

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.

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 greater than or equal to 0.1%, following a first or second complete response to induction therapy.

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

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

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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]

Document History

Revised: 02/25/2022

Document History:

- 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

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 - a. Pediatric Acute lymphoblastic Leukemia. V1.2022. Revised October 1, 2021.

b. Acute Lymphoblastic Leukemia. V4.2021. Revised January 7, 2022.

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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