09-J2000-26

Original Effective Date: 03/15/15

Reviewed: 03/11/20

Revised: 04/15/20

Subject: Blinatumomab (Blincyto™) IV

THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS MEDICAL COVERAGE GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.

DESCRIPTION:

Blinatumomab (Blincyto) is indicated to treat Philadelphia chromosome-negative relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL). The United States Food and Drug Administration granted accelerated approval for this indication, and continued approval may be contingent upon evidence of clinical benefit in additional trials. Blinatumomab produced complete remission (CR) within 2 treatment cycles in 32.4% of patients and CR with partial hematologic recovery (CRh*) within 2 treatment cycles in 9.2% of patients in a single-arm study (N=185).

NCCN Guidelines for Acute Lymphoblastic Leukemia (Version 1.2020) and Pediatric Acute Lymphoblastic Leukemia (Version 2.2020) include recommends for use of.

POSITION STATEMENT:

Initiation of blinatumomab (Blincyto) **meets the definition of medical necessity** for **ANY** of the following indications when **ALL** of the following criteria are met:

1. B-cell precursor acute lymphoblastic leukemia (ALL)
    a. Member has CD19+ disease – laboratory documentation must be provided
    b. Blinatumomab will be used for any of the following:
        i. Persistent or late clearance minimal residual disease (MRD)
        ii. Relapsed/refractory Philadelphia chromosome-negative disease

iii. Relapsed/refractory Philadelphia chromosome-positive disease **AND** member has not tolerated or had an inadequate response (or contraindication) to treatment with at least one tyrosine kinase inhibitor (e.g., imatinib, dasatinib)

c. Blinatumomab will be used as monotherapy

d. Dose does not exceed 28 mcg/day

2. Other FDA-approved or NCCN supported diagnosis (not previously listed above)

   a. Member meets **ONE** of the following:

      i. Member is diagnosed with a condition that is consistent with an indication listed in the product's FDA-approved prescribing information (or package insert) **AND** member meets any additional requirements listed in the "Indications and Usage" section of the FDA-approved prescribing information (or package insert)

      ii. Indication **AND** usage is recognized in NCCN Drugs and Biologics Compendium as a Category 1 or 2A recommendation

   b. Dose does not exceed 28 mcg/day

Duration of approval: 6 months

Continuation of blinatumomab (Blincyto) **meets the definition of medical necessity** when **ALL** of the following criteria are met:

1. Authorization/reauthorization has been previously approved by Florida Blue or another health plan in the past two years for B-cell ALL or other FDA-approved or NCCN supported diagnosis, **OR** the member has previously met all indication-specific initiation criteria
2. Blinatumomab will be used as monotherapy
3. Dose does not exceed 28 mcg/day

Duration of approval: 1 year

DOSAGE/ADMINISTRATION:

THIS INFORMATION IS PROVIDED FOR INFORMATIONAL PURPOSES ONLY AND SHOULD NOT BE USED AS A SOURCE FOR MAKING PRESCRIBING OR OTHER MEDICAL DETERMINATIONS. PROVIDERS SHOULD REFER TO THE MANUFACTURER'S FULL PRESCRIBING INFORMATION FOR DOSAGE GUIDELINES AND OTHER INFORMATION RELATED TO THIS MEDICATION BEFORE MAKING ANY CLINICAL DECISIONS REGARDING ITS USAGE.

FDA-approved

- Hospitalization is recommended for the first 9 days of the first cycle and the first 2 days of the second cycle
- A single cycle of treatment consists of 4 weeks of continuous intravenous infusion followed by a 2-week treatment-free interval
- For patients at least 45 kg in weight, in Cycle 1, administer at 9 mcg/day on Days 1–7 and at 28 mcg/day on Days 8–28. For subsequent cycles, administer at 28 mcg/day on Days 1–28

Dose Adjustments

Refer to prescribing information.

Drug Availability

- For injection: 35 mcg of lyophilized powder in a single-use vial for reconstitution

PRECAUTIONS:

Boxed Warning

- Cytokine Release Syndrome (CRS)
- Neurological toxicities, which may be severe, life-threatening, or fatal

Contraindications

- Known hypersensitivity to blinatumomab or to any component of the product formulation

Precautions/Warnings

- Infections
- Effects on ability to drive and use machines

BILLING/CODING INFORMATION:

The following codes may be used to describe:

HCPCS Coding

J9039	Injection, blinatumomab, 1 microgram

ICD-10 Diagnosis Codes That Support Medical Necessity

C91.00	Acute lymphoblastic leukemia not having achieved remission
C91.02	Acute lymphoblastic leukemia, in relapse

REIMBURSEMENT INFORMATION:

Refer to section entitled **POSITION STATEMENT**.

