Reference number(s)
2304-A

Standard Medicare Part B Management Mylotarg

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
Mylotarg	gemtuzumab ozogamicin

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 Indications[1]

Acute Myeloid Leukemia (AML)

- Newly diagnosed CD33-positive AML in adults and pediatric patients 1 month and older
- Relapsed or refractory CD33-positive AML in adults and pediatric patients 2 years and older

Compendial Uses[2]

Acute Promyelocytic Leukemia (APL)

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

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Documentation

Submission of the following information must be available, upon request, for initial requests: Testing or analysis confirming tumor is CD33-positive.

Coverage Criteria

Acute Myeloid Leukemia (AML)/Acute Promyelocytic Leukemia (APL)[1,2]

Authorization of 12 months may be granted for the treatment of AML/APL if the tumor is CD33-positve as confirmed by testing or analysis to identify the CD33 antigen.

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 the following criteria are met:

- The member is currently receiving therapy with Mylotarg.
- Mylotarg 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 Mylotarg.
- 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
- NCCN Guideline: Acute myeloid leukemia

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After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Mylotarg are covered in addition to acute promyelocytic leukemia.

Explanation of Rationale

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

Support for using Mylotarg to treat acute promyelocytic leukemia can be found in the NCCN Drugs and Biologics Compendium. Use of information in the NCCN Drugs and Biologics Compendium for off-label use of drugs and biologicals in an anti-cancer chemotherapeutic regimen is supported by the Medicare Benefit Policy Manual, Chapter 15, section 50.4.5 (Off-Label Use of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen).

References

1. Mylotarg [package insert]. Philadelphia, PA: Pfizer; August 2021.
2. The NCCN Drugs & Biologics Compendium® © 2025 National Comprehensive Cancer Network, Inc. Available at: https://www.nccn.org. Accessed December 29, 2025.

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