Blue Cross Blue Shield Blue Care Network of Michigan

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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

Arzerra® (ofatumumab)

HCPCS: J9302

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. Diagnosis of chronic lymphocytic leukemia (CLL)
   b. Prescribed by or in consultation with an oncologist or hematologist
      AND
   c. Treatment naïve patients: Use in combination with chlorambucil or bendamustine, for whom fludarabine-based therapy is considered inappropriate, as defined by:
      i. Hypersensitivity to fludarabine
      ii. Creatinine clearance less than 30 mL/min
      iii. Concomitant therapy with pentostatin
      iv. Intolerance to fludarabine
      OR
   d. Relapsed or refractory patients: Treatment in patients who failed to achieve a partial response or disease progression with 6 months of therapy with fludarabine and alemtuzumab
      OR
   e. Recurrent or progressive patients after a complete or partial response: Use as extended treatment after at least two lines of therapy
      OR
   f. Relapsed patients: Use in combination with fludarabine and cyclophosphamide

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: Treatment continued until unacceptable toxicity or disease progression

***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:

- Arzerra is a CD20-directed cytolytic monoclonal antibody indicated for the treatment of chronic lymphocytic leukemia in the following situations:
    - In combination with chlorambucil, for the treatment of previously untreated patients with CLL for whom fludarabine-based therapy is considered inappropriate
    - In combination with fludarabine and cyclophosphamide for the treatment of patients with relapsed CLL
    - For extended treatment of patients who are in complete or partial response after at least two lines of therapy for recurrent or progressive CLL
    - For the treatment of patients with CLL refractory to fludarabine and alemtuzumab
- Arzerra can be used in previously untreated patients in whom fludarabine-based therapy is considered inappropriate. The fludarabine prescribing information does not recommend use of fludarabine in patients with a creatinine clearance of less than 30 mL/min, those with hypersensitivity or intolerance to fludarabine, and those wishing to use it concurrently with pentostatin. Fludarabine has a box warning for use in combination with pentostate due to high incidence of fatal pulmonary toxicity.

References:

1. Arzerra [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; August 2016.
2. National Comprehensive Cancer Network. Chronic lymphocytic leukemia/small lymphoctic leukemia (Version 2.2022). 2022 Jan 18. Available at: https://www.nccn.org/professionals/physician_gls/pdf/cll.pdf. Accessed on February 14, 2022.
3. Oers M, Kuliczkowski K, Smolej L, et al. Ofatumumab maintenance versus observation in relapsed chronic lymphocytic leukaemia (PROLONG): an open-label, multicenter, randomized phase 3 study. Lancet Oncol. 2015; 16: 1370 - 9.
4. Hillmen P, Robak T, Janssens A, et al. Chlorambucil plus ofatumumab versus chlorambucil alone in previously untreated patients with chronic lymphocytic leukemia (COMPLEMENT 1): a randomized, multicenter, open-label phase 3 trial. Lancet. 2015 May 9; 385 (9980): 1873 – 83.
5. Robak T, Warzocha K, Babu KG, et al. Ofatumumab plus fludarabine and cyclophosphamide in relapsed chronic lymphocytic leukemia: results from the COMPLEMENT 2 trial. Leuk Lymphoma. 2017 May; 58 (5): 1084 - 93.

<table>
<tr><th colspan="3">Policy History</th></tr>
<tr><th>#</th><th>Date</th><th>Change Description</th></tr>
<tr><td>2.2</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>2.1</td><td>Effective Date: 04/14/2022</td><td>Updated approval length to allow for FDA recommended dosing or up to 6 months at a time</td></tr>
<tr><td>2.0</td><td>Effective Date: 04/08/2021</td><td>Updated authorization period to 6 months</td></tr>
<tr><td>1.9</td><td>Effective Date: 12/01/2020</td><td>UM medical management system update for BCBS
<table><tr><th>Line of Business</th><th>PA Required (Yes/No)</th></tr><tr><td>BCBS</td><td>Yes</td></tr><tr><td>BCN</td><td>Yes</td></tr><tr><td>MAPPO</td><td>Yes</td></tr><tr><td>BCNA</td><td>Yes</td></tr></table></td></tr>
<tr><td>1.8</td><td>Effective Date: 04/16/2020</td><td>Annual review of criteria was performed, no changes were made.</td></tr>
<tr><td>1.7</td><td>Effective Date: 01/01/2020</td><td>UM medical management system update for BCNA and MAPPO
<table><tr><th>Line of Business</th><th>PA Required (Yes/No)</th></tr><tr><td>BCBS</td><td>No</td></tr><tr><td>BCN</td><td>Yes</td></tr><tr><td>MAPPO</td><td>Yes</td></tr><tr><td>BCNA</td><td>Yes</td></tr></table></td></tr>
<tr><td>1.6</td><td>Effective Date: 05/09/2019</td><td>Updated criteria per oncology vendor</td></tr>
<tr><td>1.5</td><td>Effective Date: 11/01/2018</td><td>Updated criteria per oncology vendor</td></tr>
<tr><td>1.4</td><td>Effective Date: 02/08/2018</td><td>Annual review of criteria was performed, no changes were made.</td></tr>
<tr><td>1.3</td><td>Effective Date: 02/09/2017</td><td>Updated criteria – new indication for use in combination with fludarabine and cyclophosphamide for the treatment of patients with relapsed CLL.
Added drug to new template.</td></tr>
<tr><td>1.2</td><td>Effective Date: 08/11/2016</td><td>Updated criteria - new indication (extended treatment for complete or partial response after at least two lines of therapy for recurrent of progressive CLL); also added prescriber requirement.</td></tr>
<tr><td>1.1</td><td>Effective Date: 10/30/2014</td><td>Updated Criteria</td></tr>
<tr><td>1.0</td><td>Effective Date: 01/28/2010</td><td>New Policy
<table><tr><th>Line of Business</th><th>PA Required (Yes/No)</th></tr><tr><td>BCBS</td><td>No</td></tr><tr><td>BCN</td><td>Yes</td></tr><tr><td>MAPPO</td><td>No</td></tr><tr><td>BCNA</td><td>No</td></tr></table></td></tr>
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** 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.*