Belantamab Mafodotin-blmf (Blenrep®)

NDC CODE(S) 00173-0896-XX BLENREP 100MG Solution Reconstituted (GLAXO SMITH KLINE)

DESCRIPTION

Belantamab mafodotin-blmf is an antibody-drug conjugate which consists of a B-cell maturation antigen (BCMA)-directed antibody and a microtubule inhibitor conjugate. The antibody component is an afucosylated IgG1 directed against 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, belantamab mafodotin-blmf 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.

Belantamab mafodotin-blmf had 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).

POLICY

- Belantamab mafodotin-blmf for the treatment of multiple myeloma is considered ***medically necessary*** if the medical appropriateness criteria are met. **(See Medical Appropriateness below.)**

- Belantamab mafodotin-blmf for the treatment of other conditions/diseases is considered ***investigational.***

MEDICAL APPROPRIATENESS

INITIAL APPROVAL CRITERIA

- Patient is at least 18 years old; AND

Universal Criteria

- 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

- 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.)

RENEWAL CRITERIA

- Patient continues to meet indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in Initial Approval Criteria; **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.

DOSAGE/ADMINISTRATION

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.

LENGTH OF AUTHORIZATION

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

DOSING LIMITS

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

- 574 billable units (287 mg) every 21 days

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the Medical Policy and a health plan, the express terms of the health plan will govern.

ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

SOURCES

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, 20201. 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 34.20201. National Comprehensive Cancer Network, 20201. 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 May January 20201.
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.
7. Lexicomp Online. (2021, February). AHFS DI. Belantamab-mafodotin-blmf. Retrieved March 11, 2021 from Lexicomp Online with AHFS.
8. MICROMEDEX Healthcare Series. Drugdex Evaluations. (2020, September). Belantamab mafodotin-blmf. Retrieved September 10, 2020 from MICROMEDEX Healthcare Series.

EFFECTIVE DATE 6/30/2021

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