VENTURA COUNTY
HEALTH CARE PLAN

UTILIZATION REVIEW MEDICAL POLICY

POLICY: Oncology (Injectable) – Besponsa Utilization Review Medical Policy
- Besponsa™ (inotuzumab ozogamicin injection for intravenous use – Pfizer)

REVIEW DATE: 07/15/2020

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
The National Comprehensive Cancer Network (NCCN) guidelines on ALL (version 1.2020 – January 15, 2020) 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 with tyrosine kinase inhibitor intolerant or refractory disease, as a single agent or in combination with mini-hyper CVD (cyclophosphamide, dexamethasone, vincristine, methotrexate, cytarabine).[2,3]

The NCCN guidelines on pediatric ALL (version 2.2020 – November 25, 2019) 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.[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(s). 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.

RECOMMENDED AUTHORIZATION CRITERIA
Coverage of Besponsa is recommended in those who meet one of the following criteria:

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

Dosing. Approve the following dosing regimen (A and B):
A) Each individual dose must not exceed 0.8 mg/m^2 administered intravenously; AND
B) Administer no more than 3 doses in each treatment cycle (i.e., 21 days or 28 days).[1]

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™ injection for intravenous use [prescribing information]. Philadelphia, PA: Pfizer; August 2017.
2. The NCCN Acute Lymphoblastic Leukemia Clinical Practice Guidelines in Oncology (Version 1.2020 – January 15, 2020). © 2020 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed July 7, 2020.
3. The NCCN Drugs and Biologics Compendium. © 2020 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on July 7, 2020. Search term: inotuzumab.
4. The NCCN Pediatric Acute Lymphoblastic Leukemia Clinical Practice Guidelines in Oncology (Version 2.2020 – November 25, 2019). © 2019 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed July 7, 2020.

HISTORY

Type of Revision	Summary of Changes	Review Date
New policy	New policy	08/01/2018
Annual review	Revised ALL criterion by removing the descriptor "Relapsed or Refractory B-Cell Precursor" from the condition of approval and adding it as criteria, removing ≥ 15 years of age criteria based on NCCN Pediatric ALL guidelines. Added Besponsa use as a single-agent criteria. Revised dosing section to be in-line with current format. Removed Waste Management section.	07/17/2019
Annual review	**Acute lymphoblastic leukemia.** Removed criteria for Besponsa use as a single agent.	07/15/2020