Medical Policy

Utilization Management and Clinical Medical Policy

Policy Name:	Policy Number:	Scope:	Origination Date:	Effective Date:
Plerixafor (Mozobil®)	**MP-RX-FP-128-24**	☒ **MMM MA** ☒ **MMM MultiHealth**	6/28/2024 **Last Review Date:** 03/24/2026	03/24/2026 **Frequently Revision:** Annual

Service Category

☐ Anesthesia
☐ Surgery
☐ Radiology Procedures
☐ Pathology and Laboratory Procedures
☐ Medicine Services and Procedures
☐ Evaluation and Management Services
☐ DME/Prosthetics or Supplies
☒ Part B Drugs

Service Description

This document addresses the use of plerixafor (Mozobil®), a hematopoietic stem cell mobilizer approved by the Food and Drug Administration (FDA) to mobilize hematopoietic stem cells (HSCs), in combination with filgrastim, to the peripheral blood for collection and subsequent autologous transplantation in patients with non-Hodgkin's lymphoma or multiple myeloma.

Background Information

This document addresses the use of Mozobil® (plerixafor), a chemokine receptor type 4 inhibitor (CXCR4) which impairs binding of hematopoietic stem cells within the bone marrow microenvironment. Mozobil is approved in combination with granulocyte colony stimulating factors (G-CSF) to mobilize hematopoietic stem cells to the peripheral blood for subsequent autologous transplantation in individuals with non-Hodgkin's lymphoma, multiple myeloma, or other conditions as appropriate.

Mozobil in combination with G-CSF is FDA approved for mobilization of autologous hematopoietic stem cells in individuals with non- Hodgkin lymphoma or multiple myeloma. Current literature supports the use of Mozobil for mobilization prior to autologous transplant in other conditions such as Hodgkin lymphoma (Shaughnessy 2013) and testicular carcinoma (De Blasio 2013). The National Comprehensive Cancer Network (NCCN) guideline on myeloid growth factors states effective mobilization regimens in the autologous setting include growth factor alone, chemotherapy and growth factor combined, and incorporation of Mozobil (plerixafor) with either approach. The NCCN guidelines also recommend the use of Mozobil for both autologous and allogeneic donors when there is insufficient collection of stem cells with prior mobilization.

In addition, Mozobil has been utilized for autologous hematopoietic stem cell mobilization in the setting of ex vivo gene therapy development, including for the treatment of β-thalassemia with betibeglogene autotemcel (Zynteglo) and for sickle cell disease with LentiGlobin gene therapy, where effective stem cell collection is required prior to genetic modification and reinfusion.

Approved Indications

A. Mozobil is indicated by the FDA, 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 or multiple myeloma.

Policy Name:	Policy Number:	Scope:	Origination Date:	Effective Date:
Plerixafor (Mozobil®)	MP-RX-FP-128-24	☒ MMM MA ☒ MMM MultiHealth	6/28/2024	03/24/2026
			Last Review Date: 03/24/2026	Frequently Revision: Annual

Other Uses (Off-Label, Literature Supported)

A. Mobilization of hematopoietic stem cells in patients with β-thalassemia (non-β^0/β^0 genotype) undergoing betibeglogene autotemcel gene therapy. (Locatelli et al., 2022)

B. Mobilization of hematopoietic stem cells in patients with sickle cell disease undergoing LentiGlobin gene therapy (Kanter et al., 2022).

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

HCPCS	Description
J2562	Injection, plerixafor, 1 mg [Mozobil]

ICD-10	Description
C62.00-C62.92	Malignant neoplasm of testis
C81.00-C81.99	Hodgkin lymphoma
C82.00-C88.9	Non-Hodgkin lymphomas
C90.00-C90.32	Multiple myeloma and malignant plasma cell neoplasms
D56.1	Beta thalassemia
D56.0	Sickle-cell anemia
D57.0	Hb-SS disease with crisis
D57.1	Sickle-cell disease without crisis
D57.2	Double heterozygous sickling disorders
D57.3	Sickle-cell trait
D57.4	Sickle-cell thalassemia
Z52.001	Unspecified donor, stem cells
Z52.011	Autologous donor, stem cells
Z52.091	Other blood donor, stem cells
Z92.86	Personal history of gene therapy
Z94.81	Bone marrow transplant status
Z94.84	Stem cells transplant status
Z52.001	Autologous hematopoietic stem cells transplant status

Policy Name:	Policy Number:	Scope:	Origination Date:	Effective Date:
Plerixafor (Mozobil®)	MP-RX-FP-128-24	☒ MMM MA ☒ MMM MultiHealth	6/28/2024	03/24/2026
			Last Review Date: 03/24/2026	Frequently Revision: Annual

Z94.84	Stem cell transplant status

Medical Necessity Guidelines

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

Mozobil® (plerixafor)

