Medical Drug Clinical Criteria

Subject:	Blincyto (blinatumomab)		
Document #:	CC-0126	**Publish Date:**	~~03/28/2022~~03/27/2023
Status:	Revised	**Last Review Date:**	~~02/25/2022~~02/24/2023

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Overview

This document addresses the use of Blincyto (blinatumomab). Blincyto is a bispecific T-cell engager designed to promote lysis of cancer cells by binding simultaneously with both CD3 on cytotoxic T-cells and CD19 on certain cancerous B-cells. It is used to treat acute lymphoblastic leukemia (ALL). Blincyto should only be used in CD19+ B-cell ALL due to its molecular target.

The FDA approved indications for Blincyto include relapsed or refractory B-cell precursor ALL as well as B-cell ALL in first or second complete remission with minimal residual disease (MRD) great than or equal to 0.1%. The National Comprehensive Cancer Network® (NCCN) guidelines include additional 2A recommendations for the use of Blincyto in combination with certain tyrosine kinase inhibitors (TKIs) including bosutinib, dasatinib, imatinib, nilotinib, or ponatinib for Philadelphia chromosome-positive B-ALL. NCCN also recommends Blincyto in combination with mini-hyper CVD (cyclophosphamide, dexamethasone, vincristine, methotrexate, cytarabine) with Besponsa for relapsed or refractory disease and as maintenance therapy alternating with POMP (prednisone, vincristine, methotrexate, and mercaptopurine). NCCN guidelines for Pediatric Acute Lymphoblastic Leukemia also recommend the use of Blincyto in combination with Interfant regimens. Interfant regimens include certain chemotherapy combination treatment protocols specifically designed for infants diagnosed with ALL and are described in further detail within the guidelines.

Blincyto has a black box warning for cytokine release syndrome (CRS). If severe CRS occurs, Blincyto should be interrupted until resolution, or permanently discontinued if life-threatening CRS. Blincyto also has a black box warning for neurological toxicities. There is limited experience in patients with active ALL in the central nervous system (CNS) or a history of neurologic events as patients with clinically relevant CNS pathology were excluded from studies.

Definitions and Measures

Complete Response or Complete Remission (CR): The disappearance of all signs of cancer as a result of treatment; also called complete remission; does not indicate the cancer has been cured.

Line of Therapy:

- First-line therapy: The first or primary treatment for the diagnosis, which may include surgery, chemotherapy, radiation therapy or a combination of these therapies.
- Second-line therapy: Treatment given when initial treatment (first-line therapy) is not effective or there is disease progression.
- Third-line therapy: Treatment given when both initial (first-line therapy) and subsequent treatment (second-line therapy) are not effective or there is disease progression.

Refractory Disease: Illness or disease that does not respond to treatment.

Relapse or recurrence: After a period of improvement, during which time a disease (for example, cancer) could not be detected, the return of signs and symptoms of illness or disease. For cancer, it may come back to the same place as the original (primary) tumor or to another place in the body.

Clinical Criteria

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

Blincyto (blinatumomab)

Requests for Blincyto (blinatumomab) may be approved if the following criteria are met:

I. Individual has a diagnosis of CD19+ B-cell precursor acute lymphocytic leukemia (ALL); **AND**
II. Blinatumomab is used as a single agent ~~or in combination with a tyrosine kinase inhibitor (bosutinib, dasatinib, imatinib, nilotinib, or ponatinib)~~ (Label~~, NCCN 2A~~); **AND**
III. Individual is using for one of the following:
   A. Relapsed or refractory disease; **OR**
   B. Minimal residual disease (MRD) greater than or equal to 0.1%, following a first or second complete response to induction therapy; **OR**
   C. As consolidation therapy (NCCN 2A);

OR

IV. Individual has a diagnosis of CD19+ B-cell precursor acute lymphocytic leukemia (ALL) (NCCN 2A); **AND**
V. Blinatumomab is used in combination with a tyrosine kinase inhibitor (bosutinib, dasatinib, imatinib, nilotinib, or ponatinib) (NCCN 2A); **AND**
VI. Individual is using for one of the following (NCCN 2A):
   A. Relapsed or refractory disease; **OR**
   B. As consolidation therapy;

OR

VII. Individual has a diagnosis of CD19+ B-cell precursor acute lymphocytic leukemia (ALL) (NCCN 2A); **AND**
VIII. Blinatumomab is used in combination with mini-hyper CVD (cyclophosphamide, dexamethasone, vincristine, methotrexate, cytarabine) with Besponsa; **AND**
IX. Individual is using for relapsed or refractory disease;

OR

X. Individual has a diagnosis of CD19+ B-cell precursor acute lymphocytic leukemia (ALL) (NCCN 2A); **AND**
XI. Blinatumomab is used as maintenance therapy as a single agent alternating with POMP (prednisone, vincristine, methotrexate, and mercaptopurine);

OR

~~A.~~XII. Individual is using Blinatumomab in combination with Interfant regimens for infant acute lymphocytic leukemia (ALL) (NCCN 2A).

Requests for Blincyto (blinatumomab) may not be approved for the following:

~~I. Individual has evidence of active ALL central nervous system involvement; **OR**~~
~~II. Use as first line therapy for ALL; **OR**~~
~~III.~~I. Treatment of diffuse large B-Cell lymphoma (DLBCL); **OR**
~~IV.~~II. When the above criteria are not met and for all other indications.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

HCPCS

J9039	Injection,1 microgram [Blincyto]

ICD-10 Procedure

XW03351	Introduction of blinatumomab antineoplastic immunotherapy into peripheral vein, percutaneous approach, new technology group 1
XW04351	Introduction of blinatumomab antineoplastic immunotherapy into central vein, percutaneous approach, new technology group 1

ICD-10 Diagnosis

C91.00-C91.02	Acute lymphoblastic leukemia [ALL]

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Document History

Revised: 02/24/2023
Document History:

- 02/24/2023 – Annual Review: Update criteria to allow consolidation, maintenance therapy, and in combination with interfant regimens or mini-hyper CVD per NCCN; remove exclusion for CNS involvement and first line therapy per NCCN. Coding Reviewed: No changes.
- 02/25/2022 – Annual Review: Update criteria to allow combination use with TKIs per NCCN; wording and formatting changes. Coding Reviewed: No changes.
- 02/19/2021 – Annual Review: No changes. Coding Review: No changes.
- 02/21/2020 – Annual Review: No changes. Coding Review: No changes
- 05/17/2019 – Annual Review: First review of Blincyto clinical criteria. Minor wording and formatting updates. Coding Review: No changes

References

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: January 18, 2023.
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Foa R, Bassan R, Vitle A, et al. Dasatinib-blinatumumab for Ph-positive acute lymphoblastic leukemia in adults. N Engl J Med 2020; 383:1613-1623.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2023; Updated periodically.
5. NCCN Clinical Practice Guidelines in Oncology™. © 2023 National Comprehensive Cancer Network, Inc. For additional information, visit the NCCN website: http://www.nccn.org/index.asp. Accessed on January 18, 2023.
    a. Pediatric Acute lymphoblastic Leukemia. V1.2023. Revised November 9, 2022.
    b. Acute Lymphoblastic Leukemia. V1.2022. Revised April 4, 2022.

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.