Blinatumomab (Blincyto®)	Place of Service Office Administration Outpatient Facility Administration Infusion Center Administration HCPCS: J9039 per 1 mcg

Condition listed in policy (*see criteria for details*)

- Acute lymphoblastic leukemia (ALL), B-cell precursor

AHFS therapeutic class: Antineoplastic Agents

Mechanism of action: Bispecific CD19-directed CD3 T-cell engager monoclonal antibody

(1) Special Instructions and pertinent Information

Covered under the Medical Benefit, please submit clinical information for prior authorization review via fax.

(2) Prior Authorization/Medical Review is required for the following condition(s)

All requests for Blincyto® (blinatumomab) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

Acute lymphoblastic leukemia (ALL), B-cell precursor

1. Meets one of the following:
    a. Used for consolidation therapy and meets one of the following:
        i. Being used as a single agent, **or**
        ii. Being used in combination with a TKI for Philadelphia chromosome positive (Ph+)

    OR

    b. Used for maintenance therapy as a single agent alternating with POMP (prednisone, vincristine, methotrexate, and mercaptopurine) for Philadelphia chromosome negative (Ph-),

    OR

    c. Used for relapsed or refractory disease and meets one of the following:
        i. Being used as a single agent, **or**
        ii. Being used in combination with a TKI for Philadelphia chromosome positive (Ph+), **or**
        iii. Being used in combination with inotuzumab ozogamicin + mini-hyperCVD for Philadelphia chromosome negative (Ph-)

    OR

    d. Being used in combination with interfant regimens for infant ALL

Covered Doses

Consolidation:

Dosing for patients **greater** than or equal to 45 kg:

Up to 28 mcg/day IV on days 1-28, followed by a 14-day treatment-free interval

OR

Dosing for patients **less** than 45kg:

Up to 15 mcg/m^2/day IV [not to exceed 28 mcg/day] on days 1-28, followed by a 14-day treatment-free interval

A single cycle of treatment consists of 28 days of continuous IV infusion followed by a 14-day treatment-free interval (total of 42 days)

Maintenance:

Given on Cycles 4, 8, and 12 for up to 28 mcg/day IV on days 1-28, followed by a 14-day treatment-free interval. A cycle is 6 weeks.

Cycles 1-3, 5-7, 9-11, 13-15 will be with POMP (6-mercaptopurine, vincristine, methotrexate, and prednisone). A cycle is 4 weeks.

Relapsed/refractory:

Dosing for patients **greater** than or equal to 45 kg:

Cycle 1: Up to 9 mcg/day IV on Days 1-7, then up to 28 mcg/day IV on days 8-28.

Subsequent cycles: Up to 28 mcg/day IV on days 1-28.

OR

Dosing for patients **less** than 45kg:

Cycle 1: Up to 5 mcg/m^2/day (not to exceed 9 mcg/day) IV on Days 1-7, then up to 15 mcg/m^2/day (not to exceed 28 mcg/day) IV on days 8-28.

Subsequent cycles: Up to 15 mcg/m^2/day (not to exceed 28 mcg/day) IV on days 1-28.

A treatment course consists of up to 2 cycles for induction followed by 3 additional cycles for consolidation and up to 4 additional cycles of continued therapy. A single cycle of treatment of induction or consolidation consists of 28 days of continuous IV infusion followed by a 14-day treatment-free interval (total 42 days). A single cycle of treatment of continued therapy consists of 28 days of continuous IV infusion followed by a 56-day treatment-free interval (total 84 days)

Coverage Period

Consolidation: One year for up to 4 treatment cycles

Maintenance: Two years for up to 3 treatment cycles

Relapsed/refractory: Two years for up to 9 total treatment cycles

ICD-10:

C91.00-C91.02

(3) The following condition(s) DO NOT require Prior Authorization/Preservice

All requests for Blincyto® (blinatumomab) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

(4) This Medication is NOT medically necessary for the following condition(s)

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

(5) Additional Information

How supplied:
35 mcg (single-use vial)

(6) References

- AHFS®. Available by subscription at http://www.lexi.com
- Blincyto® (blinatumomab) [Prescribing information]. Thousand Oaks, CA: Amgen; 2022.
- DrugDex®. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
- National Comprehensive Cancer Network. Blincyto (Version 2023). Available at: www.nccn.org
- National Comprehensive Cancer Network. Acute Lymphoblastic Leukemia (Version 4.2021). Available at: www.nccn.org
- National comprehensive cancer network. Pediatric Acute Lymphoblastic Leukemia (Version 1.2022). Available at: www.nccn.org.

(7) Policy Update

Date of last review: 2Q2023
Date of next review: 2Q2024
Changes from previous policy version:

- Section (2): Acute lymphoblastic leukemia (ALL), B-cell precursor –
  - Expanded coverage to include select combination use based on Philadelphia chromosome status
  - Added coverage for maintenance therapy for Ph-negative B-cell ALL
  - Removed requirement for prior treatment with a TKI for coverage of relapsed/refractory Ph+ ALL
  - Added coverage for combination use with interfant regimens for infant ALL

Rationale: *NCCN Category 2A support*

BSC Drug Coverage Criteria to Determine Medical Necessity
Reviewed by P&T Committee