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.

FDA-Approved Indications
Besponsa is indicated for the treatment of adults with relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL).

All other indications are considered experimental/investigational and are not a covered benefit.

II. CRITERIA FOR INITIAL APPROVAL

Acute lymphoblastic leukemia (ALL)
Authorization of 12 months may be granted for treatment of relapsed or refractory ALL when both of the following criteria are met:
A. Member has B-cell precursor ALL, AND
B. The tumor is CD22-positive as confirmed by testing or analysis to identify the CD22 protein on the surface of the B-cell.

III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

IV. REFERENCES

1. Besponsa [package insert]. Philadelphia, PA: Wyeth Pharmaceuticals, Inc.; August 2017.
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.