BlueCross BlueShield Federal Employee Program

BESPONSA
(inotuzumab ozogamicin)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Besponsa (inotuzumab ozogamicin) is an injectable cancer agent that works as a CD22-directed antibody drug conjugate (ADC). Besponsa is indicated for the treatment of patients with relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL). B-cell precursor ALL is a rapidly progressing type of cancer in which the bone marrow makes too many B-cell lymphocytes, an immature type of white blood cell. Besponsa is a targeted therapy that is thought to work by binding to B-cell ALL cancer cells that express the CD22 antigen, blocking the growth of cancerous cells (1).

Regulatory Status

FDA-approved indication: Besponsa is a CD22-directed antibody and cytotoxic drug conjugate indicated for the treatment of relapsed or refractory CD22-positive B-cell precursor acute lymphoblastic leukemia (ALL) in adult and pediatric patients 1 year and older (1).

Besponsa has a boxed warning for hepatotoxicity that can include fatal and life-threatening hepatic veno-occlusive disease (VOD) and increased risk of post-hematopoietic stem cell transplant (HSCT) non-relapse mortality. Risk factors for VOD in patients treated with Besponsa include ongoing or prior liver disease, prior post-hematopoietic stem cell transplant (HSCT), increased age, later salvage lines and a greater number of Besponsa treatment cycles. If elevated liver tests are obtained, it may require the dose of Besponsa to be interrupted, reduced, or permanent discontinued. If VOD occurs in patients, permanent discontinuation of Besponsa will be necessary (1).

Adult patients in the clinical studies with Philadelphia chromosome-positive (Ph+) B-cell precursor ALL were required to have a failed treatment with at least 1 tyrosine kinase inhibitor and standard chemotherapy (1).

The safety and effectiveness of Besponsa in patients less than 1 year of age have not been established (1).

Summary

Besponsa (inotuzumab ozogamicin) is indicated for the treatment of relapsed or refractory CD22-positive B-cell precursor acute lymphoblastic leukemia (ALL). Safety and efficacy in pediatric

patients below the age of 1 have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Besponsa while maintaining optimal therapeutic outcomes.

References

1. Besponsa [package insert]. Philadelphia, PA: Pfizer pharmaceuticals, Inc; March 2024.
2. NCCN Drugs & Biologics Compendium® Inotuzumab ozogamicin 2025. National Comprehensive Cancer Network, Inc. Accessed on January 9, 2025.