Part B Prior Authorization Guidelines

Chemotherapy: Acute Myeloid Leukemia

Mylotarg (gemtuzumab ozogamicin) J9203 is the Non-preferred product. The preferred product is Vidaza (azacitidine) J9025 (No PA required for preferred product)

Prior Authorization Step Therapy Request
Medicare Part B Form

*Instructions: * Indicates required information – Form may be returned if required information is not provided. Please fax this request to the appropriate fax number listed at the bottom of the page.*

☐	**Standard Request– (72 Hours)**	☐	**Urgent Request** (standard time frame could place the member's life, health or ability in serious jeopardy)
	Date Requested _____		
	Requestor _____ Clinic name: _____ Phone / Fax		

MEMBER INFORMATION

*Name:_____ *ID#:_____ *DOB:_____

PRESCRIBER INFORMATION

*Name:_____ ☐MD ☐FNP ☐DO ☐NP ☐PA *Phone:_____

*Address:_____ *Fax:_____

DISPENSING PROVIDER / ADMINISTRATION INFORMATION

*Name:_____ Phone:_____

*Address:_____ Fax:_____

PROCEDURE / PRODUCT INFORMATION

HCPC Code	Name of Drug	Dose (Wt: _____ kg Ht:_____)	Frequency	End Date if known

☐ **Self-administered** ☐ **Provider-administered** ☐ **Home Infusion**

☐Chart notes attached. **Other important information:**_____

Diagnosis: ICD10: _____ **Description**: _____

☐ Provider attests the diagnosis provided is an FDA-Approved indication for this drug

CLINICAL INFORMATION

☐ New Start or Initial Request: (Clinical documentation required for all requests)

☐ **Mylotarg**

- ☐ Individual has a diagnosis of CD33+ acute myeloid leukemia (AML); AND
- ☐ Individual is using for one of the following:
  - ☐ As induction for AML; OR
  - ☐ As consolidation therapy for AML; OR
  - ☐ As treatment for relapsed or refractory AML;

OR **(No Step Therapy Required)**

- ☐ Individual has a diagnosis of high-risk acute promyelocytic leukemia;

If not, please provide **clinical rationale** for formulary exception: _____

_____

☐ Continuation Requests: (Clinical documentation required for all requests)

☐ **Provider has reviewed the attached "Criteria for Continuation" and attests the member meets ALL required PA Continuation criteria.**

☐ Patient had an adequate response or significant improvement while on this medication.

If not, please provide clinical rationale for continuing this medication: _____

_____

ACKNOWLEDGEMENT

Request By (Signature Required): _____Date:_____/____/____

Any person who knowingly files a request for authorization of coverage of a medical procedure or service with the intent to injure, defraud or deceive any insurance company by providing materially false information or conceals material information for the purpose of misleading, commits a fraudulent insurance act, which is a crime and subjects such person to criminal and civil penalties. **THIS AUTHORIZATION IS NOT A GUARANTEE OF PAYMENT.** PAYMENT IS BASED ON BENEFITS IN EFFECT AT THE TIME OF SERVICE, MEMBER ELIGIBILITY AND MEDICAL NECESSITY.

Prior Authorization Group – Oncology: Acute Myeloid Leukemia Drugs PA

Drug Name(s):

MYLOTARG	**GEMTUZUMAB OZOGAMICIN**
VIDAZA	**AZACITIDINE**

Criteria for approval of Prior Authorization Drug:

1. Prescribed for an approved FDA diagnosis (as listed below):
2. Prescribed by, or in consultation with an oncologist or other cancer specialist related to the diagnosis.
3. Drug is being used appropriately per CMS recognized compendia, authoritative medical literature, evidence-based guidelines and/or accepted standards of medical practice.
4. Member does not have any clinically relevant contraindications, or CMS/Plan exclusions, to the requested drug.

- If the member meets all these criteria, they may be approved by the Plan for the requested drug.
- Quantity limits and Tiering will be determined by the Plan.

Exclusion Criteria:

Cannot be prescribed for experimental or investigational use.

Prescriber Restrictions:

Oncologist or other cancer specialist

Coverage Duration:

New Start: Approval will be for 6 months
Continuation: Approval will be for 12 months

FDA Indications:

Mylotarg

- Acute myeloid leukemia, Newly-diagnosed, CD33-positive
- Acute myeloid leukemia, Relapsed or refractory, CD33-positive

Vidaza

- Acute myeloid leukemia, Continued treatment in patients who achieved first complete remission or complete remission with incomplete blood count recovery following intensive induction chemotherapy and are unable to complete intensive curative therapy
- Juvenile myelomonocytic leukemia
- Myelodysplastic syndrome, Refractory anemia, refractory anemia with ringed sideroblasts (if accompanied by neutropenia or thrombocytopenia or requiring transfusions), refractory anemia with excess blasts, refractory anemia with excess blasts in transformation, and chronic myelomonocytic leukemia.

Off-Label Uses:

Mylotarg

- Acute promyelocytic leukemia, FAB M3

Vidaza

- Acute myeloid leukemia

Age Restrictions:

Mylotarg

- AML, Newly-Diagnosed, CD33-positive: 1 month or older
- AML, Relapsed or refractory, CD33-positive: 2 years or older

Vidaza

- Juvenile myelomonocytic leukemia: 1 month or older

Other Clinical Considerations:

Cancer diagnoses: Criteria as per NCCN or other FDA-approved cancer related guidelines.

Resources:

https://www.micromedexsolutions.com/micromedex2/librarian/CS/17815A/ND_PR/evidencexpert/ND_P/evidencexpert/DUPLICATIONSHIELDSYNC/BB4E53/ND_PG/evidencexpert/ND_B/evidencexpert/ND_AppProduct/evidencexpert/ND_T/evidencexpert/PFActionId/evidencexpert.GoToDashboard?docId=925216&contentSetId=100&title=Gemtuzumab+Ozogamicin&servicesTitle=Gemtuzumab+Ozogamicin&brandName=Mylotarg&UserMdxSearchTerm=Mylotarg&=null#

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