Blue Cross Blue Shield Blue Care Network of Michigan

Nonprofit corporations and independent licensees of the Blue Cross and Blue Shield Association

Medical benefit drug policies are a source for BCBSM and BCN medical policy information only. These documents are not to be used to determine benefits or reimbursement. Please reference the appropriate certificate or contract for benefit information. This policy may be updated and therefore subject to change.

Retired
Effective Date: 02/02/2023

Mozobil™ (plerixafor)

HCPCS: J2562

Policy:

Requests must be supported by submission of chart notes and patient specific documentation.

A. Coverage of the requested drug is provided when all the following are met:
   a. FDA approved age
   b. FDA approved indication OR a diagnosis of Hodgkin's lymphoma
   c. Must be taken in conjunction with a granulocyte colony stimulating factor (G-CSF) 4 days prior to stem cell harvest
   d. Must be candidate for hematopoietic stem cell (HSC) harvest for autologous stem cell transplantation
   e. Must have had past trial and failure with G-CSF alone and collected HSC's in insufficient quantities (≤ 2 x 10^6 $CD34^+$ cells per kg)
   f. As a single agent used in monotherapy

B. Quantity Limitations, Authorization Period and Renewal Criteria
   a. Quantity Limits: Align with FDA recommended dosing
   b. Authorization Period: Aligns with FDA recommended or guideline supported treatment duration and provided for up to 6 months at a time
   c. Renewal Criteria: No renewal allowed

***Note: Coverage may differ for Medicare Part B members based on any applicable criteria outlined in Local Coverage Determinations (LCD) or National Coverage Determinations (NCD) as determined by Center for Medicare and Medicaid Services (CMS). See the CMS website at http://www.cms.hhs.gov/. Determination of coverage of Part B drugs is based on medically accepted indications which have supported citations included or approved for inclusion determined by CMS approved compendia.

Background Information:

- High-dose chemotherapy and autologous hematopoietic stem cell transplantation (HSCT) is the standard treatment for many patients with multiple myeloma and non-Hodgkins lymphoma. Traditionally, mobilization of peripheral blood stem cells for HSCT has been done using granulocyte colony stimulating factors (G-CSF) alone or in combination

with chemotherapy. However, these customary regimens result in poor mobilization and low stem cells counts 15% – 40% of the time.

- Mozobil is a hematopoietic stem call mobilizer indicated in combination with G-CSF's to mobilize hematopoietic stem cells to the peripheral blood for collection and subsequent autologous transplantion in patients with non-Hodgkin's lymphoma (NHL) and multiple myeloma (MM). Per the prescribing information, Mozobil treatment should be initiated after the patient has received a G-CSF once daily for 4 days. It should be given 11 hours prior to each apheresis for up to 4 consecutive days.

- National Comprehensive Cancer Network (NCCN) 2021 guidelines for hematopoietic growth factors state effective mobilization regimens include single-agent growth factor, chemotherapy in combination with growth factor, or incorporation of Mozobil in combination with either approach. The guidelines do not prefer one regimen over another. Poor mobilization is defined in the guidelines as less than or equal to 2 x 10^6 CD34+ cells per kg. Due to there being a lack of predictive factors for poor mobilization, Mozobil should be reserved for those who have truly failed G-CSF's alone previously.

- In addition to the two FDA approved indications, Mozobil has also been studied in Hodgkins lymphoma (HL). A phase 2 study of 22 patients with HL who were candidates for autologous HSCT underwent mobilization in combination with G-CSF. The patients receiced Mozobil following 4 days of G-CSF therapy. The primary endpoint was the proportion of patients with greater than or equal to 5 x 10^6 CD34+ cells per kg collected. Of the 22 patients treated with Mozobil, 15 (68%) met the primary endpoint and 21 (95%) met minimum collection requirements of greater than or equal to 2 x 10^6 cells per kg in a medical of 2 apheresis procedures.

References:

