Effective Date: 10/01/2018
Last P&T Approval/Version: 01/26/2022
Next Review Due By: 01/2023
Policy Number: C9017-A

Mozobil (plerixafor injection)

PRODUCTS AFFECTED

Mozobil (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

All transplants require prior authorization from the Corporate TransplantDepartment- 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., Neupogen)
AND
3. Documentation of member weight (within last 7days) for dosing verification

CONTINUATION OF THERAPY:
All transplants require prior authorization from the Corporate TransplantDepartment- 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., Neupogen)
AND
3. Documentation of member weight (within last 7days) for dosing verification

DURATION OF APPROVAL:
Initial authorization, NEW HSCT: ONE FILL; 4-day supply
Continuation of Therapy: None
For tandem HSCT, 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

AGE RESTRICTIONS:
18 years of age and older.

QUANTITY:
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 isa non-hospital facility-based location.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Subcutaneous

DRUG CLASS:
CXCR4 Receptor Antagonist

FDA-APPROVED USES:
peripheral blood stem cell (PBSC) mobilization for collection and subsequent autologous transplantation in patients with non-Hodgkin lymphoma and multiple myeloma, in combination with a granulocyte colony stimulating factor (G-CSF)

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 are considered experimental/investigational and therefore, will follow Molina's Off-Label policy. Leukemia is specifically excluded per package insert.

OTHER SPECIAL CONSIDERATIONS:
None

CODING/BILLING INFORMATION

Note: 1) This list of codes may not be all-inclusive. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

HCPCS CODE	DESCRIPTION
J2562	injection, plerixafor,1mg

AVAILABLE DOSAGE FORMS:
24mg/1.2ml solution for injection

REFERENCES

1. Mozobil (plerixafor) [prescribing information]. Cambridge, MA: Genzyme Corporation; August 2020.
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.