Blenrep® (belantamab mafodotin-blmf)
(Intravenous)

Document Number: IC-0561

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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:

- Patient is at least 18 years old; **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 POEMS syndrome (polyneuropathy, organomegaly, endocrinopathy, myeloma protein, and skin changes)
  - Active plasma cell leukemia; **AND**
- Will be used as single-agent therapy; **AND**

Multiple Myeloma † Φ [1,2,3,5]

- Patient has relapsed or refractory disease; **AND**
- Patient had disease progression on at least **four** prior anti-myeloma treatment regimens which must have included one or more agents from each of the following categories:
    - 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 Criteria[1]

Coverage can be renewed based upon the following criteria:

- Patient continues to meet 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 the following: ophthalmic toxicity, severe infusion related reactions, thrombocytopenia, etc.

V. Dosage/Administration[1,4,5,7,8,9,11,12,20]

Indication	Dose
Multiple Myeloma	The recommended dosage of Blenrep is 2.5 mg/kg of actual body weight given as an intravenous infusion over approximately 30 minutes once every 3 weeks until disease progression or unacceptable toxicity.

VI. Billing Code/Availability Information

HCPCS code:

- J9999 – Not otherwise classified, antineoplastic drugs *(Discontinue use effective 04/01/2021)*
- C9069 – Injection, belantamab mafodontin-blmf, 0.5 mg; 1 billable unit = 0.5 mg *(HOPPS-Hospital Outpatient Prospective Payment System Use Only) (Discontinue use effective 04/01/2021)*

- J9037 – Injection, belantamab mafodontin-blmf, 0.5 mg; 1 billable unit – 0.5 mg *(Effective 04/01/2021)*

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 2021.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for belantamab mafodotin. National Comprehensive Cancer Network, 2021. 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 2021.
3. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Multiple Myeloma Version 4.2021. National Comprehensive Cancer Network, 2021. 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 2021.
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
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

ICD-10	ICD-10 Description
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: http://www.cms.gov/medicare-coverage-database/search/advanced-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