Utilization Review Policy 152

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

EFFECTIVE DATE: 1/1/2020
LAST REVISION DATE: 09/16/2024

COVERAGE CRITERIA FOR: All UCare Plans

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.

Dosing Information
Dosing in MRD-Positive B-Cell Precursor ALL.[1] For patients ≥ 45 kg (99 lbs), the dose of Blincyto is 28 mcg/day on Days 1 through 28 of each 42 day cycle. For patients < 45 kg (99 lbs), the dose is 15 mcg/m^2/day, not to exceed 28 mcg/day on Days 1 through 28 of each 42 day cycle. A maximum of 4 cycles of Blincyto is recommended for MRD positive B-cell precursor ALL. A course of treatment consists of 1 induction cycle followed by 3 consolidation cycles. A treatment course may take 6 to 9 months to complete.[1]

Dosing in Relapsed/Refractory B-Cell Precursor ALL.[1] For patients < 45 kg (99 lbs), Blincyto is dosed based on body surface area. The recommended dose in Cycle 1 is 5 mcg/m^2/day (not to exceed 9 mcg/day) on Days 1 through 7 and 15 mcg/m^2/day (not to exceed 28 mcg/day) on Days 8 through 28. In subsequent cycles, the recommended dose is 15 mcg/m^2/day (not to exceed 28 mcg/day) on Days 1 through 28. For patients ≥ 45 kg (99 lbs), the recommended dose in Cycle 1 is 9 mcg/day on Days 1 through 7 and 28 mcg/day on Days 8 through 28. In subsequent cycles, the recommended dose is 28 mcg/day on Days 1 through 28. A maximum of 9 cycles of Blincyto is recommended for relapsed/refractory B-cell precursor ALL. A treatment course of Blincyto consists of up to 2 induction cycles, 3 consolidation cycles, and up to 4 additional cycles. A cycle of induction or consolidation therapy consists of a 28-day continuous intravenous infusion followed by 14-day treatment-free interval. A single course of continued therapy consists of a 28-day continuous intravenous infusion followed by 56-day treatment-free interval.

Dosing in B-Cell Precursor ALL in the Consolidation Phase.[1] For patients ≥ 45 kg (99 lbs), the dose of Blincyto is 28 mcg/day on Days 1 through 28 of each 42 day cycle. For patients < 45 kg (99 lbs), the dose is 15 mcg/m^2/day, not to exceed 28 mcg/day on Days 1 through 28 of each 42 day cycle. Blincyto is given in cycles 1 and 2, then chemotherapy alone in cycles 3 – 5, then Blincyto in cycle 6, chemotherapy in cycle 7, and Blincyto in cycle 8.

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 medical benefit coverage of Blincyto. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indication. Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). 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.

Dosing. Approve up to 28 mcg/day administered by intravenous infusion on Days 1 through 28 of each treatment cycle with a minimum of a 14-day treatment-free interval between cycles.[1]

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.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	**Acute Lymphoblastic Leukemia:** For Philadelphia chromosome negative disease added the medication is used for consolidation or maintenance therapy as additional options for approval. Added patient is Philadelphia chromosome-like and minimal residual disease positive as a condition of approval. For Philadelphia chromosome positive disease, added consolidation therapy as an additional option for approval.	09/07/2022
Annual Revision	**Acute Lymphoblastic Leukemia:** For Philadelphia chromosome positive disease, patient has relapsed or refractory disease and medication is used for maintenance therapy were added as additional options for approval.	09/06/2023

Annual Revision	**Acute Lymphoblastic Leukemia:** For Philadelphia chromosome negative disease, removed patient is minimal residual disease positive as an option for approval. Added the medication is used for induction therapy as an option for approval. For Philadelphia chromosome-like disease removed minimal residual disease positive and added the medication is used for consolidation therapy. For Philadelphia chromosome-positive disease added the medication is used for induction therapy as an option for approval. Removed the patient has tried at least one tyrosine kinase inhibitor, the patient does not have a complete response to induction therapy, and patient is minimal residual disease positive as options for approval.	09/04/2024
UCare P&T Review	Policy reviewed and approved by UCare P&T committee. Annual review process	09/16/2024