Evolent Clinical Guideline 3258 for Blincyto™ (blinatumomab)

Guideline Number:	Applicable Codes	
Evolent_CG_3258		
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Original Date:	**Last Revised Date:**	**Implementation Date:**
March 2015	January 2026	January 2026

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STATEMENT

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.

INDICATIONS

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

- The member has not experienced disease progression on the requested medication AND
- The requested medication was used within the last year without a lapse of more than 30 days of having an active authorization AND
- Additional medication(s) are not being added to the continuation request.

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

- Blincyto (blinatumomab) may be used in adult and pediatric members one month and older with CD19-positive B-cell ALL in the following scenarios:
  - As consolidation therapy of MRD positive or MRD negative disease (at the end of induction therapy) for both BCR-ABL negative and BCR-ABL positive B-cell ALL after standard induction chemotherapy
  - As a single agent for relapsed/refractory B-cell ALL

CONTRAINDICATIONS/WARNINGS

- Contraindications
  - Known hypersensitivity to blinatumomab or any component of the formulation.
- US Boxed Warning
  - Cytokine release syndrome (CRS), which may be life-threatening or fatal, occurred in patients receiving blinatumomab. Interrupt or discontinue blinatumomab and treat with corticosteroids as recommended.
  - Neurological toxicities, including immune effector cell-associated neurotoxicity

syndrome (ICANS), which may be severe, life-threatening, or fatal, occurred in patients receiving blinatumomab. Interrupt or discontinue blinatumomab as recommended.

EXCLUSION CRITERIA

- Disease progression on or after treatment with Blincyto (blinatumomab).
- Dosing exceeds single dose limit of Blincyto (blinatumomab) 28 mcg/day.
- Treatment exceeds the maximum duration limit of 4 cycles when used as induction and/or consolidation therapy.
- 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:
    - Whether the clinical characteristics of the patient and the cancer are adequately represented in the published evidence.
    - Whether the administered chemotherapy/biologic therapy/immune therapy/targeted therapy/other oncologic therapy regimen is adequately represented in the published evidence.
    - 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.
    - 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).
    - 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.
    - That case reports are generally considered uncontrolled and anecdotal information and do not provide adequate supportive clinical evidence for determining accepted uses of drugs.
    - 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.

CODING AND STANDARDS

Codes

- J9039 - Injection, blinatumomab, 1 microgram

Applicable Lines of Business

☐	CHIP (Children's Health Insurance Program)
☒	Commercial
☒	Exchange/Marketplace
☒	Medicaid
☐	Medicare Advantage

POLICY HISTORY

Date	Summary
January 2026	• Converted to new Evolent guideline template • This guideline replaces UM ONC_1270 Blincyto (blinatumomab) • Updated indication section • Updated exclusion criteria • Updated references
January 2025	• Added Evolent disclaimer language • Added Coding Information section with HCPCS code

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Services Clinical Guideline Review Committee

Disclaimer

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. Evolent clinical guidelines contain guidance that requires prior authorization and service limitations. A list of procedure

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.

REFERENCES

1. Litzow MR, et al. Blinatumomab for MRD-Negative Acute Lymphoblastic Leukemia in Adults. *N Engl J Med*. 2024 Jul 25;391(4):320-333. doi: 10.1056/NEJMoa2312948.
2. Locatelli F, et al. Effect of Blinatumomab vs Chemotherapy on Event-Free Survival Among Children With High-risk First-Relapse B-Cell Acute Lymphoblastic Leukemia: A Randomized Clinical Trial. *JAMA*. 2021 Mar 2;325(9):843-854. doi: 10.1001/jama.2021.0987.
3. Kantarjian H, et al. Blinatumomab versus Chemotherapy for Advanced Acute Lymphoblastic Leukemia. *N Engl J Med*. 2017 Mar 2;376(9):836-847. doi: 10.1056/NEJMoa1609783.
4. Martinelli G, et al. Long-term follow-up of blinatumomab in patients with relapsed/refractory Philadelphia chromosome-positive B-cell precursor acute lymphoblastic leukaemia: Final analysis of ALCANTARA study. *Eur J Cancer*. 2021 Mar;146:107-114. doi: 10.1016/j.ejca.2020.12.022.
5. Topp MS, et al. Blinatumomab retreatment after relapse in patients with relapsed/refractory B-precursor acute lymphoblastic leukemia. *Leukemia*. 2018 Feb;32(2):562-565. doi: 10.1038/leu.2017.306.
6. Kantarjian H, et al. Blinatumomab versus Chemotherapy for Advanced Acute Lymphoblastic Leukemia. *N Engl J Med*. 2017 Mar 2;376(9):836-847. doi: 10.1056/NEJMoa1609783.
7. Gökbuget N, et al. Blinatumomab for minimal residual disease in adults with B-cell precursor acute lymphoblastic leukemia. *Blood*. 2018 Apr 5;131(14):1522-1531. doi: 10.1182/blood-2017-08-798322.
8. Blincyto prescribing information. Amgen, Inc. Thousand Oaks, CA 2025.
9. Clinical Pharmacology Elsevier Gold Standard 2026.
10. Micromedex® Healthcare Series: Micromedex Drugdex Ann Arbor, Michigan 2026.
11. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium 2026.
12. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs. Bethesda, MD 2026.
13. 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.
14. Medicare Benefit Policy Manual Chapter 15 Covered Medical and Other Health Services: **https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf**.
15. Current and Resolved Drug Shortages and Discontinuations Reported to the FDA: **http://www.accessdata.fda.gov/scripts/drugshortages/default.cfm**.