Reference number(s)
4231-A

Standard Medicare Part B Management Blincyto

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Blincyto	blinatumomab

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indications[1]

- Blincyto is indicated for the treatment of CD19-positive B-cell precursor acute lymphoblastic leukemia (ALL) in first or second complete remission with minimal residual disease (MRD) greater than or equal to 0.1% in adults and pediatric patients one month and older.
- Blincyto is indicated for the treatment of relapsed or refractory CD19-positive B-cell precursor acute lymphoblastic leukemia (ALL) in adults and pediatric patients one month and older.
- Blincyto is indicated for the treatment of CD19-positive Philadelphia chromosome-negative B-cell precursor acute lymphoblastic leukemia (ALL) in the consolidation phase of multiphase chemotherapy in adult and pediatric patients one month and older.

Compendial Uses[2]

Acute lymphoblastic leukemia (ALL)

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All other indications will be assessed on an individual basis. Submissions for indications other than those listed in this criteria should be accompanied by supporting evidence from Medicare approved compendia.

Documentation

The following documentation must be available, upon request, for initial requests:

- Testing or analysis confirming CD19 protein on the surface of the B cell

Coverage Criteria

B-cell Precursor Acute Lymphoblastic Leukemia[1-4]

Authorization of 9 months may be granted for treatment of CD19-positive B-cell precursor acute lymphoblastic leukemia (ALL) when one of the following criteria are met:

- The requested medication will be used as induction therapy for Philadelphia chromosome-positive disease in combination with a tyrosine kinase inhibitor (e.g., bosutinib, dasatinib, imatinib, nilotinib, ponatinib).
- The requested medication will be used as consolidation or maintenance therapy.
- The requested medication will be used for relapsed or refractory disease.

Continuation of Therapy

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Authorization for 12 months may be granted when all of the following criteria are met:

- The member is currently receiving therapy with the requested medication.
- The requested medication is being used to treat an indication listed in the coverage criteria section.
- The member is receiving benefit from therapy. Benefit is defined as:
    - No evidence of unacceptable toxicity while on the current regimen and
    - No evidence of disease progression while on the current regimen

Summary of Evidence

The contents of this policy were created after examining the following resources:

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- The prescribing information for Blincyto.
- The available compendium
    - National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
    - Micromedex DrugDex
    - American Hospital Formulary Service- Drug Information (AHFS-DI)
    - Lexi-Drugs
    - Clinical Pharmacology
- NCCN Guideline: Acute lymphoblastic leukemia
- NCCN Guideline: Pediatric acute lymphoblastic leukemia

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Blincyto and are included in addition to acute lymphoblastic leukemia.

Explanation of Rationale

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

Support for acute lymphoblastic leukemia and pediatric acute lymphoblastic leukemia can be found in the NCCN Drugs and Biologics Compendium. Use of information in the NCCN Drugs and Biologics Compendium for off-label use of drugs and biologicals in an anti-cancer chemotherapeutic regimen is supported by the Medicare Benefit Policy Manual, Chapter 15, section 50.4.5 (Off-Label Use of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen).

References

1. Blincyto [package insert]. Thousand Oaks, CA: Amgen Inc.; April 2025.
2. The NCCN Drugs & Biologics Compendium® © 2025 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed June 18, 2025.
3. External Infusion Pumps (L33794) Version R32. Available at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. Accessed June 18, 2025.

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