



Prior Authorization Approval Criteria
Department of Pharmacy Services

Generic Name: gemtuzumab ozogamicin

Brand Name: Mylotarg

Medication Class: Antineoplastic antibody-drug complex

FDA Approved Uses: Treatment of patients with CD-33 positive acute myeloid leukemia in first relapse

Usual Dose: 9mg/M² x 2 doses, 14 days apart
2 hour infusion, premedicated with acetaminophen and diphenhydramine

Duration of Therapy: Indefinite

Criteria for Use: *(bullet points below are all inclusive unless otherwise noted)*

- CD33-positive acute myelocytic leukemia (AML)
- History of treatment with conventional combination chemotherapy including cytarabine and an anthracycline antibiotic such as idarubicin
- 60 years of age or older
- First time relapse

Special Issues:

- No studies available on the use of gemtuzumab as first line therapy.



P&T Approval: _____ Date: _____