Prior Authorization Review Panel

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CHC-MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: PA Health & Wellness	**Submission Date: 08/01/2021**
Policy Number: PA.CP.PHAR.323	**Effective Date: 01/2020** **Revision Date: 07/2021**
Policy Name: Plerixafor (Mozobil)	

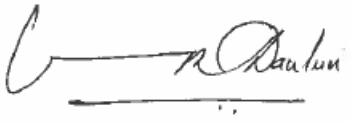
Type of Submission – Check all that apply:

- ☐ **New Policy**
- ✓ **Revised Policy***
- ☐ **Annual Review - No Revisions**
- ☐ **Statewide PDL** - *Select this box when submitting policies for Statewide PDL implementation and when submitting policies for drug classes included on the Statewide PDL.*

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any changes or clarifying information for the policy below:

3Q 2021 annual review: no significant changes; references reviewed and updated.

Name of Authorized Individual (Please type or print): **Venkateswara R. Davuluri, MD**	**Signature of Authorized Individual:** 

Clinical Policy: Plerixafor (Mozobil)

Reference Number: PA.CP.PHAR.323
Effective Date: 01/2018
Last Review Date: 07/2021

Coding Implications
Revision Log

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

FDA Approved Indication(s)
Mozobil is indicated in combination with granulocyte-colony stimulating factor (G-CSF) 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 Pennsylvania Health and Wellness ® 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. Prescribed in combination with G-CSF (e.g., Neupogen®, Granix®, Nivestym™);
   **Prior authorization is (or may be) required for G-CSF*
5. Member is scheduled to receive autologous stem cell transplantation;
6. Dose does not exceed one of the following (a or b), given for up to 4 consecutive days:
   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. Member must meet initial approval criteria for reauthorization.

Approval duration: 3 months

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

1. Currently receiving medication via Pennsylvania Health and 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 6 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; August 2020. Available at: www.mozobil.com. Accessed April 5, 2021.

2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed April 5, 2021.
3. National Comprehensive Cancer Network. Hematopoietic Growth Factors Version 2.2021. Available at: https://www.nccn.org/professionals/physician_gls/pdf/growthfactors.pdf. Accessed: April 5, 2021.
4. Plerixafor Drug Monograph. Clinical Pharmacology. Available at: http://www.clinicalpharmacology-ip.com. Accessed April 5, 2021.

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	Approval Date
4Q 2018 annual review: no significant changes; added prescriber requirement; references reviewed and updated.	08/18	
3Q 2019 annual review: No changes per Statewide PDL implementation 01-01-2020	07/17/19	
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	