

Medical Policy

| Lunsumio® (mosunetuzumab-axgb) | |
|---------------------------------------|---|
| MEDICAL POLICY NUMBER | MED_Clin_Ops-139 |
| CURRENT VERSION EFFECTIVE DATE | January 1, 2024 |
| APPLICABLE PRODUCT AND MARKET | <i>Individual Family Plan: All Plans</i> <i>Small Group: All Plans</i> <i>Medicare Advantage: All Plans</i> |

*Policy applies to all markets where IFP, SG, or MA plans are offered

Brand New Day/Central Health Medicare Plan develops policies and makes coverage determinations using credible scientific evidence including but not limited to MCG™ Health Guidelines, the ASAM Criteria™, and other third party sources, such as peer-reviewed medical literature generally recognized by the relevant medical community, physician specialty society recommendations, and expert opinion as relevant to supplement those sources. Brand New Day/Central Health Medicare Plan Medical Policies, MCG™ Guidelines, and the ASAM Criteria™ are not intended to be used without the independent clinical judgment of a qualified health care provider considering the individual circumstances of each member's case. The treating health care providers are solely responsible for diagnosis, treatment, and medical advice. Members may contact Brand New Day/Central Health Medicare Plan Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions about this Brand New Day/ Central Health Medicare Plan policy may contact the Health Plan. Brand New Day/Central Health Medicare Plan policies and practices are compliant with federal and state requirements, including mental health parity laws.

If there is a difference between this policy and the member specific plan document, the member benefit plan document will govern. for Medicare Advantage members, Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), govern. Refer to the CMS website at <http://www.cms.gov> for additional information.

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PURPOSE

The purpose of this policy is to establish the clinical review criteria that support the determination of medical necessity for Lunsumio, mosunetuzumab-axgb therapy.

POLICY

Prior Authorization and Medical Review is required.

Coverage for Lunsumio will be provided for 8 21-day cycles. Coverage may be renewed for an additional nine 21-day cycles based upon response (refer to renewal criteria).

- Max Units (per dose and over time):
 - o Cycle 1: Day 1 – 1mg, Day 8 – 2mg, Day 15 – 60mg
 - o Cycle 2: Day 1 – 60mg
 - o Cycle 3+: Day 1 – 30mg

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Initial

Follicular Lymphoma

- A. Patient is 18 years of age or older; **AND**
- B. Patient's disease is relapsed or refractory to at least two prior therapies, including an anti-CD20 monoclonal antibody and an alkylating agent; **AND**
- C. Patient has an Eastern Cooperative Oncology Group (ECOG) performance status of 0-1

Renewal

Coverage can be renewed based upon the following criteria:

- A. Patient continues to meet universal and other indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in initial criteria; **AND**
- B. 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), severe neutropenia/febrile neutropenia, severe thrombocytopenia, etc.; **AND**
- C. Patient achieved a complete response as evidenced by metabolic and radiologic response criteria; **AND**
 - a. Coverage may not be renewed after 8 cycles; **OR**
- D. Patient achieved a partial response or has stable disease as evidenced by metabolic and radiologic response criteria; **AND**
 - a. Patient has not exceeded a maximum of 17 cycles in total.

LIMITATIONS/EXCLUSIONS

- 1. Any indication other than those listed above due to insufficient evidence of therapeutic value.

DEFINITIONS

- A. Lunsumio (mosunetuzumab-axgb) injection, for intravenous use. Initial U.S. Approval: 2022
 - a. LUNSUMIO (mosunetuzumab-axgb) for injection is a sterile, colorless solution for intravenous infusion after dilution in 0.9% or 0.45% Sodium Chloride Solution. It is supplied as an individually packaged, single-dose vial.

CODING

| Applicable NDC Codes | |
|----------------------|---|
| 50242-0142-01 | Lunsumio (mosunetuzumab-axgb) 1mg/1ml-30ml solution in a single dose vial |
| 50242-0159-01 | Lunsumio (mosunetuzumab-axgb) 1mg/1ml-1ml solution in a single dose vial |

| Applicable Procedure Code | |
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| J9999 | Not otherwise classified, antineoplastic drug |

| Applicable ICD-10 Codes | |
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| C82.00 | Follicular lymphoma grade I unspecified site |

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| 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 |

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| 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 |
| C82.6 | 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 follicle 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 |

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| 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 |

EVIDENCE BASED REFERENCES

1. Lunsumio [package insert]. San Francisco, CA; Genentech, Inc; December 2022. Accessed February, 2023.
2. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for B-Cell Lymphomas, Version 5.2022. 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 February 2023.

POLICY HISTORY

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| Original Effective Date | 2/28/2023 |
| Revised Date | |
| P&T Committee Endorsement | 02/28/2023 |
| Updated to Brand New Day/Central Health Medicare Plan | 01/01/2024 |