

Clinical Policy: Tafasitamab-cxix (Monjuvi)

Reference Number: ERX.SPA.416

Effective Date: 12.01.20

Last Review Date: 11.21

Line of Business: Commercial, Medicaid

[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, 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.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ 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 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*).

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

Approval duration: 6 months

B. Other diagnoses/indications

1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

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

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions, or documentation supports that member is currently receiving Monjuvi for a covered indication and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. Prescribed in combination with Revlimid* (lenalidomide) for 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 guideline 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. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

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 policy – ERX.PA.01 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 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
First-Line Treatment Regimens - Examples		
RCHOP (rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone)	Varies	Varies
Dose-adjusted EPOCH (etoposide, prednisone, vincristine, cyclophosphamide, doxorubicin) + rituximab	Varies	Varies
Second-Line Treatment Regimens (non-candidates for transplant)- Examples		
GemOx (gemcitabine, oxaliplatin) ± rituximab	Varies	Varies
Polatuzumab vedotin ± bendamustine ± rituximab	Varies	Varies

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
CEPP (cyclophosphamide, etoposide, prednisone, procarbazine) ± rituximab	Varies	Varies
CEOP (cyclophosphamide, etoposide, vincristine, prednisone) ± rituximab	Varies	Varies
Dose-adjusted EPOCH (etoposide, prednisone, vincristine, cyclophosphamide, doxorubicin) + rituximab	Varies	Varies
GDP (gemcitabine, dexamethasone, cisplatin) ± rituximab	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: <ul style="list-style-type: none"> • 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 August 14, 2021.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed August 14, 2021.
3. National Comprehensive Cancer Network. B-Cell Lymphomas. Version 4.2021. Available at: https://www.nccn.org/professionals/physician_gls/pdf/b-cell.pdf. Accessed August 14, 2021.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	09.02.20	11.20
4Q 2021 annual review: no significant changes; updated Appendix B Therapeutic Alternatives; references reviewed and updated.	08.14.21	11.21

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.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. 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.

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