



Beleodaq[®] (belinostat) (Intravenous)

Document Number: IC-0205

Last Review Date: 03/01/2022

Date of Origin: 08/26/2014

Dates Reviewed: 08/2014, 07/2015, 05/2016, 08/2016, 11/2016, 02/2017, 05/2017, 08/2017, 11/2017, 02/2018, 05/2018, 09/2018, 12/2018, 03/2019, 06/2019, 09/2019, 12/2019, 03/2020, 06/2020, 09/2020, 03/2021, 03/2022

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) † ⊕ ¹⁻⁴
(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 ‡ ²

- Used as subsequent therapy for non-responders to first-line therapy for acute or lymphoma subtypes
- Extranodal NK/T-Cell Lymphoma (Nasal type) ‡²
 - 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 ‡^{2,4}
 - 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

† 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^{1,3,4}

| Indication | Dose |
|-----------------|--|
| 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. |

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 2022.

2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for belinostat. National Comprehensive Cancer Network, 2022. 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 2022.
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 1.2022. National Comprehensive Cancer Network, 2022. 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 2022.

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 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 |

BELEODAQ® (belinostat) Prior Auth Criteria

Proprietary Information. Restricted Access – Do not disseminate or copy without approval.

©2022, Magellan Rx Management

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

| ICD-10 | ICD-10 Description |
|--------|---|
| 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: <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 |