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. Individual is using Besponsa as (Label, NCCN 1, NCCN 2A):
        1. A single agent; **OR**
        2. In combination with a tyrosine kinase inhibitor (bosutinib, dasatinib, imatinib, nilotinib, or ponatinib) for Philadelphia chromosome-positive B-ALL; **OR**
        3. In combination with mini-hyper CVD (cyclophosphamide, dexamethasone, vincristine, methotrexate, cytarabine) and with or without blinatumomab as consolidation therapy;

OR

III. Individual has a diagnosis of CD22+ B-cell acute lymphocytic leukemia (ALL) (NCCN 2A); **AND**
IV. Individual is using Besponsa as induction (frontline) therapy for Philadelphia chromosome-negative disease; **AND**
V. Individual is using Besponsa in combination with mini-hyper CVD (cyclophosphamide, dexamethasone, vincristine, methotrexate, cytarabine) and with or without blinatumomab as consolidation therapy.

Requests for Besponsa (inotuzumab ozogamicin) may not be approved if the above criteria are not met and for all other indications not included above.

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.

Key References:

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: January 5, 2024.
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. 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.
4. Kantarjian H, Ravandi F, Short NJ, et al. Inotuzumab ozogamicin in combination with low-intensity chemotherapy for older patients with Philadelphia chromosome-negative acute lymphoblastic leukaemia: a single-arm, phase 2 study. Lancet Oncol 2018;19:240-248.
5. Jabbour E, Ravindi F, Kebriaei P, et al. Salvage chemoinnunotherapy with inotuzumab ozogamicin combined with mini-Hyper-CVD for patients with relapsed or refractory Philadephia chromosome-negative acute lymphoblastic leukemia: A phase 2 clinical trial. JAMA oncol 2018; 4:230-234.
6. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2024; Updated periodically.
7. NCCN Clinical Practice Guidelines in Oncology™. © 2024 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Accessed on December 18, 2023.
    a. Pediatric Acute lymphoblastic Leukemia. V3.2024. Revised October 31, 2023.
    b. Acute Lymphoblastic Leukemia. V3.2023. Revised October 9, 2023.

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.