Clinical Policy: Blinatumomab (Blincyto)

Reference Number: PA.CP.PHAR.312
Effective Date: 01/18
Last Review Date: 07/17/19

Coding Implications
Revision Log

Description
The intent of the criteria is to ensure that patients follow selection elements established by Pennsylvania Health and Wellness ® clinical policy for blinatumomab for injection (Blincyto®).

FDA Approved Indication(s)
Blincyto is indicated for

- MRD-positive B-cell precursor ALL
  - Treatment of B-cell precursor acute lymphoblastic leukemia (ALL) in first or second complete remission with minimal residual disease (MRD) greater than or equal to 0.1% in adults and children. This indication is approved under accelerated approval based on MRD response rate and hematological relapse-free survival. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials.
- Relapsed or refractory B-cell precursor ALL
  - Treatment of relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL) in adults and children.

Policy/Criteria
It is the policy of health plans affiliated with Pennsylvania Health and Wellness ® that Blincyto is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Acute Lymphoblastic Leukemia (must meet all):

1. Diagnosis of B-cell precursor acute lymphoblastic leukemia (B-ALL);
2. Prescribed by or in consultation with an oncologist or hematologist;
3. Requested as treatment for (a or b):
   a. B-ALL in remission but positive for minimal residual disease (MRD+);
   b. Relapsed or refractory B-ALL (i and ii):
      i. Philadelphia chromosome-negative (Ph-) disease;
      ii. Philadelphia chromosome-positive (Ph+) disease and intolerant or refractory to at least one second-generation or later tyrosine kinase inhibitor (TKI; i.e., Sprycel®, Tasigna®, Bosulif®, Iclusig®);
      **Prior authorization may be required for these agents.*
4. Dose does not exceed 28 mcg/day.

Approval duration: 6 months

B. Other diagnoses/indications: Refer to PA.CP.PMN.53

II. Continued Approval

A. Acute Lymphoblastic Leukemia (must meet all)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 28 mcg/day.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;; or
2. Refer to PA.CP.PMN.53

Background

Description/Mechanism of Action:

Blinatumomab is a bispecific CD19-directed CD3 T-cell engager that binds to CD19 expressed on the surface of cells of B-lineage origin and CD3 expressed on the surface of T cells. It activates endogenous T cells by connecting CD3 in the T-cell receptor (TCR) complex with CD19 on benign and malignant B cells. Blinatumomab mediates the formation of a synapse between the T-cell and the tumor cell, upregulation of cell adhesion molecules, production of cytolytic proteins, release of inflammatory cytokines, and proliferation of T cells, which result in redirected lysis of CD19+ cells.

Formulations:

Blincyto for injection: 35 mcg of lyophilized powder in a single-dose vial for reconstitution.

Appendices

Appendix A: Abbreviation Key

ALL: Acute lymphoblastic leukemia
CLS: Capillary leak syndrome
CRS: Cytokine release syndrome
CTCAE: Common Terminology Criteria for Adverse Events
DIC: Disseminated intravascular coagulation
HLH/MAS: Hemophgocytic lymphohistiocytosis/macrophage activation syndrome
TCR: T-cell receptor
ALT: Alanine aminotransferase
AST: Aspartate aminotransferase

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J9039	Injection, blinatumomab, 1 microgram

Reviews, Revisions, and Approvals	Date	Approval Date
3Q 2018 annual review: new indication for MRD+ B-ALL added; summarized NCCN and FDA-approved uses for improved clarity (TKI requirement reduced from 2 to 1 for Ph+ disease); added specialist involvement in care; references reviewed and updated.	05.18	
3Q 2019 annual review: No changes per Statewide PDL implementation 01-01-2020	07/17/19	

References

1. Blincyto Prescribing Information. Thousand Oaks, CA: Amgen, Inc.; March 2018. Available at: http://pi.amgen.com/~/media/amgen/repositorysites/pi-amgen-com/blincyto/blincyto_pi_hcp_english.ashx. Accessed April 2018.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at nccn.org. Accessed April 2018.
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4. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2018. Available at http://www.clinicalpharmacology-ip.com/.
5. Gökbuget N, Dombret H, Bonifacio M, et al. Blinatumomab for minimal residual disease in adults with B-precursor acute lymphoblastic leukemia. Blood 2018; doi: https://doi.org/10.1182/blood-2017-08-798322.
6. Martinelli G, Boissel N, Chevallier P, et al. Complete hematologic and molecular response in adult patients with relapsed/refractory Philadelphia chromosome–positive B-precursor acute lymphoblastic leukemia following treatment with blinatumomab: results from a phase II, single-arm, multicenter study. J Clin Oncol. 2017 Jun 1; 35(16):1795-1802. doi: 10.1200/JCO.2016.69.3531. Epub 2017 Mar 29.
7. Kim DY, Joo YD, Lim SN, et al. Nilotinib combined with multiagent chemotherapy for newly diagnosed Philadelphia-positive acute lymphoblastic leukemia. Blood 2015; 126: 746-756.
8. Gambacorti-Passerini C, Kantarjian HM, Kim DW, et al. Longterm efficacy and safety of bosutinib in patients with advanced leukemia following resistance/ intolerance to imatinib and other tyrosine kinase inhibitors. Am J Hematol 2015; 90:755-768.