Blincyto™ (blinatumomab)

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Definitions

Blincyto (blinatumomab) is a bispecific T-cell engager designed to promote the lysis of cancer cells by binding simultaneously with both the CD3 protein on cytotoxic T-cells and the CD19 protein, a B-cell specific lymphocyte antigen expressed in specific types of acute lymphocytic leukemia (ALL).

Dosing

Max units (per dose and over time)

- ALL, relapsed or refractory:
  - Induction (cycle 1): 9 billable units per day on day 1-7, and 28 billable units per day on day 8-28 of a 42 day cycle
  - Induction (cycle 2): 28 billable units per day on day 1-28 of a 42 day cycle
  - Consolidation (cycle 3-5): 28 billable units per day on day 1-28 of a 42 day cycle
  - Continuation (cycle 6-9): 28 billable units per day on day 1-28 of an 84 day cycle
- ALL, MRD+:
  - Induction (cycle 1): 28 billable units per day on day 1-28 of a 42 day cycle
  - Consolidation (cycle 2-4): 28 billable units per day on day 1-28 of a 42 day cycle

Guideline

Blincyto (blinatumomab) is considered medically necessary for the following diagnoses when the subsequent criteria are met:

B-cell precursor acute lymphocytic leukemia (ALL), relapsed or refractory:

- Patient's disease is CD19+; **AND**

- Patient's disease is Philadelphia chromosome-negative **OR** Philadelphia chromosome-positive and refractory to tyrosine kinase inhibitor (TKI) therapy; **AND**
- Blincyto will be administered as a single-agent; **AND**
- There is no evidence of active central nervous system involvement

B-cell precursor acute lymphocytic leukemia (ALL), minimal residual disease (MRD)-positive:

- Patient's disease is CD19+; **AND**
- Patient's disease is in first or second complete remission; **AND**
- Patient has minimal residual disease greater than or equal to 0.1%

Coverage for Blincyto (blinatumomab) may be renewed for the following diagnoses when subsequent criteria are met:

B-cell precursor acute lymphocytic leukemia (ALL), relapsed or refractory:

- Patient continues to meet initial approval criteria; **AND**
- Disease response or stabilization; **AND**
- Absence of unacceptable toxicity from the drug, including cytokine release syndrome, neurological toxicities, serious infections, pancreatitis, tumor lysis syndrome, neutropenia/febrile neutropenia, elevation of LFTs, leukoencephalopathy.

Limitations/Exclusions

- Approval will be granted for 30 weeks for a diagnosis of relapsed or refractory ALL and may be renewed twice for 24 weeks
- Approval will be granted for 24 weeks for a diagnosis of MRD+ ALL and may not be renewed

Applicable Procedure Codes

J9039	Injection, blinatumomab, 1 microgram

Applicable Diagnosis Codes

C91.00	Acute lymphoblastic leukemia not having achieved remission
C91.02	Acute lymphoblastic leukemia, in relapse

Revision History

10/8/2019	Annual Review
09/06/2018	Added coverage for MRD+ ALL, added approval durations, renewal criteria, and dosing
05/01/2018	"CD19+" descriptive added to refractory B-cell ALL

References

1. U.S. Food and Drug Administration (FDA). FDA approves Blincyto to treat a rare form of acute lymphoblastic leukemia. FDA News Release. Silver Spring, MD: FDA; December 3, 2014.
2. Amgen Inc. Blincyto (blinatumomab) for injection, for intravenous use. Prescribing Information. Thousand Oaks, CA: Amgen; Revised March, 2020.
3. Amgen Inc. FDA approves Blincyto (blinatumomab) immunotherapy for the treatment of relapsed or refractory B-cell precursor acute lymphoblastic leukemia. News Release. Thousand Oaks, CA: Amgen; December 3, 2014.

4. Topp MS, Gökbuget N, Zugmaier G, et al. Phase II trial of the anti-CD19 bispecific T cell-engager blinatumomab shows hematologic and molecular remissions in patients with relapsed or refractory B-precursor acute lymphoblastic leukemia. J Clin Oncol. 2014 Nov 10. [Epub ahead of print]
5. Topp MS, Gökbuget N, Zugmaier G, et al. Long-term follow-up of hematologic relapse-free survival in a phase 2 study of blinatumomab in patients with MRD in B-lineage ALL. Blood. 2012;120(26):5185-5187.
6. Topp MS, Kufer P, Gökbuget N, et al. Targeted therapy with the T-cell-engaging antibody blinatumomab of chemotherapy-refractory minimal residual disease in B-lineage acute lymphoblastic leukemia patients results in high response rate and prolonged leukemia-free survival. J Clin Oncol. 2011;29(18):2493-2498.
7. National Comprehensive Cancer Network (NCCN). Blinatumomab. NCCN Drug & Biologics Compendium. Fort Washington, PA: NCCN; 2014.