Clinical Policy: Blinatumomab (Blincyto)

Reference Number: LA.PHAR.312
Effective Date: 02.03.24
Last Review Date: 09.05.25~~02.20.25~~
Line of Business: Medicaid

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

****Please note: This policy is for medical benefit****

Description
Blinatumomab (Blincyto®) is a bispecific CD19-directed CD3 T-cell engager.

FDA Approved Indication(s)
Blincyto is indicated in adult and pediatric patients one month and older for the treatment of:

- CD19-positive B-cell precursor acute lymphoblastic leukemia (B-ALL) in first or second complete remission with minimal residual disease (MRD) ≥ 0.1%
- Relapsed or refractory CD19-positive B-ALL
- CD19-positive Philadelphia chromosome-negative (Ph-) B-ALL in the consolidation phase of multiphase chemotherapy

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of Louisiana Healthcare Connections that Blincyto is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. B-Cell Acute Lymphoblastic Leukemia (must meet all)**:**

1. Diagnosis of B-ALL;
2. Prescribed by or in consultation with an oncologist or hematologist;
3. Age ≥ 1 month;
4. Requested as treatment for (a, b, c, d, or e):
   a. B-ALL in remission but MRD-positive;
   b. Philadelphia chromosome- (Ph)-positive (~~Ph+~~)*adults*) or BCR::ABL1-positive (*pediatrics*) disease, and prescribed in one of the following ways (i or ii):
      i. In combination with a tyrosine kinase inhibitor (TKI; e.g., imatinib, Sprycel®, Tasigna®, Bosulif®, Iclusig®) for induction therapy~~,~~ (*adults only*), consolidation therapy, or relapsed or refractory disease;
      ii. As a single agent for relapsed or refractory disease or for consolidation therapy (*if request is for adult consolidation therapy, disease must be MRD-positive* ~~disease;~~);
   c. Ph-negative (*adults*) or BCR::ABL1-negative (*pediatrics*) disease, and prescribed in one of the following ways (i, ii, or iii~~, or iv~~):

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i. As consolidation therapy as a single agent ~~or~~, alternating with multiagent therapy~~;~~ (*adults only*), or combination therapy (*pediatrics only*);
ii. For relapsed or refractory disease as a single agent;
iii. For adult disease only: As maintenance therapy for MRD-negative or unavailable disease, alternating with POMP (mercaptopurine, vincristine, methotrexate, prednisone);
~~iv. For pediatric disease only: As single agent therapy after consolidation therapy;~~

d. ~~Ph~~BCR::ABL1-like pediatric ALL, and prescribed as consolidation therapy as a single agent ~~therapy after consolidation~~or combination therapy;
~~e.~~ Infant ALL, and ~~both of the following (i and ii):~~
~~i. KMT2A status (11q23 rearranged);~~
~~ii.~~e. ~~Prescribed~~prescribed in combination with an Interfant regimen (prednisone, dexamethasone, vincristine, cytarabine, daunorubicin, pegaspargase/~~-~~calaspargase, methotrexate; intrathecal therapy: cytarabine, prednisone (if initial central nervous system involvement, methotrexate, prednisone);

5. Request meets one of the following (a or b):*
   a. Dose does not exceed 28 mcg per day;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration: 6 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to LA.PMN.255
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy ~~for the relevant line of business:~~ LA.PMN.53 ~~for Medicaid~~.

II. Continued Therapy

A. B-Cell Acute Lymphoblastic Leukemia (must meet all)**:**

1. Currently receiving medication via Louisiana Healthcare Connections benefit, or documentation supports that member is currently receiving Blincyto for a covered indication and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. If request is for a dose increase, request meets one of the following (a or b):*
   a. New dose does not exceed 28 mcg per day;
   b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

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1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to LA.PMN.255
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy ~~for the relevant line of business:~~ LA.PMN.53 ~~for Medicaid~~.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – LA.PMN.53 ~~for Medicaid or evidence of coverage documents~~.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

B-ALL: B-cell precursor acute lymphoblastic leukemia
CR: complete remission
FDA: Food and Drug Administration
MRD: minimal residual disease
NCCN: National Comprehensive Cancer Network
TKI: tyrosine kinase inhibitor

Appendix B: Therapeutic Alternatives

Not applicable

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): known hypersensitivity to blinatumomab or to any component of the product formulation
- Boxed warning(s): cytokine release syndrome (CRS); neurological toxicities including immune effector cell-associated neurotoxicity syndrome

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
B-ALL (in remission and MRD-positive)	Treatment course: 1 cycle of Blincyto IV for induction followed by up to 3 additional cycles for consolidation. • Patients ≥ 45 kg receive a fixed dose o Induction cycle 1 ▪ Days 1-28: 28 mcg/day ▪ Days 29-42: 14-day treatment-free interval o Consolidation cycles 2-4 ▪ Days 1-28: 28 mcg/day ▪ Days 29-42: 14-day treatment-free interval • Patients < 45 kg based on body surface area (BSA) o Induction cycle 1 ▪ Days 1-28: 15 mcg/m^2/day ▪ Days 29-42: 14-day treatment-free interval o Consolidation cycles 2-4 ▪ Days 1-28: 15 mcg/m^2/day	28 mcg/day

