SmartHealth Ascension

Gemtuzumab Ozogamicin

(Mylotarg®) J9203 (0.1mg)

Covered with prior authorization

Gemtuzumab ozogamicin (Mylotarg®) may be authorized when the following criteria are met:

- Individual has a diagnosis of CD33+ acute myeloid leukemia (AML); **AND**

- Individual is using for one of the following:
  - Newly-diagnosed AML; **OR**
  - Relapsed or refractory AML; **AND** is 2 years of age or older
- Medication is prescribed by provider specialized in hematology or oncology.

OR

- Individual has a diagnosis of acute promyelocytic leukemia (APL); **AND**
- Individual has high-risk; **OR**
- Low risk disease when arsenic is contraindicated; **AND**
- Individual is ineligible for treatment with an anthracycline.

Exclusion criteria:
Requests for Gemtuzumab ozogamicin (Mylotarg®) may not be approved for the following:

- Product use for non-FDA approved indications or indications not supported by industry-accepted guidelines
- Doses, durations, or dosing intervals that exceed FDA maximum limits for any FDA-approved indication or are not supported by industry-accepted practice guidelines or peer-reviewed literature for the relevant off-label use

Initial authorization is up to 12 months.

Annual reauthorizations will require medical chart documentation that the patient has been seen within the past 12 months and that markers of disease are improved by therapy

Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

U.S. Food and Drug Administration:

This section is to be used for informational purposes. FDA approval alone is not a basis for coverage.

Mylotarg® is a CD33-directed antibody and cytotoxic drug conjugate indicated for:

- Treatment of newly-diagnosed CD33-positive acute myeloid leukemia (AML) in adults and pediatric patients 1 month and older.
- Treatment of relapsed or refractory CD33-positive AML in adults and pediatric patients 2 years and older.

References:

1. Amadori S, Suciu S, Selleslag D, et al. Gemtuzumab ozogamicin versus best supportive care in older patients with newly diagnosed acute myeloid leukemia unsuitable for intensive chemotherapy: results of the randomized phase III EORTC-GIMEMA AML-19 trial. J Clin Oncol. 2016; 34(9):972-979
2. Castaigne S, Pautas C, Terré C, et al; Acute Leukemia French Association. Effect of gemtuzumab ozogamicin on survival of adult patients with de-novo acute myeloid leukaemia (ALFA-0701): a randomised, open-label, phase 3 study. Lancet. 2012; 379(9825):1508-1516.
3. Hills RK, Castaigne S, Appelbaum FR, et al. Addition of gemtuzumab ozogamicin to induction chemotherapy in adult patients with acute myeloid leukaemia: a meta-analysis of individual patient data from randomised controlled trials. Lancet Oncol. 2014; 15(9):986-996.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2022; Updated periodically.
5. Mylotarg® [Prescribing Information]. Philadelphia,PA: Wyeth Pharmaceuticals., 2023.
6. NCCN Clinical Practice Guidelines in Oncology™. © 2022 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp.

Date	Summary of Changes
January 2023	Criteria for use summary developed by the Ascension Medical Specialty Prior Authorization Team.
February 2023	Criteria for use summary approved by the Ascension Hematology/Oncology Expert Review Panel.
March 2023	Criteria for use summary approved by the Ascension Therapeutic Affinity Group.

If you have questions, call 833-980-2352 to speak to a member of the Ascension Rx prior authorization team, or email your questions to smarthealthspecialty@ascension.org.