PriorityHealth

Medical prior authorization form

Fax completed form to: 877.974.4411 toll free, or 616.942.8206

This form applies to: ☒ **Commercial (Traditional)** ☒ **Commercial Individual (Optimized)** ☒ **Medicaid**

This request is: ☐ **Urgent** (life threatening) ☐ **Non-Urgent** (standard review)

Urgent means the standard review time may seriously jeopardize the life or health of the patient or the patient's ability to regain maximum function.

Mylotarg® (gemtuzumab ozogamicin)

Member

Last Name: _____ First Name: _____

ID #: _____ DOB: _____ Gender: _____

Primary Care Physician: _____

Requesting Provider: _____ Prov. Phone: _____ Prov. Fax: _____

Provider Address: _____

Provider NPI: _____ Contact Name: _____

Provider Signature: _____ Date: _____

Product and Billing Information

☐ New Request ☐ Continuation Request

Drug product: ☐ Mylotarg 4.5mg Powder for Injection

Start date (or date of next dose): _____

Date of last dose (if applicable): _____

Date of next dose (if applicable): _____

Dose:_____ **Dose Frequency**:_____

Place of administration:

☐ Physician's office

☐ Outpatient infusion

Facility: _____ NPI:_____ Fax:_____

☐ Home infusion

Facility: _____ NPI:_____ Fax:_____

Billing:

☐ Physician to buy and bill

☐ Facility to buy and bill

☐ Specialty Pharmacy

Pharmacy:_____ NPI:_____ Fax:_____

ICD-10 Diagnosis code(s): _____

All fields must be complete and legible for review. Your office will receive a response via fax.

New 03/2018
Last reviewed 03/2019

Precertification Requirements

Before this drug is covered, the following requirements must be met:

All requests require documentation of CD33 testing and expression.

For Newly Diagnosed CD33-positive AML:

1. Use as a single agent, must meet the following:
    a. Either age > 75 years, OR 60 - 74 years with World Health Organization (WHO) Performance Status (PS) >2, AND
    b. Not a candidate for, or has declined, intensive remission induction therapy
2. For use in combination with standard chemotherapy, must meet the following:
    a. Age < 60 years
        i. ECOG Performance Status (PS) of 0 to 1, AND
        ii. For post-remission/consolidation therapy:
            1. Have either favorable or intermediate-risk cytogenetics as defined by NCCN AML guidelines
    b. Age ≥ 60 years
        i. Is a candidate for intensive remission induction therapy, AND
        ii. Has de novo AML without unfavorable cytogenetics or molecular markers, no antecedent hematologic disorder, no therapy-related AML

For Relapsed or Refractory CD33-positive AML:

1. Use as a single agent, must meet the following:
    a. Age ≥ 2 years
    b. First relapse
    c.

Note: Authorization for indications, dosing, or a route of administration not approved by the Food and Drug Administration (FDA) or recognized in CMS-accepted compendia (e.g. DrugDex, AHFS, U.S. Pharmacopeia, and also Clinical Pharmacology for oncology indications only) require supporting evidence for coverage. Please provide two published peer-reviewed literature articles supporting the appropriateness of the drug, the dosing of the drug, or the route of administration to be used for the identified indication.

Priority Health Precertification Documentation

A. Provider Attestations

Mylotarg contains a Black Box Warning of hepatotoxicity, including severe or fatal hepatic veno occlusive disease (VOD). It is recommended that ALT, AST, total bilirubin, and alkaline phosphatase be assessed before each dose of Mylotarg.

☐ The provider acknowledges the above statement

For newly diagnosed CD33-positive AML, use in combination with standard chemotherapy:
Per ALFA-0701 trial, the addition of Mylotarg to standard combination chemotherapy *did not result in a significant difference in overall survival*. Additionally, in a subgroup analyses in ALFA-0701, the addition of Mylotarg to standard combination chemotherapy *did not improve event-free survival in the subgroup of patients having adverse-risk cytogenetics* (HR 1.11; 95% CI: 0.63, 1.95). For patients being treated with Mylotarg in combination with daunorubicin and cytarabine for newly-diagnosed de novo AML, when cytogenetics testing results become available consider whether the potential benefit of continuing treatment with Mylotarg outweighs the risks for the individual patient. NCCN guidelines recommend use only in patients without unfavorable-risk cytogenetics.

For newly diagnosed CD33-positive AML, used as a single agent:
Per AML-19 trial, the overall survival benefit with Mylotarg was most apparent in patients with high CD33 expression status and in patients with favorable/intermediate cytogenetic risk profiles.

☐ The provider acknowledges the above statements

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B. What condition is this drug being requested for?

- ☐ Newly Diagnosed CD33-positive AML
- ☐ Relapsed or Refractory CD33-positive AML
- ☐ Other – rationale for use: _____

C. Documentation of CD33-positive mutation has been provided with this request.

- ☐ Yes
- ☐ No

D. For newly diagnosed CD33-positive AML, use as a single agent:

Is the patient a candidate for intensive remission induction therapy?

- ☐ Yes
- ☐ No

- ☐ The patient is greater than 75 years of age
- ☐ The patient is 60 to 75 years of age

Is the patient's WHO PS>2?

- ☐ Yes
- ☐ No

E. For newly diagnosed CD33-positive AML, use in combination with standard chemotherapy:

- ☐ The patient is greater than or equal to 60 years of age

Is the patient a candidate for intensive remission induction therapy?

- ☐ Yes
- ☐ No

Does the patient have de novo AML without unfavorable cytogenetics or molecular markers, no antecedent hematologic disorder, and no therapy-related AML?

- ☐ Yes
- ☐ No

- ☐ The patient is less than 60 years of age

Is the patient's ECOG Performance Status of 0 to 1?

- ☐ Yes
- ☐ No

For post-remission/consolidation therapy, does the patient have either favorable or intermediate-risk cytogenetics?

- ☐ Yes
- ☐ No

F. For Relapsed or Refractory CD33-positive AML:

- ☐ The patient is 2 years of age or older

Is this the patient's first relapse?

- ☐ Yes
- ☐ No

Additional information

Per indication, if authorization criteria are met, the following regimens may be approved:

Newly Diagnosed CD33-positive AML, single agent:
Induction: *6 mg/m2 as a single agent on Day 1, and 3 mg/m2 on Day 8.*
Consolidation: *2 mg/m2 as a single agent on Day 1 every 4 weeks for a maximum of 8 cycles*.

Newly Diagnosed CD33-positive AML, in combination with standard chemotherapy:
Induction: *3 mg/m2 (up to one 4.5 mg vial) on Days 1, 4, and 7 in combination with daunorubicin and cytarabine. (For patients requiring a second induction cycle, Mylotarg is NOT given during the second induction cycle.)*
Consolidation: *3 mg/m2 on Day 1 (up to one 4.5 mg vial) in combination with daunorubicin and cytarabine for 2 cycles.*

For Relapsed or Refractory CD33-positive AML:
Induction: *3 mg/m2 (up to one 4.5 mg vial) on Days 1, 4, and 7.*

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