Reference number(s)
7065-A

Standard Medicare Part B 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 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.

All other indications will be assessed on an individual basis. Submissions for indications other than those listed in this criteria should be accompanied by supporting evidence from Medicare approved compendia.

Documentation

The following documentation must be available, upon request, for all submissions: chart notes or medical record documentation demonstrating failure of previous lines of therapy.

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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

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Authorization for 12 months may be granted when all of the following criteria are met:

- The member is currently receiving therapy with the requested medication
- The requested medication is being used to treat an indication listed in the coverage criteria section
- The member is receiving benefit from therapy. Benefit is defined as:
    - No evidence of unacceptable toxicity while on the current regimen, and
    - No evidence of disease progression while on the current regimen

Summary of Evidence

The contents of this policy were created after examining the following resources:

- The prescribing information for Lynozyfic.
- The available compendium
    - National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
    - Micromedex DrugDex
    - American Hospital Formulary Service- Drug Information (AHFS-DI)
    - Lexi-Drugs
    - Clinical Pharmacology

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Lynozyfic are covered.

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Explanation of Rationale

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

References

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

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