VENTURA COUNTY
HEALTH CARE PLAN

UTILIZATION MANAGEMENT MEDICAL POLICY

POLICY: Oncology (Injectable) – Monjuvi Utilization Management Medical Policy
- Monjuvi® (tafasitamab-cxix intravenous infusion – MorphoSys/Incyte)

REVIEW DATE: 09/06/2023

OVERVIEW

Monjuvi, a CD19-directed antibody-drug conjugate, is indicated in combination with lenalidomide for adults 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.[1] Monjuvi is administered as a weight-based intravenous infusion. 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 5.2023 – July 7, 2023) include Monjuvi + 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 also notes 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 the following (A, B, C, D, and E):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has been treated with at least one prior chemotherapy regimen; AND
   - **C)** According to the prescriber, the patient is not eligible for autologous stem cell transplant; AND
   - **D)** Patient meets one of the following (i or ii):

i. Monjuvi will be used in combination with Revlimid (lenalidomide capsules); OR
ii. Patient has already received 12 cycles of Monjuvi; AND

E) 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.

Other Uses with Supportive Evidence

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2. B-Cell Lymphoma. Approve for 1 year if the patient meets the following (A, B, C, D, and E):
Note: Examples include follicular lymphoma, 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) According to the prescriber, the patient is not eligible for autologous stem cell transplant; AND
D) Patient meets one of the following (i or ii):
i. Monjuvi will be used in combination with Revlimid (lenalidomide capsules); OR
ii. Patient has already received 12 cycles of Monjuvi; AND
E) 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 2021.
2. The NCCN B-Cell Lymphoma Clinical Practice Guidelines in Oncology (version 5.2023 – July 7, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on September 1, 2023.
3. The NCCN Drugs & Biologics Compendium. © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on September 1, 2023. 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