Clinical Policy: Tafasitamab-cxix (Monjuvi)

Reference Number: LA.PHAR.508
Effective Date: ~~09.29.23~~06.20.24
Last Review Date: ~~03.15~~11.24
Line of Business: Medicaid

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Please note: This policy is for medical benefit

Description

Tafasitamab-cxix (Monjuvi®) is a CD19-directed cytolytic antibody.

FDA Approved Indication(s)

Monjuvi, in combination with lenalidomide, is indicated 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 is approved under accelerated approval based on overall response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of Louisiana Healthcare Connections® that Monjuvi is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Diffuse Large B-Cell Lymphoma (must meet all)**:**

1. Diagnosis of relapsed or refractory DLBCL, including DLBCL arising from low grade lymphoma (e.g., follicular lymphoma or nodal marginal zone lymphoma);
2. Prescribed by or in consultation with an oncologist or hematologist;
3. Age ≥ 18 years;
4. Prescribed after prior therapy (*see Appendix B~~)~~*);
~~4.~~5. Monjuvi is used in combination with Revlimid®* (lenalidomide) for a maximum of 12 cycles and then subsequently as monotherapy;
   **Prior authorization may be required.*
~~5.~~6. Member is not eligible for ASCT;
~~6.~~7. Request meets one of the following (a or b):*
   a. Dose does not exceed 12 mg/kg as follows (i, ii, and iii):
      i. Cycle 1: Days 1, 4, 8, 15, and 22 of the 28-day cycle;
      ii. Cycles 2 and 3: Days 1, 8, 15, and 22 of each 28-day cycle;
      iii. Cycle 4 and beyond: Days 1 and 15 of each 28-day cycle;

b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration: 6 months

B. Additional NCCN Recommended Uses (off-label) (must meet all)**:**

1. Diagnosis of one of the following B-cell lymphoma subtypes (a, b, c, ~~d,~~ or ~~e~~d):
   a. HIV-related B-cell lymphomas;
   ~~b. Follicular lymphoma (grade 1-2);~~
   ~~c.~~b. High-grade B-cell lymphomas;
   ~~d.~~c. Histologic transformation of indolent lymphomas to DLBCL;
   ~~e.~~d. Post-transplant lymphoproliferative disorders (monomorphic);
2. Prescribed by or in consultation with an oncologist or hematologist;
3. Age ≥ 18 years;
4. Prescribed after prior therapy (*see Appendix B*~~) in combination with Revlimid®* (lenalidomide) for a maximum of 12 cycles and subsequently as monotherapy;~~);
5. Monjuvi is used in combination with Revlimid* (lenalidomide) for a maximum of 12 cycles and then subsequently as monotherapy;
   **Prior authorization may be required.*

~~5.~~6. ~~For all subtypes except follicular lymphoma:~~ Member is not eligible for ASCT;

~~6.~~7. Dose is within FDA maximum limit for any FDA-approved indication or is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).*

**Prescribed regimen must be FDA-approved or recommended by NCCN.*

Approval duration: 6 months

C. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to LA.PMN.255
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: LA.PMN.53 for Medicaid.

II. Continued Therapy

A. All Indications in Section I (must meet all)**:**

a. Currently receiving medication via Louisiana Healthcare Connections benefit or member has previously met initial approval criteria;

1. Member is responding positively to therapy;
2. ~~Prescribed~~Monjuvi is used in combination with Revlimid* (lenalidomide) for a maximum of 12 cycles and then subsequently as monotherapy;
   **Prior authorization may be required.*
3. If request is for a dose increase, request meets one of the following (a or b):*

a. Dose does not exceed 12 mg/kg as follows (i, ii, and iii):
   i. Cycle 1: Days 1, 4, 8, 15, and 22 of the 28-day cycle;
   ii. Cycles 2 and 3: Days 1, 8, 15, and 22 of each 28-day cycle;
   iii. Cycle 4 and beyond: Days 1 and 15 of each 28-day cycle;
b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to LA.PMN.255
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: LA.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – LA.PMN.53 for Medicaid, or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

ASCT: autologous stem cell transplant
DLBCL: diffuse large B-cell lymphoma
FDA: Food and Drug Administration
NCCN: National Comprehensive Cancer Network

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Revlimid® (lenalidamide)	25 mg PO on Days 1 to 21 of each 28-day cycle for a maximum of 12 cycles with Monjuvi	25 mg/day
DLBCL and histologic transformation of lymphomas to DLBCL - Examples		
First-Line Treatment Regimens - Examples		

