

Lunsumio (mosunetuzumab-axgb)

Effective Date: 7/1/2023

Revision Date(s): 6/6/2023; 3/14/2024

Review Date: 3/14/2024

Policy type: Medical Necessity

Line of Business: Commercial

Authorizations are for 6 months, after which time they must be reviewed for efficacy, safety, and tolerability. For patients who achieve a complete response (CR), no further treatment beyond 8 cycles is recommended. For patients who achieve a partial response (PR) or have stable disease (SD), a total of 17 cycles are recommended, unless the patient experiences disease progression or unacceptable toxicity.

Universal Criteria:

- Dose and frequency should be consistent with FDA labeling, NCCN, or indication specific peer-reviewed literature; **AND**
- Lunsumio is being used as a single agent; **AND**
- Patient must be 18 years of age or older; **AND**
- If a request is made in which NCCN Guidelines or NCCN Compendia make a statement that a specified use of a medication is not recommended that guidance is used to determine medical necessity. The absence of a supportive statement in the FDA indication does not imply universal support.

Indication Specific Criteria:

Follicular Lymphoma – Relapsed or Refractory (Grade 1, 2 or 3A)

- As a 3rd line or later therapy; **AND**
 - Prior therapy includes anti-CD20 therapy (e.g., rituximab) and an alkylating agent (e.g., cyclophosphamide); **AND**
 - Patient has not had prior treatment with chimeric antigen receptor T-cell (CART-T) therapy within 30 days before administration; **AND**
 - Patient has an Eastern Cooperative Oncology Group (ECOG) score of 0 or 1¹; **AND**
 - Patient has no prior history of allogeneic transplant; **AND**
 - Patient has no prior history of autologous stem cell transplant within the past 100 days; **AND**
 - Patient has no active infection (e.g. viral, bacterial, fungal) such as HIV, active hepatitis B or active hepatitis C; **AND**
 - Patient has no prior history of CNS lymphoma or CNS disorders.

¹ ECOG score of 2 or 3 will be considered on a case-by-case basis.

Approval Criteria:

Unless otherwise noted above review criteria used by OncoHealth to determine medical necessity for anticancer treatments and supportive agents include, but is not limited to:

- New drugs or regimens (combinations of drugs) approved by the United States Food and Drug Administration (FDA).
- Drugs and biologics may be used off-label if they are considered medically accepted or necessary if supported by any of the following 5 compendia below.
 - NCCN Drugs & Biologics Compendium® (Category 1 and 2a)
 - Clinical Pharmacology (Strong For)
 - American Hospital Formulary Service Drug Information (AHFS DI) (Level 1)
 - Thompson Micromedex DrugDex® (Class I and IIa)
 - Wolters Kluwer Lexi-Drugs® (Level A)
- Other uses of drugs and biologics may be considered medically accepted if supported as safe and effective according to peer-reviewed articles from one of the following journals
 - American Journal of Medicine; Annals of Internal Medicine; Annals of Oncology; Annals of Surgical Oncology; Biology of Blood and Marrow Transplantation; Blood; Bone Marrow Transplantation; British Journal of Cancer; British Journal of Hematology; British Medical Journal; Cancer; Clinical Cancer Research; Drugs; European Journal of Cancer (formerly the European Journal of Cancer and Clinical Oncology); Gynecologic Oncology; International Journal of Radiation, Oncology, Biology, and Physics; JAMA Oncology, The Journal of the American Medical Association, Journal of Clinical Oncology; Journal of the National Cancer Institute; Journal of the National Comprehensive Cancer Network (NCCN); Journal of Urology; Lancet; Lancet Oncology; Leukemia; The New England Journal of Medicine; The New England Journal of Medicine: Evidence; Radiation Oncology
 - **Meeting abstracts and case reports are excluded from consideration.**
- Non-standard protocols may be approved based on unique clinical circumstances.

Billing

Drug Name	HCPCS Code	Description
Lunsumio	J9350	Injection, mosunetuzumab-axgb, 1 mg

References

1. Lunsumio [package insert]. Genetech, South San Francisco, CA. Available at: https://www.gene.com/download/pdf/lunsumio_prescribing.pdf
2. Lunsumio. NCCN Drugs and Biologics Compendium. Available at: https://www.nccn.org/professionals/drug_compendium/content/
3. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®). National Comprehensive Cancer Network, Inc. 2024. All rights reserved. Accessed March 14th 2024. To view the most recent and complete version of the guideline, go online to NCCN.org.

Disclaimer

Consideration of medically necessary indications are based upon U.S. Food and Drug Administration (FDA) indications, recommended uses within the Centers of Medicare & Medicaid Services (CMS) five recognized compendia, including the National Comprehensive Cancer Network (NCCN) Drugs & Biologics Compendium (Category 1 or 2A recommendations), and peer-reviewed scientific literature eligible for coverage according to the CMS, Medicare Benefit Policy Manual, Chapter 15, section 50.4.5 titled, “Off-Label Use of Anti-Cancer Drugs and Biologics.” This policy evaluates whether the drug therapy is proven to be effective based on published evidence-based medicine. OncoHealth reserves the right to request medical documentation as needed to validate medical necessity determinations.

Drug Coverage Policies are developed as needed, regularly reviewed, updated at least annually, and are subject to change. Other policies and coverage determination guidelines may apply. Federal and state regulatory requirements and member specific benefit plan documents, if applicable, must be reviewed prior to this Drug Coverage Policy. This Drug Coverage Policy is for informational purposes only and does not constitute medical advice or dictate how providers should practice medicine. This policy should not be reproduced, stored in a retrieval system, or altered from its original form without written permission from OncoHealth, Inc.

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Date	Updates
6/6/23	Policy creation
3/14/24	Updated Universal Criteria; Updated Indication Specific Criteria; Updated References