Reference number(s)
4056-A

Specialty Guideline Management
Monjuvi

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Monjuvi	tafasitamab-cxix

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[1]

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[2]

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[1,2]

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[1,2]

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).

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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.

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.