PRIOR AUTHORIZATION POLICY

POLICY: Oncology (Injectable) – Besponsa Prior Authorization Policy
- Besponsa™ (inotuzumab ozogamicin intravenous infusion – Pfizer)

REVIEW DATE: 07/06/2022

OVERVIEW

Besponsa, an antibody-drug conjugate directed against human CD22, is indicated for the treatment of adults with relapsed or refractory B-cell precursor **acute lymphoblastic leukemia** (ALL).[1]

Guidelines

Besponsa is addressed in National Comprehensive Cancer Network (NCCN) guidelines:

- **ALL** (version 1.2022 – April 4, 2022): Guidelines recommend Besponsa for the treatment of relapsed/refractory Philadelphia chromosome negative (Ph-) B-cell ALL, or relapsed/refractory Philadelphia chromosome positive (Ph+) B-cell ALL, as a single agent or in combination with mini-hyper CVD (cyclophosphamide, dexamethasone, vincristine, methotrexate, cytarabine).[2,3] For Ph+ B-cell ALL only, guidelines recommend Besponsa in combination with a tyrosine kinase inhibitor. Besponsa is also recommended for induction therapy for Ph- B-cell ALL in patients ≥ 65 years of age or in patients with substantial comorbidities in combination with mini-hyper CVD.
- **Pediatric ALL** (version 1.2022 – October 1, 2021): Guidelines recommend Besponsa as a single-agent for the treatment of pediatric patients with relapsed/refractory Ph- B-cell ALL, or relapsed/refractory Ph+ B-cell ALL with tyrosine kinase inhibitor intolerant or refractory disease.[3,4]

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Besponsa. All approvals are provided for the duration noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days. Because of the specialized skills required for evaluation and diagnosis of patients treated with Besponsa as well as the monitoring required for adverse events and long-term efficacy, approval requires Besponsa to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Besponsa is recommended in those who meet the following criteria:

FDA-Approved Indication

1. **Acute Lymphoblastic Leukemia.** Approve for 6 months if the patient meets the following criteria (A and B):
   Note: This applies to Philadelphia chromosome positive and negative acute lymphoblastic leukemia.
   A) Patient has B-cell precursor acute lymphoblastic leukemia; AND
   B) Besponsa is prescribed by or in consultation with an oncologist.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Besponsa is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Besponsa™ intravenous infusion [prescribing information]. Philadelphia, PA: Pfizer; March 2018.
2. The NCCN Acute Lymphoblastic Leukemia Clinical Practice Guidelines in Oncology (version 1.2022 – April 4, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed June 29, 2022.
3. The NCCN Drugs and Biologics Compendium. © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on June 29, 2022. Search term: inotuzumab.
4. The NCCN Pediatric Acute Lymphoblastic Leukemia Clinical Practice Guidelines in Oncology (version 1.2022 – October 1, 2021). © 2021 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed June 29, 2022.