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Clinical Policy Title:	plerixafor
Policy Number:	RxA.221
Drug(s) Applied:	Mozobil®
Original Policy Date:	02/07/2020
Last Review Date:	06/10/2021
Line of Business Policy Applies to:	All lines of business

Background

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

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
plerixafor (Mozobil®)	NHL or MM	Initiate treatment after the patient has received G- CSF once daily for 4 days. Administer approximately 11 hours prior to initiation of each apheresis for up to 4 consecutive days. The recommended dose 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 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

Dosage Forms

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

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria. The provision of provider samples does not guarantee coverage under the terms of the pharmacy benefit administered by RxAdvance. All criteria for initial approval must be met in order to obtain coverage.

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

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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 a formulary G-CSF (i.e., Neupogen®, Zarxio®, Granix®, Nivestym®);*
   **Prior authorization 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 per day;
   b. Weight > 83 kg: 0.24 mg/kg (up to 40 mg per day).

Approval Duration
Commercial: 3 months
Medicaid: 3 months

II. Continued Therapy Approval

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.

III. Appendices

APPENDIX A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
G-CSF: granulocyte-colony stimulating factor
HSCs: hematopoietic stem
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.

APPENDIX D: General Information
Not applicable.

References

1. Mozobil® Prescribing Information. Cambridge, MA: Genzyme Corporation; August 2020. Available at: www.mozobil.com. Accessed April 21, 2021.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed April 21, 2021.

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3. National Comprehensive Cancer Network. Myeloid Growth Factors Version 1.2021. Available at: http://www.nccn.org/professionals/physician_gls/pdf/myeloid_growth.pdf. Accessed April 21, 2021.
4. Plerixafor Drug Monograph. Clinical Pharmacology. Available at: http://www.clinicalpharmacology-ip.com. Accessed April 21, 2021.
5. National Comprehensive Cancer Network. Hematopoietic Growth Factors Version 2.2021. Available at: https://www.nccn.org/professionals/physician_gls/pdf/growthfactors.pdf. Updated March 23, 2021. Accessed April 21, 2021.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	01/2020	02/07/2020
Policy was reviewed: 1. Clinical policy title table was updated. 2. Line of Business Policy Applies to was updated to all lines of business. 3. Initial criteria approval duration was updated to include Commercial and Medicaid approval duration as 3 months. 4. References updated.	07/08/2020	09/14/2020
Policy was reviewed: 1. Policy title was updated. 2. Dosing regimen updated for simplification. 3. Clinical policy section standard verbiage was updated to include "The provision of prescriber samples…". 4. References were updated.	04/21/2021	06/10/2021

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