CARECONTINUUM™

UTILIZATION MANAGEMENT MEDICAL POLICY

POLICY: Oncology (Injectable) – Beleodaq Utilization Management Medical Policy
- Beleodaq® (belinostat intravenous infusion – Spectrum)

REVIEW DATE: 09/04/2024

OVERVIEW
Beleodaq, a histone deacetylase inhibitor, is indicated for the treatment of relapsed or refractory **peripheral T-cell lymphoma** in adults.[1]

Guidelines
Beleodaq is addressed in the National Comprehensive Cancer Network (NCCN) **T-Cell Lymphomas** guidelines (version 4.2024 – May 28, 2024). NCCN recommends Beleodaq as a single-agent for second-line and subsequent therapy of peripheral T-cell lymphoma, breast implant-associated anaplastic large cell lymphoma, adult T-cell leukemia/lymphoma, extranodal NK/T-cell lymphoma, and hepatosplenic T-cell lymphoma.[2,3] NCCN also recommends Beleodaq for the initial palliative treatment of peripheral T-cell lymphoma.

POLICY STATEMENT
Prior Authorization is recommended for medical benefit coverage of Beleodaq. 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. Because of the specialized skills required for evaluation and diagnosis of patients treated with Beleodaq, as well as the monitoring required for adverse events and long-term efficacy, approval requires Beleodaq to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

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

FDA-Approved Indication

1. **T-Cell Lymphoma.** Approve for 1 year if Beleodaq is prescribed by or in consultation with an oncologist or a dermatologist.
   Note: Examples include peripheral T-cell lymphoma, breast implant-associated anaplastic large cell lymphoma, adult T-cell leukemia/lymphoma, hepatosplenic T-cell lymphoma, extranodal NK/T-cell lymphoma.

   Dosing. Approve up to 1,000 mg/m^2 given by intravenous infusion, once daily on Days 1 through 5 of each 21-day cycle.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Beleodaq 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. Beleodaq® intravenous infusion [prescribing information]. Irvine, CA: Spectrum Pharmaceuticals; May 2023.
2. The NCCN T-Cell Lymphomas Clinical Practice Guidelines in Oncology (version 4.2024 – May 28, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed August 28, 2024.
3. The NCCN Drugs and Biologics Compendium. © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on August 28, 2024. Search term: belinostat.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	09/06/2023
Annual Revision	No criteria changes.	09/04/2024