VENTURA COUNTY
HEALTH CARE PLAN

UTILIZATION MANAGEMENT MEDICAL POLICY

POLICY: Oncology (Injectable) – Blincyto Utilization Management Medical Policy
- Blincyto® (blinatumomab intravenous infusion – Amgen)

REVIEW DATE: 09/06/2023

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 adults and pediatric patients.
- **Relapsed or refractory CD19-positive B-cell ALL** in adults and pediatric patients.

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.

Guidelines

The National Comprehensive Cancer Network (NCCN) guidelines on **Acute Lymphoblastic Leukemia** (version 2.2023 – July 28, 2023) and **Pediatric Acute Lymphoblastic Leukemia** (version 1.2024 – August 17, 2023) recommend Blincyto for relapsed/refractory B-cell ALL; consolidation therapy in adolescents, young adults, and adults after complete response to induction therapy; maintenance therapy; and for pediatric patients with MRD positive disease, less than complete response, or for relapsed/refractory disease.[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 indications. 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 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)** Patient is minimal residual disease positive; 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 minimal residual disease positive; OR
     - **iii.** Patient is Philadelphia chromosome positive and meets one of the following (a, b, c, d, e, or f):
       - **a)** Patient has tried at least one tyrosine kinase inhibitor (TKI) used for the treatment of acute lymphoblastic leukemia; OR
         Note: Examples of a TKI include imatinib tablets, Sprycel (dasatinib tablets), Tasigna (nilotinib capsules).
       - **b)** Patient has relapsed or refractory disease; OR
       - **c)** Patient does not have a complete response to induction therapy; OR
       - **d)** Patient is minimal residual disease positive; OR
       - **e)** The medication is used for consolidation therapy; OR
       - **f)** 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 2023.

2. The NCCN Pediatric Acute Lymphoblastic Leukemia Oncology Guidelines (version 1.2024 – August 17, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed August 31, 2023.
3. The NCCN Acute Lymphoblastic Leukemia Clinical Practice Guidelines in Oncology (version 2.2023 – July 28, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed August 31, 2023.
4. The NCCN Drugs and Biologics Compendium. © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on August 31, 2023. 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