

STANDARD MEDICARE PART B 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 will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

II. 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. The requested drug will be used as a single agent, or in combination with cyclophosphamide, dexamethasone, vincristine, methotrexate, and cytarabine.
4. Member will not receive more than 6 treatment cycles of the requested drug.

III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Authorization for 12 months may be granted when all of the following criteria are met:

- A. The member is currently receiving therapy with the requested drug.
- B. The requested drug is being used to treat an indication enumerated in Section II.
- C. The member is receiving benefit from therapy.
- D. Member has not/will not receive more than 6 treatment cycles of the requested drug.

Reference number(s)
2265-A

IV. 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® © 2020 National Comprehensive Cancer Network, Inc. <https://www.nccn.org>. Accessed April 6, 2020.