I. **Medication Description**

Beleodaq (belinostat) is a histone deacetylase (HDAC) inhibitor. Overexpression of HDACs or an abnormal recruitment of HDACs to oncogenic transcription factors is present in some cancer cells. This allows the cells to grow without inhibition from the immune system. HDAC inhibitors have been shown to activate differentiation, allowing the patient’s own immune system to recognize and attack cancer cells, inhibit the cell cycle, and suppress tumor angiogenesis.

II. **Position Statement**

Coverage is determined through a prior authorization process with supporting clinical documentation for every request.

III. **Policy**

Coverage of Beleodaq is available when the following criteria have been met:

- Member is at least 18 years of age **AND**
- The medication is prescribed by a hematologist/oncologist **AND**
- The requested use is supported by the National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines (NCCN Guidelines®) and/or NCCN Drugs & Biologics Compendium (NCCN Compendium®) with a recommendation of category level 1 or 2A.

IV. **Quantity Limitations**

- Coverage is available for up to 1000mg/m2 on days 1-5 per 21 day cycle.
- Other dosages may be considered if supported by current NCCN guidelines and FDA-approved prescribing information.

V. **Coverage Duration**

Coverage is granted for 6 months and may be renewed.

VI. **Coverage Renewal Criteria**

Coverage can be renewed based upon the following criteria:

- Stabilization of disease or in absence of disease progression **AND**
- Absence of unacceptable toxicity from the drug
VII. **Billing/Coding Information**

- Available as 500 mg vials
- J9032: 1 unit = 10mg
- Pertinent indications:
  - Adult T-cell leukemia/lymphoma: C91.50, C91.52
  - MF/SS: C84.00-C84.09
  - Peripheral T-cell Lymphoma: C84.40-C84.49, C84.60-C84.79, C86.2, C86.5, Z85.72, C84.90-C84.99, C84.Z0-C84.Z9, C86.0, C86.1
  - Primary cutaneous CD30+ T-Cell Lymphoproliferative Disorders: C86.6, Z85.72

VIII. **Summary of Policy Changes**

- 1/1/15: new policy
- 6/15/15: updated policy to comply with current NCCN recommendations
- 7/1/15: formulary distinctions made
- 1/1/16: drug code updated
- 6/15/16: updated coverage to coincide with current NCCN treatment guidelines; included age requirement
- 4/5/17: no policy changes
- 5/1/18: coverage criteria updated to allow use as supported by current NCCN guidelines
- 5/15/19: updated billing/coding

IX. **References**


*These guidelines are not applicable to benefits covered under Medicare Advantage. Medicare Advantage benefit coverage requests are reviewed in accordance with the guidance set forth in Chapter 15 Section S0 of the Centers for Medicare & Medicaid Services Medicare Benefit Policy Manual.

The Plan fully expects that only appropriate and medically necessary services will be rendered. The Plan reserves the right to conduct pre-payment and post-payment reviews to assess the medical appropriateness of the above-referenced therapies.

Drug therapy initiated with samples will not be considered as meeting medical necessity for coverage for non-preferred or prior authorized medications. The preceding policy is a guideline to allow for coverage of the pertinent medication/product, and is not meant to serve as a clinical practice guideline.