PRIOR AUTHORIZATION POLICY

POLICY: Oncology (Injectable) – Mylotarg Prior Authorization Policy
- Mylotarg™ (gemtuzumab ozogamicin intravenous infusion – Pfizer)

REVIEW DATE: 07/13/2022

OVERVIEW

Mylotarg, an antibody-drug conjugate directed towards the CD33 antigen, is indicated for the following:[1]

- **CD33-positive acute myeloid leukemia (AML)**, newly diagnosed, in adults and pediatric patients ≥ 1 month of age; AND
- **CD33-positive AML**, relapsed or refractory, in adults and in pediatric patients ≥ 2 years of age.

Guidelines

The National Comprehensive Cancer Network (NCCN) guidelines for **AML** (version 2.2022 – June 14, 2022) recommend Mylotarg for induction therapy, post-remission therapy, and for relapsed/refractory CD33-positive AML.[2,3] Mylotarg can be used as a single agent or in combination with cytarabine and daunorubicin. The NCCN guidelines for AML also recommend Mylotarg in patients ≥ 18 years of age for induction and consolidation therapy for acute promyelocytic leukemia, and for relapsed disease. Mylotarg can be used in combination with tretinoin and/or arsenic trioxide.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Mylotarg. All approvals are provided for the duration noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days. Because of the specialized skills required for evaluation and diagnosis of patients treated with Mylotarg as well as the monitoring required for adverse events and long-term efficacy, approval requires Mylotarg to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Mylotarg is recommended in those who meet one of the following criteria:

FDA-Approved Indication

1. **Acute Myeloid Leukemia.** Approve for the duration noted if the patient meets ONE of the following criteria (A or B):
   - **A)** Newly diagnosed CD33-positive disease: Approve for 1 year if the patient meets the following criteria (i and ii):
     - **i.** Patient is ≥ 1 month of age; AND
     - **ii.** Mylotarg is prescribed by or in consultation with an oncologist; OR
   - **B)** Relapsed or refractory CD33-positive disease: Approve for 1 month if the patient meets the following criteria (i and ii):
     - **i.** Patient is ≥ 2 years of age; AND
     - **ii.** Mylotarg is prescribed by or in consultation with an oncologist.

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Other Uses with Supportive Evidence

2. Acute Promyelocytic Leukemia. Approve for 6 months if the patient meets the following criteria (A and B):
   A) Patient is ≥ 18 years of age; AND
   B) Mylotarg is prescribed by or in consultation with an oncologist.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Mylotarg is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Mylotarg™ intravenous infusion [prescribing information]. Philadelphia, PA: Pfizer; June 2020.
2. The NCCN Acute Myeloid Leukemia Clinical Practice Guidelines in Oncology (version 2.2022 – June 14, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on July 5, 2022.
3. The NCCN Drugs and Biologics Compendium. © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on July 5, 2022. Search term: gemtuzumab.

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