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
• RCHOP (rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone) • Pola-R-CHP (polatuzumab vedotin-piiq, rituximab, cyclophosphamide, doxorubicin, prenisone) • dose-adjusted EPOCH (etoposide, prednisone, vincristine, cyclophosphamide, doxorubicin) + rituximab	Varies	Varies
Second-Line Treatment Regimens (non-candidates for transplant) - Examples		
• CAR T-cell therapy (CD19-directed) • Polatuzumab vedotin-piiq + bendamustine + rituximab • Tafasitamab-cxixl + lenalidomide • GemOx (gemcitabine, oxaliplatin) ± rituximab • polatuzumab vedotin ± bendamustine ± rituximab, ~~• CEPP (cyclophosphamide, etoposide, prednisone, procarbazine) ± rituximab~~ • CEOP (cyclophosphamide, etoposide, vincristine, prednisone) ± rituximab • dose-adjusted EPOCH (etoposide, prednisone, vincristine, cyclophosphamide, doxorubicin) + rituximab • GDP (gemcitabine, dexamethasone, cisplatin) ± rituximab	Varies	Varies
HIV-related B-cell lymphomas - Examples		
• R-EPOCH (etoposide, prednisone, vincristine, cyclophosphamide, doxorubicin + rituximab) • RCHOP (rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone)	Varies	Varies
~~**Follicular lymphoma (grade 1-2) – Examples**~~		
~~• CHOP + Gazyva® or rituximab~~ ~~• CVP (cyclophosphamide, vincristine, prednisone) + Gazyva® or rituximab~~ ~~• Revlimid® + rituximab~~	~~Varies~~	~~Varies~~
High-grade B-cell lymphomas - Examples		
• RCHOP (rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone)	Varies	Varies

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
• Pola-R-CHP (polatuzumab vedotin-piiq, rituximab, cyclophosphamide, doxorubicin, prednisone) • DA-EPOCH-R (etoposide, prednisone, vincristine, cyclophosphamide, doxorubicin + rituximab)		
Post-transplant lymphoproliferative disorders (monomorphic) - Examples		
• rituximab • RCHOP (rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone)	Varies	Varies

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings
None reported

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
DLBCL	Administer premedications prior to starting Monjuvi. 12 mg/kg as an IV infusion according to the following dosing schedule: • Cycle 1: Days 1, 4, 8, 15 and 22 of the 28-day cycle. • Cycles 2 and 3: Days 1, 8, 15 and 22 of each 28-day cycle. • Cycle 4 and beyond: Days 1 and 15 of each 28-day cycle. Administer Monjuvi in combination with lenalidomide for a maximum of 12 cycles and then continue Monjuvi as monotherapy until disease progression or unacceptable toxicity. See prescribing information for premedication and dosing modifications.	12 mg/kg/day per dosing schedule

VI. Product Availability
Single-dose vial: 200 mg

VII. References
1. Monjuvi Prescribing Information. Boston, MA: Morphosys US, Inc.; ~~June 2021~~May 2024. Available at: https://www.monjuvi.com/pi/monjuvi-pi.pdf. Accessed July ~~10, 2023~~15, 2024.

2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed August ~~4, 2023~~20, 2024.
3. National Comprehensive Cancer Network. B-Cell Lymphomas. Version ~~5.2023~~2.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/b-cell.pdf. Accessed August ~~4, 2023~~20, 2024.

Coding Implications
Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J9349	Injection, tafasitamab-cxix, 2mg

Reviews, Revisions, and Approvals	Date	LDH Approval Date
Policy created	05.01.23	08.28.23
Annual review: no significant changes; AIDS-related B-cell lymphomas changed to HIV-related B-cell lymphomas per updated NCCN B-cell lymphoma guidelines; references reviewed and updated.	03.15.24	06.20.24
For additional NCCN recommended uses (off-label) criteria, removed follicular lymphoma (grade 1-2) as not currently supported by NCCN compendium; for Appendix B, updated first-line therapy options for B-cell lymphoma subtypes; references reviewed and updated.	11.20.24	

Important Reminder
This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. LHCC makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage

decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable LHCC administrative policies and procedures.

This clinical policy is effective as of the date determined by LHCC. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. LHCC retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom LHCC has no control or right of control. Providers are not agents or employees of LHCC.

This clinical policy is the property of LHCC. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members, and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.