Clinical Policy: Plerixafor (Mozobil)

Reference Number: CP.PHAR.323
Effective Date: 03.01.17
Last Review Date: 08.24
Line of Business: Commercial, HIM, Medicaid

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Plerixafor (Mozobil®) is a hematopoietic stem cell mobilizer.

FDA Approved Indication(s)

Mozobil is indicated in combination with filgrastim to mobilize hematopoietic stem cells (HSCs) to the peripheral blood for collection and subsequent autologous transplantation in patients with non-Hodgkin's lymphoma (NHL) or multiple myeloma (MM).

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Mozobil is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Mobilization of Hematopoietic Stem Cells (must meet all)**:**

1. Diagnosis of NHL or MM;
2. Prescribed by or in consultation with an oncologist or hematologist;
3. Age ≥ 18 years;
4. If request is for brand Mozobil, member must use generic plerixafor, unless contraindicated or clinically significant adverse effects are experienced;
5. Prescribed in combination with a formulary granulocyte-colony stimulating factor (G-CSF) (i.e., Zarxio®);
   **Prior authorization may be required for G-CSF.*
6. Member is scheduled to receive autologous stem cell transplantation;
7. Mozobil is prescribed to be administered for up to 4 consecutive days;
8. Documentation of member's current weight (in kg);
9. Dose does not exceed one of the following (a or b):
   a. Weight ≤ 83 kg: 20 mg/day fixed dose or 0.24 mg/kg per day;
   b. Weight > 83 kg: 0.24 mg/kg (up to 40 mg per day).

Approval duration: 3 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):

a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or

2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. Mobilization of Hematopoietic Stem Cells (must meet all)**:**

1. Re-authorization is not permitted. Members must meet the initial approval criteria.

Approval duration: Not applicable

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid, or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration

G-CSF: granulocyte-colony stimulating factor
HSCs: hematopoietic stem cells
MM: multiple myeloma
NHL: non-Hodgkin lymphoma

Appendix B: Therapeutic Alternatives
Not applicable

Appendix C: Contraindications/Boxed Warnings
- Contraindication(s): hypersensitivity
- Boxed warning(s): none reported

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
NHL or MM	The recommended dose of Mozobil by SC injection is based on actual body weight: • ≤ 83 kg: 20 mg fixed dose or 0.24 mg/kg of body weight • > 83 kg: 0.24 mg/kg of body weight Initiate Mozobil treatment after the patient has received G-CSF once daily for 4 days. Administer Mozobil approximately 11 hours prior to initiation of each apheresis for up to 4 consecutive days. Use actual body weight to calculate the volume of Mozobil to be administered: 0.012 x actual body weight (in kg) = volume to be administered (in mL). Mozobil dose and treatment if weight is more than 175% of ideal body weight have not been investigated.	40 mg/day

VI. Product Availability
Single-use vial for injection: 1.2 mL of a 20 mg/mL solution containing 24 mg of plerixafor

VII. References
1. Mozobil Prescribing Information. Cambridge, MA: Genzyme Corporation; September 2023. Available at: www.mozobil.com. Accessed May 6, 2024.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed May 9, 2024.
3. National Comprehensive Cancer Network. Hematopoietic Cell Transplantation Version 1.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/hct.pdf. Accessed: May 9, 2024.
4. Plerixafor Drug Monograph. Clinical Pharmacology. Available at: https://www.clinicalkey.com/pharmacology. Accessed May 9, 2024.

Coding Implications
Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J2562	Injection, plerixafor, 1 mg

Reviews, Revisions, and Approvals	Date	P&T Approval Date
3Q 2020 annual review: no significant changes; references reviewed and updated.	05.04.20	08.20
3Q 2021 annual review: no significant changes; modified HIM.PHAR.21 to HIM.PA.154; references reviewed and updated.	04.05.21	08.21
3Q 2022 annual review: no significant changes; modified examples of G-CSF products to only indicate Zarxio which is the preferred product; references reviewed and updated.	05.02.22	08.22
Template changes applied to other diagnoses/indications.	09.21.22	
3Q 2023 annual review: no significant changes; separated the following requirement for additional clarity: Mozobil is prescribed to be administered for up to 4 consecutive days; references reviewed and updated.	04.18.23	08.23
For brand requests, added redirection to generic plerixafor.	11.28.23	02.24
3Q 2024 annual review: to confirm weight-based dosing added requirement for documentation of member's current weight (in kg); references reviewed and updated.	05.06.24	08.24

Important Reminder
This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions, and

limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members, and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.