Besponsa® (inotuzumab ozogamicin)

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Definitions

Besponsa (inotuzumab ozogamicin) is a humanized CD22-directed monoclonal antibody-drug conjugate which is composed of the IgG4 kappa antibody inotuzumab (which is specific for human CD22), a calicheamicin component (a cytotoxic agent that causes double-stranded DNA breaks), and an acid-cleavable linker that covalently binds the calicheamicin to inotuzumab. After the antibody-drug conjugate binds to CD22, the CD22-conjugate complex is internalized, and releases calicheamicin. Calicheamicin binds to the minor groove of DNA to induce double strand cleavage and subsequent cell cycle arrest and apoptosis.

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

Dosing

Max Units (per dose and over time):

- Cycle 1
  - 27 billable units on Day 1, 18 billable units on Day 8 and Day 15 of a 21 to 28-day cycle
- Subsequent Cycles (maximum of 5 cycles)
  - 27 billable units on Day 1, 18 billable units on Day 8 and Day 15 of a 28-day cycle for up to 2 cycles
  - 18 billable units on Day 1, Day 8, and Day 15 of a 28-day cycle for up to 3 cycles

Guideline

Besponsa (inotuzumab ozogamicin) may be considered medically necessary for the following diagnoses when subsequent criteria are met:

B-cell precursor acute lymphoblastic leukemia (ALL):

- Patient is 18 years of age or older; **AND**
- Patient has CD22-positive disease; **AND**
- Besponsa will be used as single agent therapy; **AND**
- Patient has relapsed or refractory disease; **AND**
    - Patient is Philadelphia chromosome (Ph)-negative; **OR**
    - Patient is Philadelphia chromosome (Ph)-positive and failed previous therapy with a tyrosine kinase inhibitor; **AND**
- Besponsa will be used as single agent therapy

Limitations/Exclusions

- Approval will be granted for 6 months, and may not be renewed

Revisions

12/3/2018 – Added J9229 and removed C9028 from Applicable Procedure Codes.

Applicable Procedure Codes

J9229	Injection, inotuzumab ozogamicin, 0.1 mg

Applicable Diagnosis Codes

C91.00	Acute lymphoblastic leukemia not having achieved remission
C91.01	Acute lymphoblastic leukemia, in remission
C91.02	Acute lymphoblastic leukemia, in relapse

References

1. Besponsa [package insert]. Philadelphia, PA; Pfizer Inc., August 2017. Accessed August 2017.
2. Kantarjian HM, DeAngelo DJ, Stelljes M, et al. Inotuzumab Ozogamicin versus Standard Therapy for Acute Lymphoblastic Leukemia. N Engl J Med. 2016 Aug 25;375(8):740-53.
3. 3. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) inotuzumab ozogamicin. National Comprehensive Cancer Network, 2017. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc." To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed August 2017.