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BLINCYTO (blinatumomab)

RATIONALE FOR INCLUSION IN PA PROGRAM

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. 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 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).

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. 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.; December 2024.



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2. NCCN Drugs & Biologics Compendium® Blinatumomab 2025. National Comprehensive Cancer Network, Inc. Accessed on January 21, 2025.