A. Criteria For Initial Approval *(Provider must submit documentation [such as office chart notes, lab results, pathology reports, imaging studies, and any other pertinent clinical information] supporting the patient's diagnosis for the drug and confirming that the patient has met **all** approval criteria.)*

i. Individual is 18 years of age or older; **AND**
ii. Agent is being used to mobilize autologous hematopoietic stem cells; **AND**
iii. Individual has a diagnosis of (Hodgkin or non-Hodgkin) lymphoma, multiple myeloma, testicular carcinoma, or other diagnosis for which autologous hematopoietic stem cell transplant is indicated (Label, Shaughnessy 2013, De Blasio 2013); **AND**
iv. After stem cell mobilization and collection, a subsequent autologous hematopoietic stem cell transplant is anticipated; **AND**
v. The total number of Mozobil (plerixafor) injections has not exceed four doses per cycle for up to two cycles; **AND**
vi. Individual is using in combination with the following (Label, NCCN 2A):
   A. Filgrastim (or biosimilar or tbo-filgrastim) or pegfilgrastim (or biosimilar); **OR**
   B. Cyclophosphamide and either filgrastim (or biosimilar or tbo-filgrastim) or sargramostim; **OR**
   C. Filgrastim (or biosimilar or tbo-filgrastim) and disease-specific chemotherapy; **OR**
   D. Filgrastim (or biosimilar or tbo-filgrastim) or chemo-mobilization following insufficient collection from previous treatment with either alone;

OR

vii. Individual is 18 years of age or older; **AND**
viii. Individual is using Mozobil (plerixafor) in combination with filgrastim (or biosimilar or tbo-filgrastim)

Policy Name:	Policy Number:	Scope:	Origination Date:	Effective Date:
Plerixafor (Mozobil®)	MP-RX-FP-128-24	☒ MMM MA ☒ MMM MultiHealth	6/28/2024	03/24/2026
			Last Review Date: 03/24/2026	Frequently Revision: Annual

for allogeneic donors following insufficient collection from previous treatment with filgrastim (or biosimilar or tbo-filgrastim) alone; **AND**

ix. The total number of Mozobil (plerixafor) injections has not exceed four doses per cycle for one cycle;

OR

x. Individual is using Mozobil (plerixafor) for autologous hematopoietic stem cell (HSC) mobilization as part of the development of an FDA-approved ex vivo gene therapy (e.g., betibeglogene autotemcel [Zynteglo] or LentiGlobin for sickle cell disease) *(Locatelli 2022; Kanter 2022)*.

B. Criteria For Continuation of Therapy

Provider must submit documentation (such as office chart notes, lab results, imaging studies, or any other pertinent clinical information) confirming that the patient continues to meet approval criteria.

i. MMM considers continuation of plerixafor (Mozobil®) therapy medically necessary in members requesting reauthorization for an indication listed in Section A above (Criteria for Initial Approval) if the following criteria are met:

A. A subsequent autologous or allogeneic hematopoietic stem cell transplant is still planned or ongoing; **AND**

B. The total number of Mozobil (plerixafor) injections has not exceeded four doses per mobilization cycle, and the total number of mobilization cycles has not exceeded two for autologous use or one for allogeneic donor use; **AND**

C. Documentation is provided indicating the individual has not experienced severe or intolerable adverse effects that would preclude continued use (e.g., splenic enlargement, leukocytosis, or hypersensitivity); **AND**

D. For individuals receiving gene therapy, documentation confirms that the individual remains eligible for the gene therapy protocol and stem cell mobilization is still required as part of the treatment plan.

C. Authorization Duration

i. Initial Approval Duration: Up to 12 months

ii. Reauthorization Approval Duration: Up to 12 months

D. Conditions Not Covered

Any other use is considered experimental, investigational, or unproven, including the following (this list may not be all inclusive):

Requests for Mozobil (plerixafor) may not be approved for the following:

I. Individual is using as a mobilizer of leukemic cells;

Policy Name:	Policy Number:	Scope:	Origination Date:	Effective Date:
Plerixafor (Mozobil®)	MP-RX-FP-128-24	☒ MMM MA ☒ MMM MultiHealth	6/28/2024	03/24/2026
			Last Review Date: 03/24/2026	Frequently Revision: Annual

OR

II. When the above criteria are not met or for all other indications.

Limits or Restrictions

A. Therapeutic Alternatives

The list below includes preferred alternative therapies recommended in the approval criteria and may be subject to prior authorization.

i. N/A

B. Quantity Limitations

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines. The chart below includes dosing recommendations as per the FDA-approved prescribing information.

Mozobil® injection 24 mg/1.2 ml (20 mg/ml) SDV	
Indication	**Recommended Dosing Schedule**
Hematopoietic cell mobilization (for autologous transplantation in non-Hodgkin lymphoma and multiple myeloma)	• Initiate Mozobil after the patient has received filgrastim once daily for 4 days. • Dose based on patient weight: ○ Less than or equal to 83 kg: 20 mg dose or select dose based on 0.24 mg/kg actual body weight. ○ Greater than 83 kg: select dose based on 0.24 mg/kg actual body weight. • Repeat Mozobil dose up to 4 consecutive days.
Hematopoietic cell mobilization prior to betibeglogene autotemcel in beta thalassemia (off-label use)	• 0.24 mg/kg subcutaneous once daily in the evening on mobilization days 4 and 5 (and day 6 if needed), followed by apheresis, which usually begins on mobilization day 5.

