Beleodaq® (belinostat)
(Intravenous)

-E-

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I. Length of Authorization

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

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

– Beleodaq 500 mg powder for injection: 25 vials per 21 days

B. 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]

- 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 (ALK-negative only) ‡)

  - Used as subsequent therapy for relapsed or refractory disease; **AND**
  - Patient must demonstrate an inadequate response to romidepsin, unless there is a contraindication or intolerance, prior to approval of belinostat; **AND**

  Patients with CD30 positive PTCL only:

○ Patient must also demonstrate an inadequate response to brentuximab vedotin, unless there is a contraindication or intolerance, prior to approval of belinostat

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.

† 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 (30 mL): 72893-0002-xx

VII. References (STANDARD)

1. Beleodaq [package insert]. East Windsor, NJ; Acrotech Biopharma LLC; April 2022. Accessed March 2023.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for belinostat. National Comprehensive Cancer Network, 2023. 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 2023.

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 1.2023. National Comprehensive Cancer Network, 2023. 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 2023.

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.

13e. Kwong YL, Chan TSY, Tan D, et al. PD1 blockade with pembrolizumab. Blood. 2017 Apr 27;129(17):2437-2442. is highly effective in relapsed or refractory NK/T-cell lymphoma failing l-asparaginase.

14e. Magellan Health, Magellan Rx Management. Beleodaq Clinical Literature Review Analysis. Last updated March 2023. Accessed March 2023.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C84.40	Peripheral T-cell lymphoma, not classified, unspecified site
C84.41	Peripheral T-cell lymphoma, not classified, lymph nodes of head, face and neck
C84.42	Peripheral T-cell lymphoma, not classified, intrathoracic lymph nodes
C84.43	Peripheral T-cell lymphoma, not classified, intra-abdominal lymph nodes
C84.44	Peripheral T-cell lymphoma, not classified, lymph nodes of axilla and upper limb
C84.45	Peripheral T-cell lymphoma, not classified, lymph n odes of inguinal region of lower limb
C84.46	Peripheral T-cell lymphoma, not classified, intrapelvic lymph nodes
C84.47	Peripheral T-cell lymphoma, not classified, spleen
C84.48	Peripheral T-cell lymphoma, not classified, lymph nodes of multiple sites
C84.49	Peripheral T-cell lymphoma, not classified, 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

ICD-10	ICD-10 Description
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
C86.5	Angioimmunoblastic T-cell lymphoma

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

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 Determination (NCD), Local Coverage Determinations (LCDs), and Local Coverage Articles (LCAs) may exist and compliance with these policies is required where applicable. They can be found at: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications may be covered 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		
Jurisdiction	**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, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
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