

Market Applicability							
Market	DC	GA	KY	MD	NJ	NY	WA
Applicable	X	X	X	X	X	X	X

## Besponsa (inotuzumab ozogamicin)

Override(s)	Approval Duration
Prior Authorization	1 year

Medications
Besponsa (inotuzumab ozogamicin)

### APPROVAL CRITERIA

Requests for Besponsa (inotuzumab ozogamicin) may be approved if the following criteria are met:

- I. Individual has a diagnosis of CD22+ B-cell acute lymphocytic leukemia (ALL); **AND**
- II. Individual meets all of the following:
  - A. Relapsed or has refractory disease; **AND**
  - B. Current Eastern Cooperative Oncology Group (ECOG) performance status of 0-2 (Kantarjian 2017).

Requests for Besponsa (inotuzumab ozogamicin) may not be approved for the following:

- I. All other indications not included above; **OR**
- II. Individual is using as first-line of therapy for ALL; **OR**
- III. Individual is using in combination with other chemotherapy agents.

### **Note:**

Besponsa has a black box warning for hepatotoxicity, including fatal and life-threatening hepatic veno-occlusive disease (VOD), also known as sinusoidal obstruction syndrome (SOS). Risk of VOD was greater in patient who underwent hematopoietic stem cell transplant (HSCT) after Besponsa treatment; other risk factors include liver disease, increased age, later salvage lines, and a greater number of Besponsa treatment cycles. Besponsa should be permanently discontinued if VOD occurs. Besponsa also has a black box warning for increased risk of post-HSCT non-relapse mortality because day 100 post-HSCT mortality was higher in patients receiving Besponsa.

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Applicable	X	X	X	X	X	X	X

**Key References:**

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2020. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: December 24, 2019.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Kantarjian HM, DeAngelo DJ, Stelljes M, et al. Inotuzumab ozogamicin versus standard therapy for acute lymphoblastic leukemia. *N Engl J Med*. 2016; 375(8):740-753.
5. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2020; Updated periodically.
6. NCCN Clinical Practice Guidelines in Oncology™. © 2019 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on December 26, 2019.
  - a. Pediatric Acute lymphoblastic Leukemia. V2.2020. Revised November 25, 2019.
  - b. Acute Lymphoblastic Leukemia. V2.2019. Revised May 15, 2019.

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.