

## Mozobil<sup>®</sup> (plerixafor) (Subcutaneous)

Document Number: IC-0082

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Date of Origin: 11/28/2011

Dates Reviewed: 12/2011, 02/2013, 02/2014, 12/2014, 10/2015, 10/2016, 10/2017, 10/2018

### I. Length of Authorization

Coverage will be provided for one treatment cycle of four days and will be eligible for renewal for one additional treatment cycle.

### II. Dosing Limits

#### A. Quantity Limit (max daily dose) [Pharmacy Benefit]:

- Mozobil 24 mg vial: 8 vials per 4 day treatment cycle

#### B. Max Units (per dose and over time) [Medical Benefit]:

- 40 billable units per day

### III. Initial Approval Criteria

Coverage is provided in the following conditions:

- Patient is at least 18 years old; **AND**

**Peripheral mobilization of stem cells for autologous transplantation †**

- Patient had been diagnosed with non-Hodgkin's lymphoma (NHL) or multiple myeloma;  
**AND**
- Must be used in combination with one of the following: filgrastim, filgrastim-sndz, filgrastim-aafi, or tbo-filgrastim

† FDA-approved indication(s); ‡ Compendium recommended indication(s)

### IV. Renewal Criteria

Authorizations can be renewed based on the following criteria:

- Patient continues to meet criteria identified in section III; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: severe hypersensitivity reactions/anaphylaxis, hematologic effects (e.g.

leukocytosis, thrombocytopenia); splenic enlargement/rupture, tumor cell mobilization etc.;  
**AND**

- Patient has had only 1 previous treatment cycle

## V. Dosage/Administration

Indication	Dose
Peripheral mobilization of stem cells for autologous transplantation	<ul style="list-style-type: none"><li>• Begin treatment with Mozobil after the patient has received G-CSF once daily for 4 days</li><li>• Administer daily morning doses of G-CSF 10 mcg/kg for 4 days prior to the first evening dose of Mozobil and on each day prior to apheresis</li><li>• Administer Mozobil approximately 11 hours prior to initiation of each apheresis for up to 4 consecutive days at the following dose:<ul style="list-style-type: none"><li>○ 20 mg fixed dose or 0.24 mg/kg actual body weight for patients weighing ≤ 83 kg</li><li>○ 0.24 mg/kg actual body weight for patients weighing &gt; 83 kg; not to exceed 40 mg/day</li></ul></li></ul>

## VI. Billing Code/Availability Information

Jcode:

J2562 – Injection, plerixafor, 1 mg: 1 billable unit = 1 mg

NDC:

Mozobil 24 mg/1.2 mL solution; single-use vial: 00024-5862-xx

## VII. References

1. Mozobil [package insert]. Cambridge, MA; Genzyme Corporation; December 2017. Accessed October 2018.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) plerixafor. National Comprehensive Cancer Network, 2018. 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 October 2018.
3. Giralt S, Stadtmauer EA, Harousseau JL, et al. International Myeloma Working Group (IMWG) consensus statement and guidelines regarding the current status of stem cell collection and high-dose therapy for multiple myeloma and the role of plerixafor (AMD 3100). *Leukemia*. 2009;23(10):1904-1912.

4. Wisconsin Physicians Service Insurance Corporation. Local Coverage Determination (LCD): Drugs and Biologics (non-chemotherapy) (L34741). Centers for Medicare & Medicaid Services, Inc. Updated on 05/24/2018 with effective date 06/01/2018. Accessed October 2018.

## Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
Z52.001	Unspecified donor, stem cells
Z52.011	Autologous donor, stem cells
Z52.091	Other blood donor, stem cells
Z94.81	Bone marrow transplant status
Z94.84	Stem cells transplant status

## 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) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: <http://www.cms.gov/medicare-coverage-database/search/advanced-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):

<b>Jurisdiction(s):</b> 5, 8	<b>NCD/LCD Document (s):</b> L34741
<a href="https://www.cms.gov/medicare-coverage-database/search/lcd-date-search.aspx?DocID=L34741&amp;bc=gAAAAAAAAAAAAAAAAA==">https://www.cms.gov/medicare-coverage-database/search/lcd-date-search.aspx?DocID=L34741&amp;bc=gAAAAAAAAAAAAAAAAA==</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, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
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.

Medicare Part B Administrative Contractor (MAC) Jurisdictions

<b>Jurisdiction</b>	<b>Applicable State/US Territory</b>	<b>Contractor</b>
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC