

## **Mylotarg™ (gemtuzumab ozogamicin)** **(Intravenous)**

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### **I. Length of Authorization**

#### **Newly-Diagnosed AML**

- De novo disease in combination with daunorubicin and cytarabine (adult): Coverage will be provided for 6 months consisting of 3 cycles (1 induction and 2 consolidation) and may not be renewed.
- De novo disease in combination with daunorubicin and cytarabine (pediatric): Coverage will be provided for 6 months consisting of 2 cycles (1 induction and 1 consolidation) and may not be renewed.
- Single-agent use: Coverage will be provided for 6 months and may be renewed. Coverage is provided for 1 cycle of induction and up to a maximum of 8 cycles of continuation.

#### **Post-Induction Therapy for AML**

- Coverage will be provided for 6 months consisting of 2 cycles (2 doses) and may not be renewed.

#### **Consolidation Therapy for AML**

- Coverage will be provided for 6 months consisting of 2 cycles (2 doses) and may not be renewed.

#### **Relapsed or Refractory AML**

- Coverage will be provided for 6 months consisting of one cycle (3 doses) and may not be renewed.

#### **Acute Promyelocytic Leukemia**

- Induction/Consolidation Therapy: Coverage will be provided for 6 months and may be renewed. Coverage is provided for 1 cycle of induction therapy followed by consolidation therapy. *[Note: Duration of consolidation therapy is dependent on disease risk severity (see below)]*
  - Low-risk disease: Coverage will be provided until achievement of complete molecular response.
  - High-risk disease: Coverage will be provided until 28 weeks from complete response.

- Therapy after first relapse: Coverage will be provided for 6 months and may be renewed until bone marrow confirmation of remission.

## II. Dosing Limits

### A. Quantity Limit (max daily dose) [NDC Unit]:

- Mylotarg 4.5 mg single-dose vial: 5 vials per initial 28 days; 1 vial per 28 days thereafter

### B. Max Units (per dose and over time) [HCPCS Unit]:

|     | Induction (1 cycle only)   | Consolidation   |
|-----|--|---|
| AML | 135 billable units on Day 1 & 90 billable units on Day 8 of a 28-day cycle | 45 billable units on Day 1 of a 28-day cycle (up to a maximum of 8 subsequent cycles) |
| APL | 180 billable units on Day 1  | 180 billable units on Day 1 of a 28-day cycle   |

## III. Initial Approval Criteria <sup>1</sup>

Coverage is provided in the following conditions:

- Patient is at least 18 years of age (unless otherwise specified); **AND**
- Patient has not previously received gemtuzumab ozogamicin; **AND**
- Baseline electrocardiogram (ECG) obtained in patients with a history of or predisposition for QTc prolongation; **AND**

### Universal Criteria <sup>1</sup>

- Patient has CD33-positive disease; **AND**

### Acute Myeloid Leukemia (AML) † ⊕ <sup>1,6,10</sup>

- Patient has newly-diagnosed disease; **AND**
  - Used in combination with daunorubicin and cytarabine; **AND**
    - Patient has de novo disease †; **AND**
      - Patient is at least 1 month of age; **OR**
    - Patient has favorable-risk cytogenetics or intermediate-risk disease; **OR**
  - Used as a single agent †; **OR**
- Used as post-induction therapy; **AND**
  - Used in combination with daunorubicin and intermediate-dose cytarabine; **AND**
  - Patient is ≥ 60 years of age and obtained a complete response to previous intensive therapy; **AND**
  - Patient is able to receive conventional consolidation therapy; **OR**
- Used as consolidation therapy; **AND**
  - Patient is < 60 years of age; **AND**
    - Used in combination with high-dose cytarabine for NPM1 positive and FLT3 negative disease; **AND**

