Clinical Policy: Blinatumomab (Blincyto)

Reference Number: CP.PHAR.312
Effective Date: 02/17
Last Review Date: 02/17

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

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

Policy/Criteria
It is the policy of health plans affiliated with Centene Corporation® 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. Meets a or b:
   a. FDA approved use:
      i. ALL is Philadelphia chromosome-negative;
   b. Off-label NCCN recommended use (i and ii):
      i. ALL is Philadelphia chromosome-positive and refractory to tyrosine kinase inhibitor therapy (e.g., imatinib, dasatinib, nilotinib, bosutinib, ponatinib);
      ii. Blincyto is prescribed as single-agent therapy;
4. Live vaccine is not prescribed concurrently with Blincyto;
5. 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 CP.PHAR.57 - Global Biopharm Policy.

II. Continued Approval

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

1. Currently receiving medication via Centene benefit or member has previously met all initial approval criteria;
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) or Grade 4** (life-threatening) that takes > 14 days to resolve.

**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 Centene benefit and documentation supports positive response to therapy; or
2. Refer to 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
Policy split from CP.PHAR.182.Excellus Oncology. NCCN recommended uses added.	01/17	02/17

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.

of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

Note: For Medicare members, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at http://www.cms.gov for additional information.