

Medical Drug Clinical Criteria

Subject:	Beleodaq (belinostat)		
Document #:	CC-0176	Publish Date:	09/23/2024
Status:	Reviewed	Last Review Date:	08/16/2024

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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. Beleodaq is used for peripheral t-cell lymphoma (PTCL) and adult T-cell leukemia/lymphoma (ATLL). NCCN recently included extranodal NK/T-Cell lymphoma and hepatosplenic T-Cell Lymphoma (HGTL) as recommended indications since relapsed/refractory disease may be treated according to options for PTCL.

Subtypes of PTCLs include the following:

- PTCL-NOS (not-otherwise-specified)
- Anaplastic large cell lymphoma (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

Other Uses

NCCN recommends Beleodaq as therapy with initial palliative intent for peripheral T-cell lymphoma and as second-line or subsequent therapy for breast implant-associated T-cell lymphoma, but literature and data supporting these recommendations are not provided.

Definitions and Measures

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 one of the following:
 - A. Relapsed or refractory peripheral T-cell lymphoma (PTCL); **OR**
 - B. Relapsed or refractory breast implant associated ALCL (NCCN 2A); **OR**
 - C. Relapsed or refractory Adult T-cell leukemia/lymphoma (NCCN 2A); **OR**
 - D. Relapsed or refractory extranodal NK/T-Cell lymphoma (NCCN 2A); **OR**
 - E. Relapsed or refractory hepatosplenic 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

J9032 Injection, belinostat, 10 mg

ICD-10 Diagnosis

C84.7A	Anaplastic large cell lymphoma, ALK-negative, breast [when designated as breast implant associated anaplastic large cell lymphoma]
Z98.82	Breast implant status
Z98.86	Personal history of breast implant removal
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
C84.40	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 and 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
C91.50	Adult T-cell lymphoma/leukemia (HTLV-1-associated) not having achieved remission

C91.51	Adult T-cell lymphoma/leukemia (HTLV-1-associated), in remission
C91.52	Adult T-cell lymphoma/leukemia (HTLV-1-associated), in relapse

Document History

Reviewed: 08/16/2024

Document History:

- 08/16/2024 – Annual Review: No changes. Coding Reviewed: Added ICD-10-CM C84.7A, Z98.82, Z98.86 for breast implant associated ALCL added to criteria 08/18/2023.
- 08/18/2023- Annual Review: Add criteria for NCCN 2A recommendation for use in r/r breast implant associated ALCL. Coding Reviewed: No changes.
- 08/18/2022 – Annual Review: Remove Mycosis Fungoides/Sézary Syndrome and primary cutaneous CD30+ T-cell lymphoproliferative disorders as no longer recommended by NCCN; update extranodal NK/T-cell to remove “nasal type” and hepatosplenic T-cell to remove “gamma-delta” per NCCN; wording and formatting updates. Coding reviewed: Removed ICD-10-CM C84.40-C84.49, C91.00-C91.52, C85.80-C85.89. Added ICD-10-CM C84.90, C84.91, C84.92, C84.93, C84.94, C84.95, C84.96, C84.97, C84.98, C84.99, C84.40, C84.41, C84.42, C84.43, C84.44, C84.45, C84.46, C84.47, C84.48, C84.49. C91.50, C91.51, C92.52.
- 08/20/2021 – Annual Review: No changes. Coding reviewed: No changes.
- 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. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: June 27, 2024.
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2024; Updated periodically.
4. NCCN Clinical Practice Guidelines in Oncology™. © 2024 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on June 27, 2024.
 - a. T-Cell Lymphomas. V4.2024. Revised May 28, 2024.

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