Belinostat (Beleodaq®)	Place of Service Office Administration Outpatient Facility Administration Infusion Center Administration HCPCS: J9032 per 10 mg

Condition(s) listed in policy *(see criteria for details)*

- Adult T-Cell leukemia/lymphoma (acute or lymphoma subtypes)
- Breast implant-associated anaplastic large cell lymphoma
- Extranodal NK/T-cell lymphoma, nasal type
- Hepatosplenic gamma-delta T-cell lymphoma
- Mycosis fungoides or Sezary syndrome
- Peripheral T-cell lymphoma *(see criteria for subtypes covered)*

AHFS therapeutic class: Antineoplastic
Mechanism of action: Histone deacetylase inhibitor

(1) Special Instructions and Pertinent Information

Covered under the Medical Benefit, please submit clinical information for prior authorization review via fax.

(2) Prior Authorization/Medical Review is required for the following condition(s)

All requests for Beleodaq® (belinostat) not listed in section (3) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

Adult T-Cell leukemia/lymphoma (acute or lymphoma subtypes)

Covered dose
1000 mg/m^2 IV daily on days 1 to 5 of a 21-day cycle

Coverage period
Indefinitely

ICD-10:
C91.50, C91.52

Breast implant-associated anaplastic large cell lymphoma

Covered dose
1000 mg/m^2 IV daily on days 1 to 5 of a 21-day cycle

Coverage period
Indefinitely

ICD-10:
C84.7A

Extranodal NK/T-cell lymphoma, nasal type

Covered dose
1000 mg/m^2 IV daily on days 1 to 5 of a 21-day cycle

Coverage period
Indefinitely

ICD-10:
C86.0

Hepatosplenic gamma-delta T-cell lymphoma

Covered dose
1000 mg/m^2 IV daily on days 1 to 5 of a 21-day cycle

Coverage period
Indefinitely

ICD-10:
C86.1

Mycosis fungoides or sezary syndrome

1. Not being used in combination with other systemic therapies

Covered dose
1000 mg/m^2 IV daily on days 1 to 5 of a 21-day cycle

Coverage period
Indefinitely

ICD-10:
C84.00-C84.19

Peripheral T-cell lymphoma

1. One of the following PTCL subtypes: anaplastic large cell lymphoma (systemic and cutaneous), peripheral T-cell lymphoma not otherwise specified, angioimmunoblastic T-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, **AND**
2. Being used as a single agent

Covered dose
1000 mg/m^2 IV daily on days 1 to 5 of a 21-day cycle

Coverage period
Indefinitely

ICD-10:
C84.40-C84.49, C84.60-C84.69, C84.70-C84.79, C86.2, C86.5, C86.6, C91.50, C91.52

(3) The following condition(s) DO NOT require Prior Authorization/Preservice

All requests for Beleodaq® (belinostat) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

(4) This Medication is NOT medically necessary for the following condition(s)

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

(5) Additional Information

How Supplied:

- 500 mg (single-use vial)

(6) References

- AHFS®. Available by subscription at http://www.lexi.com
- Beleodaq® (belinostat) [Prescribing information]. East Windsor, NJ: Acrotech Biopharma LLC.; 5/2023.
- DrugDex®. Available by subscription at: http://www.micromedexsolutions.com/home/dispatch
- National Comprehensive Cancer Network. T-Cell Lymphomas (Version 1.2023). Available at www.nccn.org.

(7) Policy Update

Date of last review: 4Q2023
Date of next review: 4Q2024
Changes from previous policy version:

- No clinical change to policy following routine annual review.

BSC Drug Coverage Criteria to Determine Medical Necessity
Reviewed by P&T Committee