Medical Policy

Healthcare Services Department

Policy Name	Policy Number	Scope
Tafasitamab-cxix (Monjuvi®)	MP-RX-FP-57-23	☒ MMM MA ☒ MMM Multihealth

Service Category

☐ Anesthesia
☐ Surgery
☐ Radiology Procedures
☐ Pathology and Laboratory Procedures
☐ Medicine Services and Procedures
☐ Evaluation and Management Services
☐ DME/Prosthetics or Supplies
☒ Part B DRUG

Service Description

This document addresses the use of Tafasitamab-cxix (Monjuvi®), a CD19-directed cytolytic antibody approved by the Food and Drug Administration (FDA) to be used in in combination with lenalidomide for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) not otherwise specified, including DLBCL arising from low grade lymphoma, and who are not eligible for autologous stem cell transplant.

Background Information

Tafasitamab-cxix (Monjuvi®) is a humanized Fc-modified cytolytic monoclonal antibody that targets CD19. Tafasitamab-cxix binds to the CD19 antigen found on the surface of pre-B and mature B lymphocytes, as well as on various B-cell malignancies, such as diffuse large B-cell lymphoma (DLBCL). This binding leads to the lysis of B-cells through apoptosis and immune effector mechanisms, including antibody-dependent cellular cytotoxicity (ADCC) and antibody-dependent cellular phagocytosis (ADCP).

The National Comprehensive Cancer Network® (NCCN) provides additional recommendations with a category 2A level of evidence for the use of Monjuvi. It is recommended in combination with lenalidomide for treatment of histologic transformation to diffuse large B-cell lymphoma (DLBCL) without translocations of MYC and BCL2 and/or BCL6 in patients who are not candidates for transplant and have received.

- minimal or no chemoimmunotherapy prior to histologic transformation to DLBCL and have no response or progressive disease after chemoimmunotherapy (anthracycline- or anthracenedione-based regimens preferred unless contraindicated)
- multiple prior therapies including ≥2 lines of chemoimmunotherapy for indolent or transformed disease.

Monjuvi also has a NCCN 2A recommendation as second-line and subsequent therapy in combination with lenalidomide for partial response, no response, relapsed, progressive, or refractory disease in non-candidates for transplant.

Additionally, NCCN 2A recommendation also allows use as second-line and subsequent therapy in combination with lenalidomide for AIDS-related diffuse large B-cell lymphoma, who are not candidates for transplant, high-grade B-cell lymphomas, and monomorphic PTLD (B-cell type).

Monjuvi has an NCCN 2A recommendation for use in combination with lenalidomide as second-line and subsequent therapy for no response, relapsed or progressive disease in those with follicular lymphoma (grade 1-2) that transforms into DLBCL and are not candidates for transplant. This recommendation has no evidence to

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support its use and is not recommended for early follicular lymphoma due to current available treatment options. NCCN also recommends Monjuvi for transformation of indolent lymphomas to diffuse large B-cell lymphoma.

Definitions and Measures

- Diffuse Large B-Cell Lymphoma: or DLBCL is a cancer that starts in white blood cells. It usually grows in lymph nodes- pea sized glands in the neck, groin, armpits, and elsewhere that are part of the immune system.
- Refractory Disease: Illness or disease that does not respond to treatment.
- Relapse or recurrence: After a period of improvement, during which time a disease (for example, cancer) could not be detected, the return of signs and symptoms of illness or disease. For cancer, it may come back to the same place as the original (primary) tumor or to another place in the body.

Approved Indications

Monjuvi® isapproved by the FDA to be used in combination with lenalidomide for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) not otherwise specified, including DLBCL arising from low grade lymphoma, and who are not eligible for autologous stem cell transplant (ASCT). This indication received accelerated approval based on the overall response rate and ongoing approval may depend on the confirmation and description of clinical benefit in one or more confirmatory trials.

Other Uses

See Background section above.

