Overview
Besponsa (inotuzumab ozogamicin) is a CD22-directed antibody-drug conjugate (ADC) indicated for the treatment of relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL) in adults.

Coverage Guidelines
Authorization may be granted for members with a diagnosis of relapsed or refractory Acute Lymphoblastic Leukemia (ALL) when ALL the following criteria are met:
1. Member has B-cell precursor ALL.
2. Member has ONE of the following:
   a. Both of the following:
      i. Philadelphia chromosome-positive.
      ii. Inadequate response or adverse reaction to one tyrosine kinase inhibitor (TKI) for the treatment of ALL (see Appendix A).
   OR
   b. ALL the following:
      i. Philadelphia chromosome-negative.
      ii. B-cell precursor ALL
      iii. Documentation of prior therapy for treatment of ALL with one systemic therapy.

Limitations
1. Initial approvals will be for 12 months.

Appendix
Examples of TKIs
1. Bosutinib
2. Dasatinib  
3. Imatinib  
4. Nilotinib  
5. Ponatinib  

References  
1. NCCN guidelines version 1.2018: Acute Lymphoblastic Leukemia  
2. Besponsa (inotuzumab ozogamicin) [prescribing information]. Philadelphia, PA: Wyeth Pharmaceuticals Inc; March 2018  
3. Gleevec (imatinib mesylate) tablets [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corp.; July 2018  
4. Sprycel (dasatinib) [prescribing information]. Princeton, NJ: Bristol-Myers Squibb Company; November 2017  
5. Iclusig (ponatinib) [prescribing information]. Cambridge, MA: Ariad Pharmaceuticals Inc; October 2018  
7. Tasigna (nilotinib) [prescribing information]. East Hanover, NJ: Novartis Pharmaceutical Corp.; July 2018  

Review History  
02/20/2019 – Reviewed  
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