Clinical Policy: Belinostat (Beleodaq)

Reference Number: PA.CP.PHAR.311
Effective Date: 01/2018
Last Review Date: 10/2023

Coding Implications
Revision Log

Description
Belinostat (Beleodaq®) is a histone deacetylase inhibitor.

FDA Approved Indication(s)
Beleodaq is indicated for the treatment of patients with relapsed or refractory peripheral T-cell lymphoma (PTCL).

This indication is approved under accelerated approval based on tumor response rate and duration of response. An improvement in survival or disease-related symptoms has not been established. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trial.

Policy/Criteria
It is the policy of PA Health & Wellness ® that Beleodaq is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Peripheral T-Cell Lymphoma (must meet all):
1. Diagnosis of PTCL – (*see Appendix D for examples of PTCL subtypes*);
2. Prescribed by or in consultation with an oncologist or hematologist;
3. Age ≥ 18 years;
4. Request meets one of the following (a or b):
   a. Dose does not exceed 1,000/mg/m^2 per day on days 1-5 of a 21-day cycle;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 6 months

B. NCCN-Recommended Off-Label Indications (must meet all)**:**
1. Diagnosis of one of the following (a, b, c, d, or e):
   a. Primary cutaneous anaplastic large cell lymphoma (ALCL) with multifocal lesions, or cutaneous ALCL with regional nodes;
   b. Adult T-cell leukemia/lymphoma;
   c. Extranodal NK/T-cell lymphoma;
   d. Hepatosplenic T-cell lymphoma;
   e. Breast implant ALCL;
2. Prescribed by or in consultation with an oncologist or hematologist;
3. Age ≥ 18 years;
4. Dose is within FDA maximum limit for any FDA-approved indication or is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 6 months

C. Other diagnoses/indications: Refer to PA.CP.PMN.53

II. Continued Approval

A. All Indications in Section I (must meet all)**:**

1. Currently receiving medication via PA Health & Wellness benefit or member has previously met all initial approval criteria; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy;
3. If request is for a dose increase, request meets one of the following (a or b):
   a. New dose does not exceed 1,000/mg/m^2 per day on days 1-5 of a 21-day cycle;
   b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies; or
2. Refer to PA.CP.PMN.53

III. Diagnoses/Indications for which coverage is NOT authorized

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies –PA.CP.PMN.53

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

ALCL: anaplastic large cell lymphoma
FDA: Food and Drug Administration
NCCN: National Comprehensive Cancer Network
PTCL: peripheral T-cell lymphoma

Appendix B: Therapeutic Alternatives

Not applicable

Appendix C: Contraindications/Boxed Warnings

None reported

Appendix D: General Information

- PTCL - subtypes/histologies:
  - PTCL, not otherwise specified;
  - Anaplastic large cell lymphoma;
  - 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;

**PTLC is classified as a non-Hodgkin T-cell lymphoma. PTCL classification schemes are periodically advanced as new information becomes available; therefore, the above list is provided as general guidance. For additional information, see WHO's 2016 updated classification of hematological malignancies for a complete list of lymphoid neoplasms, including PTCL.*

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
PTCL	1,000 mg/m^2 IV on days 1-5 of a 21-day cycle. Cycles can be repeated every 21 days until disease progression or unacceptable toxicity.	1,000 mg/m^2/day

VI. Product Availability

Single-dose vial: 500 mg

VII. References

1. Beleodaq Prescribing Information. Irvine, CA: Spectrum Pharmaceuticals, Inc.; May 2023. Available at: http://www.beleodaq.com/downloads/Beleodaq_PI.pdf. Accessed Accessed August 11, 2023.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed August 11, 2023.
3. National Comprehensive Cancer Network. T-Cell Lymphomas Version 1.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/t-cell.pdf. Accessed August 11, 2023.
4. National Comprehensive Cancer Network. Primary Cutaneous Lymphomas Version 1.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/primary_cutaneous.pdf. Accessed August 11, 2023.

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J9032	Injection, belinostat, 10 mg

Reviews, Revisions, and Approvals	Date	Approval Date
4Q 2018 annual review: no significant changes; summarized NCCN and FDA-approved uses for improved clarity; added specialist involvement in care; references reviewed and updated.	07/2018	
4Q 2019 annual review: No changes per Statewide PDL implementation 01-01-2020	10/2019	

Reviews, Revisions, and Approvals	Date	Approval Date
4Q 2020 annual review: added NCCN-recommended (with Category 2A or above) off-label uses: extranodal NK/T-cell lymphoma, nasal type, hepatosplenic gamma-delta T-cell lymphoma; added additional off-label indication cutaneous CD30+ T-cell lymphoma as per NCCN 2A or above off label indication; added Appendix D: PTCL subtypes per NCCN; references reviewed and updated.	10/2020	
4Q 2021 annual review: references reviewed and updated.	10/2021	
4Q 2022 annual review: updated NCCN-recommended off-label uses: removed mycosis fungoides, cutaneous CD30+ T-cell lymphoma, and Sézary syndrome; added breast implant ALCL (Category 2A recommendation); references reviewed and updated.	10/2022	
4Q 2023 annual review: no significant changes; references reviewed and updated.	10/2023	