



Blincyto[®] (blinatumomab) – Expanded indication

- On July 11, 2017, [Amgen announced](#) the FDA approval of [Blincyto \(blinatumomab\)](#) injection, for the treatment of relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL) in adults and children.
 - Previously, Blincyto was only approved for the treatment of Philadelphia (Ph) chromosome-negative relapsed or refractory B-cell precursor ALL.
- The approval of Blincyto's expanded indication was based on a single-arm trial, which evaluated the efficacy of Blincyto in adult patients with Ph-positive relapsed or refractory B-cell precursor ALL. The endpoint was complete remission (CR) rate, duration of CR, and proportion of patients with a minimum residual disease (MRD)-negative CR/CR with partial hematological recovery (CR/CRh*) within 2 cycles of treatment.
 - CR was achieved in 31% of patients (95% CI: 18, 47). CR/CRh* was achieved in 36% of patients (95% CI: 22, 51).
 - The duration of CR was 6.7 months (range: 3.6 – 12.0 months).
- In addition, the FDA granted approval to include overall survival (OS) data to the drug label based on the TOWER study. This approval converts Blincyto's accelerated approval to a full approval.
 - In the study, Blincyto demonstrated superior improvement in median OS vs. standard of care chemotherapy (7.7 months vs. 4 months, HR = 0.71 [95% CI: 0.55, 0.93]; p = 0.012).
- Blincyto carries a boxed warning regarding the risk of cytokine release syndrome and neurological toxicities.
- A treatment course consists of up to 2 cycles of Blincyto for induction, followed by 3 additional cycles for consolidation and up to 4 additional cycles of continued therapy.
 - A single cycle of treatment of induction or consolidation consists of 28 days of continuous intravenous (IV) infusion followed by a 14 days treatment-free interval (total of 42 days).
 - A single cycle of continued therapy consists of 28 days of continuous IV infusion followed by a 56 day treatment-free interval (total of 84 days).
 - Hospitalization is recommended for the first 9 days of the first cycle and the first 2 days of the second cycle. For all subsequent cycle starts and re-initiation, supervision by a healthcare professional or hospitalization is recommended.
 - Patients should be premedicated with dexamethasone.
 - Refer to the Blincyto drug label for specific dosing recommendations by patient weight or body surface area.



OptumRx[®] specializes in the delivery, clinical management and affordability of prescription medications and consumer health products. We are an Optum[®] company — a leading provider of integrated health services. Learn more at [optum.com](#).

All Optum[®] trademarks and logos are owned by Optum, Inc. All other brand or product names are trademarks or registered marks of their respective owners.

This document contains information that is considered proprietary to OptumRx and should not be reproduced without the express written consent of OptumRx.

RxNews[®] is published by the OptumRx Clinical Services Department.

©2017 Optum, Inc. All rights reserved.