CLINICAL GUIDELINES FOR MEDICAL NECESSITY

MEDICAL ONCOLOGY

Belinostat (Beleodaq®)

Version: 1.0

EFFECTIVE DATE: 1/1/2024

NantHealth® | Eviti®

Please note the following:

Belinostat (Beleodaq®)

Note: For Medicare members/enrollees, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Please refer to the CMS website at http://www.cms.gov for additional information.

Note: For Medicaid members/enrollees, circumstances when state Medicaid coverage provisions conflict with the coverage provisions within this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

Belinostat (Beleodaq): Discussion

Belinostat is a histone deacetylase (HDAC) inhibitor. HDACs catalyze the removal of acetyl groups from the lysine residues of histones and some non-histone proteins. In vitro, belinostat caused the accumulation of acetylated histones and other proteins, inducing cell cycle arrest and/or apoptosis of some transformed cells. Belinostat shows preferential cytotoxicity towards tumor cells compared to normal cells. Belinostat inhibited the enzymatic activity of histone deacetylases at nanomolar concentrations (<250 nM).[1]

Belinostat is indicated for the treatment of adult patients with relapsed or refractory peripheral T-cell lymphoma (PTCL).[1]

Note: This indication is approved under accelerated approval based on the tumor response rate and the duration of response.

Belinostat-induced responses across all types of PTCL (with the exception of ALK-positive anaplastic large cell lymphoma (ALCL) and the response rates were significantly higher for angioimmunoblastic T-cell lymphoma (AITL) than other subtypes.[2]

The National Comprehensive Cancer Network (NCCN) endorses belinostat in the following cancer types: T-cell lymphomas - peripheral T-cell lymphomas.[2]

Belinostat: Definitions

- **Food and Drug Administration (FDA)** – The FDA is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation.
- **Histone deacetylases (HDACs)** - Enzymes that catalyze the removal of acetyl functional groups from the lysine residues of both histone and nonhistone proteins.

- **Histone deacetylases inhibitors (HDAC)** – Inhibitors that induce cancer cell cycle arrest, differentiation, and cell death, reduce angiogenesis, and modulate an immune response.
- **National Comprehensive Cancer Network (NCCN) -** An alliance of thirty-two leading cancer centers devoted to patient care, research, and education. The NCCN guidelines are utilized for Radiation Therapy and Medical Oncology standards. NCCN consensus clinical standards are periodically updated and NantHealth, Inc. reviews these and updates its policies within a timely manner.

Belinostat: Policy

Belinostat will be considered for coverage when the following criteria are met:

T-Cell Lymphomas

1. At least 18 years of age; AND
2. Prescribed by or in consultation with an oncologist; AND
3. Adult T-Cell Leukemia/Lymphoma
   Second-line or subsequent therapy as a single agent for non-responders to first-line therapy for acute or lymphoma subtypes; OR
4. Breast Implant-Associated ALCL
   Second-line and subsequent therapy for relapsed and refractory disease, as a single agent; OR
5. Extranodal NK/T-Cell Lymphomas, Nasal Type
   As a single agent (useful in certain circumstances) for relapsed/refractory disease following additional therapy with an alternate combination chemotherapy regimen (asparaginase-based) not previously used; OR
6. Hepatosplenic T-Cell Lymphoma
   Preferred therapy as a single agent for refractory disease after 2 first-line therapy regimens; OR
7. Peripheral T-Cell Lymphomas
   Initial palliative intent therapy or second-line and subsequent therapy as a single agent
   a) Relapsed/refractory peripheral T-cell lymphoma not otherwise specified (PTCL-NOS)
   b) Enteropathy-associated T-cell lymphoma (EATL)
   c) Monomorphic epitheliotropic intestinal T-cell lymphoma (MEITL)
   d) Angioimmunoblastic T-cell lymphoma (AITL)
   e) Nodal peripheral T-cell lymphoma with TFH phenotype (PTCL, TFH)
   f) Follicular T-cell lymphoma (FTCL)
   g) Anaplastic large cell lymphoma (ALCL)

Note: Coverage of belinostat will be provided for an FDA-approved indication or National Comprehensive Cancer Network (NCCN) guidelines when it is a Category 1, 2A, or 2B recommendation OR when all criteria are met.

Authorization Period and Renewal Criteria

1. Initial Authorization Period: 12 months
2. Renewal Criteria: No evidence of disease progression or unacceptable toxicity
3. Renewal Authorization Period: 12 months

Belinostat: References

1. Belinostat (Beleodaq) package insert. https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/206256s004lbl.pdf. Accessed May 17, 2023
2. National Comprehensive Cancer Network Guidelines. T-Cell Lymphomas (Version 1.2023) https://www.nccn.org/professionals/physician_gls/pdf/t-cell.pdf. Accessed May 17, 2023.

Belinostat: Coding (CPT®, ICD 10 and HCPCS) *

*Procedure codes appearing in medical policy documents are only included as a general reference. This list may not be all-inclusive and is subject to updates. In addition, the codes listed are not a guarantee of payment. CPT codes are available through the AMA.

CODE	DESCRIPTION
C84.40	Peripheral T Cell Lymphoma
C84.7A	Anaplastic Large Cell Lymphoma
C86.5	Angioimmunoblastic T Cell Lymphoma
C91.5	Acute T Cell Lymphoma/Leukemia
J9032	Belinostat (Beleodaq)

Belinostat: Revision and Review History

No.	Description	Date(s)
1	Original Effective Date:	1/1/2024
2	Policy Review Dates:	5/24/2023
3	Policy Revision Dates:	
4	Department Owner:	Medical Affairs
5	NH Advisory Committee Approval Dates:	7/17/2023
6	Revision Changes:	