Mylotarg (gemtuzumab ozogamicin)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 Year

Medications	Quantity Limit
Mylotarg (gemtuzumab ozogamicin)	May be subject to quantity limit

APPROVAL CRITERIA

Requests for Mylotarg (gemtuzumab ozogamicin) may be approved if the following criteria are met:

I. Individual has a diagnosis of CD33-positive acute myeloid leukemia (AML); **AND**
II. Individual is using for one of the following:
   A. As induction therapy for AML; **OR**
   B. As consolidation therapy for AML; **OR**
   C. As treatment for relapsed or refractory AML;

OR

III. Individual has a diagnosis of acute promyelocytic leukemia (APL) (NCCN 2A); **AND**
   A. Individual has high-risk disease.

Requests for Mylotarg (gemtuzumab ozogamicin) may not be approved if the above criteria are not met, and for all other indications.

Key References:

1. Abaza Y, Kantarjian H, Garcia-Manero G, et al. Long-term outcome of acute promyelocytic leukemia treated with all-trans-retinoic acid, arsenic trioxide, and gemtuzumab. Blood. 2017; 129(10):1275-1283.
2. 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
3. Burnett AK, Hills RK, Milligan D, et al. Identification of patients with acute myeloblastic leukemia who benefit from the addition of gemtuzumab ozogamicin: results of the MRC AML 15 trial. J Clin Oncol 2011; 29:369-377.
4. Burnett AK, Russell NH, Hills RK, et al. Arsenic trioxide and all-trans retinoic acid treatment for acute promyelocytic leukaemia in all risk groups (AML17): results of a randomised, controlled, phase 3 trial. *Lancet Oncol*. 2015;16(13):1295-1305.
5. 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.
6. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: January 20, 2023.
7. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.

8. 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.
9. Lambert J, Pautas C, Terré C et al. Gemtuzumab ozogamicin for de novo acute myeloid leukemia: final efficacy and safety updates from the open-label, phase 3 ALFA-0701 trial. Haematologica. 2018 Aug 3; Epub ahead of print.
10. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2023; Updated periodically.
11. Southwest Oncology Group. A phase III study of the addition of gemtuzumab ozogamicin (Mylotarg®) during induction therapy versus standard induction with daunomycin and cytosine arabinoside followed by consolidation and subsequent randomization to post-consolidation therapy with gemtuzumab ozogamicin (Mylotarg®) or no additional therapy for patients under age 61 with previously untreated de novo acute myeloid leukemia (AML). NLM Identifier: NCT00085709; SWOG Identifier S0106. Last updated on September 25, 2015. Available at: https://clinicaltrials.gov/ct2/show/results/NCT00085709. Accessed on March 22, 2019.
12. Petersdorf SH, Kopecky KJ, Slovak M, et al. A phase 3 study of gemtuzumab ozogamicin during induction and postconsolidation therapy in younger patients with acute myeloid leukemia. Blood. 2013; 121(24):4854-4860.
13. NCCN Clinical Practice Guidelines in Oncology™. © 2023 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Accessed on January 20, 2023.
    a. Acute Myeloid Leukemia. V3.2022. Revised January 13, 2022.

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.