Gemtuzumab ozogamicin (Mylotarg™)	Place of Service Office Administration Infusion Center Administration Outpatient Facility Administration Home Infusion HCPCS: **J9203** per 0.1 mg

Condition(s) listed in policy (*see criteria for details*)

- Acute myeloid leukemia (AML), CD33+
- Acute promyelocytic leukemia (APL)

AHFS therapeutic class: Antineoplastic

Mechanism of action: CD33-directed antibody cytotoxic drug conjugate

(1) Special Instructions and pertinent Information

Covered under the Medical Benefit, please submit clinical information for prior authorization review via fax.

(2) Prior Authorization/Medical Review is required for the following condition(s)

All requests for gemtuzumab ozogamicin (Mylotarg™) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

Acute myeloid leukemia (AML), CD33+

1. Diagnosis of CD33+ AML, **AND**
2. One of the following:
    a. Used for induction or consolidation/post-remission therapy as single agent or in combination with daunorubicin and cytarabine, OR
    b. Used for consolidation/post-remission therapy in combination with high dose cytarabine (HiDAC), OR
    c. Used for relapsed or refractory disease as a single agent

Covered Doses and Coverage Period

Induction or consolidation/post-remission therapy:

- Single-agent regimen:
    - Cycle 1 for induction: Up to 6 mg/m^2 on Day 1 and up to 3 mg/m^2 on Day 8
    - Cycles 2-9 for consolidation: Up to 2 mg/m^2 on Day 1 every 4-weeks for 8 courses *(Continuation for patients without evidence of disease progression following initial cycle)*

- Combination with daunorubicin and cytarabine:
    - One induction cycle: Up to 3 mg/m^2 (up to one 4.5 mg vial) for up to 3 doses
    - Up to two consolidation cycles: Up to 3 mg/m^2 (up to one 4.5 mg vial) as a single dose per cycle

- Combination with HiDAC:
  Up to two consolidation cycles: Up to 3 mg/m^2 (up to one 4.5 mg vial) as a single dose per cycle

Relapsed or refractory disease:

- Up to 3 mg/m^2 (up to one 4.5 mg vial) on Days 1, 4, and 7 for a single treatment course

ICD-10:
C92.00, C92.01, C92.02, C92.50, C92.51, C92.52, C92.60, C92.61, C92.62, C92.A0, C92.A1, C92.A2, C93.00, C93.01, C93.02, C94.00, C94.02, C94.20, C94.22

Acute promyelocytic leukemia (APL)

1. One of the following:
    a. Being used as induction or consolidation in high-risk disease (WBC ≤ 10,000/mcL), and used in combination with tretinoin (ATRA), **OR**
    b. Being used as induction or consolidation therapy in high risk disease (WBC > 10,000/mCL), and use in combination with tretinoin and/or arsenic trioxide, **OR**
    c. Treatment of first relapse and in combination with arsenic trioxide

Covered Dose
Up to 9 mg/m^2 IV every 4-5 weeks

Coverage period:
One year

ICD-10:
C92.40, C92.41, C92.42

(3) The following condition(s) DO NOT require Prior Authorization/Preservice
All requests for gemtuzumab ozogamicin (Mylotarg™) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

(4) This Medication is NOT medically necessary for the following condition(s)
Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

(5) Additional Information
How supplied:

- 4.5 mg (single-dose vial)

(6) References

- AHFS®. Available by subscription at http://www.lexi.com
- DrugDex®. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
- Mylotarg™ (gemtuzumab ozogamicin) [Prescribing information]. Philadelphia, PA: Pfizer, Inc.; 8/2021.
- National Comprehensive Cancer Network Drugs and Biologics Compendium. Mylotarg (2023). Available at: www.nccn.org.
- National Comprehensive Cancer Network. Acute myeloid leukemia (Version 1.2023). Available at: www.nccn.org.

(7) Policy Update

Date of last review: 2Q2023

Date of next review: 2Q2024

Changes from previous policy version:

- No clinical change to policy following routine annual review.

BSC Drug Coverage Criteria to Determine Medical Necessity
Reviewed by P&T Committee