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5.21.048

Section:	Prescription Drugs	**Effective Date:**	April 1, 2024
Subsection:	Antineoplastic Agents	**Original Policy Date:**	August 22, 2014
Subject:	Beleodaq	**Page:**	1 of 4

Last Review Date: March 8, 2024

Beleodaq

Description

Beleodaq (belinostat)

Background
Beleodaq (belinostat) is used in the treatment of relapsed or refractory peripheral T-cell lymphoma (PTCL). Beleodaq is a histone deacetylase (HDAC) inhibitor which catalyzes acetyl group removal from protein lysine residues (of histone and some nonhistone proteins). Inhibition of histone deacetylase results in accumulation of acetyl groups, leading to cell cycle arrest and apoptosis (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/m^2 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 10^9/L and the platelet count should be greater than or equal to 50 x 10^9/L prior to the start of each cycle and prior to resuming treatment following toxicity. Beleodaq should be discontinued in patients who have recurrent ANC nadirs less than 0.5 x 10^9/L and/or recurrent platelet count nadirs less than 25 x 10^9/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. Patients with advanced stage disease and/or high tumor burden should be monitored for tumor lysis syndrome (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 less than 18 years of age 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** if the conditions indicated below are met.

Beleodaq may be considered **investigational** 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

Age 18 years of age or older

Diagnosis

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

Same as above

Rationale

Summary

Beleodaq (belinostat) is used in the treatment of relapsed or refractory peripheral T-cell lymphoma (PTCL). Beleodaq is a histone deacetylase (HDAC) inhibitor which catalyzes acetyl group removal from protein lysine residues (of histone and some nonhistone proteins). Inhibition of histone deacetylase results in accumulation of acetyl groups, leading to cell cycle arrest and apoptosis. Beleodaq can cause thrombocytopenia, leukopenia (neutropenia and lymphopenia), and/or anemia. Physicians are cautioned to monitor blood counts weekly during treatment. Beleodaq can cause hepatotoxicity therefore the physician is cautioned to monitor liver function tests before treatment and at the start of each cycle. Serious and sometimes fatal infections, including pneumonia and sepsis, have occurred with Beleodaq.

Beleodaq should not be administered to patients with an active infection. The safety and effectiveness of Beleodaq in pediatric patients less than 18 years of age have not been established (1).

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

References

1. Beleodaq [package insert]. East Windsor, NJ: Acrotech Biopharma LLC; May 2023.
2. NCCN Drugs & Biologics Compendium® Belinostat 2024. National Comprehensive Cancer Network, Inc. Accessed on January 19, 2024.

Policy History

Date	Action
August 2014	Addition to PA
September 2014	Annual review and update
December 2014	Annual review and update
December 2015	Annual review
June 2016	Annual review and reference update Policy code changed from 5.04.48 to 5.21.48
June 2017	Annual editorial review
June 2018	Annual editorial review and reference update
June 2019	Annual review
June 2020	Annual review and reference update
March 2021	Annual editorial review
March 2022	Annual review and reference update
March 2023	Annual review and reference update. Changed policy number to 5.21.048
March 2024	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 8, 2024 and is effective on April 1, 2024.