

Medical Drug Clinical Criteria

Subject:	Blincyto (blinatumomab)		
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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 various other chemotherapy regimens, as consolidation therapy, 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) and neurological toxicities which may be severe, life-threatening, or fatal. Blincyto should be interrupted or discontinued as recommended if these occur. Administer corticosteroids for severe or life-threatening CRS.

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. Individual is using for one of the following (Label, NCCN 1, NCCN 2A):
 - A. Relapsed or refractory disease; **OR**
 - B. When blinatumomab is used in combination with a tyrosine kinase inhibitor (TKI) (TKI options include bosutinib, dasatinib, imatinib, nilotinib, or ponatinib); **OR**
 - C. Minimal residual disease (MRD) greater than or equal to 0.1%, following a first or second complete response to induction therapy; **OR**
 - D. As consolidation therapy;

OR

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

OR

- V. Individual is using blinatumomab in combination with interfant regimens for infant acute lymphocytic leukemia (ALL) with KMT2A status (11q23) rearranged (NCCN 2A).

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

- I. Treatment of diffuse large B-Cell lymphoma (DLBCL); **OR**
- 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, blinatumomab, 1 microgram [Blincyto]

ICD-10 Diagnosis

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

Document History

Revised: 02/21/2025

Document History:

- 02/21/2025 – Annual Review: Update NCCN 2A recommendation for Blincyto use in combination with a TKI for ALL. Coding Reviewed: Updated description for HCPCS J9030. Removed obsolete ICD-10-PCS XW03351 and XW04351.
- 02/23/2024 – Annual Review: Simplify criteria to include treatment as consolidation or for relapsed/refractory disease as a single agent or in combination per NCCN; update combination with interfant regimens to include KMT2A status (11q23) rearranged per NCCN. Coding Reviewed: No changes.
- 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 16, 2025.
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Foa R, Bassan R, Vittle 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.; 2025; Updated periodically.

5. NCCN Clinical Practice Guidelines in Oncology™. © 2025 National Comprehensive Cancer Network, Inc. For additional information, visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on January 16, 2025.
 - a. Pediatric Acute lymphoblastic Leukemia. V2.2025. Revised December 16, 2024.
 - b. Acute Lymphoblastic Leukemia. V3.2024. Revised December 20, 2024.

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

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