BlueCross BlueShield of North Carolina

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Corporate Medical Policy

Blinatumomab (Blincyto®)

File Name:	blinatumomab_blincyto
Origination:	9/2017
Last CAP Review:	11/2020
Next CAP Review:	11/2021
Last Review:	11/2020

Description of Procedure or Service

Blincyto® (blinatumomab) is a bispecific CD19-directed CD3 T-cell engager indicated for the treatment of relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL) in adults and children.

Blinatumomab is also indicated for the treatment of adults and children with B-cell precursor ALL in first or second complete remission with minimal residual disease (MRD) greater than or equal to 0.1%. This indication is approved under accelerated approval based on MRD response rate and hematological relapse-free survival. Continued approval for this indication by the U.S. Food & Drug Administration (FDA) may be contingent upon verification and description of clinical benefit in the confirmatory clinical trials.

******Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.***

Policy

BCBSNC will provide coverage for Blinatumomab (Blincyto) when it is determined to be medically necessary because the medical criteria and guidelines shown below are met.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When Blinatumomab (Blincyto) is covered

Blinatumomab (Blincyto®)

Blinatumomab (Blincyto) is considered medically necessary for the treatment of patients with relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL).

Blinatumomab (Blincyto) is considered medically necessary for the treatment of patients 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%.

Use of Blinatumomab (Blincyto) may be considered medically necessary for clinical indications not listed above when the drug is prescribed for the treatment of cancer either:

- In accordance with FDA label (when clinical benefit has been established, see Policy Guidelines); **OR**
- In accordance with specific strong endorsement or support by nationally recognized compendia, when such recommendation is based on strong/high levels of evidence, and/or uniform consensus of clinical appropriateness has been reached.

When Blinatumomab (Blincyto) is not covered

Blinatumomab (Blincyto) is considered not medically necessary and therefore not covered when the above criteria are not met.

Blinatumomab (Blincyto) is considered investigational when used for:

1. Non-cancer indications; **OR**
2. When criteria are not met regarding FDA labeling **OR** strong endorsement/support by nationally recognized compendia, as stated under "When Blinatumomab (Blincyto) is covered."

Policy Guidelines

Relapsed of Refractory B-cell Precursor ALL

A treatment course consists of up to 2 cycles of Blincyto for induction followed by 3 additional cycles for consolidation and up to 4 additional cycles of continued therapy.

A single cycle of treatment of induction or consolidation consists of 28 days of continuous intravenous infusion followed by a 14-day treatment-free interval (total 42 days).

A single cycle of treatment of continued therapy consists of 28 days of continuous intravenous infusion followed by a 56-day treatment-free interval (total 84 days).

MRD-positive B-cell Precursor ALL

A treatment course consists of 1 cycle of Blincyto for induction followed by up to 3 additional cycles for consolidation.

A single cycle of treatment of induction or consolidation consists of 28 days of continuous intravenous infusion followed by a 14-day treatment-free interval (total 42 days).

Drugs prescribed for treatment of cancer in accordance with FDA label may be considered medically necessary when clinical benefit has been established, and should not be determined to be investigational as defined in Corporate Medical Policy (CMP), "Investigational (Experimental) Services."

Please refer to CMP "Investigational (Experimental) Services" for a summary of evidence standards from nationally recognized compendia.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable service codes: J9039, S0353, S0354

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

U. S. Food and Drug Administration (FDA). Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/125557s008lbl.pdf

Senior Medical Director review 9/2017

Specialty Matched Consultant Advisory Panel 11/2018

Amgen Inc. Blincyto (blinatumomab) for injection, for intravenous use. Highlights of prescribing information. April 2019. Available at: https://www.pi.amgen.com/~/media/amgen/repositorysites/pi-amgen-com/blincyto/blincyto_pi_hcp_english.pdf. Last accessed October 2019.

Specialty Matched Consultant Advisory Panel 11/2019

Specialty Matched Consultant Advisory Panel 11/2020

Policy Implementation/Update Information

9/29/17 New policy developed. Blinatumomab (Blincyto) is considered medically necessary for the treatment of patients with relapsed or refractory B-cell precursor acute lymphoblastic

leukemia (ALL). Reference added. Senior Medical Director review 9/2017. Notification given 9/29/17 for effective date 12/29/17. (lpr)

12/14/18 Specialty Matched Consultant Advisory Panel review 11/28/2018. No change to policy intent. (krc)

12/10/19 Added the following indication to "When Covered" section: "Blinatumomab (Blincyto) is considered medically necessary for the treatment of patients 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%." Updated Description and Policy Guidelines section to reflect addition of this indication. Reference added. Specialty Matched Consultant Advisory Panel review 11/20/2019. (krc)

1/12/21 Specialty Matched Consultant Advisory Panel review 11/18/2020. No change to policy intent. (krc)