| Market Applicability | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Market** | **DC** | **FL & FHK** | **FL MMA** | **FL LTC** | **GA** | **KS** | **KY** | **MD** | **NJ** | **NV** | **NY** | **TN** | **TX** | **WA** |
| **Applicable** | X | X | NA | NA | X | NA | X | X | X | X | X | NA | NA | X |

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# Mylotarg (gemtuzumab ozogamicin)

DRUG.00112

| Override(s) | Approval Duration |
|---|---|
| Prior Authorization | 1 Year |

| Medications | Quantity Limit |
|---|---|
| Mylotarg (gemtuzumab ozogamicin) | May be subject to quantity limits |

## APPROVAL CRITERIA

I. Requests for Mylotarg (gemtuzumab ozogamicin) may be approved for the treatment of the following indications:
   A. Newly-diagnosed CD33-positive acute myeloid leukemia (AML) in adults greater than or equal to 18 years of age; **OR**
   B. Relapsed or refractory CD33-positive AML in adults and in children 2 years of age and older; **OR**
   C. Acute promyelocytic leukemia (APL) in high-risk individuals who are ineligible for treatment with anthracycline.

Requests for Mylotarg (gemtuzumab ozogamicin) may **not** be approved when the criteria above have not been met, and for all other indications.

| State Specific Mandates | | |
|---|---|---|
| State name | Date effective | Mandate details (including specific bill if applicable) |
| N/A | N/A | N/A |


1. National Cancer Institute (NCI). Available at: https://www.cancer.gov/types/leukemia/hp/adult-aml-treatment-pdq. Accessed on September 1, 2017
   - Adult Acute Myeloid Leukemia Treatment (PDQ®)–Health Professional Version. Modified January 20, 2017.
2. Mylotarg™ [Product Information], Philadelphia, PA. Wyeth Pharmaceuticals Inc. Updated on September 1, 2017. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/761060lbl.pdf. Accessed on September 11, 2017.
3. NCCN Clinical Practice Guidelines in Oncology© 2017 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org. Accessed on March 31, 2017.
   - Acute Myeloid Leukemia (V3.2017). Revised June 6, 2017.

| Market Applicability | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Market** | **DC** | **FL & FHK** | **FL MMA** | **FL LTC** | **GA** | **KS** | **KY** | **MD** | **NJ** | **NV** | **NY** | **TN** | **TX** | **WA** |
| **Applicable** | X | X | NA | NA | X | NA | X | X | X | X | X | NA | NA | X |

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3. 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 September 1, 2017.