Policy Name:	Policy Number:	Scope:	Origination Date:	Effective Date:
Plerixafor (Mozobil®)	MP-RX-FP-128-24	☒ MMM MA ☒ MMM MultiHealth	6/28/2024	03/24/2026
			Last Review Date: 03/24/2026	Frequently Revision: Annual

Hematopoietic cell mobilization prior to lovotibeglogene autotemcel in sickle cell anemia (off-label use)	• 0.24 mg/kg ~4 to 6 hours prior to apheresis; if >1 apheresis day is required, platelet count must be ≥75,000/mm^3 within 24 hours of subsequent apheresis sessions prior to plerixafor administration that day.

Exceptions

- Should be administered by subcutaneous injection approximately 11 hours prior to initiation of apheresis.
- Renal impairment: If creatinine clearance is ≤50 mL/min:
  - Patients ≤83 kg: 13 mg fixed dose or 0.16 mg/kg once daily
  - Patients >83 kg and <160 kg: 0.16 mg/kg once daily; maximum dose: 27 mg daily

  Note: Creatinine clearance estimate based on Cockcroft-Gault formula.
- Mozobil dose should not exceed 40 mg/day.

Reference Information

1. De Blasio A, Rossi L, Zappone E, et al. Plerixafor and autologous stem cell transplantation: impressive result in a chemoresistant testicular cancer patient treated with high-dose chemotherapy. Anticancer Drugs. 2013; 24(6):653-657.
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Duong HK, Savani BN, Copelan E, et al. Peripheral blood progenitor cell mobilization for autologous and allogeneic hematopoietic cell transplantation: guidelines from the American Society for Blood and Marrow Transplantation (ASBMT). Biol Blood Marrow Transplant. 2014; 20(9):1262-1273.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2025; Updated periodically.
5. Shaughnessy P, Uberti J, Devine S, et al. Plerixafor and G-CSF for autologous stem cell mobilization in patients with NHL, Hodgkin's lymphoma and multiple myeloma: results from the expanded access program. Bone Marrow Transplant. 2013; 48(6):777-781.
6. NCCN Clinical Practice Guidelines in Oncology™. © 2026 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Accessed on January 28, 2026
   a. Hematopoietic Cell Transplantation (HCT). V3.2025. Revised September 24, 2025.
7. Mozobil Prescribing Information (Sanofi) Sanofi. (2023). *Mozobil® (plerixafor) injection prescribing information*. Retrieved January 28, 2026, from https://products.sanofi.us/Mozobil/mozobil.pdf
8. National Comprehensive Cancer Network. (n.d.). *NCCN Drugs & Biologics Compendium*. Accessed January 28, 2026, from https://www.nccn.org/professionals/drug_compendium/content/
9. UpToDate. (n.d.). *Plerixafor: Drug information*. Retrieved January 28, 2026, from https://www.uptodate.com/contents/plerixafor-drug-

information?search=mozobil&source=panel_search_result&selectedTitle=1~15&usage_type=panel&kp_tab=drug_general&display_rank=1

10. Locatelli, F., Thompson, A. A., Kwiatkowski, J. L., et al. (2022). Betibeglogene autotemcel gene therapy for non-β^0/β^0 genotype β-thalassemia. *New England Journal of Medicine*, 386(5), 415–427. https://doi.org/10.1056/NEJMoa2113206. Retrieved January 28, 2026.
11. Kanter, J., Walters, M. C., Krishnamurti, L., et al. (2022). Biologic and clinical efficacy of LentiGlobin for sickle cell disease. *New England Journal of Medicine*, 386(7), 617–628. https://doi.org/10.1056/NEJMoa2117175. Retrieved January 28, 2026.

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.

Policy History

Policy Name:	Policy Number:	Scope:	Origination Date:	Effective Date:
Plerixafor (Mozobil®)	**MP-RX-FP-128-24**	☒ **MMM MA** ☒ **MMM MultiHealth**	6/28/2024	03/24/2026
			Last Review Date: 03/24/2026	**Frequently Revision:** Annual

Revision Type	Summary of Changes	P&T Approval Date	UM/CMPC Approval Date
Annual Review	Added Mozobil off-label uses for hematopoietic stem cell mobilization in gene therapy protocols (e.g., β-thalassemia and sickle cell disease) and defined recommended dosage parameters. Added criteria for initial approval and continuation of therapy, including treatment limits, transplant intent, and use in combination with approved mobilization regimens. Added dosage exceptions for individuals with renal impairment and defined maximum allowed dosing per cycle and per indication. Coding reviewed: added ICD-10 codes: D56.1, D56.0, D57.0, D57.1, D57.2, D57.3, D57.4, Z52.001, Z94.84. Wording and formatting changes. Updated references.	3/17/2026	3/24/2026
Annual Review	Validation of information to ensure is up to date. Word formatting and indent alignment. Added: ICD-10 code Z94.84 Stem cells transplant status.	4/16/2025	5/6/2025
Policy Inception	Elevance Health's Medical Policy adoption	N/A	6/28/2024