1. Bender E, Lynm C, and Glass R. Granulocyte-colony stimulating factor. JAMA. 2006; 295 (9): 1088. Available at: http://jama.jamanetwork.com/article.aspx?articleid=202466. Accessed February 7, 2013.
2. DiPersio JF, Micallef IN, Stiff PJ, et al. Phase III prospective randomized double-blind placebo-controlled trial of plerixafor plus granulocyte colony-stimulating factor compared with placebo plus granulocyte colony-stimulating factor for autologous stem-cell mobilization and transplantation for patients with non-hodgkin's lymphoma. *J Clin Oncol.* 2009; 27: 4767-4773.
3. DiPersio JF, Stadtumauer EA, and Nademanee A. Plerixafor and G-CSF versus placebo and G-CSF to mobilize hematopoietic stem cells for autologous stem cell transplantation in patients with multiple myeloma. *Blood.* 2009; 113: 5720-5726.
4. Mobizil [prescribing information]. Cambridge, MA: Genzyme Corporation.; August 2020.
5. Moreb JS. Plerixafor in non-hodgkin's lymphoma nd multiple myeloma patients underoing autologous stem cell transplantation. Onco Rev. 2011; 5: 67-73.
6. Shaughness P and Islan-Ohlmayer M. Cost and clinical analysis of autologous hematopoietic stem cell mobilization with G-CSF and plerixafor compared to G-CSF and cyclophosphamide. Biol Blood Marrow Transplant. 2011;17: 729-736.
7. Cashen A, Lopez S, Gao F, et. al. A phase II study of plerixafor (AMD3100) for G-CSF for autologous hematopoietic progenitor cell mobilization in patients with Hodgkin's lymphoma. *Biol Blood Marrow Transplant.* 2008; 14 (11): 1253-61.
8. Pierelli L, Perseghin P, Marchetti M, et. al. Best practice for peripheral blood progenitor cell mobilization and collection in adults and children: results of a Societa Italiana Di Emaferesi e Manipolazione Cellulare (SIDEM) and Gruppo Italiano Trapianto Midollo Osseo (GITMO) consensus process. Conference Report. *Transfusion.* 2012; 52 (4): 893-905.
9. National Comprehensive Cancer Network. Hematopoietic growth factors (Version 1.2022). 2021 Dec 22. Available at: https://www.nccn.org/professionals/physician_gls/pdf/growthfactors.pdf. Accessed on June 16, 2022.

<table>
<tr><th colspan="3">Policy History</th></tr>
<tr><th>#</th><th>Date</th><th>Change Description</th></tr>
<tr><td>2.0</td><td>Effective Date: 02/02/2023</td><td>Retiring policy as drug will no longer be part of the prior authorization program</td></tr>
<tr><td>1.9</td><td>Effective Date: 08/04/2022</td><td>Updated approval length to allow for FDA recommended dosing or up to 6 months at a time</td></tr>
<tr><td>1.8</td><td>Effective Date: 08/12/2021</td><td>Annual review of policy. No updated made to the criteria at this time</td></tr>
<tr><td>1.7</td><td>Effective Date: 08/13/2020</td><td>Updated approval duration and renewal criteria</td></tr>
<tr><td>1.6</td><td>Effective Date: 08/15/2019</td><td>Annual Review of Medical Policy</td></tr>
<tr><td>1.5</td><td>Effective Date: 08/09/2018</td><td>Annual Review of Medical Policy</td></tr>
<tr><td>1.4</td><td>Effective Date: 08/10/2017</td><td>Annual Review of Medical Policy</td></tr>
<tr><td>1.3</td><td>Annual Review: 08/11/2016</td><td>Annual Review of Medical Policy</td></tr>
<tr><td>1.2</td><td>Effective Date: 10/01/2014</td><td>UM medical management system update for BCBSM
<table>
<tr><th>Line of Business</th><th>PA Required in Medical Management System (Yes/No)</th></tr>
<tr><td>BCBS</td><td>No</td></tr>
<tr><td>BCN</td><td>No</td></tr>
<tr><td>MAPPO</td><td>No</td></tr>
<tr><td>BCNA</td><td>No</td></tr>
</table></td></tr>
<tr><td>1.1</td><td>Effective Date: 04/01/2014</td><td>UM medical management system update for BCBSM
<table>
<tr><th>Line of Business</th><th>PA Required in Medical Management System (Yes/No)</th></tr>
<tr><td>BCBS</td><td>Yes</td></tr>
<tr><td>BCN</td><td>No</td></tr>
<tr><td>MAPPO</td><td>No</td></tr>
<tr><td>BCNA</td><td>No</td></tr>
</table></td></tr>
<tr><td>1.0</td><td>Effective Date: 05/02/2013</td><td>New criteria document
<table>
<tr><th>Line of Business</th><th>PA Required in Medical Management System (Yes/No)</th></tr>
<tr><td>BCBS</td><td>No</td></tr>
<tr><td>BCN</td><td>No</td></tr>
<tr><td>MAPPO</td><td>No</td></tr>
<tr><td>BCNA</td><td>No</td></tr>
</table></td></tr>
</table>

** The prescribing information for a drug is subject to change. To ensure you are reading the most current information it is advised that you reference the most updated prescribing information by visiting the drug or manufacturer website or http://dailymed.nlm.nih.gov/dailymed/index.cfm.*