Beleodaq® (belinostat)
(Intravenous)

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Document Number: MODA-0381

Date Approved: 05/05/2025
Date of Origin: 07/01/2019
Dates Reviewed: 07/2019, 10/2019, 01/2020, 04/2020, 07/2020, 10/2020, 04/2021, 05/2022, 04/2023, 04/2024, 03/2025

I. Length of Authorization

Coverage will be provided for 6 months and may be renewed.

II. Dosing Limits

Max Units (per dose and over time) [HCPCS Unit]:

- All indications: 1,250 billable units every 21 days

III. Initial Approval Criteria [1]

Coverage is provided in the following conditions:

- Patient is at least 18 years of age; **AND**

Universal Criteria [1,2]

- Patient does not have a clinically significant active systemic infection; **AND**
- Patient does not have severe hepatic impairment defined as total bilirubin > 3 times the upper limit of normal; **AND**
- Patient does not have severe renal impairment defined as creatinine clearance (CrCl) < 30 mL/min; **AND**
- Used as a single agent; **AND**

T-Cell Lymphomas [1-4]

- Peripheral T-Cell Lymphoma (PTCL) † ‡ Φ [1-4,6,7,10,1e,2e,5e]

  (Including: Angioimmunoblastic T-cell lymphoma ‡; Peripheral T-cell lymphoma not otherwise specified ‡; Anaplastic large cell lymphoma ‡) Enteropathy-associated T-cell lymphoma ‡; Monomorphic epitheliotropic intestinal T-cell lymphoma ‡; Nodal peripheral T-cell lymphoma with TFH phenotype ‡; or Follicular T-cell lymphoma ‡)
  - Used as subsequent therapy for relapsed or refractory disease; **OR**
  - Used as initial palliative intent therapy **Ω**

- Hepatosplenic T-Cell Lymphoma ‡ Ω [2,4]
  - Used as subsequent therapy for refractory disease after two first-line therapy regimens
- Breast Implant-Associated Anaplastic Large Cell Lymphoma (ALCL) ‡ Ω [2,4]
  - Used as subsequent therapy for relapsed or refractory disease

Preferred therapies and recommendations are determined by review of clinical evidence. NCCN category of recommendation is taken into account as a component of this review. Regimens deemed equally efficacious (i.e., those having the same NCCN categorization) are considered to be therapeutically equivalent.

Ω *Please note that the supporting data for this indication has been assessed and deemed to be of insufficient quality based on the review conducted for the Enhanced Oncology Value (EOV) program. However, due to the absence of viable alternative treatment options, this indication will be retained in our policy and evaluated on a case-by-case basis.*

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Φ Orphan Drug

IV. Renewal Criteria [1,4,5]

Coverage may be renewed based upon the following criteria:

- Patient continues to meet the universal and other indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in section III; **AND**
- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: hematologic toxicity (e.g., thrombocytopenia, leukopenia, and/or anemia), severe infections, hepatotoxicity, tumor lysis syndrome, severe gastrointestinal toxicity, etc.

V. Dosage/Administration [1,3,4]

Indication	Dose
All indications	Administer 1,000 mg/m² intravenously daily on days 1-5 of a 21 day cycle until disease progression or unacceptable toxicity.

VI. Billing Code/Availability Information

HCPCS Code:

- J9032 – Injection, belinostat, 10 mg; 1 billable unit = 10 mg

NDC:

- Beleodaq 500 mg single-dose vial: 72893-0002-xx

VII. References (STANDARD)

1. Beleodaq [package insert]. East Windsor, NJ; Acrotech Biopharma Inc; November 2024. Accessed March 2025.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for belinostat. National Comprehensive Cancer Network, 2025. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed March 2025.
3. O'Connor OA, Masszi T, Savage KJ, et al. Belinostat, a novel pan-histone deacetylase inhibitor (HDACi), in relapsed or refractory peripheral T-cell lymphoma (R/R PTCL): Results from the BELIEF trial. Journal of Clinical Oncology 2013 31:15_suppl, 8507-8507.
4. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) T-Cell Lymphomas, Version 1.2025. National Comprehensive Cancer Network, 2025. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed March 2025.

VIII. References (ENHANCED)

1e. Pro B, Advani R, Brice P, et al. Brentuximab vedotin (SGN-35) in patients with relapsed or refractory systemic anaplastic large-cell lymphoma: results of a phase II study. J Clin Oncol. 2012 Jun 20;30(18):2190-6.

2e. Pro B, Advani R, Brice P, et al. Five-year results of brentuximab vedotin in patients with relapsed or refractory systemic anaplastic large cell lymphoma [published correction appears in Blood. 2018 Jul 26;132(4):458-459]. Blood. 2017;130(25):2709–2717.

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4e. O'Connor OA, Pro B, Pinter-Brown L, et al. Pralatrexate in patients with relapsed or refractory peripheral T-cell lymphoma: results from the pivotal PROPEL study. J Clin Oncol. 2011;29(9):1182–1189.

5e. Coiffier B, Pro B, Prince HM, et al. Results from a pivotal, open-label, phase II study of romidepsin in relapsed or refractory peripheral T-cell lymphoma after prior systemic therapy. J Clin Oncol. 2012 Feb 20;30(6):631-6.

6e. Ishida T, Fujiwara H, Nosaka K, et al. Multicenter Phase II Study of Lenalidomide in Relapsed or Recurrent Adult T-Cell Leukemia/Lymphoma: ATLL-002. J Clin Oncol. 2016; 34(34):4086-4093.

