Beleodaq

**Description**

Beleodaq (belinostat)

**Background**

Beleodaq is used in the treatment of peripheral T-cell lymphoma in patients with cancer that comes back or does not respond to other cancer treatment. T-cell lymphoma occurs when T-cells of the immune system called lymphocytes, a type white blood cell, grow uncontrollably. These cancerous cells then travel to other parts of the body and form masses called tumors. Beleodaq helps inhibit the growth of affected cells and often leads to death of the cancer cells (1).

**Regulatory Status**

FDA-approved indications: Beleodaq is a histone deacetylase inhibitor 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 (1).

Recommended dosage of Beleodaq is 1,000 mg/m² administered over 30 minutes by intravenous infusion once daily on days 1-5 of a 21-day cycle. Cycles can be repeated until disease progression or unacceptable toxicity. Beleodaq treatment discontinuation or interruption with or without dosage reductions by 25% may be needed to manage adverse reactions (1).

Beleodaq can cause thrombocytopenia, leukopenia (neutropenia and lymphopenia), and/or anemia. Physicians are cautioned to monitor blood counts weekly during treatment in order to
determine whether dosage modification is necessary. Absolute neutrophil count (ANC) should be greater than or equal to 1.0 x 10⁹/L and the platelet count should be greater than or equal to 50 x 10⁹/L prior to the start of each cycle. Beleodaq should be discontinued in patients who have recurrent ANC nadirs less than 0.5 x 10⁹/L and/or recurrent platelet count nadirs less than 25 x 10⁹/L after two dosage reductions (1).

Beleodaq can cause hepatotoxicity therefore the physician is cautioned to monitor liver function tests before treatment and at the start of each cycle in order to omit or modify dosage based on his or her medical judgment. (1).

Serious and sometimes fatal infections, including pneumonia and sepsis, have occurred with Beleodaq. Beleodaq should not be administered to patients with an active infection (1).

The safety and effectiveness of Beleodaq in pediatric patients under the age of 18 have not been established (1).

Related policies
Istodax, Zolinza

Policy
This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Beleodaq may be considered medically necessary in patients 18 years of age or older with relapsed or refractory peripheral T-cell lymphoma (PTCL) and if the conditions indicated below are met.

Beleodaq is considered investigational in patients less than 18 years of age and for all other indications.

Prior-Approval Requirements

Age
18 years of age or older

Diagnosis

Patient must have the following:

Relapsed or refractory peripheral T-cell lymphoma (PTCL)
Prior – Approval *Renewal Requirements*

**Diagnosis**

**Age**

18 years of age or older

Patient must have the following:

- Relapsed or refractory peripheral T-cell lymphoma (PTCL)
- AND ALL of the following:
  1. NO disease progression
  2. NO unacceptable toxicity from prior Beleodaq treatment

**Policy Guidelines**

**Pre - PA Allowance**

None

**Prior - Approval Limits**

**Duration**

12 months

**Prior – Approval *Renewal Limits***

**Duration**

12 months

**Rationale**

**Summary**

Beleodaq is used in the treatment of peripheral T-cell lymphoma in patients with cancer that comes back or does not respond to other cancer treatment. Beleodaq helps inhibit the growth of affected cells and often leads to death of the cancer cells (1).

Prior approval is required to ensure the safe, clinically appropriate and cost effective use of Beleodaq while maintaining optimal therapeutic outcomes.

**References**

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 20, 2019 and is effective on July 1, 2019.