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5.85.039

Section:	Prescription Drugs	**Effective Date:**	July 1, 2025
Subsection:	Hematological Agents	**Original Policy Date:**	March 13, 2020
Subject:	Mozobil	**Page:**	1 of 4

Last Review Date: June 12, 2025

Mozobil

Description

Mozobil (plerixafor)

Background
Mozobil (plerixafor) inhibits the CXCR4 chemokine receptor and blocks binding of its cognate ligand, stromal cell-derived factor-1α (SDF-1α). SDF-1α and CXCR4 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 via SDF-1α or through the induction of other adhesion molecules. Treatment with Mozobil results in leukocytosis and elevations in circulating hematopoietic progenitor cells (1).

Regulatory Status
FDA-approved indication: Mozobil 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 and multiple myeloma (1).

Serious hypersensitivity reactions, including anaphylactic-type reactions, have occurred in patients receiving Mozobil. Patients should be observed for signs and symptoms of hypersensitivity during and after Mozobil administration for at least 30 minutes and until clinically stable following completion of each administration (1).

Mozobil may cause mobilization of leukemic cells and subsequent contamination of the apheresis product. Therefore, Mozobil is not intended for HSC mobilization and harvest in patients with leukemia (1).

Leukocytosis and thrombocytopenia have been observed in patients receiving Mozobil. Platelet counts and white blood cell counts should be monitored in all patients who receive Mozobil (1).

Mozobil can cause fetal harm when administered to a pregnant woman. Advise pregnant women of the potential risk to the fetus. Advise females of reproductive potential to use an effective form of contraception during treatment with Mozobil and for one week after the final dose (1).

The safety and effectiveness of Mozobil in pediatric patients less than 18 years of age have not been established (1).

Related policies
Aphexda

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Mozobil may be considered **medically necessary** if the conditions indicated below are met.

Mozobil may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age and older

Diagnosis

Patient must be using for the following:

Mobilization of hematopoietic stem cells (HSCs)

AND ALL of the following:

1. Patient must have **ONE** of the following:
    a. Non-Hodgkin’s lymphoma
    b. Multiple myeloma

2. The hematopoietic stem cells (HSCs) will be used for subsequent autologous transplantation
3. Used in combination with granulocyte-colony stimulating factor (G-CSF)
4. Prescriber agrees to monitor platelets and white blood cell counts
5. Females of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Mozobil and for one week after the final dose

Prior–Approval *Renewal* Requirements

Same as above

Policy Guidelines

Pre–PA Allowance

None

Prior–Approval Limits

Duration 12 months

Prior–Approval *Renewal* Limits

Same as above

Rationale

Summary

Mozobil (plerixafor) inhibits the CXCR4 chemokine receptor and blocks binding of its cognate ligand, stromal cell-derived factor-1α (SDF-1α). SDF-1α and CXCR4 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 via SDF-1α or through the induction of other adhesion molecules. Treatment with Mozobil results in leukocytosis and elevations in circulating hematopoietic progenitor cells. The safety and effectiveness of Mozobil in pediatric patients less than 18 years of age have not been established (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Mozobil while maintaining optimal therapeutic outcomes.

References

1. Mozobil [package insert]. Cambridge, MA: Genzyme Corporation; September 2023.

Policy History

Date	Action
March 2020	Addition to PA
June 2020	Annual review
June 2021	Annual review and reference update
June 2022	Annual review
June 2023	Annual review. Changed policy number to 5.85.039
March 2024	Annual review and reference update
June 2025	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 12, 2025 and is effective on July 1, 2025.