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

HCPCS	Description
J9349	injection, tafasitamab-cxix, 2 mg [Monjuvi]

ICD-10	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

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ICD-10	Description
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
C83.39	Diffuse large B-cell lymphoma, extranodal and solid organ sites

Medical Necessity Guidelines

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

Tafasitamab-cxix (Monjuvi®)

A. Criteria For Initial Approval (*Provider must submit documentation [such as office chart notes, lab results, pathology reports, imaging studies, and any other pertinent clinical information] supporting the patient's diagnosis for the drug and confirming that the patient has met **all** approval criteria.)*

i. Individual has a diagnosis of one of the following B-cell lymphomas:
   A. Relapsed or refractory diffuse large B-cell lymphoma (DLBCL) (Label, NCCN 2A); **OR**
   B. AIDS-related DLBCL (NCCN 2A); **OR**
   C. High-grade B-cell lymphomas (NCCN 2A); **OR**
   D. Monomorphic PTLD (B-cell type) (Label, NCCN 2A); **OR**
   E. Follicular Lymphoma Grade 1-2 (NCCN 2A); **OR**
   F. Histologic transformation of Indolent Lymphomas to Diffuse Large B-Cell lymphoma (NCCN 2A);

   AND

ii. Individual has received one to three prior lines of therapy, and one prior therapy line must have included a CD20-targeted therapy (e.g. rituximab); **AND**

iii. Individual is not eligible for high dose chemotherapy (HDC) with autologous stem-cell transplantation (ASCT); **AND**

iv. Using in one of the following ways:
   A. In combination with lenalidomide for a maximum of 12 cycles of chemotherapy without disease progression or unacceptable toxicity; **OR**
   B. As monotherapy until disease progression or unacceptable toxicity after previously completing 12 cycles in combination with lenalidomide without disease progression/unacceptable toxicity.

B. Criteria For Continuation of Therapy

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i. MMM considers continuation of Tafasitamab-cxix (Monjuvi®) therapy medically necessary in members requesting reauthorization for an indication listed in Section A above (Criteria for Initial Approval) when there is no evidence of unacceptable toxicity or disease progression while on the current regimen. The following information should be submitted for reauthorization:
   A. A current oncology note documenting the patient's response to treatment showing no progression of disease.
   B. Current imaging studies and other objective measures, as appropriate, showing no progression of disease when compared with previous results.

C. Authorization Duration

i. Initial Approval Duration: Up to 6 months
ii. Reauthorization Approval Duration: Up to 6 months

D. **Conditions Not Covered**

Any other use is considered experimental, investigational, or unproven, including the following (this list may not be all inclusive):

i. Requests for Monjuvi (tafasitamab-cxix) may not be approved for all other indications not included above (Section A: Criteria for Initial Approval)

Limits or Restrictions

A. Quantity Limitations

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines. The chart below includes dosing recommendations as per the FDA-approved prescribing information.

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Drug	Dose	Recommended Dosing Schedule	Recommended Treatment Duration
Tafasitamab-cxix (Monjuvi®)	12 mg/kg based on actual body weight	Each treatment cycle is 28-days. Cycle 1: Days 1, 4, 8, 15, and 22 Cycles 2 and 3: Days 1, 8, 15 and 22 Cycles 4 and beyond: Days 1 and 15	Monjuvi should be administered in combination with lenalidomide for a maximum of 12 cycles and then continue as monotherapy until disease progression or unacceptable toxicity.
Exceptions			
None			

Reference Information

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2023. URL: http://www.clinicalpharmacology.com. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: July 6, 2023
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2023; Updated periodically.
5. NCCN Clinical Practice Guidelines in Oncology™. © 2022 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Accessed on July 6, 2023.
    a. B-Cell Lymphomas. V4.2023. Revised June 2, 2023.
6. Salles G, et al. Tafasitamab plus lenanlidomide in relapsed or refractory diffuse large B-cell lymphoma (L-MIND): a multicenter, prospective, single-arm, phase 2 study. Lancet Oncol 2020. Published online June 5, 2020.

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.

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Policy History

Revision Type	Summary of Changes	P&T Approval Date	MPCC Approval Date
Policy Inception	Elevance Health's Medical Policy adoption.	N/A	11/30/2023
Select Review	Update statement for criteria for initial approval: Provider must submit documentation [such as office chart notes, lab results, pathology reports, imaging studies, and any other pertinent clinical information] supporting the patient's diagnosis for the drug and confirming that the patient has met all approval criteria.	Click or tap to enter a date.	Click or tap to enter a date.

Revised: 11/15/2023