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5.21.051

Section:	Prescription Drugs	**Effective Date:**	April 1, 2024
Subsection:	Antineoplastic Agents	**Original Policy Date:**	January 1, 2015
Subject:	Blincyto	**Page:**	1 of 4

Last Review Date: March 8, 2024

Blincyto

Description

Blincyto (blinatumomab)

Background
Blincyto (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. 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 indications: Blincyto is a bispecific CD19-directed CD3 T-cell engager indicated for the treatment of adult and pediatric patients 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)

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** if the conditions indicated below are met

Blincyto 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 CD19-positive B-cell precursor type
b. Refractory CD19-positive B-cell precursor type
c. First or second complete remission CD19-positive 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 CD19-positive B-cell precursor type
b. Refractory CD19-positive B-cell precursor type
c. Remission CD19-positive 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

Same as above

Rationale

Summary

Blincyto (blinatumomab) is used for the treatment of adults with either relapsed 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

1. Blincyto [package insert]. Thousand Oaks, Ca: Amgen Inc.; June 2023.
2. NCCN Drugs & Biologics Compendium® Blinatumomab 2023. National Comprehensive Cancer Network, Inc. Accessed on January 22, 2024.

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

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 8, 2024 and is effective on April 1, 2024.