

Medical Drug Clinical Criteria

Subject: Lynozyfic (linvoseltamab-gcpt)

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Overview

This document addresses the use of. Lynozyfic is a bispecific B-cell maturation antigen (BCMA)-directed CD3 T-cell engager.

The FDA approved indicated Lynozyfic 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.

Lynozyfic can be dosed 200 mg every 4 weeks if patients achieve a very good partial response (VGPR).

The National Comprehensive Cancer Network® (NCCN) has yet to review this new drug.

The Lynozyfic label includes a Boxed Warning for cytokine release syndrome (CRS) and neurologic toxicity, including immune effector cell-associated neurotoxicity syndrome (ICANS). As a result of these risks, Lynozyfic is only available through the Lynozyfic Risk Evaluation and Mitigation Strategy (REMS).

Definitions and Measures

ECOG or Eastern Cooperative Oncology Group Performance Status: A scale and criteria used by doctors and researchers to assess how an individual's disease is progressing, assess how the disease affects the daily living abilities of the individual, and determine appropriate treatment and prognosis. This scale may also be referred to as the WHO (World Health Organization) or Zubrod score which is based on the following scale:

- 0 = Fully active, able to carry on all pre-disease performance without restriction
- 1 = Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, for example, light house work, office work
- 2 = Ambulatory and capable of all self-care but unable to carry out any work activities. Up and about more than 50% of waking hours
- 3 = Capable of only limited self-care, confined to bed or chair more than 50% of waking hours
- 4 = Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair
- 5 = Dead

Multiple myeloma: A type of cancer that begins in plasma cells (white blood cells that produce antibodies).

Refractory Disease: Illness or disease that does not respond to treatment.

Relapse or recurrence: After a period of improvement, during which time a disease (for example, cancer) could not be detected, the return of signs and symptoms of illness or disease. For cancer, it may come back to the same place as the original (primary) tumor or to another place in the body.

Clinical Criteria

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

Lynozytic (linvoseltamab-gcpt)

Requests for Lynozytic (linvoseltamab-gcpt) may be approved if the following criteria are met:

- I. Individual has a diagnosis of relapsed or refractory multiple myeloma (Label); **AND**
- II. Individual has had at least four prior therapies, including an anti-CD38 monoclonal antibody (e.g. daratumumab), a proteasome inhibitor (e.g. bortezomib, ixazomib, or carfilzomib), and an immunomodulatory agent (e.g. lenalidomide or pomalidomide); **AND**
- III. Individual has a current Eastern Cooperative Oncology Group (ECOG) performance status of 0-1; **AND**
- IV. No prior treatment with any B-cell maturation antigen (BCMA) targeted therapy.

Requests for Lynozytic (linvoseltamab-gcpt) may not be approved when the above criteria are not met and for all other indications.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

HCPCS

C9399	Unclassified drugs or biologicals [when specified as Lynozytic (linvoseltamab-gcpt)]
J9999	Not otherwise classified, antineoplastic drugs [when specified as Lynozytic (linvoseltamab-gcpt)]

ICD-10 Diagnosis

All diagnosis pend.

Document History

New: 08/15/2025

Document History:

- 08/15/2025 – Select Review: New PA criteria document for Lynozytic. Coding Reviewed: Added HCPCS NOC C9399, J9999 and all diagnosis pend for Lynozytic.

References

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Updated periodically.
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc. Updated periodically.
4. NCCN Clinical Practice Guidelines in Oncology™. © 2025 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on July 11, 2025.
 - a. Multiple Myeloma V1.2026. Revised June 24, 2025.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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