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Indication	Dosing Regimen	Maximum Dose
	▪ Days 29-42: 14-day treatment-free interval	
B-ALL (relapsed or refractory)	Treatment course: 2 cycles of Blincyto IV for induction followed by 3 cycles for consolidation and up to 4 cycles of continued therapy. • Patients ≥ 45 kg receive a fixed dose o Induction cycle 1 ▪ Days 1-7: 9 mcg/day ▪ Days 8-28: 28 mcg/day ▪ Days 29-42: 14-day treatment-free interval o Induction cycle 2 ▪ Days 1-28: 28 mcg/day ▪ Days 29-42: 14-day treatment-free interval o Consolidation cycles 3-5 ▪ Days 1-28: 28 mcg/day ▪ Days 29-42: 14-day treatment-free interval o Continued therapy cycles 6-9 ▪ Days 1-28: 28 mcg/day ▪ Days 29-84: 56-day treatment-free interval • Patients < 45 kg based on BSA o Induction cycle 1 ▪ Days 1-7: 5 mcg/m^2/day ▪ Days 8-28: 15 mcg/m^2/day ▪ Days 29-42: 14-day treatment-free interval o Induction cycle 2 ▪ Days 1-28: 15 mcg/m^2/day ▪ Days 29-42: 14-day treatment-free interval o Consolidation cycles 3-5 ▪ Days 1-28: 15 mcg/m^2/day ▪ Days 29-42: 14-day treatment-free interval o Continued therapy cycles 6-9 ▪ Days 1-28: 15 mcg/m^2/day ▪ Days 29-84: 56-day treatment-free interval	28 mcg/day
B-ALL (in the consolidation phase)	Treatment course: 1 cycle of Blincyto IV • Patients ≥ 45 kg receive a fixed dose o Consolidation cycle ▪ Days 1-28: 28 mcg/day ▪ Days 29-42: 14-day treatment-free interval • Patients < 45 kg based on BSA o Consolidation cycle ▪ Days 1-28: 15 mcg/m^2/day ▪ Days 29-42: 14-day treatment-free interval	28 mcg/day

VI. Product Availability

Single-dose vial for reconstitution: 35 mcg

VII. References

1. Blincyto Prescribing Information. Thousand Oaks, CA: Amgen, Inc.; ~~June 2024~~April 2025. Available at: http://pi.amgen.com/~/media/amgen/repositorysites/pi-amgen-com/blincyto/blincyto_pi_hcp_english.ashx. Accessed ~~June 20, 2024~~May 8, 2025.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at nccn.org. Accessed ~~June 24, 2024~~April 21, 2025.
3. National Comprehensive Cancer Network Guidelines. Acute Lymphoblastic Leukemia Version ~~1~~3.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/all.pdf. Accessed ~~June 20, 2024~~May 8, 2025.
4. National Comprehensive Cancer Network Guidelines. Pediatric Acute Lymphoblastic Leukemia Version ~~5.2024~~3.2025. Available at: https://www.nccn.org/professionals/physician_gls/pdf/ped_all.pdf. Accessed ~~June 20, 2024~~May 8, 2025.
5. Clinical Pharmacology [database online]. Elsevier, Inc.; ~~2024~~2025. Available at: https://www.clinicalkey.com/pharmacology. Accessed May ~~20, 2024~~8, 2025.

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J9039	Injection, blinatumomab, 1 microgram

Reviews, Revisions, and Approvals	Date	LDH Approval Date
Converted corporate to local policy.	06.15.23	01.23.24
Annual review, no material changes	05.28.24	09.04.24
Annual review: specified that infant ALL must have KMT2A status (11q23 rearranged) and added pathway for use as frontline consolidation therapy per NCCN; revised boxed warning in Appendix C per updated prescribing information; Added new FDA approved indication for Ph- B-ALL as consolidation therapy and added age restriction of at least 1 month per updated prescribing information; rearranged criteria into Ph+ vs Ph- disease, added pathway for use as induction therapy for Ph+ disease, removed requirement that relapsed or refractory Ph+ disease must be refractory to TKIs, added pathway for use as maintenance therapy for Ph- disease, added pathway for use after consolidation therapy and for Ph-like disease for pediatric members, and specified how Blincyto should be prescribed for all uses per NCCN. References reviewed and updated.	02.20.25	05.19.25
Annual review: per NCCN – clarified that Ph refers to adult disease and added the term BCR::ABL1 for pediatric disease; for pediatrics,	09.05.25	

Reviews, Revisions, and Approvals	Date	LDH Approval Date
removed pathways for use after consolidation therapy and added combination therapy option for BCR::ABL1-negative/like disease; for infant ALL, removed requirement for KMT2A status (11q23 rearranged); references reviewed and updated.		

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. LHCC makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable LHCC administrative policies and procedures.

This clinical policy is effective as of the date determined by LHCC. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. LHCC retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom LHCC has no control or right of control. Providers are not agents or employees of LHCC.