VENTURA COUNTY
HEALTH CARE PLAN

UTILIZATION MANAGEMENT MEDICAL POLICY

POLICY: Oncology (Injectable – Bispecific – CD20-Directed) – Lunsumio Velo Utilization Management Medical Policy
- Lunsumio Velo™ (mosunetuzumab-axgb intravenous infusion – Genentech)

REVIEW DATE: 01/14/2026

OVERVIEW

Lunsumio Velo, 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

Lunsumio Velo is administered as a subcutaneous (SC) injection on a 21-day treatment cycle for 8 cycles, unless the patient experiences unacceptable toxicity or disease progression. For patients who experience a complete response, no further treatment beyond 8 cycle is required; in patients who achieve a partial response or stable disease, treatment can continue for an additional 9 cycles (total of 17 cycles), unless the patient experiences unacceptable toxicity or disease progression. The recommended dosing of Lunsumio Velo is summarized in Table 1. Lunsumio Velo is administered SC in the abdomen or thigh over 30 seconds to 1 minute by a qualified healthcare professional. The dosing for Lunsumio Velo used in the Phase II mantle cell lymphoma study was similar to the FDA approved dosing for follicular lymphoma.[3]

Table 1. Recommended Lunsumio Velo Dosing Regimen for a 21-day Treatment Cycle.[1]

Treatment Cycle		Subcutaneous Dose of Lunsumio Velo
Cycle 1	Day 1	5 mg
	Day 8	45 mg
	Day 15	45 mg
Cycle 2+	Day 1	45 mg

Guidelines

Lunsumio Velo has not been addressed in National Comprehensive Cancer Network (NCCN) B-cell lymphoma clinical practice guidelines (version 1.2026 – December 22, 2025) for follicular lymphoma; however, it is addressed for mantle cell lymphoma.[2] For follicular lymphoma, third-line and subsequent "Preferred" therapies include Epkinly® (epcoritamab-bysp subcutaneous injection) and Lunsumio® (mosunetuzumab-axgb intravenous infusion) [both category 2A]. For mantle cell lymphoma, Lunsumio Velo + Polivy®(polatuzumab vedotin-piiq intravenous infusion) are recommended as second-line or subsequent therapy as "Useful in Certain Circumstances" for progressive disease after prior covalent Bruton tyrosine kinase inhibitor (category 2A).[2,3]

POLICY STATEMENT

Prior Authorization is recommended for medical benefit coverage of Lunsumio Velo. 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 Velo as well as the monitoring required for adverse events and long-term efficacy, approval requires Lunsumio Velo 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 Velo 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 at least two lines of systemic therapy; AND
     Note: Examples of systemic therapy include CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone) + rituximab or Gazyva (obinutuzumab intravenous infusion), CVP (cyclophosphamide, vincristine, prednisone) + rituximab or Gazyva, lenalidomide + rituximab ± Epkinly (epcoritamab-bysp subcutaneous injection) or Monjuvi (tafasitamab-cxix intravenous infusion), bendamustine + Gazyva or rituximab, or Tazverik (tazemetostat tablets).
   - **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 45 mg administered by subcutaneous injection; AND
   - **B)** Administer up to three doses during Cycle 1 followed by one dose in each subsequent cycle.

Other Uses with Supportive Evidence

2. **Mantle Cell 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 received at least one covalent Bruton tyrosine kinase inhibitor; AND
     Note: Examples of a covalent Bruton tyrosine kinase inhibitors include Brukinsa (zanubrutinib capsules and tablets), Calquence (acalabrutinib tablets), and Imbruvica (ibrutinib capsules, oral suspension, and tablets).
   - **C)** The medication will be used in combination with Polivy (polatuzumab vedotin-piiq intravenous infusion); AND
   - **D)** 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 45 mg administered by subcutaneous injection; AND
   - **B)** Administer up to three doses during Cycle 1 followed by one dose in each subsequent cycle.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Lunsumio Velo 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 Velo™ subcutaneous injection [prescribing information]. South San Francisco, CA: Genentech; December 2025.

2. The NCCN B-Cell Lymphoma Clinical Practice Guidelines in Oncology (version 1.2026 – December 22, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on January 8, 2026.
3. Budde LE, Kamdar M, Assouline S, et al. Fixed-duration outpatient subcutaneous mosunetuzumab + polatuzumab vedotin shows robust efficacy in a phase II study of relapsed/refractory post-BTKi mantle cell lymphoma [abstract MCL-1493]. Presented at: The 18th International Conference on Malignant Lymphoma (ICML) Annual Meeting; Lugano, Switzerland; June 17-21, 2025.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	01/14/2026