UTILIZATION MANAGEMENT MEDICAL POLICY

POLICY: Oncology (Injectable) – Besponsa Utilization Management Medical Policy
- Besponsa® (inotuzumab ozogamicin intravenous infusion – Pfizer)

REVIEW DATE: 07/17/2024

OVERVIEW

Besponsa, an antibody-drug conjugate directed against human CD22, is indicated for the treatment of relapsed or refractory CD-22-positive B-cell precursor **acute lymphoblastic leukemia** (ALL) in patients ≥ 1 year of age.[1]

Guidelines

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

- **ALL:** Guidelines (version 1.2024 – June 14, 2024) recommend Besponsa for the frontline treatment of relapsed/refractory Philadelphia chromosome negative (Ph-) B-cell ALL or relapsed/refractory Ph- B-cell ALL or Philadelphia chromosome positive (Ph+) B-cell ALL if refractory to tyrosine kinase inhibitors (TKI), 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 TKI. Besponsa is also recommended for induction therapy for Ph- B-cell ALL, or for relapsed or refractory disease in patients ≥ 65 years of age or in patients with substantial comorbidities.
- **Pediatric ALL:** Guidelines (version 5.2024 – April 3, 2024) for pediatric patients recommend Besponsa as a single-agent or in combination with mini-hyper-CVD for the treatment of relapsed/refractory Ph- B-cell ALL, or as a single-agent for relapsed/refractory Ph+ B-cell ALL with tyrosine kinase inhibitor intolerant or refractory disease.[3,4]

POLICY STATEMENT

Prior Authorization is recommended for medical benefit coverage of Besponsa. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indication. Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). All approvals are provided for the duration noted below. In cases where the approval is 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 ALL of the following (A, B, and C):
   Note: This applies to Philadelphia chromosome positive and negative acute lymphoblastic leukemia.
   A) Patient is ≥ 1 year of age; AND
   B) Patient has B-cell precursor acute lymphoblastic leukemia; AND
   C) Besponsa is prescribed by or in consultation with an oncologist.

   Dosing. Approve up to 0.8 mg/m^2 administered intravenously no more frequently than 3 times in each treatment cycle (i.e., 21 days or 28 days).

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 2024.
2. The NCCN Acute Lymphoblastic Leukemia Clinical Practice Guidelines in Oncology (version 1.2024 – June 14, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed July 9, 2024.
3. The NCCN Drugs and Biologics Compendium. © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on July 9, 2024. Search term: inotuzumab.
4. The NCCN Pediatric Acute Lymphoblastic Leukemia Clinical Practice Guidelines in Oncology (version 5.2024 – April 3, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed July 9, 2024.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	07/12/2023
Annual Revision	**Acute Lymphoblastic Leukemia**: Added requirement that the patient is ≥ 1 year of age.	07/17/2024