Reference number(s)
6297-A

Standard Medicare Part B 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)

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- Diffuse large B-cell lymphoma (DLBCL)
- High-grade B-cell lymphomas (HGBLs)

All other indications will be assessed on an individual basis. Submissions for indications other than those listed in this criteria should be accompanied by supporting evidence from Medicare approved compendia.

Documentation

The following documentation must be available, upon request, for all submissions: 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.

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

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Authorization for up to 12 months (12 cycles total) may be granted when all of the following criteria are met:

- The member is currently receiving therapy with the requested medication.
- The requested medication is being used to treat relapsed or refractory follicular lymphoma in combination with lenalidomide and rituximab.
- The member has not exceeded a maximum of 12 cycles.
- The member is receiving benefit from therapy. Benefit is defined as:
    - No evidence of unacceptable toxicity while on the current regimen AND
    - No evidence of disease progression while on the current regimen

Other B-Cell Lymphomas

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Authorization for 12 months may be granted when all of the following criteria are met:

- The member is currently receiving therapy with the requested medication.
- The requested medication is being used to treat an indication specified below:
    - 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)
    - Histologic transformation of indolent lymphoma to diffuse large B-cell lymphoma
    - Monomorphic post-transplant lymphoproliferative disorder (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 lymphoma (HGBLs)
- If the member has completed 12 cycles, the requested drug will be used as monotherapy.
- The member is receiving benefit from therapy. Benefit is defined as:
    - No evidence of unacceptable toxicity while on the current regimen AND
    - No evidence of disease progression while on the current regimen

Summary of Evidence

The contents of this policy were created after examining the following resources:

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- The prescribing information for Monjuvi.
- The available compendium
    - National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
    - Micromedex DrugDex
    - American Hospital Formulary Service- Drug Information (AHFS-DI)
    - Lexi-Drugs
    - Clinical Pharmacology
- NCCN Guideline: B-Cell Lymphomas

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Monjuvi are covered in addition to the following:

- 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)
- High-grade B-cell lymphomas (HGBLs)

Explanation of Rationale

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

Support for using Monjuvi to treat 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) and high-grade B-cell lymphomas (HGBLs) can be found in the NCCN Drugs and Biologics Compendium. Use of information in the NCCN Drugs and Biologics Compendium for off-label use of drugs and biologicals in an anti-cancer chemotherapeutic regimen is supported by the Medicare Benefit Policy Manual, Chapter 15, section 50.4.5 (Off-Label Use of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen).

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.

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