Besponsa

Description

Besponsa (inotuzumab ozogamicin)

Background
Besponsa is an injectable cancer agent that works as a CD22-directed antibody drug conjugate (ADC). Besponsa is indicated for the treatment of adults 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 drug conjugate (ADC) indicated for the treatment of adult patients with relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL) (1).

Besponsa has a boxed warning for hepatotoxicity that can include fatal and life-threatening hepatic veno-occlusive disease (VOD). 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).
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 has not been established in pediatric patients below 18 years of age (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** in patients that are 18 years of age and older with a relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL) and if the conditions indicated below are met.

Besponsa is considered **investigational** in patients less than 18 years of age and for all other indications.

**Prior-Approval Requirements**

**Age** 18 years of age and older

**Diagnosis**

The patient must have the following

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

**AND ALL** of the following:

1. 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 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**
18 years of age and older

**Diagnosis**

The patient must have the following

Relapsed or refractory 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 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 is indicated for the treatment of relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL) in patients 18 years of age and older. Safety and efficacy in pediatric patients below the age of 18 have not been established (1).

References

Policy History

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>August 2017</td>
<td>Addition to PA</td>
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<tr>
<td>December 2017</td>
<td>Annual editorial review</td>
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<tr>
<td></td>
<td>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</td>
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<tr>
<td>March 2018</td>
<td>Annual review</td>
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<tr>
<td>June 2019</td>
<td>Annual review and reference update</td>
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</tbody>
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Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 20, 2019 and is effective on July 1, 2019.