Medical Drug Clinical Criteria

Subject:	Mozobil (plerixafor)		
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Overview

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 lymphoma, 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.

Clinical Criteria

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.

Mozobil (plerixafor)

Requests for Mozobil (plerixafor) may be approved if the following criteria are met:

I. Individual is 18 years of age or older; **AND**
II. Agent is being used to mobilize autologous hematopoietic stem cells; **AND**
~~III. Individual is using in combination with a granulocyte colony stimulating factor (G-CSF) (such as Neupogen, Nivestym, Zarxio, Granix, or their biosimilars [NCCN]); **AND**~~
~~IV.~~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**
~~V.~~IV. After stem cell mobilization and collection, a subsequent autologous hematopoietic stem cell transplant is anticipated; **AND**
~~VI.~~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;

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OR

~~VII.~~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).

Requests for Mozobil (plerixafor) may not be approved for the following:

~~I. Individual is using as a mobilizing agent for an allogeneic stem cell donor (ASBMT 2014); **OR**~~

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

~~III. Individual is using as a component of a conditioning regimen prior to an allogeneic hematopoietic stem cell transplant; **OR**~~

~~IV.~~II. When the above criteria are not met or for all other indications.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

CPT

J2562	Injection, plerixafor, 1 mg [Mozobil]

ICD-10 Diagnosis

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
Z94.84	Stem cells transplant status

Document History

Revised: 02/23/2024
Document History:

- 02/23/2024 – Annual Review: Add NCCN-recommended combination regimens; add use in allogeneic donors for insufficient collection per NCCN; remove may not approve sections regarding allogeneic donors. Coding Reviewed: No changes.
- 02/24/2023 – Annual Review: No changes. Coding Reviewed: No changes.
- 09/12/2022 – Select Review: Expand criteria to allow use with ex vivo gene therapy. Coding Reviewed: Added ICD-10-CM Z92.86.
- 02/25/2022 – Annual Review: Update references. Coding Reviewed: No changes.
- 02/19/2021 – Annual Review: No changes. Coding Reviewed: No changes.
- 02/21/2020 – Annual Review: Clarify use with G-CSF to include the biosimilars per NCCN. Coding Reviewed: No changes
- 02/22/2019 – Annual Review: Update Mozobil criteria to include all diagnosis for which an autologous hematopoietic stem cell transplant is indicated. Wording and formatting updates for clarity. Coding update: Added ICD-10 codes: Z52.001, Z52.011, Z52.091, Z94.81, Z94.84 as a result of expansion of criteria.

References

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.

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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.