Original Effective Date: 10/01/2018
Current Effective Date: 03/08/2025
Last P&T Approval/Version: 01/29/2025
Next Review Due By: 01/2026
Policy Number: C9017-A

Mozobil (plerixafor)

PRODUCTS AFFECTED

Mozobil (plerixafor), plerixafor

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:
Non-Hodgkin Lymphoma, Multiple Myeloma

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

All transplants require prior authorization from the Corporate Transplant Department. Must document transplant approval prior to approval of Mozobil.

A. PERIPHERAL MOBILIZATION OF STEM CELLS:
1. Documentation that member has been diagnosed with non-Hodgkin’s lymphoma (NHL) or multiple

myeloma
AND

2. Documentation that plerixafor will be used in combination with a granulocyte colony stimulating factor (i.e., preferred filgrastim product)
   AND
3. Prescriber attests to (or the clinical reviewer has found that) the member not having any FDA labeled contraindications that haven't been addressed by the prescriber within the documentation submitted for review [Contraindications to Mozobil (plerixafor) include: history of hypersensitivity to Mozobil, avoid becoming pregnant, and should not be used in patients with leukemia]

CONTINUATION OF THERAPY:
N/A

DURATION OF APPROVAL:
Initial authorization: ONE FILL, 4-day supply, Continuation of Therapy: N/A
For tandem HSCT requests, criteria must be met and approved per MCP-122 Hematopoietic Stem Cell Transplantation for Multiple Myeloma.

PRESCRIBER REQUIREMENTS:
Prescribed by or in consultation with a board-certified hematologist/oncologist, or transplant specialist [If prescribed in consultation, consultation notes must be submitted with initial request]

AGE RESTRICTIONS:
18 years of age and older

QUANTITY:
≤83 kg: 20mg fixed dose or 0.24 mg/kg
>83 kg: 0.24 mg/kg
Maximum daily dose 40 mg

Maximum Quantity Limits – Mozobil 24 mg vial: 8 vials per 4 days

PLACE OF ADMINISTRATION:
The recommendation is that injectable medications in this policy will be for pharmacy or medical benefit coverage and the subcutaneous injectable products administered in a place of service that is a non-hospital facility-based location.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Subcutaneous Injection

DRUG CLASS:
CXCR4 Receptor Antagonist

FDA-APPROVED USES:
Mozobil (plerixafor) 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 or multiple myeloma.

COMPENDIAL APPROVED OFF-LABELED USES:
None

APPENDIX

APPENDIX:
None

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
The National Comprehensive Cancer Network Guidelines (NCCN Guidelines):
The guidelines recommend that high dose therapy with stem cell support is a critical component in the treatment plan for eligible newly diagnosed MM patients and that all types of stem-cell transplantations are appropriate in different clinical settings. Autologous HSCT results in high response rates and remains the standard of care following primary therapy for eligible patients and is an option for treatment of primary progressive or refractory disease post induction treatment. A tandem transplant can be considered for all patients who are candidates for stem cell transplant and is an option for patients who do not achieve at least a very good partial response after the first autologous stem cell transplant. Allogeneic HSCT may be an accepted option in the setting of a clinical trial in patients responding to primary therapy or primary progressive disease, or as salvage therapy in patients with progressive disease following an initial autologous HSCT.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
All other uses of Mozobil (plerixafor) are considered experimental/investigational and therefore, will follow Molina's Off-Label policy. Contraindications to Mozobil (plerixafor) include: history of hypersensitivity to Mozobil, avoid becoming pregnant, and should not be used in patients with leukemia.

OTHER SPECIAL CONSIDERATIONS:
None

CODING/BILLING INFORMATION

CODING DISCLAIMER. *Codes listed in this policy are for reference purposes only and may not be all-inclusive or applicable for every state or line of business. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry-standard coding practices for all submissions. Molina has the right to reject/deny the claim and recover claim payment(s) if it is determined it is not billed appropriately or not a covered benefit. Molina reserves the right to revise this policy as needed.*

HCPCS CODE	DESCRIPTION
J2562	Injection, plerixafor,1mg

AVAILABLE DOSAGE FORMS:
Mozobil SOLN 24MG/1.2ML single-dose vial
Plerixafor SOLN 24MG/1.2ML single-dose vial

REFERENCES

1. Mozobil (plerixafor) injection, for subcutaneous use [prescribing information]. Cambridge, MA: Genzyme Corporation; September 2023.
2. DiPersio J, Stadtmauer EA, Nademanee AP, et al. A Phase III, Multicenter, Randomized, Double Blind, Placebo Controlled, Comparative Trial of AMD3100 (Plerixafor)+G-CSF vs.G- CSF+Placebo for Mobilization in Multiple Myeloma (MM) Patients for Autologous Hematopoietic Stem Cell (aHSC) Transplantation. Blood. 2007; 110: 445.
3. Dipersio JF, Micallef I, Stiff PJ, et al. A Phase III, Multicenter, Randomized, Double Blind, Placebo Controlled, Comparative Trial of AMD3100 (Plerixafor)+ G-CSF vs. Placebo+G- CSF in NonHodgkin's Lymphoma (NHL) Patients for Autologous Hematopoietic Stem Cell (aHSC) Transplantation. Blood. 2007; 110: 601.
4. National Comprehensive Cancer Network. 2023. Hematopoietic Cell Transplantation (HCT) (Version 3.2023). [online] Available at: < hct.pdf (nccn.org) > [Accessed 8 December 2023].
5. National Comprehensive Cancer Network. 2025. Hematopoietic Cell Transplantation (HCT) (Version 2.2024). [online] Available at: < hct.pdf (nccn.org) > [Accessed 6 January 2025].

SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Required Medical Information Prescriber Requirements References	Q1 2025
REVISION- Notable revisions: Required Medical Information Available Dosage Forms References	Q1 2024
REVISION- Notable revisions: Required Medical Information Continuation of Therapy Duration of Approval Prescriber Requirements Quantity FDA-Approved Uses Contraindications/Exclusions/Discontinuation	Q1 2023
Q2 2022 Established tracking in new format	Historical changes on file