Blue Cross Blue Shield Blue Care Network of Michigan

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RETIRED
Effective Date: 02/02/2023

Besponsa® (inotuzumab ozogamicin)

HCPCS: J9229

Policy:

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

A. Criteria:
   a. FDA approved indication
   b. FDA approved age
   c. Prescribed by or in consultation with an oncologist
   d. Must have confirmed CD22-positive testing
   e. Must have Philadelphia chromosome testing
   f. Clinical documentation of relapsed, or refractory to prior chemotherapy
   g. Clinical documentation of relapsed, or refractory to prior tyrosine kinase inhibitor therapy, if Philadelphia chromosome positive
   h. Use as monotherapy
   i. Should not be used if treatment failure has occurred with Besponsa or another anti-CD22 monoclonal antibody

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: Not applicable as no further authorization will be provided

***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:

- Besponsa is a CD22-directed antibody-drug conjugate (ADC) indicated as monotherapy for the treatment of adults with relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL). The antibody, inotuzumab, binds CD22-expressing tumor B-cells and, once internalized by the cell, the cytotoxic N-acetyl-gamma-calicheamicin induces breaks in DNA, cell cycle arrest, and apoptosis.

- Safety and efficacy were evaluated in INO-VATE ALL, a randomized, open-label, multicenter trial of 326 patients with relapsed or refractory ALL. All patients were required to have progressed following induction chemotherapy regimens. Patients with Philadelphia chromosome-positive B-cell precursor ALL were required to have disease that failed treatment with at least one tyrosine kinase inhibitor and standard chemotherapy. Patients were randomized to Besponsa or chemotherapy. The primary endpoints included complete remission and overall survival. A complete remission rate of 80.7% was seen with Besponsa compared to 29.4% with standard chemotherapy. Besponsa resulted in a median overall survival of 7.7 months compared to 6.7 months for standard chemotherapy.

- There are no studies to support use of Besponsa following failure of its use. National Comprehensive Cancer Network 2022 acute lymphoplastic leukemia guidelines also do not recommend use of Besponsa or any other CD22-directed therapies following a previous failure.

References:

1. Besponsa [prescribing information]. Philadelphia, PA: Pfizer Inc.; March 2018.
2. Kantarjian HM, DeAngelo DJ, Stelljes M, et al. Inotuzumab ozogamicin versus standard therapy for acute lymphoblastic leukemia. NEJM. 2016; 375: 740 – 53.
3. National Comprehensive Cancer Network. Acute lymphoblastic leukemia (Version 1.2022). 2022 April 4. Available at: https://www.nccn.org/professionals/physician_gls/pdf/all.pdf. Accessed on August 5, 2022.
4. Terwilliger T & Abdul-Hay M. Acute lymphoblastic leukemia: a comprehensive review and 2017 update. Blood Cancer. 2017; 7 (6): e577.
5. Topp MS, Gokbuget N, Zugmaier G, et al. Phase II trial of the anti-CD19 bispecific t-cell engager blinatumomab shows hematologic and molecular remissions in patients with relapsed or refractory b-cell precursor acute lymphoblastic leukemia. J Clin Onc. 2014; 32 (36): 4134 – 42.

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<tr><th colspan="3">Policy History</th></tr>
<tr><th>#</th><th>Date</th><th>Change Description</th></tr>
<tr><td>1.9</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>1.8</td><td>Effective Date: 10/06/2022</td><td>Updated approval length to allow for FDA recommended dosing or up to 6 months at a time</td></tr>
<tr><td>1.7</td><td>Effective Date: 10/07/2021</td><td>Annual review of criteria was performed, no changes were made</td></tr>
<tr><td>1.6</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 in Medical Management System (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>1.5</td><td>Effective Date: 10/08/2020</td><td>Annual Review</td></tr>
<tr><td>1.4</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 in Medical Management System (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>1.3</td><td>Effective Date: 11/07/2019</td><td>Annual Review of Medical Policy</td></tr>
<tr><td>1.2</td><td>Effective Date: 11/01/2018</td><td>Updated criteria per oncology vendor</td></tr>
<tr><td>1.1</td><td>Effective Date: 08/09/2018</td><td>Full Drug Review
<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>Yes</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: 11/09/2017</td><td>Preliminary Criteria</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.*