# Clinical Criteria

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| **Subject:** | **Beleodaq (belinostat)** | | |
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## Overview

**This document addresses the use of Beleodaq (belinostat), an intravenously administered histone deacetylase (HDAC) inhibitor. HDAC inhibitors are useful as antineoplastic agents as they cause accumulation of acetylated histones, inducing cell cycle arrest and/or apoptosis of some transformed cells.**

**Beleodaq is FDA approved for the treatment of relapsed or refractory peripheral T-cell lymphoma, which is a type of Non-Hodgkin Lymphoma (NHL). The National Comprehensive Cancer Network® (NCCN) provide additional recommendations with a category 2A level of evidence for the use of Beleodaq in other NHLs.**

**NHLs are a broad and diverse group of malignancies affecting both B- and T-lymphocytes. Beleodaq is used for T-Cell Lymphomas. These can broadly be classified as cutaneous or non-cutaneous. Cutaneous T-cell lymphomas where Beleodaq is recommended include mycosis fungoides (MF) and sezary syndrome (SS), and the cutaneous form of anaplastic large cell lymphoma (ALCL), known as primary cutaneous ALCL. Other T-cell lymphomas where Beleodaq may be used include peripheral t-cell lymphoma (PTCL) and adult T-cell leukemia/lymphoma (ATLL). NCCN recently included extranodal NK/T-Cell lymphoma, nasal type (NKTL) and hepatosplenic gamma-delta T-Cell Lymphoma (HGTL) as indications, indicating that relapsed/refractory disease may be treated with options for PTCL.**
**Subtypes of PTCLs include the following:**

- **PTCL-NOS (not-otherwise-specified)**
- **Systemic ALCL**
- **Angioimmunoblastic t-cell lymphoma**
- **Enteropathy-associated T-cell lymphoma**
- **Monomorphic epitheliotropic intestinal T-cell lymphoma**
- **Nodal peripheral T-cell lymphoma with TFH phenotype**
- **Follicular T-cell lymphoma**

### Definitions and Measures

**Mycosis fungoides/ Sézary Syndrome (MF/SS): Cutaneous T-cell Lymphomas (CTCLs) are a group of NHLs of mature T-cells that primarily present in the skin, and at times progress to involve lymph nodes, blood, and visceral organs. MF is the most common subtype with primary cutaneous involvement and SS is an erythrodermic, leukemic variant of CTCL that is characterized by significant blood involvement and lymphadenopathy.**

**Refractory Disease: Illness or disease that does not respond to treatment.**

**Relapse or recurrence: After a period of improvement, during which time a disease (for example, cancer) could not be detected, the return of signs and symptoms of illness or disease. For cancer, it may come back to the same place as the original (primary) tumor or to another place in the body.**

## Clinical Criteria

**When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.**

**Beleodaq (belinostat)**

**Requests for Beleodaq (belinostat) may be approved if the following criteria are met:**

I. **Individual has a diagnosis of Non-Hodgkin Lymphoma (NHL) as:**
   A. **Relapsed or refractory peripheral T-cell lymphoma (PTCL); OR**
   B. **Mycosis Fungoides/Sézary Syndrome (NCCN 2A); OR**
   C. **Relapsed or refractory Adult T-cell leukemia/lymphoma (NCCN 2A); OR**
   D. **Relapsed or refractory primary cutaneous CD30+ T-cell lymphoproliferative disorders – cutaneous anaplastic large cell lymphoma (NCCN 2A); OR**
   E. **Relapsed or refractory extranodal NK/T-Cell lymphoma, nasal type (NCCN 2A); OR**
   F. **Relapsed or refractory hepatosplenic gamma-delta T-Cell Lymphoma (NCCN 2A).**

**Requests for Beleodaq (belinostat) may not be approved when the above criteria are not met and for all other indications.**

# Coding

**The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.**

***HCPCS***

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| **J9032** | **Injection, belinostat, 10 mg** |

***ICD-10 Diagnosis***

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| **C85.80-C85.89** | **Non-Hodgkin lymphoma** |
| **C84.40-C84.49** | **Peripheral T-cell lymphoma** |
| **C91.00-C91.52** | **Lymphoid leukemia** |

# Document History

**Reviewed: 08/21/2020**
**Document History:**

- **08/21/2020 – Annual Review: No changes. Coding review: Added HCPCS J9032, Added ICD-10-CM C85.80-C85.89, C84.40-C84.49 , C91.00-C91.52**
- **11/15/2019 – Annual Review: Add detail to NCCN recommendations, including extranodal NK/T-Cell lymphoma and hepatosplenic gamma-delta T-Cell lymphoma; wording and formatting changes.**

# References


1. **Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2020. URL: http://www.clinicalpharmacology.com. Updated periodically.**
2. **DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: June 22, 2020.**
3. **DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.**
4. **Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2020; Updated periodically.**
5. **NCCN Clinical Practice Guidelines in Oncology™. © 2019 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Accessed on June 22, 2020.**
   a. **Primary Cutaneous Lymphomas. V2.2020. Revised April 10, 2020.**
   b. **T-Cell Lymphomas. V1.2020. Revised January 6, 2020.**


**Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.**