Mozobil® (plerixafor)
(Subcutaneous)

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I. Length of Authorization

Coverage will be provided for 1 treatment cycle of 4 days and will be eligible for renewal for 1 additional treatment cycle.

II. Dosing Limits

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

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

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

- 40 billable units per day

III. Initial Approval Criteria [1]

Coverage is provided in the following conditions:

- Patient is at least 18 years of age; **AND**

Peripheral mobilization of stem cells for transplantation † ‡ Φ [1,2]

- Used in the autologous transplant setting; **AND**
    - Used in combination with filgrastim (or its biosimilars) or tbo-filgrastim; **OR**
    - Used in combination with pegfilgrastim (or its biosimilars); **OR**
    - Used in combination with sargramostim and cyclophosphamide; **OR**
- Used in the allogeneic transplant setting; **AND**
    - Used as additional therapy for insufficient collection of stem cells in combination with filgrastim following single-agent filgrastim therapy

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

IV. Renewal Criteria [1]

Coverage can be renewed based on the following criteria:

- Patient continues to meet indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in section III; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: 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 [1]

Indication	Dose

Peripheral mobilization of stem cells for transplantation	• Begin treatment with Mozobil after the patient has received G-CSF once daily for 4 days
	• 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
	• Administer Mozobil approximately 11 hours prior to initiation of each apheresis for up to 4 consecutive days at the following dose:
	  ○ 20 mg fixed dose or 0.24 mg/kg actual body weight for patients weighing ≤ 83 kg
	  ○ 0.24 mg/kg actual body weight for patients weighing > 83 kg; not to exceed 40 mg/day

VI. Billing Code/Availability Information

HCPCS code:

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

NDC:

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

VII. References

1. Mozobil [package insert]. Cambridge, MA; Genzyme Corporation; August 2020. Accessed October 2022.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) plerixafor. 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 October 2022.

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.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
Z52.011	Autologous donor, stem cells
Z52.091	Other blood donor, stem cells
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), Local Coverage Articles (LCAs), and Local Coverage Determinations (LCDs) 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/LCA/LCD):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, 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.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC