

Lunsumio™ (mosunetuzumab-axgb) (Intravenous)

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I. Length of Authorization ^{1,4-5}

- Coverage will be provided for eight 21-day cycles
- Coverage may be renewed for an additional nine 21-day cycles based upon response (refer to section IV for details)

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

- Lunsumio 1 mg/1 mL single-dose vial: 3 vials on cycle 1, initially (1 vial on day 1 and 2 vials on day 8 of cycle 1 only)
- Lunsumio 30 mg/30 mL single-dose vial: 2 vials on cycle 1 D15 and cycle 2 D1, then 1 vial every cycle thereafter

B. Max Units (per dose and over time) [HCPCS Unit]:

- Cycle 1: Day 1 – 1 billable unit (1 mg), Day 8 – 2 billable units (2 mg), Day 15 – 60 billable units (60 mg)
- Cycle 2: Day 1 – 60 billable units (60 mg)
- Cycle 3+: Day 1 – 30 billable units (30 mg)

III. Initial Approval Criteria ¹

Coverage is provided in the following conditions:

- Patient is at least 18 years of age; **AND**

Universal Criteria ¹

- Patient does not have an active infection, including clinically important localized infections; **AND**
- Prophylaxis for infection will be followed according to standard institutional guidelines; **AND**
- Patient does not have central nervous system (CNS) lymphoma; **AND**

Follicular Lymphoma † ‡ Φ ¹⁻⁴

- Used for histologically confirmed grades 1-3a disease; **AND**

- Patient disease is relapsed or refractory to at least two prior therapies, including an anti-CD20 monoclonal antibody and an alkylating agent; **AND**
- Patient has an Eastern Cooperative Oncology Group (ECOG) performance status of 0-1

† FDA-Labeled Indication(s); ‡ Compendia Recommended Indication(s); Ⓞ Orphan Drug

IV. Renewal Criteria ^{1,3}

- Patient continues to meet the universal and other indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in section III; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: cytokine release syndrome (CRS), serious neurologic toxicity including Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS), serious infections (bacterial, fungal, or viral), cytopenias (e.g., severe neutropenia/febrile neutropenia, anemia, and thrombocytopenia), tumor flare (e.g., new or worsening pleural effusions, localized pain and swelling at the sites of lymphoma lesions, tumor inflammation), etc.; **AND**
 - Patient achieved a complete response as evidenced by metabolic and radiologic response criteria; **AND**
 - Coverage may not be renewed after 8 cycles; **OR**
 - Patient achieved a partial response or has stable disease as evidenced by metabolic and radiologic response criteria; **AND**
 - Patient has not exceeded a maximum of 17 cycles in total

V. Dosage/Administration ^{1,4-5}

Indication	Dose
Follicular Lymphoma	<p>Administer for eight 21-day treatment cycles, unless patient experiences unacceptable toxicity or disease progression.</p> <ul style="list-style-type: none"> • Cycle 1: 1 mg day 1, 2 mg day 8, then 60 mg day 15 • Cycle 2: 60 mg day 1 • Cycle 3+: 30 mg day 1 <p>For patients who achieve a complete response, no further treatment beyond 8 cycles is required. For patients who achieve a partial response or have stable disease in response to treatment with Lunsumio after 8 cycles, an additional 9 cycles of treatment (17 cycles total) should be administered, unless a patient experiences unacceptable toxicity or disease progression.</p>
<ul style="list-style-type: none"> – Administer Lunsumio to well-hydrated patients. – Premedicate before each dose in Cycle 1 and Cycle 2. – Lunsumio should only be administered by a qualified healthcare professional with appropriate medical support to manage severe reactions such as cytokine release syndrome and neurologic toxicity. 	

