CARECONTINUUM™

UTILIZATION MANAGEMENT MEDICAL POLICY

POLICY: Oncology (Injectable – Bispecific – BCMA-Directed) – Lynozyfic Utilization Management Medical 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 (PI), an immunomodulatory agent (IMiD), 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).

Dosing Information

The dosing schedule of Lynozyfic includes step-up doses of 5 mg (Day 1), 25 mg (Day 8), and 200 mg (Day 15), followed by 200 mg weekly for 10 doses (Week 4 to Week 13), followed by 200 mg every 2 weeks thereafter (Week 14 and every 2 weeks). At Week 24 or beyond, in patients who have achieved and maintained a very good partial response or better and received at least 17 doses of 200 mg every 2 weeks, the dosing interval may be extended to every 4 weeks.

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 medical benefit coverage of Lynozyfic. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indication. Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). 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

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1. Multiple Myeloma. Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):
- **A)** Patient is ≥ 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.

Dosing. Approve the following dosing regimen (A and B):
- **A)** Step-up dosing (i, ii, and iii):
  - **i.** Dose 1: Approve 5 mg administered via intravenous infusion on Day 1; AND
  - **ii.** Dose 2: Approve 25 mg administered via intravenous infusion on Day 8; AND
  - **iii.** Dose 3: Approve 200 mg administered via intravenous infusion on Day 15; AND
- **B)** Approve 200 mg administered via intravenous infusion no more frequently than once weekly.

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 2.2026 – 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.	--