Reference number(s)
2261-A

Specialty Guideline Management Besponsa

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Besponsa	inotuzumab ozogamicin

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.

FDA-Approved Indications[1]

Besponsa is indicated 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.

Compendial Uses[2-4]

- Pediatric acute lymphoblastic leukemia (ALL)
- ALL – frontline/consolidation therapy
- Lymphoblastic Lymphoma

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

Documentation

Submission of testing or analysis confirming CD22 protein on the surface of the B-cell is necessary to initiate the prior authorization review for applicable indications as outlined in the coverage criteria section.

Coverage Criteria

Acute Lymphoblastic Leukemia (ALL)/Lymphoblastic Lymphoma[1-4]

Authorization of 12 months may be granted for treatment of ALL/lymphoblastic lymphoma as frontline (induction/consolidation) therapy when all of the following criteria are met:

- Member has B-cell precursor ALL/lymphoblastic lymphoma.
- The tumor is CD22-positive as confirmed by testing or analysis to identify the CD22 protein on the surface of the B-cell.
- Member has Philadelphia chromosome-negative disease.
- The requested medication will be used in combination with mini-hyper-CVD (mini-hyperfractionated cyclophosphamide, vincristine, dexamethasone, methotrexate, and cytarabine) with or without blinatumomab.
- Member will not receive more than 6 treatment cycles of the requested medication.

Authorization of 12 months may be granted for treatment of relapsed or refractory ALL/lymphoblastic lymphoma when all of the following criteria are met:

- Member has B-cell precursor ALL/lymphoblastic lymphoma.
- The tumor is CD22-positive as confirmed by testing or analysis to identify the CD22 protein on the surface of the B-cell.
- Member meets one of the following criteria:
  - Member has Philadelphia chromosome-positive disease.
  - Member has Philadelphia chromosome-negative disease.
- Member meets one of the following criteria:
  - The requested medication will be used as a single agent.
  - The requested medication will be used in combination with a tyrosine kinase inhibitor for Philadelphia chromosome-positive disease (e.g., imatinib, dasatinib, nilotinib, bosutinib, ponatinib).
  - The requested medication will be used in combination with mini-hyper-CVD (mini-hyperfractionated cyclophosphamide, vincristine, dexamethasone, methotrexate, and cytarabine) with or without blinatumomab.
- Member will not receive more than 6 treatment cycles of the requested medication.

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 the coverage criteria section when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

References

1. Besponsa [package insert]. Philadelphia, PA: Wyeth Pharmaceuticals LLC; March 2024.
2. The NCCN Drugs & Biologics Compendium® © 2025 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed June 12, 2025.
3. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Pediatric Acute Lymphoblastic Leukemia. Version 3.2025.Available at: https://nccn.org. Accessed June 12, 2025.
4. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Acute Lymphoblastic Leukemia. Version 2.2025.Available at: https://nccn.org. Accessed September 29, 2025.