- Patient has core binding factor (CBF) cytogenetic translocations and minimal residual disease (MRD) negative; **OR**
- Used in combination with daunorubicin and intermediate-dose cytarabine; **AND**
  - Patient has core binding factor (CBF) cytogenetic translocations and minimal residual disease (MRD) negative; **OR**
  - Patient has intermediate-risk cytogenetics and/or molecular abnormalities, including MRD positive; **OR**
- Patient has relapsed or refractory disease; **AND**
  - Used as a single agent †; **AND**
    - Patient is at least 2 years of age; **OR**
  - Used as a component of repeating the initial successful induction regimen if late relapse ( $\geq 12$  months since induction regimen); **OR**
- Patient has acute promyelocytic leukemia (APL) ‡; **AND**
  - Used as induction or consolidation therapy in patients with low-risk disease (white blood cell count  $\leq 10 \times 10^9/L$ ); **AND**
    - Used in combination with tretinoin (ATRA); **AND**
    - Arsenic is not available or is contraindicated; **OR**
  - Used as induction or consolidation therapy in patients with high risk disease (white blood cell count  $> 10 \times 10^9/L$ ); **AND**
    - Used in combination with tretinoin (ATRA) and/or arsenic trioxide (ATO); **OR**
  - Used for first relapse (morphologic or molecular) in combination with arsenic trioxide (ATO); **AND**
    - Used for late relapse ( $\geq 6$  months) after an arsenic trioxide (ATO) containing regimen; **OR**
    - Used for early relapse ( $< 6$  months) after tretinoin (ATRA) + anthracycline-containing regimen; **OR**
    - Patient is arsenic trioxide (ATO)-naïve

† FDA Approved Indication(s); ‡ Compendium Recommended Indication(s);  $\Phi$  Orphan Drug

#### IV. Renewal Criteria <sup>1,6</sup>

Coverage can be renewed based upon the following criteria:

- Patient continues to meet the universal and indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in section III; **AND**
- Disease stabilization or improvement as evidenced by a complete response [CR] (i.e., morphologic, cytogenetic or molecular complete response CR), complete hematologic response or a partial response by CBC, bone marrow cytogenetic analysis, QPCR, or FISH; **AND**

- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: severe infusion-related reactions (including anaphylaxis), hemorrhage, hepatotoxicity including hepatic veno-occlusive disease (VOD)/sinusoidal obstruction syndrome (SOS), QT interval prolongation, etc.; **AND**
  - Patients receiving single-agent treatment for newly-diagnosed AML have not exceeded the maximum of 8 cycles of continuation (adult only); **OR**
  - Patients receiving consolidation therapy for acute promyelocytic leukemia (APL):
    - Low-risk disease: Therapy will be discontinued once there is achievement of complete molecular response; **OR**
    - High-risk disease: Therapy will be discontinued after 28 weeks from achievement of complete response; **OR**
  - Patients receiving therapy for first relapse of acute promyelocytic leukemia (APL):
    - Therapy will be discontinued once there is bone marrow confirmation of remission

**Note:** treatment of newly diagnosed de novo AML, relapsed or refractory AML, post-induction therapy for AML, and consolidation therapy for AML are not renewable.

## V. Dosage/Administration <sup>1,5-8,11</sup>

| Indication             | Dose  |
|------------------------|---|
| Acute Myeloid Leukemia | <p><b>Newly Diagnosed AML</b></p> <p><u>Adult (≥ 18 years old) – Combination regimen (De Novo AML):</u></p> <ul style="list-style-type: none"> <li>• Induction Therapy (1 cycle only):               <ul style="list-style-type: none"> <li>○ 3 mg/m<sup>2</sup> (up to one 4.5 mg vial) on Days 1, 4, and 7 in combination with daunorubicin and cytarabine</li> <li>○ For patients requiring a second induction cycle, do not administer gemtuzumab ozogamicin during the second induction cycle</li> </ul> </li> <li>• Consolidation Therapy (maximum of 2 cycles):               <ul style="list-style-type: none"> <li>○ 3 mg/m<sup>2</sup> (up to one 4.5 mg vial) on Day 1 in combination with daunorubicin and cytarabine</li> </ul> </li> </ul> <p><u>Pediatric (1 month to &lt; 18 years old) – Combination regimen (De Novo AML):</u></p> <ul style="list-style-type: none"> <li>• Induction Therapy (1 cycle only):               <ul style="list-style-type: none"> <li>○ 3 mg/m<sup>2</sup> (BSA ≥ 0.6 m<sup>2</sup>) or 0.1 mg/kg (BSA &lt; 0.6 m<sup>2</sup>) on Day 6 in combination with daunorubicin and cytarabine</li> <li>○ For patients requiring a second induction cycle, do not administer gemtuzumab ozogamicin during the second induction cycle</li> </ul> </li> <li>• Consolidation/Intensification Therapy (1 cycle only):               <ul style="list-style-type: none"> <li>○ 3 mg/m<sup>2</sup> (BSA ≥ 0.6 m<sup>2</sup>) or 0.1 mg/kg (BSA &lt; 0.6 m<sup>2</sup>) on Day 7 in Intensification 2</li> </ul> </li> </ul> <p><u>Single-agent regimen:</u></p> <ul style="list-style-type: none"> <li>• Induction Therapy (1 cycle only):               <ul style="list-style-type: none"> <li>○ 6 mg/m<sup>2</sup> as a single agent on Day 1, and 3 mg/m<sup>2</sup> on Day 8</li> </ul> </li> <li>• Continuation Therapy (maximum of 8 cycles):               <ul style="list-style-type: none"> <li>○ 2 mg/m<sup>2</sup> as a single agent on Day 1 every 4 weeks</li> </ul> </li> </ul> <p><b>Post-Induction Therapy for AML</b></p> |

