



Medical Policy Manual **Draft Revised Policy: Do Not Implement**

Inotuzumab Ozogamicin (Besponsa™)

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the medical policy and a health plan or government program (e.g., TennCare), the express terms of the health plan or government program will govern.

POLICY

The proposal is to add text/statements in red and to delete text/statements with strikethrough:

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indication

Besponsa is indicated for the treatment of ~~adults with~~ relapsed or refractory **CD22-positive** B-cell precursor acute lymphoblastic leukemia (ALL) **in adult and pediatric patients 1 year and older.**

B. Compendial Use

1. Pediatric acute lymphoblastic leukemia (ALL)
2. **ALL- frontline/consolidation therapy**

All other indications are considered experimental/investigational and not medically necessary.

II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review:
Testing or analysis confirming CD22 protein on the surface of the B-cell

III. CRITERIA FOR INITIAL APPROVAL

Acute lymphoblastic leukemia (ALL)

- A. Authorization of 12 months may be granted for treatment of ALL as frontline (induction) therapy when all of the following criteria are met:
 1. Member has B-cell precursor ALL
 2. The tumor is CD22-positive as confirmed by testing or analysis to identify the CD22 protein on the surface of the B-cell
 3. Member has Philadelphia chromosome-negative disease.
 4. The requested drug will be used in combination with cyclophosphamide, dexamethasone, vincristine, methotrexate and cytarabine **with or without blinatumomab**
 5. Member will not receive more than 6 treatment cycles of the requested drug.

- B. Authorization of 12 months may be granted for treatment of ALL as consolidation therapy when all of the following criteria are met:**



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1. Member has B-cell precursor ALL.
 2. The tumor is CD22-positive as confirmed by testing or analysis to identify the CD22 protein on the surface of the B-cell.
 3. Member meets one of the following:
 - i. Member has Philadelphia chromosome-positive disease and the requested drug will be used in combination with a tyrosine kinase inhibitor (e.g., imatinib, dasatinib, nilotinib, bosutinib, ponatinib)
 - ii. Member has Philadelphia chromosome-negative disease and meets one of the following criteria:
 - a. The requested drug will be used as a single agent
 - b. The requested drug will be used in combination with cyclophosphamide, dexamethasone, vincristine, methotrexate and cytarabine with or without blinatumomab
 4. Member will not receive more than 6 treatment cycles of the requested drug
- C.** Authorization of 12 months may be granted for treatment of relapsed or refractory ALL when all of the following criteria are met:
1. Member has B-cell precursor ALL.
 2. The tumor is CD22-positive as confirmed by testing or analysis to identify the CD22 protein on the surface of the B-cell.
 3. Member meets one of the following:
 - i. Member has Philadelphia chromosome-positive disease
 - ii. Member has Philadelphia chromosome-negative disease.
 4. The requested drug will be used in one of the following settings:
 - i. As a single agent
 - ii. In combination with a tyrosine kinase inhibitor for Philadelphia chromosome-positive disease (e.g., imatinib, dasatinib, nilotinib, bosutinib, ponatinib)
 - iii. In combination with cyclophosphamide, dexamethasone, vincristine, methotrexate and cytarabine with or without blinatumomab
 5. Member will not receive more than 6 treatment cycles of the requested drug.

IV. CONTINUATION OF THERAPY

Authorization of 12 months (up to 6 cycles total) may be granted for continued treatment in members requesting reauthorization for an indication listed in Section III when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).



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REFERENCES

1. Besponsa [package insert]. Philadelphia, PA: Wyeth Pharmaceuticals LLC, Inc.; March 2024.
2. Kantarjian Hagop M, DeAngelo Daniel J., Stelljes Matthias, et al. Inotuzumab Ozogamicin versus Standard Therapy for Acute Lymphoblastic Leukemia. *N Engl J Med.* 2016; 375: 740-53.
3. The NCCN Drugs & Biologics Compendium® © 2024 National Comprehensive Cancer Network, Inc. <https://www.nccn.org>. Accessed June 25, 2024.

EFFECTIVE DATE

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