Utilization Review Policy 229

POLICY: Oncology (Injectable – Antibody-Drug Conjugate – CD19) – Monjuvi Utilization Management Medical Policy

- Monjuvi® (tafasitamab-cxix intravenous infusion – MorphoSys/Incyte)

EFFECTIVE DATE: 12/1/2020
LAST REVISION DATE: 07/16/2025

COVERAGE CRITERIA FOR: All UCare Plans

OVERVIEW

Monjuvi, a CD19-directed antibody-drug conjugate, is indicated for the treatment of:[1]

- **Diffuse large B-cell lymphoma** (DLBCL), in combination with lenalidomide for the treatment of relapsed or refractory disease not otherwise specified, including DLBCL arising from low grade lymphoma, and who are not eligible for autologous stem cell transplant in adults.
- **Follicular lymphoma,** in combination with lenalidomide and rituximab for the treatment of relapsed or refractory disease in adult patients.

Dosing Information

Monjuvi is administered as a weight-based intravenous infusion.[1] It should be given in combination with lenalidomide for a maximum of 12 cycles, then as monotherapy until disease progression or unacceptable toxicity.

Guidelines

The National Comprehensive Cancer Network (NCCN) guidelines for B-cell lymphomas (version 2.2025 – February 10, 2025) include Monjuvi in combination with lenalidomide among the alternatives for second-line and subsequent therapy of DLBCL, follicular lymphoma, histologic transformation of indolent lymphomas to DLBCL, human immunodeficiency virus (HIV)-related B-cell lymphoma, post-transplant lymphoproliferative disorders, and high-grade B-cell lymphoma.[2,3] NCCN guidelines note that it is unclear if Monjuvi would have a negative impact on the efficacy of subsequent anti-CD19 CAR T-cell therapy.

POLICY STATEMENT

Prior Authorization is recommended for medical benefit coverage of Monjuvi. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indications. Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Monjuvi as well as the monitoring required for adverse events and long-term efficacy, approval requires Monjuvi to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Monjuvi is recommended in those who meet one of the following criteria:

FDA-Approved Indication

1. **Diffuse Large B-Cell Lymphoma.** Approve for 1 year if the patient meets ALL of the following (A, B, and C):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has been treated with at least one prior chemotherapy regimen; AND
     Note: Examples of chemotherapy regimens include RCHOP (rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone) and dose-adjusted EPOCH (etoposide, prednisone, vincristine, cyclophosphamide, doxorubicin) plus rituximab.
   - **C)** The medication is prescribed by or in consultation with an oncologist.

   Dosing. Approve the following dosing regimen (A and B):
   - **A)** The dose is 12 mg/kg administered as an intravenous infusion; AND
   - **B)** The agent is administered in 28-day cycles that meet ALL of the following (i, ii, and iii):
     - **i.** Cycle 1: Maximum of five infusions; AND
     - **ii.** Cycle 2 and 3: Maximum of four infusions per cycle; AND
     - **iii.** Cycle 4 and beyond: Maximum of two infusions per cycle.

2. **Follicular Lymphoma**. Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has been treated with at least one prior systemic regimen; AND
   - **C)** The medication will be used in combination with lenalidomide and rituximab; AND
   - **D)** The medication is prescribed by or in consultation with an oncologist.

   Dosing. Approve the following dosing regimen (A and B):
   - **A)** The dose is 12 mg/kg administered as an intravenous infusion; AND
   - **B)** The agent is administered in 28-day cycles that meet ALL of the following (i and ii):
     - **i.** Cycle 1 to 3: Maximum of four infusions per cycle; AND
     - **ii.** Cycle 4 and beyond: Maximum of two infusions per cycle.

Other Uses with Supportive Evidence

3. **B-Cell Lymphoma.** Approve for 1 year if the patient meets ALL of the following (A, B, and C):
   Note: Examples include high-grade B-cell lymphoma, HIV-related B-cell lymphoma, post-transplant lymphoproliferative disorders, histologic transformation of indolent lymphomas to diffuse large B-cell lymphoma.
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has been treated with at least one prior chemotherapy regimen; AND
     Note: Examples of chemotherapy regimens include CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone) plus rituximab or Gazyva (obinutuzumab intravenous infusion), CVP (cyclophosphamide, vincristine, prednisone) plus rituximab or Gazyva, or lenalidomide plus rituximab.
   - **C)** The medication is prescribed by or in consultation with an oncologist.

Dosing. Approve the following dosing regimen (A and B):
A) The dose is 12 mg/kg administered as an intravenous infusion; AND
B) The agent is administered in 28-day cycles that meet ALL of the following (i, ii, and iii):
i. Cycle 1: Maximum of five infusions; AND
ii. Cycle 2 and 3: Maximum of four infusions per cycle; AND
iii. Cycle 4 and beyond: Maximum of two infusions per cycle.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Monjuvi is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Monjuvi® intravenous infusion [prescribing information]. Boston, MA: MorphoSys/Incyte; June 2025.
2. The NCCN B-Cell Lymphoma Clinical Practice Guidelines in Oncology (version 2.2025 – February 10, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on July 7, 2025.
3. The NCCN Drugs & Biologics Compendium. © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on July 7, 2025. Search term: tafasitamab.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	**B-Cell Lymphoma:** To align with NCCN guidelines, this indication was added as an Other Use with Supportive Evidence.	09/07/2022
Annual Revision	**B-Cell Lymphoma:** AIDS-related B-cell lymphoma was changed to HIV-related B-cell lymphoma in the Note.	09/06/2023
Annual Revision	**B-Cell Lymphoma:** Follicular lymphoma removed from the Note with the examples of B-cell lymphomas.	09/04/2024
UCare P&T Review	Policy reviewed and approved by UCare P&T committee. Annual review process	09/16/2024
Annual Revision	The name of the policy was changed to as listed. Previously, it was ***Oncology (Injectable) – Monjuvi UM Medical Policy*.** **Follicular Lymphoma:** Added as a new condition for approval. **B-Cell Lymphoma, Diffuse Large B-Cell Lymphoma:** Removed the requirements according to the prescriber, the patient is not eligible for autologous stem cell transplant, Monjuvi will be used in combination with Revlimid (lenalidomide capsules), and patient has already received 12 cycles of Monjuvi.	07/16/2025
UCare P&T Review	Policy reviewed and approved by UCare P&T committee. Annual review process	09/15/2025