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Section:	Prescription Drugs	**Effective Date:**	January 1, 2026
Subsection:	Antineoplastic Agents	**Original Policy Date:**	August 1, 2025
Subject:	Lynozyfic	**Page:**	1 of 4

Last Review Date: December 12, 2025

Lynozyfic

Description

Lynozyfic (linvoseltamab-gcpt)

Background
Lynozyfic (linvoseltamab-gcpt) is a bispecific T-cell engaging antibody that binds to the CD3 receptor expressed on the surface of T-cells and B-cell maturation antigen (BCMA) expressed on the surface of multiple myeloma cells and some healthy B-lineage cells. In vitro, Lynozyfic activated T-cells, caused the release of various proinflammatory cytokines, and resulted in the lysis of multiple myeloma cells (1).

Regulatory Status
FDA-approved indication: Lynozyfic is a bispecific BCMA-directed CD3 T-cell engager 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 (1).

Lynozyfic has a boxed warning regarding cytokine release syndrome (CRS) and neurotoxicity. Initiate treatment with Lynozyfic step-up dosing schedule to reduce risk of CRS. Withhold dose until CRS resolves or permanently discontinue based on severity. Neurotoxicity, including immune effector cell-associated neurotoxcitiy syndrome (ICANS), and serious and life-threatening reactions, can occur. Monitor patients for signs or symptoms of neurologic toxicity, including ICANS, during treatment. Withold dose until neurologic toxicity resolves or permanently discontinue based on severity. Lynozyfic is only available through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS), called the Lynozyfic REMS (1).

Lynozyfic may cause hepatotoxicity, neutropenia, and infections. Monitor liver enzymes, bilirubin, and complete blood count (CBC) at baseline and during treatment as clinically indicated. Signs and symptoms of infection should be monitored and treated appropriately. Do not initiate treatment in patients with active infections (1).

Lynozyfic can cause fetal harm when administered to a pregnant woman. Pregnant women should be advised of the potential risk to a fetus. Females of reproductive potential should be advised to use effective contraception during treatment with Lynozyfic and for 3 months after the last dose (1).

The safety and effectiveness of Lynozyfic in pediatric patients less than 18 years of age have not been established (1).

Related Policies
Blenrep, Elrexfio, Talvey, Tecvayli

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Lynozyfic may be considered **medically necessary** if the conditions indicated below are met.

Lynozyfic may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Relapsed or refractory multiple myeloma (MM)

AND ALL of the following:

a. Patient has received at least 4 prior therapies, including **ALL** of the following:
   i. Anti-CD38 monoclonal antibody
   ii. Proteasome inhibitor
   iii. Immunomodulatory agent
b. Prescriber is certified with the Lynozyfic REMS program
c. Prescriber agrees to monitor for signs and symptoms of cytokine release syndrome (CRS) and neurologic toxicity
d. Prescriber agrees to monitor liver enzymes, bilirubin, and complete blood cell counts (CBC) at baseline and during treatment as clinically indicated
e. Female patients of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Lynozyfic and for 3 months after the last dose

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Relapsed or refractory multiple myeloma (MM)

AND ALL of the following:
a. **NO** disease progression or unacceptable toxicity
b. Prescriber is certified with the Lynozyfic REMS program
c. Prescriber agrees to monitor for signs and symptoms of cytokine release syndrome (CRS) and neurologic toxicity
d. Prescriber agrees to monitor liver enzymes, bilirubin, and complete blood cell counts (CBC) during treatment as clinically indicated
e. Female patients of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Lynozyfic and for 3 months after the last dose

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Lynozyfic is indicated for the treatment of relapsed or refractory multiple myeloma who have received at least four prior lines of therapy. Lynozyfic has a boxed warning for cytokine release syndrome and neurologic toxicity. Hepatotoxicity, neutropenia, and infections can occur in patients treated with Lynozyfic; therefore liver enzymes, bilirubin, complete blood cell counts, and signs and symptoms of infections must be monitored. The safety and effectiveness of Lynozyfic in pediatric patients less than 18 years of age have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Lynozyfic while maintaining optimal therapeutic outcomes.

References

1. Lynozyfic [package insert]. Tarrytown, NY: Regeneron Pharmaceuticals, Inc.; July 2025.
2. NCCN Drugs & Biologics Compendium® Linvoseltamab-gcpt 2025. National Comprehensive Cancer Network, Inc. Accessed on October 15, 2025.

Policy History

Date	Action
August 2025	Addition to PA
September 2025	Annual review and reference update
December 2025	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 12, 2025 and is effective on January 1, 2026.