Medical Policy:

Monjuvi™ (tafasitamab-cxix) Intravenous

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.323	March 17, 2025	November 11, 2020

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

Monjuvi (tafasitamab-cxix) is an Fc-modified monoclonal antibody that binds to CD19 antigen expressed on the surface of pre-B and mature B lymphocytes and on several B-cell malignancies, including diffuse large B-cell lymphoma (DLBCL).

Upon binding to CD19, tafasitamab-cxix mediates B-cell lysis through apoptosis and immune effector mechanisms, including antibody-dependent cellular cytotoxicity (ADCC) and antibody-dependent cellular phagocytosis (ADCP). In studies conducted in vitro in DLBCL tumor cells, tafasitamab-cxix in combination with lenalidomide resulted in increased ADCC activity compared to tafasitamab-cxix or lenalidomide alone.

Length of Authorization

Coverage will be provided for 12 months and may be renewed.

Dosing Limits [Medical Benefit]

Each treatment cycle is 28-days.

Cycle 1:

- 12 mg/kg (actual weight) on Days 1, 4, 8, 15 and 22

Cycle 2 and 3:

- 12 mg/kg (actual weight) on Days 1, 8, 15 and 22

Cycle 4 and beyond:

- 12 mg/kg (actual weight) on Days 1 and 15

Guideline

I. INITIAL APPROVAL CRITERIA

Coverage is provided when the following criteria are met:

1. Diffuse Large B-Cell Lymphoma.

A. Patient is 18 years of age or older; **AND**
B. Monjuvi is prescribed by, or in consultation with, an oncologist; **AND**
C. The patient has a diagnosis of diffuse large B-cell lymphoma (DLBCL) not otherwise specified (may include DLBCL arising from low grade lymphoma); **AND**
D. The patient has relapsed or refractory disease; **AND**
E. The patient is not a candidate for autologous stem cell transplantation (ASCT); **AND**
F. Patient has been treated with at least ONE prior chemotherapy regimen; **AND**
G. Monjuvi will be administered in combination with lenalidomide for a maximum of 12 cycles and will then be continued as monotherapy.

II. **RENEWAL APPROVAL CRITERIA**

Coverage can be renewed 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: infusion-related and hypersensitivity reactions, myelosuppression, infections, etc.; **AND**
3. Monjuvi will be used as monotherapy after the initial 12 combination therapy cycles with lenalidomide.

Applicable Procedure Codes

Code	Description
J9349	Monjuvi, Injection tafasitamab-cxix, 2 mg

Applicable NDCs

Code	Description
73535-0208-01	Monjuvi (tafasitamab-cxix) 200mg powder single-dose vial
50881-0013-03	Monjuvi 200mg single dose vial

ICD-10 Diagnoses

Code	Description
C83.30	Diffuse large B-cell lymphoma, unspecified site
C83.31	Diffuse large B-cell lymphoma, lymph nodes of head, face, and neck
C83.32	Diffuse large B-cell lymphoma, intrathoracic lymph nodes
C83.33	Diffuse large B-cell lymphoma, intra-abdominal lymph nodes
C83.34	Diffuse large B-cell lymphoma, lymph nodes of axilla and upper limb
C83.35	Diffuse large B-cell lymphoma, lymph nodes of inguinal region and lower limb

C83.36	Diffuse large B-cell lymphoma, intrapelvic lymph nodes
C83.37	Diffuse large B-cell lymphoma, spleen
C83.38	Diffuse large B-cell lymphoma, lymph nodes of multiple sites

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	3/17/2025	Annual Review: Updated NDCs and ICD-10 Codes. No criteria changes.
EmblemHealth & ConnectiCare	2/1/2024	Annual Review: Initial Criteria: Added: "Patient has been treated with at least one prior chemotherapy regimen"
EmblemHealth & ConnectiCare	06/05/2023	Annual Review: No criteria changes
EmblemHealth & ConnectiCare	09/08/2022	Transferred policy to new template
EmblemHealth & ConnectiCare	7/7/2021	Updated billing codes – new J code and expired C Code
EmblemHealth & ConnectiCare	1/1/2021	Updated C-code 9070
EmblemHealth & ConnectiCare	11/11/2020	New Policy

References

1. Monjuvi [package insert]. MorphoSys US Inc. Summit, NJ 07901; September 2020
2. Tafasitamab. Lexi-Drugs. Lexicomp. Wolters Kluwer Health, Inc. Riverwoods, IL. October 2020.
3. Tafasitamab-cxix. IBM Micromedex® DRUGDEX®. IBM Watson Health, Greenwood Village, Colorado, USA. September 2020.