

Medical Policy: BLINCYTO™ (blinatumomab)

| POLICY NUMBER | LAST REVIEW | ORIGIN DATE |
|---------------|---------------|-------------|
| MG.MM.PH.22 | July 24, 2023 | |

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The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as “EmblemHealth”), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

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)

1. ALL, relapsed or refractory:
 - a. Induction (cycle 1): 9 billable units per day on day 1-7, and 28 billable units per day on day 8-28 of a 42 day cycle
 - b. Induction (cycle 2): 28 billable units per day on day 1-28 of a 42 day cycle
 - c. Consolidation (cycle 3-5): 28 billable units per day on day 1-28 of a 42 day cycle
 - d. Continuation (cycle 6-9): 28 billable units per day on day 1-28 of an 84 day cycle
2. ALL, MRD+:
 - a. Induction (cycle 1): 28 billable units per day on day 1-28 of a 42 day cycle
 - b. Consolidation (cycle 2-4): 28 billable units per day on day 1-28 of a 42 day cycle

Guideline

I. Blincyto (blinatumomab) is considered medically necessary for the following diagnoses when the subsequent criteria are met:

1. **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

2. **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%

II. Coverage for Blincyto (blinatumomab) may be renewed for the following diagnoses when subsequent criteria are met:

1. **B-cell precursor acute lymphocytic leukemia (ALL), relapsed or refractory:**

- Patient continues to meet initial approval criteria; **AND**
- Disease response or stabilization; **AND**
- 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

- Approval will be granted for 30 weeks for a diagnosis of relapsed or refractory ALL and may be renewed twice for 24 weeks
- 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 |

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| 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

| Company(ies) | DATE | REVISION | |
|-----------------------------|------------|--|--|
| EmblemHealth & ConnectiCare | 7/25/2023 | Annual Review: <u>B-cell precursor acute lymphocytic leukemia (ALL), relapsed or refractory: Initial Criteria: Removed”</u> c. Blincyto will be administered as a single-agent; AND d. There is no evidence of active central nervous system involvement” Added ICD-10 Codes: | |
| | | 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 |
| | | C91.01 | Acute lymphoblastic leukemia, in remission |
| | | EmblemHealth & ConnectiCare | 4/05/2022 |
| 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