Clinical Policy: Blinatumomab (Blincyto)

Reference Number: PA.CP.PHAR.312
Effective Date: 01/18
Last Review Date: 11/17

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®).

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 (ALL):
2. ALL is relapsed or refractory;
3. Live vaccine is not prescribed concurrently with Blincyto;
4. Member has no known hypersensitivity to blinatumomab or to any component of the product formulation.

Approval duration: 3 months

B. Other diagnoses/indications: Refer to PA.CP.PHAR.57 - Global Biopharm Policy.

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 has none of the following reasons to discontinue:
   a. Disease progression or unacceptable toxicity;
   b. Known hypersensitivity to blinatumomab or to any component of the product formulation;
   c. Cytokine release syndrome (CRS)*: Grade 4 (life-threatening);
   d. More than one seizure;
   e. Neurological toxicities (e.g., headache, tremor, dizziness, altered state of consciousness, encephalopathy, convulsions, coordination and balance disorder): Grade 3** (severe; takes > 7 days to resolve) or Grade 4** (life-threatening);
   f. Any adverse reaction/toxicity: Grade 3** (severe) that takes > 14 days to resolve or Grade 4** (life-threatening).

**CRS symptoms may include pyrexia, headache, nausea, asthenia, hypotension, increased alanine aminotransferase (/ aspartate aminotransferase (ALT/AST), increased total bilirubin. The following conditions may occur in the CRS setting: disseminated intravascular coagulation (DIC); capillary leak syndrome (CLS); hemophgocytic lymphohistiocytosis/macrophage activation syndrome (HLH/MAS).*
***Grading is based on the Common Terminology Criteria for Adverse Events (CTCAE).*

Approval duration: 6 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.PHAR.57 - Global Biopharm Policy**.**

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.

FDA Approved Indications:

Blincyto is a bispecific CD19-directed CD3 T-cell engager/intravenous formulation indicated for:

- Treatment of Philadelphia chromosome-negative relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL).
  - This indication is approved under accelerated approval. Continued approval for this indication may be contingent upon verification of clinical benefit in subsequent trials.

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

References

1. Blincyto prescribing information. Thousand Oaks, CA: Amgen, Inc.; September 2016. Available at http://pi.amgen.com/~/media/amgen/repositorysites/pi-amgen-com/blincyto/blincyto_pi_hcp_english.ashx. Accessed January 17, 2017.
2. Blinatumomab. In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at NCCN.org. Accessed January 17, 2017.
3. Acute lymphoblastic leukemia (Version 2.2016). In: National Comprehensive Cancer Network Guidelines. Available at NCCN.org. Accessed January 17, 2017.