



**Acute Lymphoblastic Leukemia, Single Agent Therapies**  
**Besponsa (inotuzumab ozogamicin)**  
**Blinicyto (blinatumomab)**  
**Effective TBD**

<b>Plan</b>	<input checked="" type="checkbox"/> MassHealth UPPL <input type="checkbox"/> Commercial/Exchange	<b>Program Type</b>	<input checked="" type="checkbox"/> Prior Authorization
<b>Benefit</b>	<input checked="" type="checkbox"/> Pharmacy Benefit <input checked="" type="checkbox"/> Medical Benefit (NLX)		<input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
<b>Specialty Limitations</b>	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
<b>Contact Information</b>	<b>Specialty Medications</b>		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	<b>Non-Specialty Medications</b>		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
Exchange	Phone: 855-582-2022	Fax: 855-245-2134	
	<b>Medical Specialty Medications (NLX)</b>		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
<b>Exceptions</b>	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.

Blinicyto (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 <sup>®</sup> (inotuzumab ozogamicin)
Augmented Hyper CVAD (cyclophosphamide, vincristine, doxorubicin, dexamethasone and pegaspargase) alternating with high-dose methotrexate and cytarabine	Blinicyto <sup>®</sup> (blinatumomab)

**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:

Acute Lymphoblastic Leukemia (ALL)



Prescriber provides documentation of **ALL** of the following:

1. Appropriate diagnosis
2. Prescriber is an oncologist or hematologist
3. Appropriate dosing (weight is required)
4. If the request is for Besponsa®, member is  $\geq 18$  years of age
5. **ONE** of the following:
  - a. If the request is for Blincyto®, member with complete remission and MRD positive B-ALL
  - b. **ALL** 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 + vincristine + dexamethasone

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 pegaspargase)
- 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 ALL regimen based on CCG-1882 regimen: daunorubicin, vincristine, prednisone and methotrexate with augmented pegaspargase
- Linker 4-drug regimen: daunorubicin, vincristine, prednisone and pegaspargase
- 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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### **Review History**

09/21/22 – Reviewed and Created for Sept P&T; matched MH UPPL.

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