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Section:	Prescription Drugs	**Effective Date:**	January 1, 2025
Subsection:	Antineoplastic Agents	**Original Policy Date:**	September 8, 2017
Subject:	Besponsa	**Page:**	1 of 5

Last Review Date: December 13, 2024

Besponsa

Description

Besponsa (inotuzumab ozogamicin)

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).

Related policies
Blincyto, Erwinaze, Gleevec, Iclusig, Marqibo, Sprycel, Tasigna

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Besponsa may be considered **medically necessary** if the conditions indicated below are met.

Besponsa may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 1 year of age or older

Diagnosis

Patient must have the following

Relapsed or refractory CD22-positive B-cell precursor acute lymphoblastic leukemia (ALL)

AND ALL of the following:

1. Age 18+ **only**: if Philadelphia chromosome-positive (Ph+), patient must have failed treatment with at least **ONE** tyrosine kinase inhibitor and standard chemotherapy

2. Prescriber agrees to obtain ALT, AST, total bilirubin, and alkaline phosphatase prior to and following each dose of Besponsa
3. Prescriber agrees to monitor for signs and symptoms of hepatic veno-occlusive disease during treatment of Besponsa
4. Prescriber agrees **NOT** to add HSCT conditioning regimens containing alkylating agents

Prior – Approval *Renewal* Requirements

Age 1 year of age or older

Diagnosis

Patient must have the following

Relapsed or refractory CD22-positive B-cell precursor acute lymphoblastic leukemia (ALL)

AND ALL of the following:

1. **NO** disease progression or unacceptable toxicities
2. Prescriber agrees to obtain ALT, AST, total bilirubin, and alkaline phosphatase prior to and following each dose of Besponsa
3. Prescriber agrees to monitor for signs and symptoms of hepatic veno-occlusive disease during treatment of Besponsa
4. Prescriber agrees **NOT** to add HSCT conditioning regimens containing alkylating agents

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Duration 3 months

Prior – Approval *Renewal* Limits

Duration 6 months

Rationale

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 2024. National Comprehensive Cancer Network, Inc. Accessed on October 3, 2024.

Policy History

Date	Action
August 2017	Addition to PA
December 2017	Annual editorial review Addition of the requirement for Philadelphia chromosome-positive (Ph+) patients must having failed treatment with at least **ONE** tyrosine kinase inhibitor and standard chemotherapy per SME
March 2018	Annual review
June 2019	Annual review and reference update
June 2020	Annual review
March 2021	Annual editorial review
March 2022	Annual review and reference update
March 2023	Annual review and reference update
December 2023	Annual review and reference update
March 2024	Annual review and reference update
April 2024	Per PI update, reduced age requirement to 1 and older and changed indication to CD22-positive B-cell precursor ALL. Added “and following each dose” to monitoring requirement
June 2024	Annual review and reference update
December 2024	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 13, 2024 and is effective on January 1, 2025.