

PRIOR AUTHORIZATION POLICY

- POLICY:** Oncology (Injectable – Bispecific – BCMA-Directed) – Lynozyfic Prior Authorization Policy
- Lynozyfic™ (linvoseltamab-gcpt intravenous infusion – Regeneron)

REVIEW DATE: 07/09/2025

OVERVIEW

Lynozyfic, a bispecific B-cell maturation antigen (BCMA)-directed CD3 T-cell engager, is indicated for the treatment of **relapsed or refractory multiple myeloma** in adults who have received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody.¹

This indication is approved under accelerated approval based on response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s).

Guidelines

National Comprehensive Cancer Network (NCCN) multiple myeloma (version 1.2026 – July 16, 2025) recommend chimeric antigen receptor (CAR) T-cell therapies (Abecma™ [idecabtagene vicleucel intravenous infusion] and Carvykti® [ciltacabtagene autoleucel intravenous infusion]) as “Preferred” for relapsed or refractory disease after 3 prior therapies.² Bispecific antibodies (i.e., Lynozyfic, Elrexfio® [elranatamab-bcmm subcutaneous injection], Talvey® [talquetamab-tgvs subcutaneous injection], and Tecvayli® [teclistamab cqyv subcutaneous injection]) are “Preferred” for relapsed or refractory disease after at least 4 therapies, including an anti-CD38 monoclonal antibody, a PI, an IMiD (all category 2A).

Safety

Lynozyfic was approved with a Risk Evaluation and Mitigation Strategy (REMS) program due to the risk of cytokine release syndrome and neurotoxicity, including immune effector cell-associated neurotoxicity syndrome (ICANS).¹

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Lynozyfic. All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Lynozyfic as well as the monitoring required for adverse events and long-term efficacy, approval requires Lynozyfic to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Lynozyfic is recommended in those who meet the following criteria:

FDA-Approved Indication

1. **Multiple Myeloma.** Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):
 - A) Patient is \geq 18 years of age; AND
 - B) Patient has tried at least four systemic regimens; AND
 - C) Among the previous regimens tried, the patient has received at least one drug from each of the following classes (i, ii, and iii):
 - i. Proteasome inhibitor; AND
Note: Examples include bortezomib, Kyprolis (carfilzomib intravenous infusion), Ninlaro (ixazomib capsules).
 - ii. Immunomodulatory drug; AND
Note: Examples include lenalidomide, Pomalyst (pomalidomide capsules), Thalomid (thalidomide capsules).
 - iii. Anti-CD38 monoclonal antibody; AND
Note: Examples include Darzalex (daratumumab intravenous infusion), Darzalex Faspro (daratumumab and hyaluronidase-fihj subcutaneous injection), or Sarclisa (isatuximab-irfc intravenous infusion).
 - D) The medication will be prescribed by or in consultation with an oncologist.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Lynozyfic is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Lynozyfic™ intravenous infusion [prescribing information]. Tarrytown, NY: Regeneron.; July 2025.
2. The NCCN Multiple Myeloma Clinical Practice Guidelines in Oncology (version 1.2026 – July 16, 2025). © 2025 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on July 16, 2025.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	07/09/2025
Update	The overview section was updated to include recommendations for Lynozyfic from the National Comprehensive Cancer Network (NCCN) guidelines.	--