

## Mylotarg (gemtuzumab ozogamicin)

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**Line(s) of Business:**

HMO; PPO; QUEST Integration  
Medicare Advantage

**Original Effective Date:**

12/01/2018

**POLICY**

**A. 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

Acute myeloid leukemia:

For the treatment induction for patients with CD33-positive AML

- in patients age <60 years in combination with standard-dose cytarabine and daunorubicin (the addition of gemtuzumab ozogamicin may benefit patients with core binding factor (CBF) abnormalities)
- in patients age ≥60 years in combination with standard-dose cytarabine and daunorubicin in candidates for intensive remission induction therapy with de novo AML without unfavorable cytogenetics/molecular markers/no antecedent hematologic disorder/no therapy-related AML
- in patients age ≥60 years as a single agent when not a candidate for intensive remission induction therapy or declines intensive therapy

For post-remission therapy for patients with CD33-positive AML

- in combination with intermediate-dose cytarabine and daunorubicin for patients age <60 years with core binding factor (CBF) cytogenetic translocations without KIT mutation or favorable-risk molecular abnormalities, or intermediate-risk cytogenetics and/or molecular abnormalities
- in combination with intermediate-dose cytarabine and daunorubicin for patients age ≥60 years with complete response to previous intensive therapy
- as a single agent following response to previous lower intensity therapy

For relapsed/refractory disease for patients with CD33-positive AML

- as a component of repeating the initial successful induction regimen if late relapse (≥12 months)
- as a single agent

Acute promyelocytic leukemia:

For treatment induction in high-risk disease (white blood cell count >10,000/mcL) in patients with no cardiac issues in combination with tretinoin (ATRA) and arsenic trioxide (preferred regimen)

For treatment induction in high-risk disease (white blood cell count >10,000/mcL) in patients with cardiac issues (low ejection fraction [EF] or prolonged QTc)

- in combination with tretinoin (ATRA) and arsenic trioxide
- in combination with ATRA (for patients not able to tolerate arsenic trioxide for reasons including prolonged QTc)

For consolidation therapy in high-risk disease (white blood cell count >10,000/mcL) in patients with no cardiac issues

- in combination with tretinoin (ATRA) if arsenic trioxide was discontinued due to toxicity (preferred regimen)
- in combination with arsenic trioxide if ATRA was discontinued due to toxicity (preferred regimen)

For consolidation therapy in high-risk disease (white blood cell count >10,000/mcL) in patients with cardiac issues (low ejection fraction [EF] or prolonged QTc)

- in combination with tretinoin (ATRA) if arsenic trioxide was discontinued due to toxicity
- in combination with arsenic trioxide if ATRA was discontinued due to toxicity
- in combination with ATRA (for patients not able to tolerate arsenic trioxide for reasons which may include prolonged QTc)

Therapy for first relapse (morphologic or molecular)

- in combination with arsenic trioxide, with or without tretinoin (ATRA), in patients with no prior exposure to arsenic trioxide or early relapse (<6 months) after ATRA + anthracycline-containing regimen
- in combination with arsenic trioxide, with or without ATRA, in patients with late relapse (≥6 months) after arsenic trioxide-containing regimen

## **B. REQUIRED DOCUMENTATION**

The following information is necessary to initiate the prior authorization review:

- Initial therapy
  - Documentation showing tumor is CD33-positive as confirmed by testing or analysis to identify the CD33 antigen.
- Continuation of therapy
  - Documentation showing benefit from receiving Mylotarg therapy.

## **C. EXCLUSIONS**

- Tumors that are not CD33-positive
- Use for any other indication other than Acute Myeloid Leukemia (AML) or Acute Promyelocytic Leukemia (APL).

## **D. CRITERIA FOR APPROVAL**

### **1. Acute Myeloid Leukemia (AML)**

Authorization of 12 months may be granted for the treatment of AML if the tumor is CD33-positive as confirmed by testing or analysis to identify the CD33 antigen when the member has any of the following conditions:

- a. For treatment induction in CD33 positive AML
  - i. Members over the age of 60

- ii. In combination with cytarabine and daunorubicin
- iii. Candidates for intensive remission

## **2. Acute Promyelocytic Leukemia (APL)**

Authorization of 12 months may be granted for the treatment of APL if the tumor is CD33-positive as confirmed by testing or analysis to identify the CD33 antigen when the member has the following conditions:

- a. For treatment induction in high risk disease
  - i. In combination with tretinoin and arsenic trioxide
  - ii. In combination with ATRA
- b. For consolidation therapy in high risk disease
  - i. In combination with arsenic trioxide
  - ii. In combination with tretinoin
  - iii. In combination with ATRA

## **E. CONTINUATION OF THERAPY**

### **Acute Myeloid Leukemia (AML)/ Acute Promyelocytic Leukemia (APL)**

1. No previous authorization/precertification:  
All members (including new members and members currently receiving treatment without prior authorization) must meet criteria for initial approval in section D.
2. Reauthorization:  
Members who were previously approved for Mylotarg by HMSA/CVS may request reauthorizations after their initial approval. Approval for an additional 3 months may be granted when the following documentation shows no progression of disease:
  - A current oncology note documenting the patient's response to treatment showing no progression of disease
  - Current imaging studies and other objective measures showing no progression of disease when compared with previous results

## **F. DOSAGE AND ADMINISTRATION**

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

## **G. ADMINISTRATIVE GUIDELINES**

Precertification is required. Please refer to the [HMSA medical policy web site](#) for the fax form.

## **H. IMPORTANT REMINDER**

The purpose of this Medical Policy is to provide a guide to coverage. This Medical Policy is not intended to dictate to providers how to practice medicine. Nothing in this Medical Policy is intended to discourage or prohibit providing other medical advice or treatment deemed appropriate by the treating physician.

Benefit determinations are subject to applicable member contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control.

This Medical Policy has been developed through consideration of the medical necessity criteria under Hawaii's Patients' Bill of Rights and Responsibilities Act (Hawaii Revised Statutes §432E-1.4),

generally accepted standards of medical practice and review of medical literature and government approval status. HMSA has determined that services not covered under this Medical Policy will not be medically necessary under Hawaii law in most cases. If a treating physician disagrees with HMSA/ CVS's determination as to medical necessity in a given case, the physician may request that HMSA reconsider the application of the medical necessity criteria to the case at issue in light of any supporting documentation.

## I. REFERENCES

1. Mylotarg [package insert]. Philadelphia, PA: Pfizer; Sept 2017.
2. The NCCN Drugs & Biologics Compendium™. © 2018 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed March 27th 2018.

## Document History

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