Mylotarg® (gemtuzumab ozogamicin)
Effective 08/01/2022

Plan	☒ MassHealth ☐ MassHealth UPPL ☐Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☐ Medical Benefit (NLX)		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	**Specialty Medications**		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	Non-Specialty Medications		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	Medical Specialty Medications (NLX)		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
Exceptions	N/A		

Overview

Mylotarg® (gemtuzumab ozogamicin) is a CD33-directed antibody-drug conjugate (ADC) indicated for the treatment of newly-diagnosed CD33-positive acute myeloid leukemia (AML) in adults and pediatric patients one month and older (as combination therapy and as monotherapy) and the treatment of relapsed or refractory CD33-positive AML in adults and in pediatric patients two years and older (as monotherapy).

No PA	Drugs that require PA
Cytarabine	Mylotarg® (gemtuzumab ozogamicin)
Daunorubicin	
Please refer to the NCCN guidelines for the treatment of AML for complete treatment regimens.	

AML=acute myeloid leukemia, NCCN=National Comprehensive Cancer Network

Coverage Guidelines

Authorization may be granted for members who are currently receiving treatment with Mylotarg, excluding when the product is obtained as samples or via manufacturer's patient assistance programs

OR

Authorization may be granted for members when all the following criteria are met, and documentation is provided:

<u>Newly-diagnosed CD33-positive AML in adults and pediatric patients 1 month and older</u>

Prescriber documents **ALL** of the following:

1. Appropriate diagnosis
2. Prescriber is an oncologist or hematologist
3. Member ≥1 month of age
4. Appropriate dosing
5. **ONE** of the following:
    a. Physician documentation that requested agent will be used in combination with cytarabine and daunorubicin or fludarabine
    b. Clinical rationale why combination therapy with cytarabine and daunorubicin or fludarabine is not appropriate
    c. If member is ≥ 60 years of age and requested agent will be used as a single agent therapy with gemtuzumab ozogamicin

<u>Relapsed or refractory CD33-positive AML in adults and in pediatric patients two years and older</u>
Prescriber documents **ALL** of the following:

1. Appropriate diagnosis
2. Prescriber is an oncologist or hematologist
3. Appropriate dosing
4. Member ≥2 years of age
5. **ONE** of the following:
    a. Documentation of relapsed or refractory AML
    b. Physician documentation of prior therapy for the treatment of AML with one systemic therapy *(refer to Appendix for common AML treatment regimens)*

Limitations

1. Initial approvals:
    a. Newly-diagnosed CD33-positive AML in adults and pediatric patients 1 month and older: Three cycles
    b. Relapsed or refractory CD33-positive AML in adults and in pediatric patients two years and older: One treatment cycle
2. Reauthorizations for newly-diagnosed CD33-positive AML in adults and pediatric patients 1 month and older for monotherapy: maximum of one cycle of induction and eight cycles of continuation
3. Dosing

Drug	Dosing
Mylotarg® (gemtuzumab ozogamicin) Vial: 4.5 mg	<u>Newly-diagnosed de novo CD33-positive AML in adults (combination regimen):</u> *A treatment course consists of one induction cycle and two consolidation cycles.* • Induction cycle: 3 mg/m^2 (up to one 4.5 mg vial) on days one, four and seven in combination with daunorubicin and cytarabine (for patients requiring a second induction cycle, do NOT administer gemtuzumab ozogamicin during the second induction cycle) • Consolidation cycle: 3 mg/m^2 on day one (up to one 4.5 mg vial)

	Newly-diagnosed de novo CD33-positive AML in pediatric patients one month and older (combination regimen): • 3 mg/m^2 for patients with BSA greater than or equal to 0.6 m^2 • 0.1 mg/kg for patients with BSA less than 0.6 m^2 • For Induction 1, given once in combination with standard chemotherapy. No dose is given in the second induction cycle • No dose is given in the first or third intensification cycles. For Intensification 2, dose is given once in combination with standard chemotherapy. • Consider the risks and potential benefits before giving the agent during Intensification 2 Newly-diagnosed CD33-positive AML (single-agent regimen): *A treatment course consists of one cycle of induction and up to eight cycles of continuation therapy.* • Induction cycle: 6 mg/m^2 (not limited to one 4.5 mg vial) on day one and 3 mg/m^2 (not limited to one 4.5 mg vial) on day eight • Continuation cycle: 2 mg/m^2 (not limited to one 4.5 mg vial) on day one every four weeks R/R CD33-positive AML (single-agent regimen): *Maximum one treatment course.* 3 mg/m^2 (up to one 4.5 mg vial) on days 1, 4, and 7

