Clinical Policy: Plerixafor (Mozobil)

Reference Number: CP.PHAR.323
Effective Date: 03/17
Last Review Date: 03/17

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
The intent of the criteria is to ensure that patients follow selection elements established by Centene® clinical policy for plerixafor for injection (Mozobil®).

Policy/Criteria
It is the policy of health plans affiliated with Centene Corporation® that Mozobil is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Mobilization of Hematopoietic Stem Cells (must meet all):

1. Meets a or b:
   a. FDA approved use (i, ii and iii):
      i. Prescribed to mobilize hematopoietic stems cells (HSCs) in the autologous* setting for collection and transplantation;
      ii. Will be administered in combination with a granulocyte-colony stimulating factor** (G-CSF) (i.e., filgrastim, filgrastim-sndz, or tbo-filgrastim);
      iii. Diagnosis of non-Hodgkin's lymphoma (NHL) or multiple myeloma (MM);
   b. Off-label NCCN recommended use:
      i. Prescribed to mobilize HSCs in the allogeneic* setting for collection and transplantation (i.e., member is donating HSCs);
2. Member does not have leukemia;
3. Prescribed dose does not exceed 40 mg/day administered before each HSC collection for up to four consecutive days;
4. No known history of hypersensitivity to Mozobil, including anaphylaxis.

**Autologous stem cell transplantation (a procedure in which stem cells are collected and later given back to the same person); allogeneic stem cell transplantation (procedure in which stem cells are collected from one person and given to another).*
***G-CSFs FDA labeled for autologous HSC collection/transplantation: filgrastim, filgrastim-sndz, tbo-filgrastim.*

Approval duration: 1 week

B. Other diagnoses/indications: Refer to CP.PHAR.57 - Global Biopharm Policy.

Background
Description/Mechanism of Action:
Plerixafor is an inhibitor of the CXCR4 chemokine receptor and blocks binding of its cognate ligand, stromal cell-derived factor-1α (SDF-1α). SDF-1α and CXCR4 are recognized to play a role in the trafficking and homing of human hematopoietic stem cells (HSCs) to the marrow

compartment. Once in the marrow, stem cell CXCR4 can act to help anchor these cells to the marrow matrix, either directly in leukocytosis and elevations in circulating hematopoietic progenitor cells in mice, dogs and humans. CD34+ cells mobilized by plerixafor were capable of engraftment iwth long-term repopulating capacity up to one year in canine transplantation models.

Formulations:
Each single-use vial is filled to deliver 1.2 mL of 20 mg/mL solution containing 24 mg of plerixafor. Each vial of Mozobil is intended for single use only.

FDA Approved Indications:
Mozobil is a hematopoietic stem cell mobilizer/subcutaneous injectable formulation 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 (NHL) and multiple myeloma (MM).

Appendices
Appendix A: Abbreviation Key
G-CSF: Granulocyte-colony stimulating factor
HSC: Hematopoietic stem cell
MM: Multiple myeloma
NHL: Non-Hodgkin's lymphoma

Coding Implications
Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J2562	Injection, plerixafor, 1 mg

Reviews, Revisions, and Approvals	Date	Approval Date
Policy is split from CP.PHAR.182 Excellus Oncology. NCCN off-label recommended use in the allogeneic setting is added.	02/17	03/17

References
1. Mozobil prescribing information. Cambridge, MA: Genzyme Corporation; October 2015. Available at http://products.sanofi.us/Mozobil/mozobil.pdf. Accessed February 1, 2017.
2. Plerixafor. In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at NCCN.org. Accessed February 1, 2017.

3. Myeloid growth factors (Version 2.2016). In: National Comprehensive Cancer Network Guidelines. Available at NCCN.org. Accessed February 1, 2017.

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed

herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

Note: For Medicare members, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at http://www.cms.gov for additional information.