Reference number(s)
2299-A

SPECIALTY GUIDELINE MANAGEMENT

Mylotarg (gemtuzumab ozogamicin)

POLICY

I. 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.

A. FDA-Approved Indications
Acute Myeloid Leukemia (AML)
1. Newly diagnosed CD33-positive acute myeloid leukemia in adults and pediatric patients 1 month and older
2. Relapsed or refractory CD33-positive AML in adults and pediatric patients 2 years and older

B. Compendial Uses
Acute promyelocytic leukemia (APL)

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

II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review: For AML and APL: medical record documentation of CD33-positive tumor as confirmed by testing or analysis to identify the CD33 antigen.

III. CRITERIA FOR INITIAL APPROVAL

A. Acute Myeloid Leukemia (AML)
Authorization of 12 months may be granted for the treatment of AML when the tumor is CD33-positive as confirmed by testing or analysis to identify the CD33 antigen.

B. Acute Promyelocytic Leukemia (APL)
Authorization of 12 months may be granted for the treatment of APL when the tumor is CD33-positive as confirmed by testing or analysis to identify the CD33 antigen.

IV. CONTINUATION OF THERAPY

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

V. REFERENCES

Reference number(s)
2299-A

1. Mylotarg [package insert]. Philadelphia, PA: Pfizer; August 2021.
2. The NCCN Drugs & Biologics Compendium® © 2024 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed January 5, 2024.
3. Lo Coco F, Ammatuna E, Noguera N. Treatment of acute promyelocytic leukemia with gemtuzumab ozogamicin. *Clin Adv Hematol Oncol*. 2006;4(1):57-77.