OncoHealth

Blincyto (Blinatumomab)

Effective Date: 12/1/2022
Revision Date(s): n/a
Review Date: 10/19/2022
Policy type: Medical Necessity

Authorizations are for 6 months, after which time they must be reviewed for efficacy, safety, and tolerability.

Initial Approval Criteria

Coverage is provided for the following conditions:

Universal Criteria Applied to All Requests

- Dose and frequency should be consistent with FDA labeling, NCCN, or indication specific peer-reviewed literature.
- Member has B-cell precursor acute lymphoblastic leukemia (ALL).

Indication Specific Criteria

Acute Lymphoblastic Leukemia, Pediatric

- Used as a single agent; AND
- Member has one of the following:
    - Philadelphia chromosome-negative or Philadelphia chromosome-like-disease[1]; OR
    - Philadelphia chromosome-positive disease; AND
        - Member has MRD+ (minimal residual disease) at end of consolidative chemotherapy; OR
        - Member has relapsed/refractory Philadelphia chromosome-positive tyrosine kinase inhibitor (TKI[2]) intolerant/refractory disease

Acute Lymphoblastic Leukemia, Adult

- Used as consolidation therapy:
    - With or without a TKI in patients with persistent MRD following a complete response (CR) to induction therapy[3]; OR
    - With a TKI in patients with negative MRD following a CR to induction therapy in those who are not candidates for chemotherapy[2]; OR
    - As a single agent in patients with persistent MRD following a CR to induction therapy[4]; OR

[1] Member may be relapsed/refractory and/or have MRD after consolidative chemotherapy.
[2] Select examples of TKIs include dasatinib and imatinib.
[3] For Philadelphia chromosome-positive disease.
[4] For Philadelphia chromosome-negative disease.

- As a single agent in patients with negative MRD after receiving induction therapy with inotuzumab ozogamicin + mini-hyperCVD[5], or in patients for whom chemotherapy is contraindicated[3]; OR

- Used as maintenance therapy:
  - In Philadelphia chromosome-negative disease in patients as a single agent alternating with POMP[6] in patients with negative MRD after receiving induction therapy with inotuzumab ozogamicin + mini-hyperCVD[4]; OR
  - As treatment for relapsed/refractory disease with or without a TKI[2]; OR
  - As treatment for relapsed/refractory disease as a single agent[3]; OR
  - As treatment for relapsed/refractory Philadelphia chromosome-positive disease (if refractory to TKIs) or relapsed/refractory Philadelphia chromosome-negative disease as a component of inotuzumab ozogamicin + mini-hyperCVD[1] + blinatumomab

Billing

Drug Name	HCPCS Code	Description
Blincyto	J9039	Inj., blinatumomab, 1 mcg

References

1. Blincyto. NCCN Drugs & Biologics Compendium. Available at: https://www.nccn.org/professionals/drug_compendium/content/. Accessed 8/9/2022
2. Blincyto [package insert]. Amgen, Inc., Thousand Oaks, CA. Available at: https://www.pi.amgen.com/-/media/Project/Amgen/Repository/pi-amgen-com/blincyto/blincyto_pi_hcp_english.pdf
3. Acute Lymphoblastic Leukemia: NCCN Clinical Practice Guidelines in Oncology. Available at: https://www.nccn.org/professionals/physician_gls/pdf/all.pdf. Accessed 8/9/22
4. Pediatric Acute Lymphoblastic Leukemia: NCCN Clinical Practice Guidelines in Oncology. Available at: https://www.nccn.org/professionals/physician_gls/pdf/ped_all.pdf. Accessed 8/9/22

Disclaimer

Consideration of medically necessary indications are based upon U.S. Food and Drug Administration (FDA) indications, recommended uses within the Centers of Medicare & Medicaid Services (CMS) five recognized compendia, including the National Comprehensive Cancer Network (NCCN) Drugs & Biologics Compendium (Category 1 or 2A recommendations), and peer-reviewed scientific literature eligible for coverage according to the CMS, Medicare Benefit Policy Manual, Chapter 15, section 50.4.5 titled, "Off-Label Use of Anti-Cancer Drugs and Biologics." This policy evaluates whether the drug therapy is proven to be effective based on published evidence-based medicine. OncoHealth reserves the right to request medical documentation as needed to validate medical necessity determinations.

Drug Coverage Policies are developed as needed, regularly reviewed, updated at least annually, and are subject to change. Other policies and coverage determination guidelines may apply. Federal and state

[5] Mini-hyperCVD= mini-hyper fractionated cyclophosphamide, vincristine, and dexamethasone, alternating with methotrexate and cytarabine.
[6] POMP= prednisone, vincristine, methotrexate, and mercaptopurine.

regulatory requirements and member specific benefit plan documents, if applicable, must be reviewed prior to this Drug Coverage Policy. This Drug Coverage Policy is for informational purposes only and does not constitute medical advice or dictate how providers should practice medicine. This policy should not be reproduced, stored in a retrieval system, or altered from its original form without written permission from OncoHealth, Inc.