Clinical Policy: Tafasitamab-cxix (Monjuvi)

Reference Number: PA.CP.PHAR.508
Effective Date: 10/2020
Last Review Date: 10/2023

Coding Implications
Revision Log

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 PA Health & Wellness® 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*) in combination with Revlimid®* (lenalidomide) for a maximum of 12 cycles and subsequently as monotherapy;
   **Prior authorization may be required.*
5. Member is not eligible for ASCT;
6. 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*).

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):

a. HIV-related B-cell lymphomas;
b. Follicular lymphoma (grade 1-2);
c. High-grade B-cell lymphomas;
d. Histologic transformation of lymphomas to DLBCL;
e. 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;
   **Prior authorization may be required.*
5. For all subtypes except follicular lymphoma: Member is not eligible for ASCT;
6. 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*).
   Approval duration: 6 months

C. Other diagnoses/indications

1. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

II. Continued Therapy

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

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy;
3. Prescribed in combination with Revlimid* (lenalidomide) for a maximum of 12 cycles and subsequently as monotherapy;
   **Prior authorization may be required.*
4. 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*).

Approval duration: 12 months

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

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

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 – PA.CP.PMN.53

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 (lenolidamide)	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		
• RCHOP (rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone) • dose-adjusted EPOCH (etoposide, prednisone, vincristine, cyclophosphamide, doxorubicin) + rituximab	Varies	Varies
Second-Line Treatment Regimens (non-candidates for transplant) -		
• 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

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
• R-EPOCH (etoposide, prednisone, vincristine, cyclophosphamide, doxorubicin + rituximab) RCHOP (rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone)	Varies	Varies
• CHOP + Gazyva® or rituximab • CVP (cyclophosphamide, vincristine, prednisone) + Gazyva® or rituximab Revlimid® + rituximab	Varies	Varies
• RCHOP (rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone) DA-EPOCH-R (etoposide, prednisone, vincristine, cyclophosphamide, doxorubicin + rituximab)	Varies	Varies
• 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. Available at www.monjuvihcp.com. Accessed July 10, 2023.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed August 4, 2023.
3. National Comprehensive Cancer Network. B-Cell Lymphomas. Version 5.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/b-cell.pdf. Accessed August 4, 2023.

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
Policy created	10/2020
4Q 2021 annual review: no significant changes; references reviewed and updated.	10/2021
4Q 2022 annual review: added NCCN-supported category 2A indications of AIDS-related B-cell lymphomas, follicular lymphoma (grade 1-2), high-grade B-cell lymphomas, post-transplant lymphoproliferative disorders, and histologic transformation of lymphomas to DLBCL; added qualifier of "a maximum of" 12 cycles in combination with Revlimid per the PI; updated Appendix B Therapeutic Alternatives; references reviewed and updated.	10/2022
4Q 2023 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.	10/2023