Clinical Policy: Plerixafor (Mozobil)

Reference Number: PA.CP.PHAR.323
Effective Date: 01/2018
Last Review Date: 07/2024

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) and multiple myeloma (MM).

Policy/Criteria
It is the policy of PA Health & Wellness ® that plerixafor 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 granulocyte-colony stimulating factor (G-CSF) (e.g., Zarxio®);
   **Prior authorization is (or 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/day;
   b. Weight > 83 kg: 0.24 mg/kg (up to 40 mg per day).

Approval duration: 3 months

B. Other diagnoses/indications: Refer to PA.CP.PMN.53

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: N/A

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

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;

Approval duration: Duration of request or 3 months (whichever is less); or

2. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized)

III. Diagnoses/Indications for which coverage is NOT authorized

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 – PA.CP.PMN.53

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 TransplantationVersion 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
4Q 2018 annual review: no significant changes; added prescriber requirement; references reviewed and updated.	08/2018
3Q 2019 annual review: No changes per Statewide PDL implementation 01-01-2020	07/2019
3Q 2020 annual review: added age limit; added biosimilar Nivestym to list of G-CSF products which should be prescribed in combination with Mozobil; references reviewed and updated.	07/2020
3Q 2021 annual review: no significant changes; references reviewed and updated.	07/2021
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.	07/2022
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.	07/2023
For brand requests, added redirection to generic plerixafor.	01/2024
3Q 2024 annual review: to confirm weight-based dosing added requirement for documentation of member's current weight (in kg); references reviewed and updated.	017/25024