

POLICY: Oncology (Injectable) – Lunsumio Utilization Management Medical Policy

- Lunsumio™ (mosunetuzumab-axgb intravenous infusion – Genentech)

EFFECTIVE DATE: 5/15/2023**LAST REVISION DATE:** 01/29/2025**COVERAGE CRITERIA FOR:** All UCare Plans

OVERVIEW

Lunsumio, a bispecific CD20-directed CD3 T-cell engager, is indicated for the treatment of relapsed or refractory follicular lymphoma in adults after two or more lines of systemic therapy.¹

Dosing Information

The recommended dose of Lunsumio is administered by intravenous (IV) infusion and is given on a 21-day cycle.¹ Treatment should continue for a total of 8 cycles in patients who achieve a complete response. For patients achieving a partial response or stable disease after 8 cycles of therapy, treatment may continue for a total of 17 cycles. The recommended dosage is as follows:

- Cycle 1, Day 1: 1 mg
- Cycle 1, Day 8: 2 mg
- Cycle 1, Day 15: 60 mg
- Cycle 2, Day 1: 60 mg
- Subsequent Cycles, Day 1: 30 mg

Patients should be pre-medicated with a corticosteroid, an antihistamine, and an antipyretic prior to each dose of Lunsumio in Cycles 1 and 2.¹ In subsequent cycles, patients experiencing cytokine release syndrome with the previous dose should also be pre-medicated.

Guidelines

The National Comprehensive Cancer Network (NCCN) B-Cell Lymphoma (version 1.2025 – December 20, 2024) clinical practice guidelines recommend Lunsumio for the third-line and subsequent treatment of follicular lymphoma (category 2A).^{2,3} NCCN also recommends Lunsumio in combination with Polivy (polatuzumab vedotin-piiq IV infusion) as second-line and subsequent treatment of diffuse large B-cell lymphoma, high-grade B-cell lymphoma, human immunodeficiency virus (HIV)-related B-cell lymphomas, and post-transplant lymphoproliferative disorders (category 2A).

Safety

Lunsumio has a Boxed Warning for cytokine release syndrome.¹

POLICY STATEMENT

Prior Authorization is recommended for medical benefit coverage of Lunsumio. 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 Lunsumio as well as the monitoring required

for adverse events and long-term efficacy, approval requires Lunsumio to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

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

FDA-Approved Indication

1. Follicular 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 received \geq two lines of systemic therapy; AND

Note: Examples of systemic therapy include CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone) plus rituximab or Gazyva (obinutuzumab intravenous infusion) and CVP (cyclophosphamide, vincristine, prednisone) plus rituximab or Gazyva.

C) The medication is prescribed by or in consultation with an oncologist.

Dosing. Approve the following dosing regimens (A and B):

A) Each dose must not exceed 60 mg administered by intravenous infusion; AND

B) Administer up to three doses during Cycle 1 and then one dose in each subsequent cycle.

Other Uses with Supportive Evidence

2. B-Cell Lymphoma. Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):

Note: Examples of B-cell lymphomas include diffuse large B-cell lymphoma, high-grade B-cell lymphoma, human immunodeficiency virus (HIV)-related B-cell lymphomas, and post-transplant lymphoproliferative disorders.

A) Patient is ≥ 18 years of age; AND

B) Patient has received \geq one line of systemic therapy; AND

3. Note: Examples of systemic therapy include RCHOP (rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone) and Pola-R-CHP (Polivy [polatuzumab vedotin-piiq intravenous infusion], rituximab, cyclophosphamide, doxorubicin, prednisone).

A) Medication will be used in combination with Polivy; AND

B) The medication is prescribed by or in consultation with an oncologist.

Dosing. Approve the following dosing regimens (A and B):

A) Each dose must not exceed 60 mg administered by intravenous infusion; AND

B) Administer up to three doses during Cycle 1 and then one dose in each subsequent cycle.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Lunsumio 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. Lunsumio intravenous infusion [prescribing information]. South San Francisco, CA: Genentech; November 2024.

2. The NCCN Drugs and Biologics Compendium. © 2025 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on January 22, 2025. Search term: mosunetuzumab.

3. The NCCN B-Cell Lymphomas Clinical Practice Guidelines in Oncology (version 1.2025 – December 20, 2024). © 2024 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on January 22, 2025.

HISTORY

| Type of Revision | Summary of Changes | Review Date |
|------------------|--|-------------|
| New Policy | -- | 01/11/2023 |
| Annual Revision | No criteria changes. | 01/10/2024 |
| UCare P&T Review | Policy reviewed and approved by UCare P&T committee. Annual review process | 09/16/2024 |
| Annual Revision | B-Cell Lymphoma: Added new condition of approval. | 01/29/2025 |
| UCare P&T Review | Policy reviewed and approved by UCare P&T committee. Annual review process | 09/15/2025 |