7e. Ishida T, Joh T, Uike N, et al. Defucosylated anti-CCR4 monoclonal antibody (KW-0761) for relapsed adult T-cell leukemia-lymphoma: a multicenter phase II study. J Clin Oncol. 2012 Mar 10;30(8):837-42.

8e. Ishida T, Utsunomiya A, Jo T, et al. Mogamulizumab for relapsed adult T-cell leukemia-lymphoma: Updated follow-up analysis of phase I and II studies. Cancer Sci. 2017;108(10):2022–2029.

9e. Phillips AA, Fields P, Hermine O, et al. A prospective, multicenter, randomized study of anti-CCR4 monoclonal antibody mogamulizumab (moga) vs investigator's choice (IC) in the treatment of patients (pts) with relapsed/refractory (R/R) adult T-cell leukemia-lymphoma (ATL). J Clin Oncol. 2016;34(15_suppl):7501-7501.

10e. Sharma K, Janik JE, O'Mahony D, et al. Phase II Study of Alemtuzumab (CAMPATH-1) in Patients with HTLV-1-Associated Adult T-cell Leukemia/lymphoma. Clin Cancer Res. 2016;23(1):35–42.

11e. Ishitsuka K, Utsunomiya A, Katsuya H, et al. A phase II study of bortezomib in patients with relapsed or refractory aggressive adult T-cell leukemia/lymphoma. Cancer Sci. 2015;106(9):1219–1223.

12e. Lunning MA, Gonsky J, Ruan J, et al. Pralatrexate in Relapsed/Refractory HTLV-1 Associated Adult T-Cell Lymphoma/Leukemia: A New York City Multi-Institutional Experience. Blood. 2012;120:2735.

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14e. Brammer JE, Zinzani PL, Zain J, et al. Duvelisib in Patients with Relapsed/Refractory Peripheral T-Cell Lymphoma from the Phase 2 Primo Trial: Results of an Interim Analysis [abstract]. Blood 2021;138:Abstract 2456.

15e. Prime Therapeutics Management. Beleodaq Clinical Literature Review Analysis. Last updated March 2025. Accessed March 2025.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C84.40	Peripheral T-cell lymphoma, not elsewhere classified, unspecified site
C84.41	Peripheral T-cell lymphoma, not elsewhere classified, lymph nodes of head, face, and neck
C84.42	Peripheral T-cell lymphoma, not elsewhere classified, intrathoracic lymph nodes
C84.43	Peripheral T-cell lymphoma, not elsewhere classified, intra-abdominal lymph nodes
C84.44	Peripheral T-cell lymphoma, not elsewhere classified, lymph nodes of axilla and upper limb
C84.45	Peripheral T-cell lymphoma, not elsewhere classified, lymph nodes of inguinal region and lower limb
C84.46	Peripheral T-cell lymphoma, not elsewhere classified, intrapelvic lymph nodes
C84.47	Peripheral T-cell lymphoma, not elsewhere classified, spleen
C84.48	Peripheral T-cell lymphoma, not elsewhere classified, lymph nodes of multiple sites

ICD-10	ICD-10 Description
C84.49	Peripheral T-cell lymphoma, not elsewhere classified, extranodal and solid organ sites
C84.60	Anaplastic large cell lymphoma, ALK-positive, unspecified site
C84.61	Anaplastic large cell lymphoma, ALK-positive, lymph nodes of head, face, and neck
C84.62	Anaplastic large cell lymphoma, ALK-positive, intrathoracic lymph nodes
C84.63	Anaplastic large cell lymphoma, ALK-positive, intra-abdominal lymph nodes
C84.64	Anaplastic large cell lymphoma, ALK-positive, lymph nodes of axilla and upper limb
C84.65	Anaplastic large cell lymphoma, ALK-positive, lymph nodes of inguinal region and lower limb
C84.66	Anaplastic large cell lymphoma, ALK-positive, intrapelvic lymph nodes
C84.67	Anaplastic large cell lymphoma, ALK-positive, spleen
C84.68	Anaplastic large cell lymphoma, ALK-positive, lymph nodes of multiple sites
C84.69	Anaplastic large cell lymphoma, ALK-positive, extranodal and solid organ sites
C84.70	Anaplastic large cell lymphoma, ALK-negative, unspecified site
C84.71	Anaplastic large cell lymphoma, ALK-negative, lymph nodes of head, face, and neck
C84.72	Anaplastic large cell lymphoma, ALK-negative, intrathoracic lymph nodes
C84.73	Anaplastic large cell lymphoma, ALK-negative, intra-abdominal lymph nodes
C84.74	Anaplastic large cell lymphoma, ALK-negative, lymph nodes of axilla and upper limb
C84.75	Anaplastic large cell lymphoma, ALK-negative, lymph nodes of inguinal region and lower limb
C84.76	Anaplastic large cell lymphoma, ALK-negative, intrapelvic lymph nodes
C84.77	Anaplastic large cell lymphoma, ALK-negative, spleen
C84.78	Anaplastic large cell lymphoma, ALK-negative, lymph nodes of multiple sites
C84.79	Anaplastic large cell lymphoma, ALK-negative, extranodal and solid organ sites
C84.7A	Anaplastic large cell lymphoma, ALK-negative, breast
C86.10	Hepatosplenic T-cell lymphoma, not having achieved remission
C86.20	Enteropathy-type (intestinal) T-cell lymphoma, not having achieved remission
C86.50	Angioimmunoblastic T-cell lymphoma, not having achieved remission

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdictio	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC