Drug Policy:

Blincyto™ (blinatumomab)

POLICY NUMBER UM ONC_1270	**SUBJECT** Blincyto™ (blinatumomab)		**DEPT/PROGRAM** UM Dept	**PAGE 1 of 3**
DATES COMMITTEE REVIEWED 03/27/15, 05/24/16, 06/29/17, 07/26/17, 07/19/18, 06/12/19, 12/11/19, 04/08/20, 10/14/20, 09/08/21, 11/15/21, 05/11/22, 08/10/22, 01/11/23, 02/22/23, 01/10/24, 01/08/25	**APPROVAL DATE** January 08, 2025	**EFFECTIVE DATE** January 31, 2025	**COMMITTEE APPROVAL DATES** 03/27/15, 05/24/16, 06/29/17, 07/26/17, 07/19/18, 06/12/19, 12/11/19, 04/08/20, 10/14/20, 09/08/21, 11/15/21, 05/11/22, 08/10/22, 01/11/23, 02/22/23, 01/10/24, 01/08/25	
PRIMARY BUSINESS OWNER: UM		**COMMITTEE/BOARD APPROVAL** Evolent Specialty Services Clinical Guideline Review Committee		
NCQA STANDARDS UM 2		**ADDITIONAL AREAS OF IMPACT**		
CMS REQUIREMENTS	**STATE/FEDERAL REQUIREMENTS**		**APPLICABLE LINES OF BUSINESS** Commercial, Exchange, Medicaid	

Evolent Clinical Guidelines do not constitute medical advice. Treating health care professionals are solely responsible for diagnosis, treatment, and medical advice. Evolent uses clinical guidelines in accordance with its contractual obligations to provide utilization management. Coverage for services varies for individual members according to the terms of their health care coverage or government program. Individual members' health care coverage may not utilize some Evolent Clinical Guidelines. A list of codes, services or drugs may not be all inclusive and does not imply that a service or drug is a covered or non-covered service or drug. Evolent reserves the right to review and update this clinical guideline in its sole discretion. Notice of any changes shall be provided as required by applicable provider agreements and laws or regulations. Members should contact their plan customer service representative for specific coverage information.

I. PURPOSE

To define and describe the accepted indications for Blincyto (blinatumomab) usage in the treatment of cancer, including FDA approved indications, and off-label indications.

Evolent is responsible for processing all medication requests from network ordering providers. Medications not authorized by Evolent may be deemed as not approvable and therefore not reimbursable.

The use of this drug must be supported by one of the following: FDA approved product labeling, CMS-approved compendia, National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO) clinical guidelines, or peer-reviewed literature that meets the requirements of the CMS Medicare Benefit Policy Manual Chapter 15.

II. INDICATIONS FOR USE/INCLUSION CRITERIA

A. Continuation requests for a not-approvable medication shall be exempt from this Evolent policy provided:

1. The requested medication was used within the last year, AND
2. The member has not experienced disease progression and/or no intolerance to the requested medication, AND
3. Additional medication(s) are not being added to the continuation request.

B. Acute Lymphoblastic Leukemia (ALL) (Both Philadelphia chromosome positive and negative subtypes)

1. Blincyto (blinatumomab) consolidation may be used for MRD positive disease (at the end of induction therapy) for both BCR-ABL negative and BCR-ABL positive B-Cell ALL
2. Blincyto (blinatumomab) may be used for consolidation of MRD negative disease (at the end of induction therapy) for BCR-ABL negative B-Cell ALL after standard induction chemotherapy.
3. Blincyto (blinatumomab) may be used as a single agent for members with relapsed/refractory CD19 positive B-cell ALL.

III. EXCLUSION CRITERIA

A. Disease progression on or after treatment with Blincyto (blinatumomab).

B. Dosing exceeds single dose limit of Blincyto (blinatumomab) 28 mcg.

C. Treatment exceeds the maximum duration limit of 4 cycles when used as induction and/or consolidation therapy.

D. Investigational use of Blincyto (blinatumomab) with an off-label indication that is not sufficient in evidence or is not generally accepted by the medical community. Sufficient evidence that is not supported by CMS recognized compendia or acceptable peer reviewed literature is defined as any of the following:

1. Whether the clinical characteristics of the patient and the cancer are adequately represented in the published evidence.
2. Whether the administered chemotherapy/biologic therapy/immune therapy/targeted therapy/other oncologic therapy regimen is adequately represented in the published evidence.
3. Whether the reported study outcomes represent clinically meaningful outcomes experienced by patients. Generally, the definitions of Clinically Meaningful outcomes are those recommended by ASCO, e.g., Hazard Ratio of less than 0.80 and the recommended survival benefit for OS and PFS should be at least 3 months.
4. Whether the experimental design, considering the drugs and conditions under investigation, is appropriate to address the investigative question. (For example, in some clinical studies, it may be unnecessary or not feasible to use randomization, double blind trials, placebos, or crossover).
5. That non-randomized clinical trials with a significant number of subjects may be a basis for supportive clinical evidence for determining accepted uses of drugs.
6. That case reports are generally considered uncontrolled and anecdotal information and do not provide adequate supportive clinical evidence for determining accepted uses of drugs.
7. That abstracts (including meeting abstracts) without the full article from the approved peer-reviewed journals lack supporting clinical evidence for determining accepted uses of drugs.

IV. CODING INFORMATION

HCPCS Code	Description
J9039	Injection, blinatumomab, 1 microgram

V. MEDICATION MANAGEMENT

A. Please refer to the FDA label/package insert for details regarding these topics.

VI. APPROVAL AUTHORITY

A. Review – Utilization Management Department

B. Final Approval – Utilization Management Committee

VII. ATTACHMENTS

A. None

VIII. REFERENCES

A. Litzow, et al. Consolidation Therapy with Blinatumomab Improves Overall Survival in Newly Diagnosed Adult Patients with B-Lineage Acute Lymphoblastic Leukemia in Measurable Residual Disease Negative Remission: Results from the ECOG-ACRIN E1910 Randomized Phase III National Cooperative Clinical Trials Network Trial. *Blood* 2022; 140 (Supplement 2): LBA–1.

B. Hagop, et. al. Blinatumomab versus Chemotherapy for Advanced Acute Lymphoblastic Leukemia. N Engl J Med 2017;376:836-47.

C. Giovanni, et al. Complete Molecular and Hematologic Response in Adult Patients with Relapsed/Refractory (R/R) Philadelphia Chromosome-Positive B-Precursor Acute Lymphoblastic Leukemia (ALL) Following Treatment with Blinatumomab: Results from a Phase 2 Single-Arm, Multicenter Study (ALCANTARA). Blood 2015 126:679.

D. Gokbuget, et al. Blinatumomab for minimal residual disease in adults with B-cell precursor acute lymphoblastic leukemia. Blood. 2018 Apr 5;131(14):1522-1531.

E. Blincyto prescribing information 2024. Amgen, Inc. Thousand Oaks, CA

F. Clinical Pharmacology Elsevier Gold Standard 2025.

G. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, C) 2025.

H. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium 2025.

I. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs. Bethesda, MD 2025.

J. Ellis LM, et al. American Society of Clinical Oncology perspective: Raising the bar for clinical trials by defining clinically meaningful outcomes. J Clin Oncol. 2014 Apr 20;32(12):1277-80.

K. Medicare Benefit Policy Manual Chapter 15 Covered Medical and Other Health Services: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf.

L. Current and Resolved Drug Shortages and Discontinuations Reported to the FDA: http://www.accessdata.fda.gov/scripts/drugshortages/default.cfm.