Blinatumomab (Blincyto®)

Prior Authorization Drug Coverage Policy

Effective Date: 9/1/2020
Revision Date: n/a
Review Date:9/20/2021
Lines of Business: Commercial
Policy type: Prior Authorization

This Drug Coverage Policy provides parameters for the coverage of blinatumomab. Consideration of medically necessary indications are based upon U.S. Food and Drug Administration (FDA) indications, recommended uses within the Centers of Medicare & Medicaid Services (CMS) five recognized compendia, including the National Comprehensive Cancer Network (NCCN) Drugs & Biologics Compendium (Category 1 or 2A recommendations), and peer-reviewed scientific literature eligible for coverage according to the CMS, Medicare Benefit Policy Manual, Chapter 15, section 50.4.5 titled, "Off-Label Use of Anti-Cancer Drugs and Biologics." This policy evaluates whether the drug therapy is proven to be effective based on published evidence-based medicine.

Drug Description[1]

Blinatumomab is a bispecific CD19-directed CD3 T-cell engager that binds to CD19 expressed on the surface of cells of B-lineage origin and CD3 expressed on the surface of T cells. It activates endogenous T cells by connecting CD3 in the T-cell receptor (TCR) complex with CD19 on benign and malignant B cells. Blinatumomab mediates the formation of a synapse between the T-cell and the tumor cell, upregulation of cell adhesion molecules, production of cytolytic proteins, release of inflammatory cytokines, and proliferation of T cells, which result in redirected lysis of CD19+ cells.

FDA Indications[1]

Blinatumomab is FDA indicated for the following:

- For the treatment of adults and children with:
    - 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%.
    - Relapsed or refractory B-cell precursor acute lymphoblastic leukemia

Coverage Determinations[1,2]

Blinatumomab will require prior authorization. This agent is considered medically necessary for the following oncology indications if all criteria below are met:

MRD-positive B-cell Precursor ALL

- The member has a diagnosis of B-cell precursor acute lymphoblastic leukemia **AND**
- The member is in either first or second complete remission **AND**
- The member has minimal residual disease (MRD)

Recommended dosage:
Patients ≥45 kg (fixed dose): Cycles 1 to 4: 28 mcg daily administered as a continuous infusion on days 1 to 28 of a 6-week treatment cycle

Patients <45 kg (dose based on BSA): Cycles 1 to 4: 15 mcg/m^2/day (maximum: 28 mcg/day) as a continuous infusion on days 1 to 28 of a 6-week treatment cycle

Relapsed or Refractory B-cell Precursor ALL

- The member has a diagnosis of Philadelphia chromosome-negative relapsed or refractory B-cell ALL ***OR***
- The member has a diagnosis of Philadelphia chromosome-positive (Ph+) ALL that is refractory to tyrosine kinase inhibitor therapy (e.g. imatinib, dasatinib, ponatinib) **AND**
- Blinatumomab will be used as monotherapy

Recommended dosage:
Patients ≥45 kg (fixed dose):

- Cycle 1: 9 mcg daily administered as a continuous infusion on days 1 to 7, followed by 28 mcg daily as a continuous infusion on days 8 to 28 of a 6-week treatment cycle
- Cycles 2 through 5: 28 mcg daily administered as a continuous infusion on days 1 to 28 of a 6-week treatment cycle
- Cycles 6 through 9: 28 mcg daily administered as a continuous infusion on days 1 to 28 of a 12-week treatment cycle

Patients <45 kg (dose based on BSA):

- Cycle 1: 5 mcg/m^2/day (maximum: 9 mcg/day) administered as a continuous infusion on days 1 to 7, followed by 15 mcg/m^2/day (maximum: 28 mcg/day) as a continuous infusion on days 8 to 28 of a 6-week treatment cycle
- Cycles 2 through 5: 15 mcg/m^2/day (maximum: 28 mcg/day) administered as a continuous infusion on days 1 to 28 of a 6-week treatment cycle
- Cycles 6 through 9: 15 mcg/m^2/day (maximum: 28 mcg/day) administered as a continuous infusion on days 1 to 28 of a 12-week treatment cycle

All indications:

- Blinatumomab will be approved through clinical review for up to a 6-month duration.

Coverage Limitations

- Indications not supported by NCCN category 2A or higher recommendations may not be considered medically necessary

Contraindications/Warnings/Precautions[1]

- Known hypersensitivity to blinatumomab or to any component of the product formulation.
- Warnings/precautions:
    - Cytokine release syndrome (Boxed warning)
    - Neurological toxicities (Boxed warning)
    - Infections
    - Effects on ability to drive and use machines
    - Pancreatitis
    - Preparation and administration errors
    - Risk of serious adverse reactions in pediatric patients due to benzyl alcohol preservative

For specific recommendations on contraindications, warnings and precautions, patient monitoring, and on dose adjustments and discontinuation, please refer to the current prescribing information.

Billing

- Description: injection, blinatumomab, 1 mcg
    - J9039

Disclaimer

Drug Coverage Policies are developed as needed, regularly reviewed, updated at least annually, and are subject to change. Other policies and coverage determination guidelines may apply. Federal and state regulatory requirements and member specific benefit plan documents, if applicable, must be reviewed prior to this Drug Coverage Policy. This Drug Coverage Policy is for informational purposes only and does not constitute medical advice or dictate how providers should practice medicine. This policy should not be reproduced, stored in a retrieval system, or altered from its original form without written permission from Oncology Analytics, Inc.

References

1. Blincyto [package insert]. Amgen, Inc., Thousand Oaks, CA. Available at: https://www.pi.amgen.com/~/media/amgen/repositorysites/pi-amgen-com/blincyto/blincyto_pi_hcp_english.pdf
2. Blinatumomab. NCCN Drugs & Biologics Compendium. Available at https://www.nccn.org/professionals/drug_compendium/content/
3. Gökbuget N, Dombret H, Bonifacio M, et al. Blinatumomab for minimal residual disease in adults with B-cell precursor acute lymphoblastic leukemia. Blood. 2018;131(14):1522-1531.
4. Kantarjian H, Stein A, Gökbuget N, et al. Blinatumomab versus chemotherapy for advanced acute lymphoblastic leukemia. N Engl J Med. 2017;376(9):836-847.