CARECONTINUUM™

UTILIZATION MANAGEMENT MEDICAL POLICY

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

REVIEW DATE: 09/30/2026

OVERVIEW

Beleodaq, a histone deacetylase inhibitor, is indicated for the treatment of relapsed or refractory **peripheral T-cell lymphoma** in adults.[1] This indication is approved under accelerated approval based on tumor response rate and duration of response. An improvement in survival or disease-related symptoms has not been established. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trial.

Guidelines

Beleodaq is addressed in the National Comprehensive Cancer Network (NCCN) T-Cell Lymphomas guidelines (version 2.2026 – February 13, 2026). 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. 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 the patient meets ALL of the following (A, B, and C):
   Note: Examples of T-cell lymphoma include nodal peripheral T-cell lymphoma, T-follicular helper lymphoma, follicular T-cell lymphoma, anaplastic large cell lymphoma, enteropathy-associated T-cell lymphoma, monomorphic epitheliotropic intestinal T-cell lymphoma, angioimmunoblastic T-cell lymphoma, peripheral T-cell lymphoma not otherwise specified, breast implant-associated anaplastic

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large cell lymphoma, adult T-cell leukemia/lymphoma, hepatosplenic T-cell lymphoma, extranodal NK/T-cell lymphoma.

A) Patient is ≥ 18 years of age; AND

B) Patient meets ONE of the following (i, ii, iii or iv):

- **i.** Patient has nodal peripheral T-cell lymphoma, T-follicular helper lymphoma, follicular T-cell lymphoma, anaplastic large cell lymphoma, enteropathy-associated T-cell lymphoma, monomorphic epitheliotropic intestinal T-cell lymphoma, angioimmunoblastic T-cell lymphoma, or peripheral T-cell lymphoma not otherwise specified; OR
- **ii.** Patient meets ALL of the following (a, b, and c):
  - **a)** Patient has adult T-cell leukemia/lymphoma; AND
  - **b)** Patient has chronic high risk, acute, or lymphoma subtypes; AND
  - **c)** The medication is used as second-line or subsequent therapy; OR
- **iii.** Patient meets BOTH of the following (a and b):
  - **a)** Patient has breast implant-associated anaplastic large cell lymphoma or extranodal NK/T-cell lymphoma; AND
  - **b)** Patient has relapsed or refractory disease; OR
- **iv.** Patient meets BOTH of the following (a and b)
  - **a)** Patient has hepatosplenic T-cell lymphoma; AND
  - **b)** The medication is used as subsequent therapy after two systemic regimens.
    Note: Examples of systemic regimens include ICE (ifosfamide, carboplatin, etoposide), DHAP (dexamethasone, cytarabine, cisplatin), DHAX (dexamethasone, cytarabine, oxaliplatin), IVAC (ifosfamide, etoposide, cytarabine).

C) The medication is prescribed by or in consultation with an oncologist

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; April 2025.
2. The NCCN T-Cell Lymphomas Clinical Practice Guidelines in Oncology (version 22.2026 – February 13, 2026). © 2026 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on September 23, 2026.
3. The NCCN Drugs and Biologics Compendium. © 2026 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on September 23, 2026. Search term: belinostat.

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HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	09/04/2024
Update	04/08/2025: The policy name was changed from "Oncology (Injectable) – Beleodaq UM Medical Policy" to "Oncology (Injectable – Histone Deacetylase Inhibitor) – Beleodaq UM Medical Policy".	N/A
Annual Revision	**T-Cell Lymphoma**: The requirement that patient is ≥ 18 years of age was added. Additionally, the following options of approval were added: the patient has adult T-cell leukemia/lymphoma, chronic high risk, acute, or lymphoma subtypes, and the medication is used as second-line or subsequent therapy; the patient has breast implant-associated anaplastic large cell lymphoma and relapsed or refractory disease; the patient has extranodal NK/T-cell lymphoma and relapsed or refractory disease; the patient has hepatosplenic T-cell lymphoma and the medication is used as subsequent therapy after two systemic regimens.	09/03/2025
Annual Revision	No criteria changes.	09/30/2026

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