|  |  |
|--|--|
|  | <p><b>&gt; 60 years of age – Combination regimen:</b></p> <ul style="list-style-type: none"> <li>3 mg/m<sup>2</sup> (up to one 4.5 mg vial) on day 1 in combination with daunorubicin and intermediate-dose cytarabine (2 cycles only)</li> </ul>  |
|  | <b>Consolidation Therapy for AML</b>   |
|  | <p><b>&lt; 60 years of age – Combination regimen:</b></p> <ul style="list-style-type: none"> <li>3 mg/m<sup>2</sup> (up to one 4.5 mg vial) on day 1 in combination with daunorubicin and intermediate-dose cytarabine (2 cycles only)</li> <li>3 mg/m<sup>2</sup> (up to one 4.5 mg vial) on day 1 in combination with high-dose cytarabine (2 cycles only)</li> </ul>  |
|  | <b>Relapsed or Refractory AML (single agent)</b>   |
|  | <ul style="list-style-type: none"> <li>3 mg/m<sup>2</sup> (up to one 4.5 mg vial) on Days 1, 4, and 7 (1 cycle only)</li> </ul>  |
|  | <b>Acute Promyelocytic Leukemia</b>  |
|  | <p><b>Combination regimen:</b></p> <ul style="list-style-type: none"> <li>Induction Therapy for <b>low-risk</b> disease (1 cycle only): <ul style="list-style-type: none"> <li>9 mg/m<sup>2</sup> on Day 5 in combination with ATRA</li> </ul> </li> <li>Induction Therapy for <b>high-risk</b> disease (1 cycle only): <ul style="list-style-type: none"> <li>6-9 mg/m<sup>2</sup> on Day 1 (or Day 2 or Day 3 or Day 4) in combination with ATRA+ATO</li> </ul> </li> <li>Consolidation Therapy for <b>low-risk</b> disease: <ul style="list-style-type: none"> <li>9 mg/m<sup>2</sup> given monthly until achievement of complete molecular response.</li> </ul> </li> <li>Consolidation Therapy for <b>high-risk</b> disease: <ul style="list-style-type: none"> <li>ATRA and ATO are used for consolidation. If ATRA or ATO are discontinued due to toxicity then: Mylotarg, single agent, dosed at 9mg/m<sup>2</sup> once every 4-5 weeks until 28 weeks from complete remission.</li> </ul> </li> <li>Therapy for First Relapse <ul style="list-style-type: none"> <li>6-9 mg/m<sup>2</sup> on Day 1 in combination with ATO until count recovery with marrow confirmation of remission.</li> </ul> </li> </ul> |

## VI. Billing Code/Availability Information

### HCPCS Code:

- J9203 – Injection, gemtuzumab ozogamicin, 0.1 mg: 1 billable unit = 0.1 mg

### NDC:

- Mylotarg 4.5 mg single-dose vial: 00008-4510-xx

## VII. References

1. Mylotarg [package insert]. Philadelphia, PA; Pfizer Inc., August 2021. Accessed September 2022.
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6. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Acute Myeloid Leukemia. Version 2.2022. National Comprehensive Cancer Network, 2022. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed September 2022.
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9. Gamis AS, Alonzo TA, Meshinchi S, et al. Gemtuzumab ozogamicin in children and adolescents with de novo acute myeloid leukemia improves event-free survival by reducing relapse risk: results from the randomized phase III Children's Oncology Group trial AAML0531. *J Clin Oncol*. 2014;32(27):3021-3032. doi:10.1200/JCO.2014.55.3628.
10. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) gemtuzumab ozogamicin. National Comprehensive Cancer Network, 2022. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed September 2022.
11. Estey EH, Giles FJ, Beran M, et al. Experience with gemtuzumab ozogamycin ("mylotarg") and all-trans retinoic acid in untreated acute promyelocytic leukemia. *Blood*. 2002 Jun 1;99(11):4222-4. doi: 10.1182/blood-2001-12-0174. PMID: 12010830.

