SmartHealth

Ascension

Blinatumomab

(Blincyto®) J9039 (1 mcg)

Covered with prior authorization

Blinatumomab (Blincyto®) may be authorized when the following criteria are met:

- Individual has a diagnosis of:
  - 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%; **AND**
- Medication is being used independently (or in combination with a tyrosine kinase inhibitor); **AND**
- This medication is not being used as first line; **AND**
- Medication is prescribed by providers specialized in hematology or oncology.

Exclusion criteria:
Requests may not be approved for the following:

- Product use for non-FDA approved indications or indications not supported by industry-accepted guidelines;
- Doses, durations, or dosing intervals that exceed FDA maximum limits for any FDA-approved indication or are not supported by industry-accepted practice guidelines or peer-reviewed literature for the relevant off-label use;
- Individuals with significant known risk factors unless the record provides an assessment of clinical benefit that outweighs the risk.

Initial authorization for approved indications is up to 12 months.

Continuation requests may be approved if there is confirmation of clinically significant improvement or stabilization in clinical signs and symptoms of the disease. Clinical documentation provided must be from within the most recent 12 months.

Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

U.S. Food and Drug Administration:
This section is to be used for informational purposes. FDA approval alone is not a basis for coverage.

Blincyto® is a CD19-directed CD3 T-cell engager indicated for the treatment 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%.
- Relapsed or refractory B-cell precursor acute lymphoblastic leukemia.

References:

1. National Comprehensive Cancer Network, Inc. (Copyright © National Comprehensive Cancer Network, Inc). *NCCN Guidelines: Treatment by Cancer Type*. NCCN Clinical Practice Guidelines in Oncology. Retrieved April 25, 2022, from https://www.nccn.org/guidelines/category_1
2. *Blincyto® (Blinatumomab) Label*. (2018, March). Accessdata.fda.gov. Retrieved January 24, 2023, from https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/125557s013lbl.pdf

Criteria History/ Revision Information:

Date	Summary of Changes
September 2021	Criteria for use summary developed by the Ascension Ambulatory Care Expert Review Panel.
January 2023	Criteria for use summary revised by the Ascension Medical Specialty Prior Authorization Team.
February 2023	Criteria for use summary approved by the Ascension Hematology/Oncology Expert Review Panel.
March 2023	Criteria for use summary approved by the Ascension Therapeutic Affinity Group.

If you have questions, call 833-980-2352 to speak to a member of the Ascension Rx prior authorization team or email your questions to smarthealthspecialty@ascension.org.