Clinical Policy: Plerixafor (Mozobil)

Reference Number: ERX.SPA.211
Effective Date: 01.11.17
Last Review Date: 08.21
Line of Business: Commercial, Medicaid

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 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) 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.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ 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 (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 per 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

1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. Mobilization of Hematopoietic Stem Cells

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. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to ERX.PA.01 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:

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 – ERX.PA.01 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's 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 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.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created.	12.16	01.17
4Q17 Annual Review	09.13.17	11.17

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Converted to new template. Added age restriction as safety and efficacy in pediatric patients have not been established per PI. Updated max dose requirement to include "up to 4 consecutive days" per PI. Increased initial approval duration from 4 days to 1 week. Added continued therapy section to clarify that member must meet initial approval criteria for reauthorization. Updated references.		
3Q 2018 annual review: added prescriber requirement; modified approval duration to 3 months; references reviewed and updated.	05.01.18	08.18
3Q 2019 annual review: no significant changes; added biosimilar Nivestym to list of G-CSF products which should be prescribed in combination with Mozobil; references reviewed and updated.	05.15.19	08.19
3Q 2020 annual review: no significant changes; references reviewed and updated.	05.04.20	08.20
3Q 2021 annual review: no significant changes; references reviewed and updated.	04.05.21	08.21

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.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. 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.