Clinical Policy: Tafasitamab-cxix (Monjuvi)

Reference Number: PA.CP.PHAR.508
Effective Date: 10/2020
Last Review Date: 10/2025

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

FDA Approved Indication(s)
Monjuvi, is indicated for the treatment of adult patients:

- In combination with lenalidomide, for 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)*
- In combination with lenalidomide and rituximab, for relapsed or refractory follicular lymphoma (FL)^

*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).
^Limitations of use: Monjuvi is not indicated and is not recommended for the treatment of patients with relapsed or refractory marginal zone lymphoma (MZL) outside of controlled clinical trials.

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

1. Diagnosis of one of the following B-cell lymphomas (a-f):
   a. Relapsed or refractory DLBCL, including DLBCL arising from low grade lymphoma (*see Appendix D for DLBCL subtypes);*
   b. Relapsed or refractory (e.g., no response or progressive) FL;
   c. HIV-related B-cell lymphomas;
   d. High-grade B-cell lymphomas;
   e. Histologic transformation of indolent lymphomas to DLBCL;
   f. 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*);
5. For requests other than FL and histologic transformation of indolent lymphomas to DLBCL, member has one of the following (a, b, or c):
   a. Relapsed or refractory disease;

b. Relapsed disease < 12 months in non-candidates for chimeric antigen receptor (CAR) T-cell therapy (includes members who do not have access to CAR T-cell therapy);
c. Relapsed disease > 12 months after completion of first-line therapy if no intention to proceed to transplant;

6. One of the following (a or b):*
   a. For FL: Monjuvi is used in combination with lenalidomide (cycles 1 to 12) and rituximab (cycles 1-5);
   b. For DLBCL and other B-cell lymphomas: Monjuvi is used in combination with lenalidomide for a maximum of 12 cycles and then subsequently as monotherapy;

   **Prior authorization may be required.*
7. For histologic transformation of indolent lymphomas to DLBCL: Member has no intention to proceed to transplant;
8. (a or b):
   a. Dose does not exceed 12 mg/kg as follows (i, orii):
      i. For DLBCL:
         1. Cycle 1: Days 1, 4, 8, 15, and 22 of the 28-day cycle;
         2. Cycles 2 and 3: Days 1, 8, 15, and 22 of each 28-day cycle;
         3. Cycle 4 and beyond: Days 1 and 15 of each 28-day cycle;

      ii. For FL:
         1. Cycles 1 to 3: Days 1, 8, 15, and 22 of each 28-day cycle;
         2. Cycles 4 to 12: 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: 12 months

B. 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. PHARM.01) applies;
2. Member is responding positively to therapy;
3. One of the following (a or b):*
   a. For FL: Monjuvi is used in combination with lenalidomide (cycles 1 to 12) and rituximab (cycles 1-5);
   b. For DLBCL and other B-cell lymphomas:Monjuvi is used in combination with Revlimid® (lenalidomide) for a maximum of 12 cycles and then 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. New dose does not exceed 12 mg/kg as follows (i, or ii):
      i. For DLBCL:

1. Cycle 1: Days 1, 4, 8, 15, and 22 of the 28-day cycle;
2. Cycles 2 and 3: Days 1, 8, 15, and 22 of each 28-day cycle;
3. Cycle 4 and beyond: Days 1 and 15 of each 28-day cycle;

ii. For FL:

1. Cycles 1 to 3: Days 1, 8, 15, and 22 of each 28-day cycle;
2. Cycles 4 to 12: 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.PHARM.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;

B. Relapsed or refractory MZL (*see Appendix E*).

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
FL: follicular lymphoma
HGBL: high-grade B-cell lymphoma
MZL: marginal zone lymphoma
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 and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
DLBCL and histologic transformation of lymphomas to DLBCL - Examples		
First-Line Treatment Regimens - Examples		
• RCHOP (rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone) • Pola-R-CHP (polatuzumab vedotin-piiq [Polivy ®], rituximab, cyclophosphamide, doxorubicin, prenisone)	Varies	Varies

