Reference number(s)
4056-A

SPECIALTY GUIDELINE MANAGEMENT

MONJUVI (tafasitamab-cxix)

POLICY

I. 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.

A. 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).

B. Compendial Uses
B-cell lymphomas
1. Human immunodeficiency virus (HIV)-related B-cell lymphoma
2. Histologic transformation of indolent lymphomas to diffuse large B-cell lymphoma
3. Follicular lymphoma
4. Monomorphic post-transplant lymphoproliferative disorders (B-cell type)
5. Diffuse large B-cell lymphoma (DLBCL)
6. High-grade B-cell lymphomas (HGBLs)

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

II. 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.

III. 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:
A. The member has one of the following B-cell lymphoma subtypes:
1. 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)
2. Histologic transformation of indolent lymphomas to diffuse large B-cell lymphoma
3. Follicular lymphoma
4. Monomorphic post-transplant lymphoproliferative disorders (PTLD) (B-cell type)

5. Diffuse large B-cell lymphoma (DLBCL) (including DLBCL arising from low grade lymphoma and DLBCL not otherwise specified)
6. High-grade B-cell lymphomas (HGBLs)

B. The member is not eligible for an autologous stem cell transplant
C. The requested medication will be used in combination with lenalidomide for up to a maximum of 12 cycles

IV. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in 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.

V. REFERENCES

1. Monjuvi [package insert]. Boston, MA: Morphosys US, Inc; June 2021.
2. The NCCN Drugs & Biologics Compendium® © 2023 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed June 7, 2023.