## Appendix 1 – Covered Diagnosis Codes

| ICD-10 | ICD-10 Description   |
|--------|--|
| C92.00 | Acute myeloblastic leukemia not having achieved remission                        |
| C92.01 | Acute myeloblastic leukemia in remission   |
| C92.02 | Acute myeloblastic leukemia in relapse   |
| C92.40 | Acute promyelocytic leukemia not having achieved remission                       |
| C92.41 | Acute promyelocytic leukemia in remission  |
| C92.42 | Acute promyelocytic leukemia in relapse  |
| C92.50 | Acute myelomonocytic leukemia not having achieved remission                      |
| C92.51 | Acute myelomonocytic leukemia in remission                                       |
| C92.52 | Acute myelomonocytic leukemia in relapse   |
| C92.60 | Acute myeloid leukemia with 11q23-abnormality not having achieved remission      |
| C92.61 | Acute myeloid leukemia with 11q23-abnormality in remission                       |
| C92.62 | Acute myeloid leukemia with 11q23-abnormality in relapse                         |
| C92.A0 | Acute myeloid leukemia with multilineage dysplasia not having achieved remission |
| C92.A1 | Acute myeloid leukemia with multilineage dysplasia in remission                  |
| C92.A2 | Acute myeloid leukemia with multilineage dysplasia in relapse                    |
| C93.00 | Acute monoblastic/monocytic leukemia not having achieved remission               |
| C93.01 | Acute monoblastic/monocytic leukemia in remission                                |
| C93.02 | Acute monoblastic/monocytic leukemia in relapse                                  |

## Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD), Local Coverage Determinations (LCDs), and Local Coverage Articles (LCAs) may exist and compliance with these policies is required where applicable. They can be found at: <https://www.cms.gov/medicare-coverage-database/search.aspx>. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

| Medicare Part B Administrative Contractor (MAC) Jurisdictions |                                     |   |
|---|-------------------------------------|---|
| Jurisdiction  | Applicable State/US Territory       | Contractor                                  |
| E (1)   | CA, HI, NV, AS, GU, CNMI            | Noridian Healthcare Solutions, LLC          |
| F (2 & 3)   | AK, WA, OR, ID, ND, SD, MT, WY, UT, | Noridian Healthcare Solutions, LLC          |
| 5   | KS, NE, IA, MO                      | Wisconsin Physicians Service Insurance Corp |
| 6   | MN, WI, IL                          | National Government Services, Inc. (NGS)    |



| Medicare Part B Administrative Contractor (MAC) Jurisdictions |   |   |
|---|---|---|
| Jurisdiction  | Applicable State/US Territory   | Contractor                                  |
| H (4 & 7)   | LA, AR, MS, TX, OK, CO, NM  | Novitas Solutions, Inc.                     |
| 8   | MI, IN  | Wisconsin Physicians Service Insurance Corp |
| N (9)   | FL, PR, VI  | First Coast Service Options, Inc.           |
| J (10)  | TN, GA, AL  | Palmetto GBA, LLC                           |
| M (11)  | NC, SC, WV, VA (excluding below)  | Palmetto GBA, LLC                           |
| L (12)  | DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA) | Novitas Solutions, Inc.                     |
| K (13 & 14)   | NY, CT, MA, RI, VT, ME, NH  | National Government Services, Inc. (NGS)    |
| 15  | KY, OH  | CGS Administrators, LLC                     |



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PreferredOne Community Health Plan  
PO Box 59052  
Minneapolis, MN 55459-0052  
Phone: 1.800.940.5049 (TTY: 763.847.4013)  
Fax: 763.847.4010  
[customerservice@preferredone.com](mailto:customerservice@preferredone.com)

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, a Grievance Specialist is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf>, or by mail or phone at:

U.S. Department of Health and Human Services  
200 Independence Avenue, SW  
Room 509F, HHH Building  
Washington, D.C. 20201  
1-800-368-1019, 800-537-7697 (TDD)

Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>.

