Medical Policy:

Blincyto™ (blinatumomab) Intravenous

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.22	March 28, 2024	

Definitions

Blincyto (blinatumomab) is a bispecific T-cell engager designed to promote the lysis of cancer cells by binding simultaneously with both the CD3 protein on cytotoxic T-cells and the CD19 protein, a B-cell specific lymphocyte antigen expressed in specific types of acute lymphocytic leukemia (ALL).

Dosing Limits [Medical Benefit]

Max Units (per dose and over time) [HCPCS Unit]:

Acute Lymphoblastic Leukemia (ALL) (Adult/Pediatric)

Cycle 1 – 5 (Induction/Consolidation): 980 billable units per 42 days

Cycle 6 – 9 (Continued Therapy): 980 billable units per 84 days

Guideline

I. INITIAL CRITERIA

1. **Acute Lymphoblastic Leukemia.** Approve 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.

II. RENEWAL CRITERIA

1. **B-cell precursor acute lymphocytic leukemia (ALL), relapsed or refractory:**
    A. Patient continues to meet initial approval criteria; **AND**
    B. Disease response or stabilization; **AND**
    C. Absence of unacceptable toxicity from the drug, including cytokine release syndrome, neurological toxicities, serious infections, pancreatitis, tumor lysis syndrome, neutropenia/febrile neutropenia, elevation of LFTs, leukoencephalopathy.

Limitations/Exclusions

1. Approval will be granted for 30 weeks for a diagnosis of relapsed or refractory ALL and may be renewed twice for 24 weeks
2. Approval will be granted for 24 weeks for a diagnosis of MRD+ ALL and may not be renewed

Applicable Procedure Codes

Code	Description
J9039	Injection, blinatumomab, 1 microgram

Applicable NDCs

Code	Description
55513-0160-01	Blincyto 35mcg Solution Reconstituted J9039 Injection, blinatumomab, 1 microgram

ICD-10 Diagnoses

Code	Description
C83.50	Lymphoblastic (diffuse) lymphoma unspecified site

C83.51	Lymphoblastic (diffuse) lymphoma lymph nodes of head, face, and neck
C83.52	Lymphoblastic (diffuse) lymphoma intrathoracic lymph nodes
C83.53	Lymphoblastic (diffuse) lymphoma intra-abdominal lymph nodes
C83.54	Lymphoblastic (diffuse) lymphoma lymph nodes of axilla and upper limb
C83.55	Lymphoblastic (diffuse) lymphoma lymph nodes of inguinal region and lower limb
C83.56	Lymphoblastic (diffuse) lymphoma intrapelvic lymph nodes
C83.57	Lymphoblastic (diffuse) lymphoma spleen
C83.58	Lymphoblastic (diffuse) lymphoma lymph nodes of multiple sites
C83.59	Lymphoblastic (diffuse) lymphoma extranodal and solid organ sites
C91.00	Acute lymphoblastic leukemia not having achieved remission
C91.01	Acute lymphoblastic leukemia, in remission
C91.02	Acute lymphoblastic leukemia, in relapse

Revision History

<table>
<tr><th>Company(ies)</th><th>DATE</th><th>REVISION</th></tr>
<tr><td>EmblemHealth & ConnectiCare</td><td>3/28/2024</td><td>Annual Review: Updated dosing limits, Initial Criteria: Streamlined and reworded: deleted: “B-cell precursor acute lymphocytic leukemia (ALL), relapsed or refractory: Patient’s disease is CD19+; AND Patient’s disease is Philadelphia chromosome-negative OR Philadelphia chromosome-positive and refractory to tyrosine kinase inhibitor (TKI) therapy. B-cell precursor acute lymphocytic leukemia (ALL), minimal residual disease (MRD)-positive: Patient’s disease is CD19+; AND Patient’s disease is in first or second complete remission; AND Patient has minimal residual disease greater than or equal to 0.1%
And Added “Acute Lymphoblastic Leukemia. Approve if the patient meets the following (A, B, and C): Patient has B-cell precursor disease; AND Patient meets one of the following (i, ii, or iii): Patient is Philadelphia chromosome negative and meets one of the following (a, b, c, or d): Patient has relapsed or refractory disease; OR Patient is minimal residual disease positive; OR The medication is used for consolidation therapy; OR The medication is used for maintenance therapy; OR Patient is Philadelphia chromosome-like and minimal residual disease positive; OR Patient is Philadelphia chromosome positive and meets one of the following (a, b, c, d, e, or f) 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). Patient has relapsed or refractory disease; OR Patient does not have a complete response to induction therapy; OR Patient is minimal residual disease positive; OR The medication is used for consolidation therapy; OR The medication is used for maintenance therapy; AND Blincyto is prescribed by or in consultation with an oncologist.”</td></tr>
<tr><td>EmblemHealth & ConnectiCare</td><td>7/25/2023</td><td>Annual Review:
<u>B-cell precursor acute lymphocytic leukemia (ALL), relapsed or refractory:</u> Initial Criteria: Removed” Blincyto will be administered as a single-agent; AND There is no evidence of active central nervous system involvement”
Added ICD-10 Codes:
<table>
<tr><td>C83.50</td><td>Lymphoblastic (diffuse) lymphoma unspecified site</td></tr>
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		C83.57	Lymphoblastic (diffuse) lymphoma spleen
		C83.58	Lymphoblastic (diffuse) lymphoma lymph nodes of multiple sites
		C83.59	Lymphoblastic (diffuse) lymphoma extranodal and solid organ sites
		C91.01	Acute lymphoblastic leukemia, in remission
EmblemHealth & ConnectiCare	4/05/2022	Transferred policy to new template	
EmblemHealth & ConnectiCare	10/8/2019	Annual Review	
EmblemHealth & ConnectiCare	09/06/2018	Added coverage for MRD+ ALL, added approval durations, renewal criteria, and dosing	
EmblemHealth & ConnectiCare	05/01/2018	"CD19+" descriptive added to refractory B-cell ALL	

References

1. U.S. Food and Drug Administration (FDA). FDA approves Blincyto to treat a rare form of acute lymphoblastic leukemia. FDA News Release. Silver Spring, MD: FDA; December 3, 2014.
2. Amgen Inc. Blincyto (blinatumomab) for injection, for intravenous use. Prescribing Information. Thousand Oaks, CA: Amgen; Revised March, 2020.
3. Amgen Inc. FDA approves Blincyto (blinatumomab) immunotherapy for the treatment of relapsed or refractory B-cell precursor acute lymphoblastic leukemia. News Release. Thousand Oaks, CA: Amgen; December 3, 2014.
4. Topp MS, Gökbuget N, Zugmaier G, et al. Phase II trial of the anti-CD19 bispecific T cell-engager blinatumomab shows hematologic and molecular remissions in patients with relapsed or refractory B-precursor acute lymphoblastic leukemia. J Clin Oncol. 2014 Nov 10. [Epub ahead of print]
5. Topp MS, Gökbuget N, Zugmaier G, et al. Long-term follow-up of hematologic relapse-free survival in a phase 2 study of blinatumomab in patients with MRD in B-lineage ALL. Blood. 2012;120(26):5185-5187.
6. Topp MS, Kufer P, Gökbuget N, et al. Targeted therapy with the T-cell-engaging antibody blinatumomab of chemotherapy-refractory minimal residual disease in B-lineage acute lymphoblastic leukemia patients results in high response rate and prolonged leukemia-free survival. J Clin Oncol. 2011;29(18):2493-2498.
7. National Comprehensive Cancer Network (NCCN). Blinatumomab. NCCN Drug & Biologics Compendium. Fort Washington, PA: NCCN; 2014