Medical Policy:

Lynozyfic (linvoseltamab-gcpt) injection

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.441	August 7, 2025	August 7, 2025

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. 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

LYNOZYFIC is indicated for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody.

Length of Authorization

Initial: Prior authorization validity will be provided initially for 6 months, following initial inpatient administration of 2 doses (step-up dose 1, step-up dose 2).

Renewal: Prior authorization validity may be renewed every 6 months thereafter.

Dosing Limits [Medical Benefit]

Recommended Linvoseltamab IV Dosing Schedule[e]

Dosing schedule	Day[a]	Linvoseltamab dose and infusion duration	
Step-up dosing schedule	Day 1	Step-up dose 1	**IV:** 5 mg over 4 hours
	Day 8	Step-up dose 2	**IV:** 25 mg over 4 hours
	Day 15	First treatment dose	**IV:** 200 mg over 4 hours
Weekly dosing schedule	Beginning 1 week after day 15 of treatment. Administer once weekly from week 4 to week 13 (total: 10 treatment doses)	Second treatment dose and subsequent treatment doses	**IV:** 200 mg over 1 hour (for second treatment dose), and over 30 minutes (for subsequent treatment doses)[b]
Biweekly (every 2 weeks) dosing schedule	Beginning week 14 and every 2 weeks thereafter	Subsequent treatment doses	**IV:** 200 mg over 30 minutes
Patients who achieve and maintain VGPR[d] or better at or after week 24 **and** have received at least 17 doses of linvoseltamab 200 mg may decrease dosing frequency to every 4 weeks.			
Every 4-week dosing schedule	Beginning on or after week 24 and every 4 weeks thereafter[c]	Subsequent treatment doses	**IV:** 200 mg over 30 minutes

[a] Administer weekly doses at least 5 days apart, biweekly doses at least 10 days apart, and every 4-week doses at least 24 days apart.

[b] If cytokine release syndrome (CRS) occurred with the previous dose, maintain the infusion duration at the rate from the previous infusion; reduce the duration of infusion sequentially in subsequent doses in patient who do not experience CRS (eg, 4 hours, 1 hour, then 30 minutes).

[c] Continue linvoseltamab until disease progression or unacceptable toxicity.

[d] VGPR = very good partial response.

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

- Step-up Dosing
  - Day 1: 5 mg
  - Day 8: 25 mg
- Treatment Dosing
  - Day 15: 200 mg
  - Weekly (starting one week after day 15 through week 13 for ten doses): 200 mg
  - Bi-weekly (starting week 14 and every 2 weeks thereafter for at least 17 doses: 200 mg
- Maintenance Dosing
  - Every 4 weeks (starting after at least week 24 and after at least 17 doses): 200 mg

Guideline

INITIAL CRITERIA

Prior authorization validity is provided in the following conditions:

- Patient is at least 18 years of age; **AND**
- Used as continuation therapy following inpatient administration of all step-up doses; **AND**
- Patient had an absence of unacceptable toxicity while on inpatient administration; **AND**
- Patient does not have an active infection, including clinically important localized infections; **AND**
- Patient will be administered prophylaxis for infection (*e.g., antimicrobials, antibiotics, antifungals, antivirals, vaccines, and subcutaneous or intravenous immunoglobulin (IVIG*)) according to local guidelines; **AND**
- Patient immunoglobulin levels will be monitored prior to and during therapy and treated appropriately; **AND**

- Patient does not have active CNS involvement or clinical signs of meningeal involvement from multiple myeloma; **AND**
- Patient has not had an allogeneic stem cell transplant or an autologous stem cell transplant within the previous 12 weeks; **AND**

Multiple Myeloma †

- Patient has relapsed or refractory disease; **AND**
- Used as a single agent; **AND**
- Patient has received at least four (4) prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent and an anti-CD38 monoclonal antibody

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Φ Orphan Drug

RENEWAL CRITERIA

Prior authorization validity may be renewed based upon the following criteria:

- 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 Initial Criteria; **AND**
- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: neurologic toxicity including Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS), severe administration-related/local injection-site reactions, cytokine release syndrome (CRS), hepatotoxicity, neutropenia/febrile neutropenia, severe infections, etc.

Applicable Procedure Codes

Code	Description
C9399	Unclassified drugs or biologicals
J9999	Not otherwise classified, antineoplastic drugs

Applicable NDCs

Code	Description
61755-0054-00	Lynozyfic 5 mg/2.5mL
61755-0054-01	Lynozyfic 5 mg/2.5mL
61755-0056-00	Lynozyfic 200 mg/10mL
61755-0056-01	Lynozyfic 200 mg/10mL

ICD-10 Diagnoses

Code	Description
C90.00	Multiple Myeloma Not Having Achieved Remission
C90.02	Multiple Myeloma In Relapse
C90.10	Plasma cell leukemia not having achieved remission
C90.12	Plasma cell leukemia in relapse
C90.20	Extramedullary plasmacytoma not having achieved remission
C90.22	Extramedullary plasmacytoma in relapse

C90.30	Solitary plasmacytoma not having achieved remission
C90.32	Solitary plasmacytoma in relapse
Z85.79	Personal history of other malignant neoplasms of lymphoid, hematopoietic and related tissues

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	08/07/2025	New Policy

References

1. Lynozyfic (linvoseltamab) [prescribing information]. Tarrytown, NY: Regeneron Pharmaceuticals Inc; July 2025.