Clinical Policy: Belinostat (Beleodaq)

Reference Number: PA.CP.PHAR.311
Effective Date: 01/18
Last Review Date: 10/30/2019

Coding Implications
Revision Log

Description
The intent of the criteria is to ensure that patients follow selection elements established by Pennsylvania Health and Wellness ® clinical policy for belinostat for injection (Beleodaq®).

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

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

I. Initial Approval Criteria

A. Peripheral T-Cell Lymphoma:

1. Diagnosis of PTCL;
2. Prescribed by or in consultation with an oncologist or hematologist;
3. 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 conditions:
   a. Mycosis Fungoides or Sézary Syndrome;
   b. Primary cutaneous anaplastic large cell lymphoma (ALCL) with multifocal lesions, or cutaneous ALCL with regional nodes;
   c. Adult T-cell leukemia/lymphoma;
2. Prescribed by or in consultation with an oncologist or hematologist;
3. 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

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

II. Continued Approval

A. Peripheral T-Cell Lymphoma (must meet all)**:**

1. Currently receiving medication via Pennsylvania Health and 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 Pennsylvania Health and 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

Background

Description/Mechanism of Action:
Beleodaq 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).

Formulations:
Beleodaq (belinostat) for injection is supplied in single vial cartons; each 30 mL clear vial contains sterile, lyophilized powder, for reconstitution, equivalent to 500 mg belinostat.

Appendices

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
Not applicable

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.	07/18	
4Q 2019 annual review: No changes per Statewide PDL implementation 01-01-2020	10/30/19	

References

1. Beleodaq Prescribing Information. Irvine, CA: Spectrum Pharmaceuticals, Inc.; April 2017. Available at: http://www.beleodaq.com/downloads/Beleodaq_PI.pdf. Accessed July 19, 2018.
2. Belinostat. In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed July 19, 2018.