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
• dose-adjusted EPOCH (etoposide, prednisone, vincristine, cyclophosphamide, doxorubicin) + rituximab		
Second-Line Treatment Regimens (non-candidates for transplant) -		
• CAR T-cell therapy (CD19-directed) • Polatuzumab vedotin-piiq [Polivy ®] ± bendamustine ± rituximab • GemOx (gemcitabine, oxaliplatin) ± rituximab • polatuzumab vedotin ± bendamustine ± rituximab, • CEOP (cyclophosphamide, etoposide, vincristine, prednisone) ± rituximab • dose-adjusted EPOCH (etoposide, prednisone, vincristine, cyclophosphamide, doxorubicin) + rituximab • GDP (gemcitabine, dexamethasone, cisplatin) ± rituximab	Varies	Varies
FL - Examples		
• rituximab • bendamustine + Gazyva® (obinutuzumab) • CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone) • CVP (cyclophosphamide, vincristine, prednisone) + Gazyva® (obinutuzumab) • lenalidomide + 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
HGBL - Examples		
• RCHOP (rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone) • Pola-R-CHP (polatuzumab vedotin-piiq [Polivy ®], rituximab, cyclophosphamide, doxorubicin, prednisone) DA-EPOCH-R (etoposide, prednisone, vincristine, cyclophosphamide, doxorubicin + rituximab)	Varies	Varies
Post-transplant lymphoproliferative disorders (monomorphic) - Examples		

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
• 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.

Appendix D: DLBCL Subtypes per the National Comprehensive Cancer Network (NCCN)
- DLBCL, not otherwise specified (includes germinal center and non-germinal center) (*FDA-approved use*)
- Follicular lymphoma grade 3B/follicular large B-cell lymphoma
- Intravascular LBCL
- DLBCL associated with chronic inflammation
- Fibrin-associated LBCL
- Epstein-Barr virus-positive DLBCL, NOS
- T-cell/histiocyte-rich LBCL
- LBCL with *IRF4/MUM1* rearrangement
- High-grade B-cell lymphoma (HGBL) with *MYC* and *BCL6* rearrangements
- Primary cutaneous DLBCL, leg type
- ALK-positive LBCL
- Mediastinal gray zone lymphoma
- Primary mediastinal large B-cell lymphoma
- HGBL
- HGBL, not otherwise specified
- LBCL with 11q aberration/HGBL with 11q aberrations
- DLBCL arising from FL or MZL
- Primary DLBCL of the central nervous system
- DLBCL arising from chronic lymphocytic leukemia (Richter transformation)

Appendix E: Lack of Efficacy in Relapsed or Refractory MZL
- Per the Prescribing Information, Monjuvi is not indicated and is not recommended for the treatment of patients with relapsed or refractory MZL outside of controlled clinical trials. Lack of efficacy in patients with relapsed or refractory MZL was observed in the inMIND trial, a prospective, randomized clinical trial in which a cohort of 106 patients with relapsed or refractory MZL were randomized 1:1 to receive Monjuvi or placebo in combination with lenalidomide and rituximab. There was no evidence of improvement in investigator-assessed progression-free survival in the Monjuvi arm. At the time of the progression-free survival analysis, the median overall survival had not been reached in either arm with a total of 8 deaths: 7 deaths (13.2%) in the Monjuvi arm and 1 death (1.9%) in the placebo arm.

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
FL	Administer premedications prior to starting Monjuvi. 12 mg/kg as an IV infusion according to the following dosing schedule: • Cycles 1 to 3: Days 1, 8, 15 and 22 of each 28-day cycle • Cycles 4 to 12: Days 1 and 15 of each 28-day cycle Administer Monjuvi in combination with lenalidomide (Cycles 1 to 12) and rituximab (Cycles 1 to 5) for a maximum of 12 cycles. 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 2025. Available at https://www.monjuvi.com/pi/monjuvi-pi.pdf. Accessed July 11, 2025.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed August 31, 2025.
3. National Comprehensive Cancer Network. B-Cell Lymphomas. Version 3.2025. Available at: https://www.nccn.org/professionals/physician_gls/pdf/b-cell.pdf. Accessed August 31, 2025.

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
4Q 2024 annual review: 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.	10/2024
RT4: added updated indication of FL and revised section I.A. header from DLBCL to "B-cell Lymphoma"; moved additional NCCN recommended off-label indications from section I.B. to fall under section I.A. B-cell lymphomas; replaced examples of DLBCL with complete NCCN subtype list in Appendix D; added NCCN Compendium supported off-label use in B-cell lymphomas other than FL and histologic transformation of indolent lymphomas to DLBCL; revised wording for "Member is not eligible for ASCT" to "no intention to proceed to transplant" per NCCN Compendium; added relapsed or refractory MZL to Section III diagnoses/indications for which coverage is not authorized due to lack of efficacy in this patient population observed in the inMIND trial.	07/2025
4Q 2025 annual review: no significant changes; extended initial approval duration from 6 months to 12; references reviewed and updated.	10/2025