

Beleodaq® (belinostat) (Intravenous)

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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 ^{1,2,4}

- Peripheral T-Cell Lymphoma (PTCL) † ⊕ ³
(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 in transplant ineligible patients
- Adult T-Cell Leukemia/Lymphoma ‡

- Used as subsequent therapy for non-responders to first-line therapy for acute or lymphoma subtypes
- Extranodal NK/T-Cell Lymphoma (Nasal type) ‡
 - Patient has relapsed or refractory disease; **AND**
 - Patient has previously received at least 2 different prior lines of therapy including an asparaginase-based combination chemotherapy regimen
- Hepatosplenic Gamma-Delta T-Cell Lymphoma ‡
 - Used as subsequent therapy for refractory disease after two first-line therapy regimens
- Breast Implant-Associated Anaplastic Large Cell Lymphoma (ALCL) ‡²
 - Used as subsequent therapy for relapsed or refractory disease

Primary Cutaneous Lymphomas ^{2,5}

- Mycosis Fungoides (MF)/Sezary Syndrome ‡
 - Patient has relapsed, persistent, or refractory disease; **OR**
 - Used as primary treatment for Stage IV non Sezary or visceral disease (solid organ): **OR**
 - Used as primary treatment for large cell transformation (LCT) with generalized cutaneous or extra-cutaneous lesions
- Primary Cutaneous CD30+ T-Cell Lymphoproliferative Disorders ‡
 - Patient has relapsed or refractory disease; **AND**
 - Patient has primary cutaneous anaplastic large cell lymphoma (pcALCL) with multifocal lesions; **OR**
 - Patient has cutaneous ALCL with regional nodes (excludes systemic ALCL)

† FDA-labeled indication(s); ‡ Compendia Recommended Indication(s); ◻ Orphan Drug

IV. Renewal Criteria ^{1,4,5}

Coverage can be renewed based upon the following criteria:

- Patient continues to meet 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 ^{1,4,5}

Indication	Dose
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All indications	Administer 1,000 mg/m ² intravenously daily on days 1-5 of a 21-day cycle until disease progression or unacceptable toxicity.
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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

1. Beleodaq [package insert]. Acrotech Biopharma, East Windsor, NJ; January 2020. Accessed January 2021.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for belinostat. National Comprehensive Cancer Network, 2021. 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 January 2021.
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®) for T-Cell Lymphomas 1.2021. National Comprehensive Cancer Network, 2021. 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 Guidelines, go online to NCCN.org. Accessed January 2021.
5. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Primary Cutaneous Lymphomas 1.2021. National Comprehensive Cancer Network, 2021. 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 Guidelines, go online to NCCN.org. Accessed February 2021.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C84.00	Mycosis fungoides unspecified site
C84.01	Mycosis fungoides lymph nodes of head, face, and neck
C84.02	Mycosis fungoides intrathoracic lymph nodes

ICD-10	ICD-10 Description
C84.03	Mycosis fungoides intra-abdominal lymph nodes
C84.04	Mycosis fungoides lymph nodes of axilla and upper limb
C84.05	Mycosis fungoides lymph nodes of inguinal region and lower limb
C84.06	Mycosis fungoides intrapelvic lymph nodes
C84.07	Mycosis fungoides spleen
C84.08	Mycosis fungoides lymph nodes of multiple sites
C84.09	Mycosis fungoides extranodal and solid organ sites
C84.10	Sézary disease, unspecified site
C84.11	Sézary disease, lymph nodes of head, face, and neck
C84.12	Sézary disease, intrathoracic lymph nodes
C84.13	Sézary disease, intra-abdominal lymph nodes
C84.14	Sézary disease, lymph nodes of axilla and upper limb
C84.15	Sézary disease, lymph nodes of inguinal region and lower limb
C84.16	Sézary disease, intrapelvic lymph nodes
C84.17	Sézary disease, spleen
C84.18	Sézary disease, lymph nodes of multiple sites
C84.19	Sézary disease, extranodal and solid organ sites
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 nodes 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
C84.60	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

ICD-10	ICD-10 Description
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
C84.90	Mature T/NK-cell lymphomas, unspecified, unspecified site
C84.91	Mature T/NK-cell lymphomas, unspecified, lymph nodes of head, face, and neck
C84.92	Mature T/NK-cell lymphomas, unspecified, intrathoracic lymph nodes
C84.93	Mature T/NK-cell lymphomas, unspecified, intra-abdominal lymph nodes
C84.94	Mature T/NK-cell lymphomas, unspecified, lymph nodes of axilla and upper limb
C84.95	Mature T/NK-cell lymphomas, unspecified, lymph nodes of inguinal region and lower limb
C84.96	Mature T/NK-cell lymphomas, unspecified, intrapelvic lymph nodes
C84.97	Mature T/NK-cell lymphomas, unspecified, spleen
C84.98	Mature T/NK-cell lymphomas, unspecified, lymph nodes of multiple sites
C84.99	Mature T/NK-cell lymphomas, unspecified, extranodal and solid organ sites
C84.Z0	Other mature T/NK-cell lymphomas, unspecified site
C84.Z1	Other mature T/NK-cell lymphomas, lymph nodes of head, face, and neck
C84.Z2	Other mature T/NK-cell lymphomas, intrathoracic lymph nodes
C84.Z3	Other mature T/NK-cell lymphomas, intra-abdominal lymph nodes
C84.Z4	Other mature T/NK-cell lymphomas, lymph nodes of axilla and upper limb
C84.Z5	Other mature T/NK-cell lymphomas, lymph nodes of inguinal region and lower limb
C84.Z6	Other mature T/NK-cell lymphomas, intrapelvic lymph nodes
C84.Z7	Other mature T/NK-cell lymphomas, spleen
C84.Z8	Other mature T/NK-cell lymphomas, lymph nodes of multiple sites
C84.Z9	Other mature T/NK-cell lymphomas, extranodal and solid organ sites
C86.0	Extranodal NK/T-cell lymphoma, nasal type
C86.1	Hepatosplenic T-cell lymphoma
C86.2	Enteropathy-type (intestinal) T-cell lymphoma
C86.5	Angioimmunoblastic T-cell lymphoma
C86.6	Primary cutaneous CD30-positive T-cell proliferations

ICD-10	ICD-10 Description
C91.50	Adult T-cell lymphoma/leukemia (HTLV-1-associated) not having achieved remission
C91.52	Adult T-cell lymphoma/leukemia (HTLV-1-associated) in relapse

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), Local Coverage Articles (LCAs) may exist and compliance with these policies is required where applicable. They can be found at: <http://www.cms.gov/medicare-coverage-database/search/advanced-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