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# 5.21.051

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<b>Section:</b>	Prescription Drugs	<b>Effective Date:</b>	April 1, 2025
<b>Subsection:</b>	Antineoplastic Agents	<b>Original Policy Date:</b>	January 1, 2015
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**Last Review Date:** March 7, 2025

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## Blinicyto

### Description

#### Blinicyto (blinatumomab)

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#### Background

Blinicyto (blinatumomab) is used for the treatment of adults with B-cell acute lymphoblastic leukemia (ALL), an uncommon form of ALL. Precursor B-cell ALL is a rapidly growing type of cancer in which the bone marrow makes too many B-cell lymphoblasts, an immature type of white blood cell. Blinicyto is the first approved drug that engages the body's T-cells, a type of white blood cell or lymphocyte, to destroy leukemia cells (1).

#### Regulatory Status

FDA-approved indications: Blinicyto is a bispecific CD19-directed CD3 T-cell engager indicated for the treatment of adult and pediatric patients one month and older with: (1)

1. CD19-positive B-cell precursor acute lymphoblastic leukemia (ALL) in first or second complete remission with minimal residual disease (MRD) greater than or equal to 0.1%.
2. Relapsed or refractory CD19-positive B-cell precursor acute lymphoblastic leukemia (ALL).
3. CD19-positive Philadelphia chromosome-negative B-cell precursor acute lymphoblastic leukemia (ALL) in the consolidation phase of multiphase chemotherapy.

Blinicyto has boxed warnings that patients must be monitored for neurological toxicities and symptoms of Cytokine Release Syndrome (CRS) (1).

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#### Related policies

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## Policy

*This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.*

Blinicyto may be considered **medically necessary** if the conditions indicated below are met.

Blinicyto may be considered **investigational** in patients with all other indications.

## Prior-Approval Requirements

### Diagnosis

Patient must have the following:

Acute lymphoblastic leukemia (ALL)

**AND ONE** of the following:

- a. Relapsed or refractory CD19-positive B-cell precursor type
- b. First or second complete remission CD19-positive B-cell precursor type
  - i. Minimal residual disease (MRD) is greater than or equal to 0.1%
- c. CD19-positive Philadelphia chromosome-negative B-cell precursor type
  - i. In the consolidation phase of multiphase chemotherapy

**AND** the following:

- a. Prescriber agrees to monitor for neurological toxicities and symptoms of Cytokine Release Syndrome (CRS)

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## Prior – Approval *Renewal* Requirements

### Diagnosis

Patient must have the following:

Acute lymphoblastic leukemia (ALL)

**AND ONE** of the following:

- a. Relapsed or refractory CD19-positive B-cell precursor type

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- b. Remission CD19-positive B-cell precursor type
- c. CD19-positive Philadelphia chromosome-negative B-cell precursor type

**AND** the following:

- a. Prescriber agrees to monitor for neurological toxicities and symptoms of Cytokine Release Syndrome (CRS)

## Policy Guidelines

### Pre - PA Allowance

None

### Prior - Approval Limits

**Duration** 12 months

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### Prior – Approval *Renewal* Limits

Same as above

## Rationale

### Summary

Blinicyto (blinatumomab) is used for the treatment of CD19-positive B-cell precursor ALL in first or second complete remission with MRD greater than or equal to 0.1%, relapsed or refractory CD19-positive B-cell precursor ALL, or Philadelphia chromosome-negative CD19-positive B-cell precursor ALL in the consolidation phase of multiphase chemotherapy. Blinicyto has boxed warnings that patients must be monitored for neurological toxicities and Cytokine Release Syndrome (CRS) symptoms (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Blinicyto while maintaining optimal therapeutic outcomes.

### References

1. Blinicyto [package insert]. Thousand Oaks, Ca: Amgen Inc.; December 2024.
2. NCCN Drugs & Biologics Compendium<sup>®</sup> Blinatumomab 2025. National Comprehensive Cancer Network, Inc. Accessed on January 21, 2025.

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## Policy History

Date	Action/Reason
January 2015	Addition to PA
March 2015	Annual review and reference update
June 2016	Annual editorial review and reference update Policy change from 5.04.51 to 5.21.51
September	Removal of the age requirement
December 2016	Annual review
June 2017	Annual editorial review and reference update
August 2017	Removal of the Philadelphia chromosome-negative (Ph-) from the relapsed B-cell precursor type
September 2017	Annual review
December 2017	Annual review
April 2018	Addition of B-cell precursor acute lymphoblastic leukemia (ALL) in first or second complete remission with minimal residual disease (MRD) greater than or equal to 0.1%
June 2018	Annual review
June 2019	Annual editorial review and reference update. Added requirement to monitor for neurological toxicities and symptoms of CRS
June 2020	Annual review and reference update
March 2021	Annual editorial review and reference update. Revised requirement so B-cell precursor types have to be CD19-positive
March 2022	Annual review and reference update
March 2023	Annual review and reference update. Changed policy number to 5.21.051
March 2024	Annual review and reference update
July 2024	Per PI update, added indication of CD19-positive Philadelphia chromosome-negative B-cell precursor type ALL
September 2024	Annual review and reference update
March 2025	Annual review and reference update

## Keywords

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**This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 7, 2025 and is effective on April 1, 2025.**