

Medical Policy:

Blenrep (belantamab mafodotin-blmf) Intravenous

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.322	April 1, 2024	November 11, 2020

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The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as “EmblemHealth”), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

Definitions

Blenrep (belantamab mafodotin-blmf) is an antibody-drug conjugate (ADC). 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).

Length of Authorization

Coverage will be provided for 6 months and may be renewed.

Dosing Limits [Medical Benefit]

The recommended dosage is 2.5 mg/kg as an intravenous infusion over approximately 30 minutes once every 3 weeks.

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

574 billable units (287 mg) every 21 days

Guideline

I. INITIAL APPROVAL CRITERIA

1. Multiple Myeloma

Coverage will be provided when the following criteria are met:

- A. Patient is 18 years of age or older; **AND**
- B. Blenrep is prescribed by, or in consultation with, an oncologist; **AND**
- C. The patient has a diagnosis multiple myeloma; **AND**
- D. The patient has relapsed or refractory disease; **AND**
- E. The patient has previously received at least four systemic lines of therapy for the treatment of multiple myeloma, including one drug from each of the following classes:
 - i. Anti-CD38 monoclonal antibody
 - ii. Proteasome inhibitor
 - iii. Immunomodulatory agent; **AND**
- F. Blenrep will be prescribed and dispensed in accordance with the BLENREP REMS program.

II. RENEWAL CRITERIA

Coverage can be renewed in 6-month intervals based on the following conditions:

- 1. Stabilization of disease or absence of disease progression; **AND**
- 2. Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: ocular toxicity, infusion-related and hypersensitivity reactions, myelosuppression, etc.

Applicable Procedure Codes

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

Applicable NDCs

Code	Description
00173-0896-01	Blenrep 100-mg single-dose vial

ICD-10 Diagnoses

Code	Description
C90.0	Multiple myeloma
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
C90.02	Multiple myeloma in relapse
Z85.79	Personal history of other malignant neoplasms of lymphoid, hematopoietic and related tissues

Revision History

Company(ies)	DATE	REVISION																				
EmblemHealth & ConnectiCare	4/1/2024	Annual Review: Updated dosing limits, no criteria changes																				
EmblemHealth & ConnectiCare	7/25/2023	Annual Review: Added ICD-10 Codes: <table border="1" data-bbox="722 674 1521 1100"> <tr> <td>C90.02</td> <td>Multiple myeloma in relapse</td> </tr> <tr> <td>C90.10</td> <td>Plasma cell leukemia not having achieved remission</td> </tr> <tr> <td>C90.12</td> <td>Plasma cell leukemia in relapse</td> </tr> <tr> <td>C90.20</td> <td>Extramedullary plasmacytoma not having achieved remission</td> </tr> <tr> <td>C90.22</td> <td>Extramedullary plasmacytoma in relapse</td> </tr> <tr> <td>C90.30</td> <td>Solitary plasmacytoma not having achieved remission</td> </tr> <tr> <td>C90.32</td> <td>Solitary plasmacytoma in relapse</td> </tr> <tr> <td>D47.2</td> <td>Monoclonal gammopathy</td> </tr> <tr> <td>C90.02</td> <td>Multiple myeloma in relapse</td> </tr> <tr> <td>Z85.79</td> <td>Personal history of other malignant neoplasms of lymphoid, hematopoietic and related tissues</td> </tr> </table>	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	C90.02	Multiple myeloma in relapse	Z85.79	Personal history of other malignant neoplasms of lymphoid, hematopoietic and related tissues
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EmblemHealth & ConnectiCare	4/05/2022	Transferred policy to new template																				
EmblemHealth & ConnectiCare	7/2/2021	Removed C9069 – no longer active																				
EmblemHealth & ConnectiCare	4/5/2021	Updated J-Code 9037																				
EmblemHealth & ConnectiCare	1/1/2021	Updated C-Code 9069																				
EmblemHealth & ConnectiCare	11/11/2020	New Policy																				

References

1. Product Information: BLENPREP intravenous injection, belantamab mafodotin-blmf intravenous injection. GlaxoSmithKline (per FDA), Research Triangle Park, NC, 2020.