Medical Policy

Healthcare Services Department

Policy Name	Policy Number	Scope
Plerixafor (Mozobil®)	MP-RX-FP-128-24	☒ MMM MA ☒ MMM Multihealth

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 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 lymphomalymphoma, 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 for insufficient collection of stem cells from prior treatment. Mozobil has also been used for autologous hematopoietic stem cell (HSC) mobilization during the development of ex vivo gene therapy, most recently with Zynteglo for treatment of beta thalassemia.

Approved Indications

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.

Other Uses

N/A

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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
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

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.

Plerixafor (Mozobil®)

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) 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., Zynteglo).

B. Criteria For Continuation of Therapy

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) and the recommended total duration of therapy has not been exceeded. 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.

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:

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

Drug	Recommended Dosing Schedule

Mozobil	• 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.

Exceptions	
• Should be administered by subcutaneous injection approximately 11 hours prior to initiation of apheresis. • Renal impairment: If creatinine clearance is ≤50 mL/min, decrease dose by one-third to 0.16 mg/kg.	

Reference Information

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: January 11, 2024.

2. 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.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. 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.
5. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2024; Updated periodically.
6. 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.
7. NCCN Clinical Practice Guidelines in Oncology™. © 2023 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Accessed on January 11, 2024.
    a. Hematopoietic Cell Transplantation (HCT). V3.2023. Revised October 9, 2023.

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

Revision Type	Summary of Changes	P&T Approval Date	UM/CMPC Approval Date
Policy Inception	Elevance Health's Medical Policy adoption	N/A	6/28/2024

Revised: 04/10/2024