Blue Cross Blue Shield Blue Care Network of Michigan

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Retired
Effective Date: 02/02/2023

Blincyto® (blinatumomab)

HCPCS: J9039

Policy:

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

A. Criteria:
   a. FDA approved age
   b. Diagnosis of relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL)
      i. If Philadelphia chromosome negative, must be refractory or relapsed following prior chemotherapy
      ii. If Philadelphia chromosome positive, must be refractory or intolerant to tyrosine kinase inhibitors (TKI)
   c. Diagnosis of B-cell precursor ALL
      i. Must be in either first or second complete remission
      ii. Must have minimal residual disease (MRD) greater than or equal to 0.1% after prior chemotherapy
   d. Must be used as monotherapy
   e. Limited to a single line therapy

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:

- Blincyto is indicated for the treatment of children and adults with B-cell precursor acute lymphoblastic leukemia in first or second complete remission with minimal residual disease greater than or equal to 0.1% and relapsed or refractory B-cell precursor acute lymphoblastic leukemia.

- The efficacy of Blincyto for relapsed or refactory B-cell precursor ALL was evaluated in 4 trials: TOWER, a randomized, open-label, multicenter study of Philadelphia chromosome negative patients; MT103-211, an open-label, multicenter, single-arm study of Philadelphia chromosome negative patients; ALCANTARA, an open-label, multicenter, single-arm trial of Philadelphia chromosome positive patients; and MT103-205, an open-label, multicenter, single-arm study in pediatric patients. In all studies, if patients were Philadelphia chromosome negative, they were required to have been refractory or relapsed following chemotherapy. Philadelphia chromosome positive patients were required to be refractory or intolerant to a tyrosine kinase inhibitor.

- For MDR-positive B-cell precursor ALL, Blincyto is administered as monotherapy with one treatment course consisting of 1 cycle of Blincyto for induction followed by up to 3 additional cycles for consolidation. For relapsed or refractory B-cell precursor ALL, Blincyto is administered as monotherapy with a treatment course consisting of up to 2 cycles of Blincyto for induction followed by 3 additional cycles for consolidation and up to 4 additional cycles of continued therapy. Blincyto has not been studied in combination with any other drugs used to treat acute lymphocytic leukemia.

- There are no studies to support use of Blincyto following failure of its use. National Comprehensive Cancer Network 2022 acute lymphoplastic leukemia guidelines also do not recommend use of Blincyto or any other CD19-directed CD3 T-cell engager therapies following a previous failure.

References:

1. Blincyto [prescribing information]. Thousand Oaks, CA: Amgen, Inc.; Feb 2022.
2. 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.
3. National Comprehensive Cancer Network. Pediatric acute lymphoblastic leukemia (Version 1.2022). 2021 Oct 21. Available at: https://www.nccn.org/professionals/physician_gls/pdf/ped_all.pdf. Accessed on August 5, 2022.
4. Dombret H, Topp MS, Schuh AC, et al. Blinatumomab versus chemotherapy in first salvage or in later salvage for B-cell precursor acute lymphoblastic leukemia. Leuk Lymphoma. 2019 Sep; 60 (9): 2214 – 22.
5. Goekbuget N, Dombret H, Bonifacio M, et al. BLAST: a confirmatory, single-arm, phase 2 study of blinatumomab, a bispecific t-cell engager antibody construct, in patients with minimal residual Disease B-precursor acute lymphoblastic leukemia (ALL). Blood. 2014 Dec 6; 124 (21): 379.
6. Clinicaltrials.gov. An open label, multicenter, phase II study to evaluate efficacy and safety of the BiTE antibody blinatumomab in adult patients with relapsed/refractory b-precursor acute lymphoblastic Leukemia (ALL). Available at: https://clinicaltrials.gov/ct2/show/NCT01466179?term=NCT01466179&draw=2&rank=1. Accessed on July 28, 2020.
7. von Stackelberg A, Locatelli F, Zugmaier G, et al. Phase I/phase II study of blinatumomab in pediatric patients with relapsed/refractory acute lymphoblastic leukemia. J Clin Oncol. 2016 Dec 20; 34 (36): 4381 – 89.

<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: 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>1.8</td><td>Effective Date: 10/07/2021</td><td>Annual review – no changes made to the criteria at this time</td></tr>
<tr><td>1.7</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>1.6</td><td>Effective Date: 10/08/2020</td><td>Annual Review</td></tr>
<tr><td>1.5</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>1.4</td><td>Effective Date: 11/07/2019</td><td>Annual Review of Medical Policy</td></tr>
<tr><td>1.3</td><td>Effective Date: 11/01/2018</td><td>Criteria update to include MRD positive after first or second complete remission ALL Criteria update to add single agent/monotherapy
Criteria update to require step therapy for relapsed refractory B-cell ALL based on nccn guidelines delineated based on categorical ratings
Removal of requirement for hospitalization during the beginning of treatment cycles 1 and 2</td></tr>
<tr><td>1.2</td><td>Effective Date: 05/03/2018</td><td>Criteria updated to include full approval for treatment for B-cell precursor acute lymphoblastic leukemia (ALL) in adults and children.</td></tr>
<tr><td>1.1</td><td>Effective Date: 02/09/2017</td><td>Criteria updated to include pediatric indication</td></tr>
<tr><td>1.0</td><td>Effective Date: 05/07/2015</td><td>New 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>
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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.*