Clinical Policy: Plerixafor (Mozobil)

Reference Number: LA.PHAR.323
Effective Date: 11.04.23
Last Review Date: 02.05.25~~04.04.24~~ Coding Implications
Line of Business: Medicaid Revision Log

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

****Please note: This policy is for medical benefit****

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)~~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 Louisiana Healthcare Connections® 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);
~~8.~~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 LA.PMN.255
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 LA.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: 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 LA.PMN.255
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 LA.PMN.53

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 LA.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	40 mg/day

Indication	Dosing Regimen	Maximum Dose
	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.	

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.~~September 2023. Available at: www.mozobil.com. Accessed ~~April 18, 2023.~~May 6, 2024.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed May 9, ~~2023~~2024.
3. National Comprehensive Cancer Network. Hematopoietic Cell Transplantation Version 1.~~2023~~2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/hct.pdf. Accessed: May 9, ~~2023~~2024.
4. Plerixafor Drug Monograph. Clinical Pharmacology. Available at: https://www.clinicalkey.com/pharmacology. Accessed May 9, ~~2023~~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	LDH Approval Date
Converted corporate policy to local policy.	06.26.23	10.05.23
Annual review; separated the following requirement for additional clarity: Mozobil is prescribed to be administered for up to 4 consecutive days; For brand requests, added redirection to generic plerixafor; references reviewed and updated.	04.04.24	07.10.25

Reviews, Revisions, and Approvals	Date	LDH Approval Date
Annual review: to confirm weight-based dosing added requirement for documentation of member's current weight (in kg); references reviewed and updated.	02.05.25	

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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. LHCC 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.

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 LHCC administrative policies and procedures.

This clinical policy is effective as of the date determined by LHCC. 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. LHCC 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 LHCC has no control or right of control. Providers are not agents or employees of LHCC.

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