Lynozyfic® (linvoseltamab-gcpt)

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the policy is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. The indications below including FDA-approved indications and compendial uses are considered covered benefits provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

Lynozyfic is indicated for the treatment 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.

POLICY

Required Documentation

Submission of the following information is necessary to initiate the prior authorization review: chart notes or medical record documentation demonstrating failure of previous lines of therapy.

Criteria for Initial Approval

Multiple Myeloma

Authorization of 12 months may be granted for treatment of relapsed or refractory multiple myeloma when the member has received at least 4 prior therapies, including at least one drug from each of the following categories:

1. Proteasome inhibitor (e.g., bortezomib, ixazomib, carfilzomib)
2. Immunomodulatory agent (e.g., lenalidomide, pomalidomide, thalidomide)
3. Anti-CD38 monoclonal antibody (e.g., daratumumab, isatuximab)

Continuation of Therapy

Multiple Myeloma
Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in the criteria for initial approval section when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

Other
Lynozyfic (linvoseltamab-gcpt) is considered **not medically necessary** for members who do not meet the criteria set forth above.

Dosing and Administration
Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

- C9307 – Injection, linvoseltamab-gcpt, 1 mg (cancelled 3/31/2026)
- J9601 – Injection, linvoseltamab-gcpt, 1 mg (effective 4/1/26)
- J3490 – unclassified drugs
- J3590 – unclassified biologics
- J9999 – not otherwise classified, antineoplastic drugs
- C9399 – unclassified drugs or biologicals

REFERENCES

Lynozyfic [package insert]. Tarrytown, NY: Regeneron Pharmaceuticals, Inc.; July 2025.

POLICY HISTORY

Policy #: 05.06.01

Original Effective Date: September 27, 2025

Reviewed:

Revised:

Current Effective Date: September 27, 2025