Mass General Brigham
Health Plan

Acute Lymphoblastic Leukemia, Single Agent Therapies
Besponsa (inotuzumab ozogamicin)
Blincyto (blinatumomab)
Effective 06/05/2023

Plan	☒ MassHealth UPPL ☐Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☐ Pharmacy Benefit ☒ Medical Benefit		
Specialty Limitations	These medications have been designated specialty and must be filled at a contracted specialty pharmacy when obtained through the pharmacy benefit.		
Contact Information	**Medical and Specialty Medications**		
	All Plans	Phone: 877-519-1908	Fax: 855-540-3693
	Non-Specialty Medications		
	All Plans	Phone: 800-711-4555	Fax: 844-403-1029
Exceptions	N/A		

Overview

Besponsa (inotuzumab ozogamicin) is a CD22-directed antibody-drug conjugate (ADC) indicated for the treatment of relapsed or refractory B-cell precursor acute lymphoblastic leukemia (B-ALL) in adults.

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

No PA	Drug that require PA
Alkylator-containing regimens	Besponsa® (inotuzumab ozogamicin) [MB]
Augmented Hyper CVAD (cyclophosphamide, vincristine, doxorubicin, dexamethasone and pegaspargase) alternating with high-dose methotrexate and cytarabine	Blincyto® (blinatumomab) [MB]

MB This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. The plan does not pay for this drug to be dispensed through the retail pharmacy.

Coverage Guidelines

Authorization may be reviewed on a case by case basis for members who are new to the plan currently receiving treatment with requested medication excluding when the product is obtained as samples or via manufacturer's patient assistance programs.

OR

Authorization may be granted for members when all the following criteria are met, and documentation is provided:

1. Diagnosis of Acute Lymphoblastic Leukemia (ALL)
2. Prescriber is an oncologist or hematologist

3. Appropriate dosing (weight is required)
4. If the request is for Besponsa®, member is ≥ 18 years of age
5. **ONE** of the following:
    a. If the request is for Blincyto®, member with complete remission following initial treatment
    b. **BOTH** of the following:
        i. Philadelphia chromosome-positive
        ii. Paid claims or physician documented inadequate response or adverse reaction to one tyrosine kinase inhibitor for the treatment of ALL (e.g., bosutinib, dasatinib, imatinib, ponatinib, nilotinib)
    c. **ALL** of the following
        i. Philadelphia chromosome-negative
        ii. B-cell precursor ALL
        iii. Paid claims or physician documents of prior therapy for the treatment of ALL with one prior systemic therapy *(see Appendix)*

Continuation of Therapy
Reauthorization by prescriber will infer a positive response to therapy.

Limitations
1. Initial approvals will be granted for 6 months.
2. Reauthorizations will be granted for 12 months.

Appendix
Systemic Therapies for ALL
Induction regimens for ALL noted by the NCCN are listed below. Please note that this list may not be all inclusive.

Philadelphia Chromosome Positive-ALL
EsPhALL: TKI plus (cyclophosphamide, vincristine, daunorubicin, dexamethasone, cytarabine, methotrexate, pegaspargase, and prednisone)
TKI + Hyper-CVAD: hyperfractionated cyclophosphamide, vincristine, doxorubicin and dexamethasone, alternating with high-dose methotrexate and cytarabine
TKI + multi-agent chemotherapy: daunorubicin, vincristine, prednisone and cyclophosphamide
TKI + corticosteroid
TKI
TKI + vincristine + dexamethasone
CALGB 10701 regimen: TKI + multiagent chemotherapy (dexamethasone, vincristine, daunorubicin, methotrexate, etoposide, and cytarabine)
Blinatumomab +/- TKI

Philadelphia Chromosome Negative-ALL
- CALGB 10403 regimen: daunorubicin, vincristine, prednisone and pegaspargase
- COG AALL0232 regimen: daunorubicin, vincristine, prednisone and pegaspargase
- COG AALL0434 with nelarabine (daunorubicin, vincristine, prednisone and pegasparagase)
- DFCI ALL regimen based on DFCI Protocol 00-01: doxorubicin, vincristine, prednisone, high-dose methotrexate and pegaspargase
- GRAALL-2005 regimen: daunorubicin, vincristine, prednisone, pegaspargase and cyclophosphamide
- PETHEMA ALL-96 regimen: daunorubicin, vincristine, prednisone, pegaspargase and cyclophosphamide

- Hyper-CVAD with or without rituximab: hyperfractionated cyclophosphamide, vincristine, doxorubicin and dexamethasone, alternating with high-dose methotrexate and cytarabine; with or without rituximab
- USC/MSKCC ALL regimen based on CCG-1882 regimen: daunorubicin, vincristine, prednisone and methotrexate with augmented pegaspargase
- Linker 4-drug regimen: daunorubicin, vincristine, prednisone and pegaspargase
- Blinatumomab
- CALGB 8811 Larson regimen: daunorubicin, vincristine, prednisone, pegaspargase and cyclophosphamide
- MRC UKALLXII/ECOG2993 regimen: daunorubicin, vincristine, prednisone and pegaspargase; and cyclophosphamide, cytarabine and 6-MP

References

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3. Blincyto® [package insert on the Internet]. Thousand Oaks, (CA): Amgen; 2021 Mar.
4. FDA granted accelerated approval to blinatumomab (Blincyto, Amgen Inc.) for the treatment of adult and pediatric patients with B-cell precursor acute lymphoblastic leukemia [press release on the Internet]. Food and Drug Administration: 2018 Mar 29 [cited 2021 Oct 12]. Available from: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-granted-accelerated-approval-blinatumomab-blincyto-amgen-inc-treatment-adult-and-pediatric
5. Topp MS, Gökbuget N, Stein AS, Zugmaier G, O'Brien S, Bargou RC et al. Safety and activity of blinatumomab for adult patients with relapsed or refractory B-precursor acute lymphoblastic leukemia: a multicentre, single-arm, phase 2 study. Lancet Oncol. 2015 Jan;16(1):57-66. doi: 10.1016/S1470- 2045(14)71170-2. Epub 2014 Dec 16.
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9. Amgen slaps record-breaking $178K price on rare leukemia drug Blincyto [press release on the Internet]. Fierce Pharma: 2014 Dec 18 [cited 2021 Oct 19]. Available from: http://www.fiercepharmamarketing.com/story/amgen-slaps-record-breaking-178k-price-rare-leukemia-drug-blincyto/2014-12-18.
10. Goebeler ME, Knop S, Viardot A, Kufer P, Topp MS, Einsele H, et al. Bispecific T-Cell Engager (BiTE) Antibody Construct Blinatumomab for the Treatment of Patients With Relapsed/Refractory Non-Hodgkin Lymphoma: Final Results From a Phase I Study. J Clin Oncol. 2016 Apr 1;34(10):1104-11. doi: 10.1200/JCO.2014.59.1586. Epub 2016 Feb 16.

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Review History

09/21/22 – Reviewed and Created for Sept P&T; matched MH UPPL. Effective 01/01/2023
05/10/23 – Reviewed and updated for P&T. Criteria update to align Blincyto criteria with NCCN guideline by removing requirement the member be MDR positive. Updated references and appendix. Effective 6/5/23.