Mozobil (plerixafor injection)
Policy Number: C9017-A

CRITERIA EFFECTIVE DATES:

ORIGINAL EFFECTIVE DATE	LAST REVIEWED DATE	NEXT REVIEW DUE BY OR BEFORE
10/1/2018	12/2/2020	1/26/2022
HCPCS CODING	**TYPE OF CRITERIA**	**LAST P&T APPROVAL/VERSION**
J2562-injection, plerixafor, 1mg	RxPA	Q1 2021 20210127C917-A

PRODUCTS AFFECTED:
Mozobil (plerixafor)

DRUG CLASS:
CXCR4 Receptor Antagonist

ROUTE OF ADMINISTRATION:
Subcutaneous

PLACE OF SERVICE:
Buy and Bill

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

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

COVERAGE CRITERIA: INITIAL AUTHORIZATION

DIAGNOSIS:
Non-Hodgkin Lymphoma, Multiple Myeloma

REQUIRED MEDICAL INFORMATION:
** INTERNAL USE ONLY** 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. 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.

QUANTITY:
Mozobil 24 mg vial: 8 vials per 4 days

PRESCRIBER REQUIREMENTS:
Prescribed by or in consultation with a board-certified hematologist/ oncologist

AGE RESTRICTIONS:
18 years of age and older.

CONTINUATION OF THERAPY:
** INTERNAL USE ONLY** 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. Neupogen)
   AND
3. Documentation of member weight (within last 7days) for dosing verification

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

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.

APPENDIX:
None

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, member 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.

REFERENCES:

1. Mozobil (plerixafor) [prescribing information]. Cambridge, MA: Genzyme Corporation; May 2019.
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.