Reference number(s)
2299-A

Specialty Guideline 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 acute myeloid leukemia 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 are considered experimental/investigational and not medically necessary.

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2299-A

Documentation

Submission of the following information is necessary to initiate the prior authorization review: 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 when the tumor is CD33-positive as confirmed by testing or analysis to identify the CD33 antigen.

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

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.