blmf) (Intravenous)

Document Number: MH-0561

Last Review Date: 07/20/2022

Date of Origin: 09/01/2020

Dates Reviewed: 09/2020, 01/2021, 03/2021, 04/2021, 03/2022, 07/2022

Customization Date: 07/20/2022

Effective Date: 01/01/2023

I. Length of Authorization

Coverage will be provided for six months and may be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

- Blenrep 100 mg powder for injection: 3 vials per 21 day supply

B. Max Units (per dose and over time) [HCPCS Unit]:

- 574 billable units (287 mg) every 21 days

III. Initial Approval Criteria ¹

Coverage is provided in the following conditions:

Submission of medical records (chart notes) related to the medical necessity criteria is **REQUIRED** on all requests for authorizations. Records will be reviewed at the time of submission. Please provide documentation related to diagnosis, step therapy, and clinical markers (i.e. genetic and mutational testing) supporting initiation when applicable. Medical records may be submitted via direct upload through the PA web portal or by fax.

- Patient is at least 18 years of age; **AND**

Universal Criteria ¹

- Patient has an ophthalmic exam (i.e., visual acuity and slit lamp) at baseline, prior to each dose, and as needed; **AND**

- Both patient AND prescriber are enrolled in the BLENREP REMS® program; **AND**
- Therapy will be used in combination with preservative-free lubricant eye drops; **AND**
- Patient does not have current corneal epithelial disease (*Note: excludes mild punctate keratopathy*); **AND**
- Patient has not had a prior allogeneic stem cell transplant; **AND**
- Patient does not have any of the following comorbidities:
 - Symptomatic amyloidosis
 - Active polyneuropathy, organomegaly, endocrinopathy, myeloma protein, and skin changes (POEMS) syndrome
 - Active plasma cell leukemia; **AND**
- Used as single-agent therapy; **AND**

Multiple Myeloma † Φ 1,2,3,5

- Patient has relapsed or refractory disease; **AND**
- Patient has received at least four (4) prior anti-myeloma treatment regimens; **AND**
 - Patient is refractory to a proteasome inhibitor (e.g., bortezomib, ixazomib, carfilzomib, etc.); **AND**
 - Patient is refractory to an immunomodulatory agent (IMiD) (e.g., thalidomide, lenalidomide, pomalidomide, etc.); **AND**
 - Patient is refractory or intolerant to an anti-CD38 monoclonal antibody (e.g., daratumumab, isatuximab-irfc, etc.)

† FDA Approved Indication(s); ‡ Compendia Approved Indication(s); Φ Orphan Drug

IV. Renewal Criteria¹

Coverage may be renewed based upon the following criteria:

- Patient continues to meet the indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in section III; **AND**
- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: ophthalmic toxicity, severe infusion-related reactions, thrombocytopenia, etc.

V. Dosage/Administration^{1,4,5,7,8,9,11,12,20}

Indication	Dose
Multiple Myeloma	Administer 2.5 mg/kg (actual body weight) intravenously every 3 weeks until disease progression or unacceptable toxicity.

VI. Billing Code/Availability Information

HCPCS Code:

- J9037 – Injection, belantamab mafodotin-blmf, 0.5 mg; 1 billable unit = 0.5 mg

NDC:

- Blenrep 100 mg lyophilized powder in single-dose vial for injection: 00173-0896-xx

VII. References

1. Blenrep [package insert]. Brentford, Middlesex, UK; GlaxoSmithKline, Ltd; August 2020. Accessed January 2022.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for belantamab mafodotin. National Comprehensive Cancer Network, 2022. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed January 2022.
3. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Multiple Myeloma Version 4.2022. National Comprehensive Cancer Network, 2022. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc.” To view the most recent and complete version of the Guidelines, go online to NCCN.org. Accessed January 2022.
4. BGM Durie, J-L Harousseau, J S Miguel, et al on behalf of the International Myeloma Working Group. International uniform response criteria for multiple myeloma. *Leukemia*. Sep; 20(9):1467-73.
5. Lonial S, Lee HC, Badros A, et al. Pivotal DREAMM-2 study: Single-agent belantamab mafodotin (GSK2857916) in patients with relapsed/refractory multiple myeloma (RRMM) refractory to proteasome inhibitors (PIs), immunomodulatory agents, and refractory and/or intolerant to anti-CD38 monoclonal antibodies (mAbs). *Journal of Clinical Oncology* 2020 38:15_suppl, 8536-8536. DOI: [10.1200/JCO.2020.38.15_suppl.8536](https://doi.org/10.1200/JCO.2020.38.15_suppl.8536)
6. Farooq AV, Degli Esposti S, Popat R, et al. Corneal Epithelial Findings in Patients with Multiple Myeloma Treated with Antibody-Drug Conjugate Belantamab Mafodotin in the Pivotal, Randomized, DREAMM-2 Study. *Ophthalmol Ther*. 2020 Jul 25. doi: 10.1007/s40123-020-00280-8.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C90.00	Multiple myeloma not having achieved remission
C90.02	Multiple myeloma in relapse
C90.10	Plasma cell leukemia not having achieved remission
C90.12	Plasma cell leukemia in relapse
C90.20	Extramedullary plasmacytoma not having achieved remission
C90.22	Extramedullary plasmacytoma in relapse
C90.30	Solitary plasmacytoma not having achieved remission
C90.32	Solitary plasmacytoma in relapse
D47.2	Monoclonal gammopathy
Z85.79	Personal history of other malignant neoplasms of lymphoid, hematopoietic and related tissues

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD), Local Coverage Determinations (LCDs), and Local Coverage Articles (LCAs) may exist and compliance with these policies is required where applicable. They can be found at: <https://www.cms.gov/medicare-coverage-database/search.aspx>. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC