PRIOR AUTHORIZATION POLICY

POLICY: Oncology (Injectable) – Blincyto Prior Authorization Policy
- Blincyto® (blinatumomab intravenous infusion – Amgen)

REVIEW DATE: 09/04/2024

OVERVIEW

Blincyto, a bispecific CD19-directed CD3 T-cell engager, is indicated for the following uses:[1]

- **Minimal residual disease (MRD)-positive, CD19-positive B-cell precursor acute lymphoblastic leukemia** (ALL) in first or second complete remission with MRD ≥ 0.1% in patients ≥ 1 month of age.
- **Relapsed or refractory CD19-positive B-cell ALL** in patients ≥ 1 month of age.
- **B-cell precursor, CD-19-positive Philadelphia chromosome-negative ALL** in the consolidation phase of multiphase chemotherapy in patients ≥ 1 month of age.

Guidelines

The National Comprehensive Cancer Network (NCCN) guidelines on **Acute Lymphoblastic Leukemia** (version 2.2024 – July 19, 2024) and **Pediatric Acute Lymphoblastic Leukemia** (version 1.2025 – August 28, 2024) recommend Blincyto for relapsed/refractory B-cell ALL, induction therapy, consolidation therapy, and maintenance therapy.[2-4]

Safety

Blincyto contains a boxed warning for cytokine release syndrome which may be life-threatening or fatal and neurologic toxicities which may be severe, life-threatening, or fatal.[1] Stop or discontinue Blincyto as recommended for either toxicity.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Blincyto. All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Blincyto, as well as the monitoring required for adverse events and long-term efficacy, approval requires Blincyto to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Blincyto is recommended in those who meet the following criteria:

FDA-Approved Indication

1. **Acute Lymphoblastic Leukemia.** Approve for 1 year if the patient meets ALL of the following (A, B, and C):
   - **A)** Patient has B-cell precursor disease; AND
   - **B)** Patient meets ONE of the following (i, ii, or iii):
     - **i.** Patient is Philadelphia chromosome negative and meets ONE of the following (a, b, c, or d):

a) Patient has relapsed or refractory disease; OR
b) The medication is used for induction therapy; OR
c) The medication is used for consolidation therapy; OR
d) The medication is used for maintenance therapy; OR

ii. Patient is Philadelphia chromosome-like and the medication is used for consolidation therapy; OR

iii. Patient is Philadelphia chromosome positive and meets ONE of the following (a, b, c, or d):
a) Patient has relapsed or refractory disease; OR
b) The medication is used for induction therapy; OR
c) The medication is used for consolidation therapy; OR
d) The medication is used for maintenance therapy; AND

C) Blincyto is prescribed by or in consultation with an oncologist.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Blincyto is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Blincyto® intravenous infusion [prescribing information]. Thousand Oaks, CA: Amgen; June 2024.
2. The NCCN Pediatric Acute Lymphoblastic Leukemia Oncology Guidelines (version 1.2025 – August 28, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed August 29, 2024.
3. The NCCN Acute Lymphoblastic Leukemia Clinical Practice Guidelines in Oncology (version 2.2024 – July 19, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed August 29, 2024.
4. The NCCN Drugs and Biologics Compendium. © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on August 29, 2024. Search term: blinatumomab.