Clinical Policy: Plerixafor (Mozobil)
Reference Number: ERX.SPA.211
Effective Date: 01.11.17
Last Review Date: 11.17

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

Description
Plerixafor (Mozobil®) is a hematopoietic stem cell mobilizer.

FDA Approved Indication(s)
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 (NHL) and multiple myeloma (MM).

Policy/Criteria
Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ 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. Diagnosis of NHL or MM;
      2. Age ≥ 18 years;
      3. Prescribed to mobilize HSCs in the autologous* setting for collection and transplantation;
      4. Will be administered in combination with a G-CSF** (i.e., filgrastim, filgrastim-sndz, or tbo-filgrastim);
         *Prior authorization may be required
      5. Dose does not exceed 40 mg/day before each HSC collection for up to 4 consecutive days.
         Approval duration: 1 week

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

B. Other diagnoses/indications
   1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy
   A. Mobilization of Hematopoietic Stem Cells (must meet all):
      1. Member must meet initial approval criteria for reauthorization.
         Approval duration: N/A

B. Other diagnoses/indications (must meet 1 or 2):
   1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
      Approval duration: Duration of request or 1 week (whichever is less); or
   2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:
A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – ERX.PA.01 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

- FDA: Food and Drug Administration
- G-CSF: granulocyte-colony stimulating factor
- HSCs: hematopoietic stem cells
- NHL: non-Hodgkin's lymphoma
- MM: multiple myeloma

Appendix B: Therapeutic Alternatives

N/A

V. Dosage and Administration

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dosing Regimen</th>
<th>Maximum Dose</th>
</tr>
</thead>
</table>
| HSC mobilization | The recommended dose of Mozobil by subcutaneous injection is based on actual body weight:  
                      • ≤ 83 kg: 20 mg fixed dose or 0.24 mg/kg of body weight  
                      • > 83 kg: 0.24 mg/kg of body weight  
                      Initiate Mozobil treatment after the patient has received G-CSF once daily for 4 days. Administer Mozobil approximately 11 hours prior to initiation of each apheresis for up to 4 consecutive days. | 40 mg/day    |

VI. Product Availability

Injection (single-use vial): 1.2 mL of 20 mg/mL solution containing 24 mg of plerixafor

VII. References


Reviews, Revisions, and Approvals

<table>
<thead>
<tr>
<th>Description</th>
<th>Date</th>
<th>P&amp;T Approval Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Policy created.</td>
<td>12.16</td>
<td>01.17</td>
</tr>
<tr>
<td>4Q17 Annual Review</td>
<td>09.13.17</td>
<td>11.17</td>
</tr>
<tr>
<td>Converted to new template.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Added age restriction as safety and efficacy in pediatric patients have not been established per PI.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Updated max dose requirement to include “up to 4 consecutive days” per PI.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Increased initial approval duration from 4 days to 1 week. Added continued therapy section to clarify that member must meet initial approval criteria for reauthorization. Updated references.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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.
This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. 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 policy is the property of Envolve Pharmacy Solutions. Unauthorized copying, use, and distribution of this Policy or any information contained herein is strictly prohibited. By accessing this policy, you agree to be bound by the foregoing terms and conditions, in addition to the Site Use Agreement for Health Plans associated with Envolve Pharmacy Solutions.

©2017 Envolve Pharmacy Solutions. All rights reserved. All materials are exclusively owned by Envolve Pharmacy Solutions and are protected by United States copyright law and international copyright law. No part of this publication may be reproduced, copied, modified, distributed, displayed, stored in a retrieval system, transmitted in any form or by any means, or otherwise published without the prior written permission of Envolve Pharmacy Solutions. You may not alter or remove any trademark, copyright or other notice contained herein.