Reference number(s)
5713-A

Standard Medicare Part B Management Lunsumio

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
Lunsumio	mosunetuzumab-axgb
Lunsumio Velo	mosunetuzumab-axgb

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]

Lunsumio and Lunsumio Velo are indicated for the treatment of adult patients with relapsed or refractory follicular lymphoma after two or more lines of systemic therapy.

Compendial Uses (Lunsumio IV only)[2]

- Follicular Lymphoma
- Diffuse large B-cell lymphoma
- High-grade B-cell lymphoma
- Human immunodeficiency virus (HIV)-related B-cell lymphomas
- Post-transplant lymphoproliferative disorders (B-cell type)

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.

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Coverage Criteria

Follicular Lymphoma[1,2]

Authorization of 12 months may be granted for treatment of follicular lymphoma when both of the following criteria are met:

- The disease had a partial or no response to treatment or the disease is relapsed or progressive.
- The member has tried at least 2 prior lines of systemic therapy.

Diffuse Large B-cell Lymphoma, High-Grade B-cell Lymphoma, HIV-Related B-cell Lymphomas, Post-Transplant Lymphoproliferative Disorders (PTLD) (Lunsumio IV only)[2]

Authorization of 12 months may be granted for subsequent treatment of diffuse large B-cell lymphoma, high-grade B-cell lymphoma, HIV-related diffuse large B-cell lymphoma, primary effusion lymphoma, human herpesvirus-8 (HHV8)-positive diffuse large B-cell lymphoma, HIV-related plasmablastic lymphoma, and monomorphic post-transplant lymphoproliferative disorders (B-cell type) when both of the following criteria are met:

- The disease is relapsed or refractory.
- The requested medication will be used in combination with polatuzumab vedotin.

Continuation of Therapy

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

Authorization for 12 months (up to 17 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 an indication listed in the coverage criteria section.
- 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 Lunsumio and Lunsumio Velo
- 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 Lunsumio are covered in addition to the following:

- Follicular lymphoma that is progressive or partially responded to prior therapy
- Diffuse large B-cell lymphoma
- High-grade B-cell lymphoma
- Human immunodeficiency virus (HIV)-related B-cell lymphomas
- Post-transplant lymphoproliferative disorders (B-cell type)

Explanation of Rationale

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

Support for the compendial uses in summary of evidence section 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. Lunsumio [package insert]. South San Francisco, CA: Genentech, Inc.; December 2025.
2. Lunsumio Velo [package insert]. South San Francisco, CA: Genentech, Inc.; December 2025.
3. The NCCN Drugs & Biologics Compendium® © 2025 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed December 31, 2025.

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