# POLICY Document for LYNOZYFIC

The overall objective of this policy is to support the appropriate and cost-effective use of the medication, specific to use of preferred medication options, and overall, clinically appropriate use. This document provides specific information to both sections of the overall policy.

**Section 1: Clinical Criteria**

- Policy information specific to the clinical appropriateness for the medication

**Section 2: Oncology Clinical Policy**

- Policy information specific to regimen review per NCCN Guidelines.

## Section 1: Clinical Criteria

# Specialty Guideline Management
# Lynozyfic

## Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

| Brand Name | Generic Name |
|---|---|
| Lynozyfic | linvoseltamab-gcpt |

## Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

### FDA-approved Indication[1]

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.

All other indications are considered experimental/investigational and not medically necessary.

# 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.

# Coverage Criteria

## Multiple Myeloma[1]

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:

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

# Continuation of Therapy

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

**REFERENCES:**


**SECTION 1**

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

**SECTION 2**

1. National Comprehensive Cancer Network. *About NCCN*. Available at: https://www.nccn.org/home/about. Accessed September 10, 2025.
2. National Comprehensive Cancer Network. *NCCN Guidelines*. Available at: https://www.nccn.org/guidelines/category_1. Accessed September 10, 2025. *(Note: An account may be required.)*
3. National Comprehensive Cancer Network. *NCCN Drugs and Biologics Compendium*. Available at: https://www.nccn.org/compendia-templates/compendia/drugs-and-biologics-compendia. Accessed September 10, 2025. *(Note: A subscription may be required.)*
4. National Comprehensive Cancer Network. *NCCN Categories of Evidence and Consensus*. Available at: https://www.nccn.org/guidelines/guidelines-process/development-and-update-of-guidelines. Accessed September 10, 2025.