VI. Billing Code/Availability Information

HCPCS Code:

- J9350 – Injection, mosunetuzumab-axgb, 1 mg; 1 billable unit = 1 mg

NDC:

- Lunsumio 1 mg/1 mL single-dose vial: 50242-0159-xx
- Lunsumio 30 mg/30 mL single-dose vial: 50242-0142-xx

VII. References

1. Lunsumio [package insert]. South San Francisco, CA; Genentech, Inc; December 2022. Accessed January 2024.
2. Referenced with permission from the NCCN Drugs and Biologics Compendium (NCCN Compendium[®]) mosunetuzumab. National Comprehensive Cancer Network, 2024. The NCCN Compendium[®] is a derivative work of the NCCN Guidelines[®]. NATIONAL COMPREHENSIVE CANCER NETWORK[®], NCCN[®], and NCCN GUIDELINES[®] are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed January 2024.
3. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines[®]) for B-Cell Lymphomas, Version 6.2023. National Comprehensive Cancer Network, 2022. NATIONAL COMPREHENSIVE CANCER NETWORK[®], NCCN[®], and NCCN GUIDELINES[®] are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Guidelines, go online to NCCN.org. Accessed January 2024.
4. Budde LE, Sehn LH, Matasar M, et al. Safety and efficacy of mosunetuzumab, a bispecific antibody, in patients with relapsed or refractory follicular lymphoma: a single-arm, multicentre, phase 2 study. *Lancet Oncol.* 2022 Aug;23(8):1055-1065. doi: 10.1016/S1470-2045(22)00335-7. Epub 2022 Jul 5.
5. Bartlett NL, Sehn LH, Matasar MJ, et al. Mosunetuzumab Monotherapy Demonstrates Durable Efficacy with a Manageable Safety Profile in Patients with Relapsed/Refractory Follicular Lymphoma Who Received ≥ 2 Prior Therapies: Updated Results from a Pivotal Phase II Study [abstract]. *Blood* 2022;140:1467-1470.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C82.00	Follicular lymphoma grade I unspecified site
C82.01	Follicular lymphoma grade I lymph nodes of head, face, and neck
C82.02	Follicular lymphoma grade I intrathoracic lymph nodes
C82.03	Follicular lymphoma grade I intra-abdominal lymph nodes
C82.04	Follicular lymphoma grade I lymph nodes of axilla and upper limb

C82.05	Follicular lymphoma grade I lymph nodes of inguinal region and lower limb
C82.06	Follicular lymphoma grade I intrapelvic lymph nodes
C82.07	Follicular lymphoma grade I spleen
C82.08	Follicular lymphoma grade I lymph nodes of multiple sites
C82.09	Follicular lymphoma grade I extranodal and solid organ sites
C82.10	Follicular lymphoma grade II unspecified site
C82.11	Follicular lymphoma grade II lymph nodes of head, face, and neck
C82.12	Follicular lymphoma grade II intrathoracic lymph nodes
C82.13	Follicular lymphoma grade II intra-abdominal lymph nodes
C82.14	Follicular lymphoma grade II lymph nodes of axilla and upper limb
C82.15	Follicular lymphoma grade II lymph nodes of inguinal region and lower limb
C82.16	Follicular lymphoma grade II intrapelvic lymph nodes
C82.17	Follicular lymphoma grade II spleen
C82.18	Follicular lymphoma grade II lymph nodes of multiple sites
C82.19	Follicular lymphoma grade II extranodal and solid organ sites
C82.20	Follicular lymphoma grade III unspecified site
C82.21	Follicular lymphoma grade III lymph nodes of head, face, and neck
C82.22	Follicular lymphoma grade III intrathoracic lymph nodes
C82.23	Follicular lymphoma grade III intra-abdominal lymph nodes
C82.24	Follicular lymphoma grade III lymph nodes of axilla and upper limb
C82.25	Follicular lymphoma grade III lymph nodes of inguinal region and lower limb
C82.26	Follicular lymphoma grade III intrapelvic lymph nodes
C82.27	Follicular lymphoma grade III spleen
C82.28	Follicular lymphoma grade III lymph nodes of multiple sites
C82.29	Follicular lymphoma grade III extranodal and solid organ sites
C82.30	Follicular lymphoma grade IIIa unspecified site
C82.31	Follicular lymphoma grade IIIa lymph nodes of head, face, and neck
C82.32	Follicular lymphoma grade IIIa intrathoracic lymph nodes
C82.33	Follicular lymphoma grade IIIa intra-abdominal lymph nodes
C82.34	Follicular lymphoma grade IIIa lymph nodes of axilla and upper limb
C82.35	Follicular lymphoma grade IIIa lymph nodes of inguinal region and lower limb
C82.36	Follicular lymphoma grade IIIa intrapelvic lymph nodes
C82.37	Follicular lymphoma grade IIIa spleen
C82.38	Follicular lymphoma grade IIIa lymph nodes of multiple sites
C82.39	Follicular lymphoma grade IIIa extranodal and solid organ sites
C82.40	Follicular lymphoma grade IIIb unspecified site

