

Medical Policy:

Lunsumio (mosunetuzumab-axgb), intravenous injection

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.378	February 2, 2024	February 9, 2023

Medical Guideline Disclaimer Property of EmblemHealth. All rights reserved.

The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as "EmblemHealth"), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

Definitions

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

Length of Authorization

17 cycles

Dosing Limits [Medical Benefit]

- The recommended dosage for LUNSUMIO is presented in Table 1.
- Administer for 8 cycles, unless patients experience unacceptable toxicity or disease progression.
- 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.

Table 1. Recommended LUNSUMIO Dose and Schedule (21-Day Treatment Cycles)

Day of Treatment		Dose of LUNSUMIO	Rate of Infusion
Cycle 1	Day 1	1 mg	Administer over a minimum of 4
	Day 8	2 mg	hours.
	Day 15	60 mg	
Cycle 2	Day 1	60 mg	Administer over 2 hours if infusions
Cycles 3+	Day 1	30 mg	from Cycle 1 were well-tolerated.

Guideline

I. INITIAL CRITERIA

- 1. <u>Follicular Lymphoma.</u> Approve for 1 year if the patient meets the following criteria (A, B, and C):
 - A. Patient is ≥ 18 years of age; AND
 - B. Patient has received ≥ two lines of systemic therapy; **AND**<u>Note</u>: Examples of systemic therapy include CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone) plus rituximab or Gazyva (obinutuzumab intravenous infusion) and CVP (cyclophosphamide, vincristine, prednisone) plus rituximab or Gazyva.
 - C. The medication is prescribed by or in consultation with an oncologist.

Applicable Procedure Codes

Code	Description
J9399	Lunsumio 30mg/30mL Solution Unclassified drugs or biologicals
J9999	Lunsumio 1mg/mL Solution J9999 Not otherwise classified, antineoplastic drugs
J9350	Lunsumio 1mg/mL Solution J9350 Injection, mosunetuzumab-axgb, 1 mg (Code reused effective 7/1/2023)

Applicable NDCs

Code	Description
50242-0142-01	Lunsumio 1mg/1ml -30mL
50242-0159-01	Lunsumio 1mg/ml-1mL

ICD-10 Diagnoses

Code	Description
C8293	Follicular lymphoma, unspecified, intra-abdominal lymph nodes
C8294	Follicular lymphoma, unspecified, lymph nodes of axilla and upper limb
C8295	Follicular lymphoma, unspecified, lymph nodes of inguinal region and lower limb
C8296	Follicular lymphoma, unspecified, lymph nodes of intrapelvic regions

Revision History

Company(ies) DATE	REVISION
-------------------	----------

EmblemHealth & ConnectiCare	2/2/2024	Annual Review: No criteria changes
EmblemHealth & ConnectiCare	6/06/2023	Annual Review: No criteria changes Added coded J9350
EmblemHealth & ConnectiCare	02/09/2023	New Policy

References

1. Product Information: LUNSUMIO™ intravenous injection, mosunetuzumab-axgb intravenous injection. Genentech Inc (per FDA), South San Francisco, CA, 2022.