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.

FDA-Approved Indications
1. Newly diagnosed CD33-positive acute myeloid leukemia in adults
2. Relapsed or refractory CD33-positive AML in adults and pediatric patients 2 years and older

Compendial Use
Mylotarg is indicated in high risk patients with acute promyelocytic leukemia (APL).

All other indications are considered experimental/investigational and are not a covered benefit.

II. CRITERIA FOR INITIAL APPROVAL

Acute Myeloid Leukemia (AML)/ Acute Promyelocytic Leukemia (APL)
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.

III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

IV. REFERENCES

1. Mylotarg [package insert]. Philadelphia, PA: Pfizer; Sept 2017.
2. Clinical Consult. CVS Caremark Clinical Programs Review. Focus on Hem-Onc UM programs. September 12, 2017.