Tafasitamab-cxix (Monjuvi™)

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the medical policy and a health plan or government program (e.g., TennCare), the express terms of the health plan or government program will govern.

POLICY

INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

Monjuvi is indicated:

- In combination with lenalidomide 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).
- In combination with lenalidomide and rituximab for the treatment of adult patients with relapsed or refractory follicular lymphoma (FL).

Compendial Uses

B-cell lymphomas

- Human immunodeficiency virus (HIV)-related B-cell lymphoma
- Histologic transformation of indolent lymphomas to diffuse large B-cell lymphoma
- Monomorphic post-transplant lymphoproliferative disorders (B-cell type)
- Diffuse large B-cell lymphoma (DLBCL)
- High-grade B-cell lymphomas (HGBLs)

All other indications are considered experimental/investigational and not medically necessary.

DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review: Chart notes, medical record documentation or claims history supporting previous lines of therapy.

COVERAGE CRITERIA

Follicular Lymphoma

Authorization of 12 months may be granted for treatment of relapsed or refractory follicular lymphoma when used in combination with lenalidomide and rituximab for up to a maximum of 12 cycles.

Other B-Cell Lymphomas

Authorization of 12 months may be granted for treatment of relapsed or refractory B-cell lymphomas for up to a maximum of 12 cycles in combination with lenalidomide, when one of the following criteria is met:

- The member has human immunodeficiency virus (HIV)-related B-cell lymphoma (including HIV-related diffuse large B-cell lymphoma, primary effusion lymphoma, HIV-related plasmablastic lymphoma, and human herpes virus-8 [HHV8]-positive diffuse large B-cell lymphoma).
- The member has histologic transformation of indolent lymphoma to diffuse large B-cell lymphoma and is not eligible for an autologous stem cell transplant.
- The member has monomorphic post-transplant lymphoproliferative disorder (PTLD) (B-cell type).
- The member has diffuse large B-cell lymphoma (DLBCL) (including DLBCL arising from low grade lymphoma and DLBCL not otherwise specified).
- The member has high-grade B-cell lymphoma (HGBL).

CONTINUATION OF THERAPY

Follicular Lymphoma

Authorization of up to 12 months total may be granted for the continued treatment in members requesting reauthorization for relapsed or refractory follicular lymphoma when there is no evidence of unacceptable toxicity or disease progression while on the current regimen and the member has not exceeded a maximum of twelve cycles.

Other B-Cell Lymphomas

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in the other B-cell lymphoma coverage criteria section when there is no evidence of unacceptable toxicity or disease progression while on the current regimen and if the member has completed 12 cycles, the requested drug will be used as monotherapy.

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

REFERENCES

1. Monjuvi [package insert]. Wilmington, DE: Incyte Corporation; June 2025.
2. The NCCN Drugs & Biologics Compendium® © 2025 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed June 13, 2025.

BlueCross BlueShield of Tennessee

Policy

Medical Policy Manual **Approved Rev: Do Not Implement until 4/2/26**

EFFECTIVE DATE 4/2/2026

ID_CHS_2025