Mass General Brigham
Health Plan

Acute Lymphoblastic Leukemia, Single Agent Therapies
Besponsa (inotuzumab ozogamicin)
Blincyto (blinatumomab)
Effective 10/01/2025

Plan	☒ MassHealth ☐Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☐ Pharmacy Benefit ☒ Medical Benefit		
Specialty Limitations	N/A		
Contact Information	**Medical Benefit** **Pharmacy Benefit**	Phone: 833-895-2611 Phone: 800-711-4555	Fax: 888-656-6671 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.

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 B-cell precursor acute lymphoblastic leukemia (B-ALL)
2. Prescriber is an oncologist or hematologist
3. Appropriate dosing (weight is required)
4. For Besponsa, member is ≥ 1 years of age
5. **ONE** of the following:
    a. For Blincyto, member with complete remission following initial treatment
    b. **BOTH** of the following:
        i. Philadelphia chromosome-positive
        ii. **ONE** of the following:
            1. Inadequate response or adverse reaction to **ONE** or contraindication to **ALL** of the following:
                a. bosutinib
                b. dasatinib
                c. imatinib

d. ponatinib
e. nilotinib

2. Agent will be used in combination with **ONE** of the following:
    a. bosutinib
    b. dasatinib
    c. imatinib
    d. ponatinib
    e. nilotinib

c. **BOTH** of the following
    i. Philadelphia chromosome-negative
    ii. Prior therapy for the treatment of ALL with **ONE** prior systemic therapy

Continuation of Therapy

Reauthorization by prescriber will infer a positive response to therapy.

Limitations

1. Initial approvals and reauthorizations will be granted for 6 months.

References

1. Besponsa® [prescribing information]. Philadelphia (PA): Wyeth Pharmaceuticals; 2018 Mar.
2. Kantarjian HM, DeAngelo DJ, Stelljes M, Martinelli G, Liedtke M, Stock W, et al. Inotuzumab Ozogamicin versus Standard Therapy for Acute Lymphoblastic Leukemia. N Engl J Med. 2016 Aug 25;375(8):740-53. doi: 10.1056/NEJMoa1509277. Epub 2016 Jun 12.
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.
6. Topp MS, Kufer P, Gökbuget N, Goebeler M, Klinger M, Neumann S, et al. Targeted therapy with the T-cell-engaging antibody blinatumomab of chemotherapy-refractory minimal residual disease in B-lineage acute lymphoblastic leukemia patients results in high response rate and prolonged leukemia-free survival. J Clin Oncol. 2011 Jun 20;29(18):2493-8. doi: 10.1200/JCO.2010.32.7270. Epub 2011 May 16.
7. Topp MS, Gökbuget N, Zugmaier G, Klappers P, Stelljes M, Neumann S, et al. Phase II trial of the anti-CD19 bispecific T cell-engager blinatumomab shows hematologic and molecular remissions in patients with relapsed or refractory B-precursor acute lymphoblastic leukemia. J Clin Oncol. 2014 Dec 20;32(36):4134-40. doi: 10.1200/JCO.2014.56.3247. Epub 2014 Nov 10.
8. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Acute Lymphoblastic Leukemia Version 2.2021 [guideline on the Internet]. [Cited 2021 Oct 12]. Available from: https://www.nccn.org/professionals/physician_gls/pdf/all.pdf.
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.
11. Cyle L, Morley NJ, Rambaldi A, Mason KD, Verhoef G, Furness CL et al. Open-Label, phase 2 study of blinatumomab as second salvage therapy in adults with relapsed/refractory aggressive B-cell non-Hodgkin lymphoma. 2020 Sep;61(9):2103-2112.

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.
09/11/24 – Reviewed and updated for P&T. Criteria updated for expanded age indication of Besponsa for the treatment of relapsed or refractory CD22-positive B-cell precursor acute lymphoblastic leukemia (ALL) in adult and pediatric patients 1 year and older. Effective 10/1/24
08/13/25 – Reviewed and updated for P&T. Part of annual UM review. Removed Appendix as info can be accessed via NCCN. Updated formatting. Effective 9/1/25
09/10/25 – Reviewed and updated for P&T. Criteria updated to reflect expanded indication for Blincyto and address trial of combination therapy with TKIs per NCCN. Reauth duration was updated to 6 months. Effective 10/1/25