Drug and Biologic Coverage Policy

Effective Date ........................................... 7/1/2021
Next Review Date ........................................... 7/1/2022
Coverage Policy Number ................................. IP0139

Plerixafor

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Overview

This policy supports medical necessity review for Plerixafor (Mozobil).

Medical Necessity Criteria

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

- Non-Hodgkin’s lymphoma (NHL) OR Multiple myeloma (MM)
- For mobilization of stem cells for autologous transplantation
- 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.

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

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.
Authorization Duration

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

Conditions Not Covered

Plerixafor (Mozobil) is considered experimental, investigational or unproven for ANY other use including the following (this list may not be all inclusive):
- As a mobilizing agent for an allogeneic stem cell donor
- Following myeloablative allogeneic hematopoietic stem cell transplant to augment hematopoietic recovery

Coding / Billing Information

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:

<table>
<thead>
<tr>
<th>HCPCS Codes</th>
<th>Description</th>
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<tbody>
<tr>
<td>J2562</td>
<td>Injection, plerixafor, 1 mg</td>
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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 > 83 kg.

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:
\[ 0.012 \times \text{patient’s actual body weight (in kg)} = \text{volume to be administered (in mL)} \]

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.

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

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.
Pharmacology
Higher stem cell concentrations in the peripheral blood result in greater stem collection, improving the chances of a successful HSCT. Strategies to mobilize stem cells from the bone marrow include colony-stimulating factors alone or during recovery after chemotherapy. Stem cell CXCR4 binds to stromal cell derived factor-1-alpha (SDF-1), anchoring stem cells within the bone marrow and inducing chemotaxis of more stem cells into the marrow. Plerixafor prevents this binding, increasing stem cell mobility and reducing chemotaxis, keeping more stem cells in the peripheral blood for collection.

Professional Societies/Organizations
National Comprehensive Cancer Network
The NCCN provides a recommendation for effective mobilization regimens that include growth factor alone, chemotherapy and growth factor combined, and incorporation of plerixafor with either approach. The combination chemotherapy followed by filgrastim or tbo-filgrastim with the goal of mobilization during count recovery that may result in higher collection yields with fewer days of apheresis but increased rate of hospitalizations for neutropenic fever. This approach may also rescue burden of residual tumor. Existing literature suggests that a preemptive “just in time” strategy of adding plerixafor for patients who do not mount a sufficient CD34+ cell count is highly successful. There are limited data on parameters for predicting poor mobilization and which patients may benefit from upfront use of plerixafor. Risk factors that have been associated with poor mobilization include older age, extensive use prior therapy, prior radiation to marrow-containing regions or multiple cycles of certain agents such as fludarabine or lenalidomide. (NCCN, 2021)

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.

References