

## SPECIALTY GUIDELINE MANAGEMENT

### BLINCYTO (blinatumomab)

#### POLICY

##### I. 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.

###### A. 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.
2. Blincyto is indicated for the treatment of relapsed or refractory CD19-positive B-cell precursor acute lymphoblastic leukemia (ALL) in adults and pediatric patients.

###### B. Compendial Uses

Acute lymphoblastic leukemia (ALL)

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

##### II. 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

##### III. CRITERIA FOR INITIAL APPROVAL

###### **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:

- A. The requested medication will be used as consolidation or maintenance therapy.
- B. The requested medication will be used for relapsed or refractory disease.

##### IV. CONTINUATION OF THERAPY

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

##### V. REFERENCES

1. Blincyto [package insert]. Thousand Oaks, CA: Amgen Inc.; June 2023.

Reference number(s)
2228-A

2. The NCCN Drugs & Biologics Compendium 2023 National Comprehensive Cancer Network, Inc.  
<http://www.nccn.org>. Accessed May 23, 2023.