C82.41	Follicular lymphoma grade IIIb lymph nodes of head, face, and neck
C82.42	Follicular lymphoma grade IIIb intrathoracic lymph nodes
C82.43	Follicular lymphoma grade IIIb intra-abdominal lymph nodes
C82.44	Follicular lymphoma grade IIIb lymph nodes of axilla and upper limb
C82.45	Follicular lymphoma grade IIIb lymph nodes of inguinal region and lower limb
C82.46	Follicular lymphoma grade IIIb intrapelvic lymph nodes
C82.47	Follicular lymphoma grade IIIb spleen
C82.48	Follicular lymphoma grade IIIb lymph nodes of multiple sites
C82.49	Follicular lymphoma grade IIIb extranodal and solid organ sites
C82.50	Diffuse follicle center lymphoma unspecified site
C82.51	Diffuse follicle center lymphoma lymph nodes of head, face, and neck
C82.52	Diffuse follicle center lymphoma intrathoracic lymph nodes
C82.53	Diffuse follicle center lymphoma intra-abdominal lymph nodes
C82.54	Diffuse follicle center lymphoma lymph nodes of axilla and upper limb
C82.55	Diffuse follicle center lymphoma lymph nodes of inguinal region and lower limb
C82.56	Diffuse follicle center lymphoma intrapelvic lymph nodes
C82.57	Diffuse follicle center lymphoma spleen
C82.58	Diffuse follicle center lymphoma lymph nodes of multiple sites
C82.59	Diffuse follicle center lymphoma extranodal and solid organ sites
C82.60	Cutaneous follicle center lymphoma unspecified site
C82.61	Cutaneous follicle center lymphoma lymph nodes of head, face, and neck
C82.62	Cutaneous follicle center lymphoma intrathoracic lymph nodes
C82.63	Cutaneous follicle center lymphoma intra-abdominal lymph nodes
C82.64	Cutaneous follicle center lymphoma lymph nodes of axilla and upper limb
C82.65	Cutaneous follicle center lymphoma lymph nodes of inguinal region and lower limb
C82.66	Cutaneous follicle center lymphoma intrapelvic lymph nodes
C82.67	Cutaneous follicle center lymphoma spleen
C82.68	Cutaneous follicle center lymphoma lymph nodes of multiple sites
C82.69	Cutaneous follicle center lymphoma extranodal and solid organ sites
C82.80	Other types of follicular lymphoma unspecified site
C82.81	Other types of follicular lymphoma lymph nodes of head, face, and neck
C82.82	Other types of follicular lymphoma intrathoracic lymph nodes
C82.83	Other types of follicular lymphoma intra-abdominal lymph nodes
C82.84	Other types of follicular lymphoma lymph nodes of axilla and upper limb
C82.85	Other types of follicular lymphoma lymph nodes of inguinal region and lower limb
C82.86	Other types of follicular lymphoma intrapelvic lymph nodes

C82.87	Other types of follicular lymphoma spleen lymph nodes of multiple sites
C82.88	Other types of follicular lymphoma lymph nodes of multiple sites
C82.89	Other types of follicular lymphoma extranodal and solid organ sites
C82.90	Follicular lymphoma, unspecified site
C82.91	Follicular lymphoma, unspecified lymph nodes of head, face, and neck
C82.92	Follicular lymphoma, unspecified intrathoracic lymph nodes
C82.93	Follicular lymphoma, unspecified intra-abdominal lymph nodes
C82.94	Follicular lymphoma, unspecified lymph nodes of axilla and upper limb
C82.95	Follicular lymphoma, unspecified lymph nodes of inguinal region and lower limb
C82.96	Follicular lymphoma, unspecified intrapelvic lymph nodes
C82.97	Follicular lymphoma, unspecified spleen
C82.98	Follicular lymphoma, unspecified lymph nodes of multiple sites
C82.99	Follicular lymphoma, unspecified extranodal and solid organ sites

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: <https://www.cms.gov/medicare-coverage-database/search.aspx>. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp.(WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp. (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC

Medicare Part B Administrative Contractor (MAC) Jurisdictions

Jurisdiction	Applicable State/US Territory	Contractor
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC