**Blincyto**

**Description**

Blincyto (blinatumomab)

**Background**

Blincyto 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. Blincyto 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 indication: Blincyto is a bi-specific CD19-directed CD3 T-cell engager indicated for the treatment of adults and children with: (1)

1. 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 B-cell precursor acute lymphoblastic leukemia (ALL)

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

**Related policies**

**Policy**

*This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.*
Blincyto may be considered **medically necessary** in patients with acute lymphoblastic leukemia (ALL) and if the conditions indicated below are met.

Blincyto is 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 B-cell precursor type
- b. Refractory B-cell precursor type
- c. First or second complete remission B-cell precursor type
  i. Minimal residual disease (MRD) is greater than or equal to 0.1%

**AND** the following:

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

**Prior – Approval ** **Renewal Requirements**

**Diagnosis**

Patient must have the following:

- Acute lymphoblastic leukemia (ALL)

**AND ONE** of the following:

- a. Relapsed B-cell precursor type
- b. Refractory B-cell precursor type
- c. Remission 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

**Prior – Approval Renewal Limits**

**Duration** 12 months

**Rationale**

**Summary**

Blincyto is used for the treatment of adults with either refractory or refractory B-cell precursor acute lymphoblastic leukemia (ALL), or 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%. Blincyto 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 Blincyto while maintaining optimal therapeutic outcomes.

**References**


**Policy History**

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<td>January 2015</td>
<td>Addition to PA</td>
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<td>March 2015</td>
<td>Annual review and reference update</td>
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<td>June 2016</td>
<td>Annual editorial review and reference update</td>
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<td>September</td>
<td>Policy change from 5.04.51 to 5.21.51</td>
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<td>Removal of the age requirement</td>
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<td>August 2017</td>
<td>Removal of the Philadelphia chromosome-negative (Ph-) from the relapsed B-cell precursor type</td>
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<tr>
<td>April 2018</td>
<td>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%</td>
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<td>June 2018</td>
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<td>June 2019</td>
<td>Annual editorial review and reference update. Added requirement to monitor for neurological toxicities and symptoms of CRS</td>
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**Keywords**

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 20, 2019 and is effective on July 1, 2019.