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Part D: Florida Blue has delegated to Prime Therapeutics authority to make coverage determinations for the Medicare Part D services referenced in this guideline.

Medicare Advantage: No National Coverage Determination (NCD) and/or Local Coverage Determination (LCD) were found at the time of the last guideline revised date.

DEFINITIONS:

Acute lymphoblastic leukemia: an aggressive (fast-growing) type of leukemia (blood cancer) in which too many immature white blood cells are found in the blood and bone marrow. Also called acute lymphocytic leukemia and ALL.

Chronic myelogenous leukemia: also known as chronic granulocytic leukemia (CGL), is a cancer of the white blood cells. It is a form of leukemia characterized by the increased and unregulated growth of predominantly myeloid cells in the bone marrow and the accumulation of these cells in the blood

Philadelphia chromosome or Philadelphia translocation: is a specific chromosomal abnormality that is associated CML or ALL.

Relapse: the return of a disease or the signs and symptoms of a disease after a period of improvement.

Refractory: cancer that does not respond to treatment; the cancer may be resistant at the beginning of treatment or it may become resistant during treatment. Also called resistant cancer.

RELATED GUIDELINES:

Dasatinib (Sprycel®) Tablets, 09-J1000-43

Imatinib Mesylate (Gleevec®) Tablets, 09-J1000-46

Nilotinib (Tasigna®) Capsules, 09-J1000-48

Immune Globulin Therapy, 09-J0000-06

Ponatinib (Iclusig®) Tablet, 09-J1000-89

OTHER:

None

REFERENCES:

1. Amgen. Blincyto (blinatumomab). 2014 [cited 3/28/20]. In: DailyMed [Internet]. Bethesda (MD): National Library of Medicine. Available from: http://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=38b482a8-960b-4591-9857-5031ecb830aa/.
2. Clinical Pharmacology [Internet]. Tampa (FL): Gold Standard, Inc.; 2020 [cited 3/28/20]. Available from: http://www.clinicalpharmacology.com/.
3. ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine; 2000 Feb 29 - [cited 3/28/20]. Available from: http://clinicaltrials.gov/.
4. DRUGDEX® System [Internet]. Greenwood Village (CO): Thomson Micromedex; Updated periodically [cited 3/28/20]. Available from: http://www.thomsonhc.com/.
5. National Comprehensive Cancer Network®. NCCN clinical practice guidelines in oncology (NCCN Guidelines®). Acute Lymphoblastic Leukemia, version 1.2020. [cited 3/28/20]. Available from: http://www.nccn.org/professionals/physician_gls/f_guidelines.asp.
6. National Comprehensive Cancer Network®. NCCN clinical practice guidelines in oncology (NCCN Guidelines®). Pediatric Acute Lymphoblastic Leukemia, version 2.2020. [cited 3/28/20]. Available from: http://www.nccn.org/professionals/physician_gls/f_guidelines.asp.
7. NCCN Drugs & Biologics Compendium [Internet]. Fort Washington (PA): National Comprehensive Cancer Network; 2020 [cited 3/28/20]. Available from: http://www.nccn.org/professionals/drug_compendium/content/contents.asp/.

8. Orphan Drug Designations and Approval [Internet]. Silver Spring (MD): US Food and Drug Administration; 2020 [cited 3/28/20]. Available from: http://www.accessdata.fda.gov/scripts/opdlisting/oopd/index.cfm/.

COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Pharmacy Policy Committee on 03/11/20.

GUIDELINE UPDATE INFORMATION:

03/15/15	New Medical Coverage Guideline.
07/15/15	Revision to guideline; consisting of description, position statement, references.
11/01/15	Revision: ICD-9 Codes deleted.
01/01/16	Annual HCPCS coding update: added code J9039 and deleted codes C9399 and J9999.
03/15/16	Review and revision; consisting of updating position statement, references, and description.
03/15/17	Review and revision; consisting of updating position statement, references, description.
4/15/18	Review and revision; consisting of updating position statement, references.
05/15/19	Review and revision; consisting of updating position statement, references.
04/15/20	Review and revision; consisting of updating description, position statement, references.