Drug and Biologic Coverage Policy

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Coverage Policy Number IP0139

Plerixafor

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Related Coverage Resources

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

This policy supports medical necessity review for the following products:

- **Mozobil® (plerixafor)**
- **Plerixafor**

Receipt of sample product does not satisfy any criteria requirements for coverage.

Medical Necessity Criteria

Plerixafor (Mozobil®) is considered medically necessary when ONE of the following criteria are met:

1. **Non-Hodgkin's lymphoma (NHL).** Individual meets **ALL** of the following criteria:
   A. Use is for mobilization of stem cells for autologous transplantation
   B. Use is in combination with granulocyte-colony stimulating factor (G-CSF)

2. **Multiple myeloma (MM).** Individual meets **ALL** of the following criteria:

A. Use is for mobilization of stem cells for autologous transplantation
B. Use is in combination with granulocyte-colony stimulating factor (G-CSF)

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Authorization Duration

Authorization is for a maximum of 4 consecutive doses per cycle for up to 2 cycles.

Conditions Not Covered

Any other use is considered experimental, investigational or unproven, including the following (this list may not be all inclusive):

1. **Acute Leukemia**
2. **As a mobilizing agent for an allogeneic stem cell donor**
3. **Following myeloablative allogeneic hematopoietic stem cell transplant to augment hematopoietic recovery**

Coding

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.

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

HCPCS Codes	Description
J2562	Injection, plerixafor, 1 mg

Background

FDA Approved Indication

Mozobil (plerixafor injection) 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 (NHL) and multiple myeloma (MM).

FDA Recommended Dosing

Begin treatment with Mozobil after the patient has received G-CSF once daily for four days. Administer Mozobil approximately 11 hours prior to initiation of each apheresis for up to 4 consecutive days.

The recommended dose of Mozobil by subcutaneous injection is based on body weight:

- 20 mg fixed dose or 0.24 mg/kg of body weight for patients weighing ≤ 83 kg.
- 0.24 mg/kg of body weight for patients weighing > 83kg.

Based on increasing exposure with increasing body weight, the plerixafor dose should not exceed 40 mg/day.

Use the patient's actual body weight to calculate the volume of Mozobil to be administered. Each vial delivers 1.2 mL of 20 mg/mL solution, and the volume to be administered to patients should be calculated from the following equation:

0.012 X patient's actual body weight (in kg) = volume to be administered (in mL)

In clinical studies, Mozobil dose has been calculated based on actual body weight in patients up to 175% of ideal body weight. Mozobil dose and treatment of patients weighing more than 175% of ideal body weight have not been investigated.

Recommended Concomitant Medications

Administer daily morning doses of G-CSF 10 micrograms/kg for 4 days prior to the first evening dose of Mozobil and on each day prior to apheresis.

Dose Modifications in Renal Impairment

In patients with moderate and severe renal impairment (estimated creatinine clearance (CLCR) less than or equal to 50 mL/min), reduce the dose of Mozobil by one-third based on body weight category as shown in Table 1. If CLCR is less than or equal to 50 mL/min the dose should not exceed 27 mg/day, as the mg/kg-based dosage results in increased plerixafor exposure with increasing body weight [see Clinical Pharmacology (12.3)]. Similar systemic exposure is predicted if the dose is reduced by one-third in patients with moderate and severe renal impairment compared with subjects with normal renal function [see Clinical Pharmacology (12.3)].

Table 1: Recommended Dosage of Mozobil in Patients with Renal Impairment

Estimated Creatinine Clearance (mL/min)	**Dose**	
	Body Weight less than or equal to **83 kg**	**Body Weight** greater than **83 kg and** less than **160 kg**
greater than 50	20 mg or 0.24 mg/kg once daily	0.24 mg/kg once daily (not to exceed 40 mg/day)
less than or equal to 50	13 mg or 0.16 mg/kg once daily	0.16 mg/kg once daily (not to exceed 27 mg/day)

The following (Cockcroft-Gault) formula may be used to estimate CL_{CR}:

Males:

$$\text{Creatinine clearance (mL/min)} = \frac{\text{weight (kg)} \times (140 - \text{age in years})}{72 \times \text{serum creatinine (mg/dL)}}$$

Females:

Creatinine clearance (mL/min) = 0.85 × value calculated for males

There is insufficient information to make dosage recommendations in patients on hemodialysis.

Experimental, Investigational, Unproven Uses

There is insufficient evidence in the peer-reviewed published scientific literature to support safety and efficacy of plerixafor in the allogeneic stem cell transplant setting, or following myeloablative allogeneic hematopoietic stem cell transplant to augment hematopoietic recovery.

For the purpose of HSC mobilization, 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]

References

1. Mozobil (plerixafor injection) [product information]. Cambridge, MA: Genzyme Corporation. August 2020.
2. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology (NCCN Guidelines®): Hematopoietic Growth Factors v1.2022 – December 22, 2021 https://www.nccn.org/professionals/physician_gls/pdf/growthfactors.pdf. Accessed 3/8/2021.