Prior Authorization Review Panel

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CHC-MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: PA Health & Wellness	**Submission Date: 08/01/2021**
Policy Number: PA.CP.PHAR.312	**Effective Date: 01/2020** **Revision Date: 07/2021**
Policy Name: Blinatumomab (Blincyto)	

Type of Submission – Check all that apply:

- ☐ **New Policy**
- ✓ **Revised Policy***
- ☐ **Annual Review - No Revisions**
- ☐ **Statewide PDL** - *Select this box when submitting policies for Statewide PDL implementation and when submitting policies for drug classes included on the Statewide PDL.*

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any changes or clarifying information for the policy below:

3Q 2021 annual review: updated FDA-indication to clarify B-ALL is CD19-positive; references reviewed and updated.

Name of Authorized Individual (Please type or print): **Venkateswara R. Davuluri, MD**	**Signature of Authorized Individual:**

Clinical Policy: Blinatumomab (Blincyto)

Reference Number: PA.CP.PHAR.312
Effective Date: 01/2018
Last Review Date: 07/2021

Coding Implications
Revision Log

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

FDA Approved Indication(s)
Blincyto is indicated in adults and children 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%.*
  **This indication is approved under accelerated approval based on MRD response rate and hematological relapse-free survival. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials.*
- Relapsed or refractory CD19-positive B-ALL.

Policy/Criteria
It is the policy of health plans affiliated with Pennsylvania Health and Wellness ® that Blincyto is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Acute Lymphoblastic Leukemia (must meet all):

1. Diagnosis of B-ALL;
2. Prescribed by or in consultation with an oncologist or hematologist;
3. Requested as treatment for (a or b):
   a. B-ALL in remission but positive for minimal residual disease (MRD+);
   b. Relapsed or refractory B-ALL (i and ii):
      i. Philadelphia chromosome-negative (Ph-) disease;
      ii. Philadelphia chromosome-positive (Ph+) disease and intolerant or refractory to at least one second- or subsequent-generation tyrosine kinase inhibitor* (TKI; i.e., imatinib, Sprycel®, Tasigna®, Bosulif®, Iclusig®);
      **Prior authorization may be required for these agents.*
4. 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: Refer to PA.CP.PMN.53

II. Continued Approval

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

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;;
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)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies; or
2. Refer to PA.CP.PMN.53

III. 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

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen*	Dose Limit/ Maximum Dose
Sprycel® (dasatinib)	Ph+ ALL: Labeled use Adults: 140 mg PO QD *(resistance or intolerance to prior therapy)* Children and adolescents: PO QD weight-based *(newly diagnosed disease)*	Adults: 180 mg/day Children: 100 mg/day
Iclusig® (ponatinib)	Ph+ ALL: Labeled use Adults: 45 mg PO QD *(T315I-positive disease or no other TKI is indicated)*	45 mg/day
Tasigna® (nilotinib)	Ph+ ALL: Off-label use	Varies
Bosulif® (bosutinib)	Ph+ ALL: Off-label use	Varies
imatinib (Gleevec®)	Ph+ ALL: Labeled use Adults: 600 mg PO once daily until disease progression	600 mg/day

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.
**The above-referenced TKIs are NCCN recommended for PH+ ALL (category 1 or 2a).*

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

IV. 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 ▪ Days 29-42: 14-day treatment-free interval	28 mcg/day
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 body surface area (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	28 mcg/day

Indication	Dosing Regimen	Maximum Dose
	▪ 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	

V. Product Availability

Single-dose vial for reconstitution: 35 mcg

VI. References

1. Blincyto Prescribing Information. Thousand Oaks, CA: Amgen, Inc.; March 2021. Available at: http://pi.amgen.com/~/media/amgen/repositorysites/pi-amgen-com/blincyto/blincyto_pi_hcp_english.ashx. Accessed March 24, 2021.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at nccn.org. Accessed March 15, 2021.
3. National Comprehensive Cancer Network Guidelines. Acute Lymphoblastic Leukemia Version 1.2021. Available at nccn.org. Accessed March 15, 2021.
4. National Comprehensive Cancer Network Guidelines. Pediatrics Acute Lymphoblastic Leukemia Version 2.2021. Available at nccn.org. Accessed March 15, 2021.
5. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2021. Available at http://www.clinicalpharmacology-ip.com/. Accessed March 24, 2021.

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	Approval Date
3Q 2018 annual review: new indication for MRD+ B-ALL added; summarized NCCN and FDA-approved uses for improved clarity (TKI requirement reduced from 2 to 1 for Ph+ disease); added specialist involvement in care; references reviewed and updated.	05.18	
3Q 2019 annual review: No changes per Statewide PDL implementation 01-01-2020	07/17/19	
3Q 2020 annual review: Addition of dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence); references reviewed and updated.	07/20	

Reviews, Revisions, and Approvals	Date	Approval Date
3Q 2021 annual review: updated FDA-indication to clarify B-ALL is CD19-positive; references reviewed and updated.	07/2021	