

## Medical Policy Manual

**Draft Revised Policy: Do Not Implement**

### 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.

**The proposal is to add text/statements in red and to delete text/statements with strikethrough:  
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 Indication

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).

##### Compendial Uses

##### B-cell lymphomas

- Human immunodeficiency virus (HIV)-related B-cell lymphoma
- Histologic transformation of indolent lymphomas to diffuse large B-cell lymphoma
- ~~Follicular 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 FOR INITIAL APPROVAL**

##### **B-Cell Lymphomas**

Authorization of 12 months may be granted for treatment of relapsed or refractory B-cell lymphomas when all of the following criteria are met:

- The member has one of the following B-cell lymphoma subtypes:



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- 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 herpesvirus-8 (HHV8)-positive diffuse large B-cell lymphoma)
- Histologic transformation of indolent lymphomas to diffuse large B-cell lymphoma
- ~~Follicular lymphoma~~
- Monomorphic post-transplant lymphoproliferative disorders (PTLD) (B-cell type)
- Diffuse large B-cell lymphoma (DLBCL) (including DLBCL arising from low grade lymphoma and DLBCL not otherwise specified)
- High-grade B-cell lymphomas (HGBLs)
- The member is not eligible for an autologous stem cell transplant
- The requested medication will be used in combination with lenalidomide for up to a maximum of 12 cycles

### CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in **the coverage criteria section III** 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]. Boston, MA: Morphosys US, Inc; **May 2024**.
2. The NCCN Drugs & Biologics Compendium® © 2024 National Comprehensive Cancer Network, Inc. <https://www.nccn.org>. Accessed June 7, 2024.

### EFFECTIVE DATE

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