Reference number(s)
2228-A

Specialty Guideline 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

- 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

Acute lymphoblastic leukemia (ALL)

All other indications are considered experimental/investigational and not medically necessary.

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Documentation

Submission of the following information is necessary to initiate the prior authorization review:

- Testing or analysis confirming CD19 protein on the surface of the B cell
- KMT2A (11q23) rearrangement status (where applicable)

Coverage Criteria

B-cell Precursor Acute Lymphoblastic Leukemia

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 consolidation or maintenance therapy.
- The requested medication will be used for relapsed or refractory disease.
- The requested medication will be used in combination with interfant regimens for infant ALL with KMT2A (11q23) status rearranged.

Continuation of Therapy

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in the coverage criteria section when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

References

1. Blincyto [package insert]. Thousand Oaks, CA: Amgen Inc.; June 2024.
2. The NCCN Drugs & Biologics Compendium® © 2024 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed June 14, 2024.