

SPECIALTY GUIDELINE MANAGEMENT

BESPONSA (inotuzumab ozogamicin)

POLICY

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 relapsed or refractory CD22-positive B-cell precursor acute lymphoblastic leukemia (ALL) in adult and pediatric patients 1 year and older.

B. Compendial Uses

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:
 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.

V. 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.