Clinical Policy: Tafasitamab-cxix (Monjuvi)

Reference Number: CP.PHAR.508
Effective Date: 12.01.20
Last Review Date: 11.24
Line of Business: Commercial, HIM, Medicaid

Coding Implications
Revision Log

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

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 health plans affiliated with Centene Corporation® 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, b, c, d, e, or 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 lymphoma (off-label);
   d. High-grade B-cell lymphoma (HGBL) (off-label);
   e. Histologic transformation of indolent lymphomas to DLBCL (off-label);
   f. Monomorphic post-transplant lymphoproliferative disorder (off-label);
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 and rituximab for a maximum of 12 cycles;
   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. Request meets one of the following (a or b):*
   a. 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. 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. 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 one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
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: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Therapy

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

1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B);*
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 and rituximab for a maximum of 12 cycles;
   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.*
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*).

   **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 one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
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: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.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 – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid, or evidence of coverage documents;

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

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

ASCT: autologous stem cell transplant
CAR: chimeric antigen receptor
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 for all relevant lines of business 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 (Polivy® [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) • Polivy® (polatuzumab vedotin-piiq) ± bendamustine ± rituximab • GemOx (gemcitabine, oxaliplatin) ± rituximab • polatuzumab vedotin ± bendamustine ± rituximab, • CEOP (cyclophosphamide, etoposide, vincristine, prednisone) ± rituximab	Varies	Varies

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
• dose-adjusted EPOCH (etoposide, prednisone, vincristine, cyclophosphamide, doxorubicin) + rituximab • GDP (gemcitabine, dexamethasone, cisplatin) ± rituximab		
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 (Polivy® [polatuzumab vedotin-piiq], rituximab, cyclophosphamide, doxorubicin, prednisone) • DA-EPOCH-R (etoposide, prednisone, vincristine, cyclophosphamide, doxorubicin + rituximab)	Varies	Varies
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

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

Indication	Dosing Regimen	Maximum Dose
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 7, 2025.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed July 7, 2025.
3. National Comprehensive Cancer Network. B-Cell Lymphomas. Version 2.2025. Available at: https://www.nccn.org/professionals/physician_gls/pdf/b-cell.pdf. Accessed July 7, 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	P&T Approval Date
Policy created	09.02.20	11.20
4Q 2021 annual review: no significant changes; modified reference from HIM.PHAR.21 to HIM.PA.154; references reviewed and updated.	08.14.21	11.21
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	08.05.22	11.22

Reviews, Revisions, and Approvals	Date	P&T Approval Date
B Therapeutic Alternatives; references reviewed and updated. Template changes applied to other diagnoses/indications and continued therapy section.		
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.	07.10.23	11.23
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.	07.15.24	11.24
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.	07.07.25	

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. The Health Plan 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. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

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 Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. 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. The Health Plan 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 the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. 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.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.