

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) [Pharmacy Benefit]:

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

B. Max Units (per dose and over time) [Medical Benefit]:

- 1,250 billable units every 21 days

III. Initial Approval Criteria

Coverage is provided in the following conditions:

- Patient is at least 18 years old; **AND**
- Used as single agent systemic therapy; **AND**

Non-Hodgkin's Lymphoma

- Peripheral T-cell lymphoma (PTCL) †
 - (Including: Angioimmunoblastic T-cell lymphoma ‡; 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 ‡)
 - Patient's PTCL is relapsed or refractory to prior treatment; **AND**
 - Patient is using this as second-line or greater therapy
- Adult T-Cell Leukemia/Lymphoma ‡
 - Used in patients who have acute disease or lymphoma which did not respond to first-line therapy; **AND**
 - Used as second-line therapy prior to high-dose therapy/allogeneic hematopoietic cell transplantation (HDT/allogeneic HCT); **OR**
 - Used as subsequent therapy to HDT/allogeneic HCT
- Mycosis Fungoides (MF) ‡

- Used for stage IB-IIA disease; **AND**
 - Used as primary treatment in disease with histologic evidence of folliculotropic or large-cell transformed MF; **OR**
- Used for stage IIB disease; **OR**
- Used for stage IV disease
- Primary Cutaneous CD30+ T-Cell Lymphoproliferative Disorders †
 - Patient has relapsed or refractory disease; **AND**
 - Patient has primary cutaneous anaplastic large cell lymphoma (ALCL) with multifocal lesions; **OR**
 - Patient has cutaneous ALCL with regional nodes (excludes systemic ALCL)

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

IV. Renewal Criteria

Coverage can be renewed based upon the following criteria:

- Continues to meet the criteria identified in Section III; **AND**
- Tumor response with 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 (thrombocytopenia, leukopenia, and/or anemia), severe infections, hepatotoxicity, tumor lysis syndrome, severe gastrointestinal toxicity, etc.

V. Dosage/Administration

Indication	Dose
All indications	1,000 mg/m ² intravenously daily on days 1-5 of a 21 day cycle (Treatment discontinuation or interruption with or without dosage reductions by 25% may be needed to manage adverse reactions)

VI. Billing Code/Availability Information

Jcode:

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

NDC:

- Beleodaq 500 mg single dose vial (30 mL): 68152-0108-xx

VII. References

1. Beleodaq [package insert]. Spectrum Pharmaceuticals; April 2017. Accessed October 2018.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for belinostat. National Comprehensive Cancer Network, 2018. 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 October 2018.

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
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
C84.40	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
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

ICD-10	ICD-10 Description
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
C86.2	Enteropathy-type (intestinal) T-cell lymphoma
C86.5	Angioimmunoblastic T-cell lymphoma
C86.6	Primary cutaneous CD30-positive T-cell proliferations
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
Z85.72	Personal history of non-Hodgkin lymphomas

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) and Local Coverage Determinations (LCDs) 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): 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