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LUS CEEV: Yog tias koj hais lus Hmoob, cov kev pab txog lus, muaj kev pab dawb rau koj. Hu rau 1.800.940.5049 (TTY: 763.847.4013).

XIYYEEFFANNAA: Afaan dubbattu Oroomiffa, taiaajiila qarqaarsa afaanii, kanfaltiidhaan ala, ni argama. Bilbilaa 1.800.940.5049 (TTY: 763.847.4013).

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- Qualified interpreters
- Information written in other languages

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Phone: 1.800.940.5049 (TTY: 763.847.4013)  
Fax: 763.847.4010  
[customerservice@preferredone.com](mailto:customerservice@preferredone.com)

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, a Grievance Specialist is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf>, or by mail or phone at:

U.S. Department of Health and Human Services  
200 Independence Avenue, SW  
Room 509F, HHH Building  
Washington, D.C. 20201  
1-800-368-1019, 800-537-7697 (TDD)

Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>.

## Language Assistance Services

ATTENTION: If you do not speak English, language assistance services, free of charge, are available to you. Call 1.800.940.5049 (TTY: 763.847.4013).

ATENCIÓN: si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al 1.800.940.5049 (TTY: 763.847.4013).

LUS CEEV: Yog tias koj hais lus Hmoob, cov kev pab txog lus, muaj kev pab dawb rau koj. Hu rau 1.800.940.5049 (TTY: 763.847.4013).

XIYEEFFANNAA: Afaan dubbattu Oroomiffa, tajaajila gargaarsa afaanii, kanfaltiidhaan ala, ni argama. Bilbilaa 1.800.940.5049 (TTY: 763.847.4013).

CHÚ Ý: Nếu bạn nói Tiếng Việt, có các dịch vụ hỗ trợ ngôn ngữ miễn phí dành cho bạn. Gọi số 1.800.940.5049 (TTY: 763.847.4013).

注意：如果您使用繁體中文，您可以免費獲得語言援助服務。請致電 1.800.940.5049 (TTY: 763.847.4013)。

ВНИМАНИЕ: Если вы говорите на русском языке, то вам доступны бесплатные услуги перевода. Звоните 1.800.940.5049 (телетайп: 763.847.4013).

បំពេញ: ប្រសិនបើ អ្នកនិយាយភាសាខ្មែរ, សេវាជំនួយភាសា ដោយមិនគិតថ្លៃ គឺអាចមានសំរាប់អ្នក។ ហៅ 1.800.940.5049 (TTY: 763.847.4013).

ማስታወሻ: የሚናገሩት ቋንቋ አማርኛ ከሆነ የትርጉም እርዳታ ድርጅቶች፡ በነጻ ሊያገኙት ተዘጋጅተዋል፡ ወደ ሚከተለው ቁጥር ይደውሉ 1.800.940.5049 (ማስማት ለተሳናቸው: 763.847.4013) .

ဟံသာဝတီ: နမူနာတို့ ကညီ ကျိအသိ, နမူနာ ကျိအတိအကျတို့ တလက်ကွက်လက်စွာ နှိတ်မိသည့်သို့လည်း ကိ: 1.800.940.5049 (TTY: 763.847.4013).

ACHTUNG: Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienstleistungen zur Verfügung. Rufnummer: 1.800.940.5049 (TTY: 763.847.4013).

ប្រយ័ត្ន: បើសិនជាអ្នកនិយាយភាសាខ្មែរ, សេវាជំនួយភាសា ដោយមិនគិតថ្លៃ គឺអាចមានសំរាប់អ្នក។ ហៅ 1.800.940.5049 (TTY: 763.847.4013).

ملحوظة: إذا كنت تتحدث اذكر اللغة، فإن خدمات المساعدة اللغوية تتوافر لك بالمجان. اتصل برقم 1.800.940.5049 (رقم هاتف الصم والبكم: 763.847.4013).

ATTENTION : Si vous parlez français, des services d'aide linguistique vous sont proposés gratuitement. Appelez le 1.800.940.5049 (TTY: 763.847.4013).

주의: 한국어를 사용하시는 경우, 언어 지원 서비스를 무료로 이용하실 수 있습니다. 1.800.940.5049 (TTY: 763.847.4013). 번으로 전화해 주십시오.

PAUNAWA: Kung nagsasalita ka ng Tagalog, maaari kang gumamit ng mga serbisyo ng tulong sa wika nang walang bayad. Tumawag sa 1.800.940.5049 (TTY: 763.847.4013).