Appendix

Common AML Treatment Regimens

Treatment Induction Regimens

- Patients <60 Years of Age
  - Cytarabine 1.5 to 3 g/m^2 every 12 hours X6 days
  - Standard-dose cytarabine with idarubicin or daunorubicin
  - Standard-dose cytarabine with daunorubicin or oral midostaurin (FLT3 mutated)
  - Dual drug liposomal encapsulation of cytarabine and daunorubicin
- Patients ≥60 Years of Age
  - Standard-dose cytarabine (100 to 200 mg/m^2 x seven days) with idarubicin 12 mg/m^2 or daunorubicin 60 to 90 mg/m^2 x three days or mitoxantrone 12 mg/m^2 x three days
  - Low-intensity therapies: azacytidine, decitabine
  - Dual-drug liposomal encapsulation of daunorubicin 44 mg/m^2 and cytarabine 100 mg/m2 on days one, three and five for one cycle (category 1)
  - Standard dose cytarabine 200 mg/m^2 x seven days with daunorubicin 60 mg/m^2 x three days and oral midostaurin 50 mg every 12 hours, days 8 to 21 (FLT3-mutated AML)
  - Venetoclax once daily by mouth and decitabine 20 mg/m^2 (days one to five of each 28 day cycle)
  - Venetoclax once daily by mouth and azacytidine 75 mg/m^2 (days one to seven of each 28-day cycle)
  - Venetoclax once daily by mouth and low-dose cytarabine 20 mg/m^2/day (days 1 to 10 of each 28-day cycle)

- Standard-dose cytarabine 200 mg/m2 x seven days with daunorubicin 60 mg/m2 x three days and a single dose of gemtuzumab ozogamicin 3 mg/m2 given on day one, or day two, or day three, or day four; alternatively, three total doses may be given on days one, four and seven (CD33-positive)

References

1. Mylotarg® [prescribing information]. Phildelphia (PA): Wyeth Pharmaceticals, Inc (Pfizer); 2020 Jun.
2. FDA approves Mylotarg for treatment of acute myeloid leukemia [press release on the internet]. FDA; 2017 Sept 1 [cited 2021 Aug 31].
3. FDA: Pfizer Voluntarily Withdraws Cancer Treatment Mylotarg from U.S. Market [press release on the internet]. Fierce Pharma; 2010 Jun 21 [cited 2021 Aug 31]. Available from: http://www.fiercepharma.com/pharma/fda-pfizer-voluntarily-withdraws-cancer-treatment-mylotarg-from-u-s-market.
4. SEER Stat Fact Sheets: Acute Myeloid Leukemia (AML). http://seer.cancer.gov/statfacts/html/amyl.html. Accessed September 1, 2021.
5. Amadori S, Suciu S, Selleslag D, Aversa F, Gaidano G, Musso M, et al. Gemtuzumab Ozogamicin Versus Best Supportive Care in Older Patients With Newly Diagnosed Acute Myeloid Leukemia Unsuitable for Intensive Chemotherapy: Results of the Randomized Phase III EORTC-GIMEMA AML-19 Trial. J Clin Oncol. 2016 Mar 20;34(9):972-9. doi: 10.1200/JCO.2015.64.0060. Epub 2016 Jan 25.
6. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology Acute Myeloid Leukemia. Version 3.2021. 2021 Mar 2 [cited 2021 Sep 1]. Available from: https://www.nccn.org/professionals/physician_gls/pdf/aml.pdf.
7. Castaigne S, Pautas C, Terré C, Raffoux E, Bordessoule D, Bastie JN, et al. Effect of gemtuzumab ozogamicin on survival of adult patients with de-novo acute myeloid leukaemia (ALFA-0701): a randomised, open-label, phase 3 study. Lancet. 2012 Apr 21;379(9825):1508-16.
8. Taksin AL, Legrand O, Raffoux E, de Revel T, Thomas X, Contentin N, et al. High efficacy and safety profile of fractionated doses of Mylotarg as induction therapy in patients with relapsed acute myeloblastic leukemia: a prospective study of the alfa group. Leukemia. 2007 Jan;21(1):66-71. Epub 2006 Oct 19.

Review History

5/18/2022 – Created and Reviewed June P&T; matched MH UPPL. Created criteria to be in compliance with Masshealth criteria. Effective 8/1/22.

Disclaimer

AllWays Health Partners complies with applicable federal civil rights laws and does not discriminate or exclude people on the basis of race, color, national origin, age, disability, or sex.