Reference number(s)
2261-A

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 adults with relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL).

B. Compendial Use
Pediatric acute lymphoblastic leukemia (ALL)

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)
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 and is intolerant or refractory to tyrosine kinase inhibitor therapy (e.g., imatinib, dasatinib, nilotinib, bosutinib, ponatinib).
   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 cyclophosphamide, dexamethasone, vincristine, methotrexate and cytarabine
   iii. In combination with bosutinib for Philadelphia chromosome-positive B-ALL
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, Inc.; March 2018.
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® © 2021 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed April 14, 2021.