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# 5.21.015

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| **Section:** | Prescription Drugs | **Effective Date:** | April 1, 2024 |
| **Subsection:** | Antineoplastic Agents | **Original Policy Date:** | September 8, 2011 |
| **Subject:** | Zolinza | **Page:** | 1 of 4 |

***Last Review Date:*** March 8, 2024

# Zolinza

## Description

### Zolinza (vorinostat)

**Background**
Zolinza is a histone deacetylase inhibitor approved in the treatment of cutaneous manifestations in patients with cutaneous T-cell lymphoma. Cutaneous T-cell lymphomas (CTCLs) are the largest group of cutaneous lymphomas, with mycosis fungoides (MF) and Sézary syndrome representing ~60% and ~5% of CTCL cases, respectively. A group of non-Hodgkin's lymphomas (1, 5), MF is characterized by primary cutaneous involvement, whereas Sézary syndrome is characterized by significant blood and lymph node involvement. Initial treatment for patients with patch/plaque disease consists of skin-directed therapies (e.g., topical corticosteroids) with the addition of systemic therapy for refractory or progressive disease (1-2).

**Regulatory Status**
FDA-approved indication: Zolinza is indicated for the treatment of cutaneous manifestations in patients with cutaneous T cell lymphoma (CTCL) who have progressive, persistent or recurrent disease on or following two systemic therapies (3).

The drug has the potential for serious side effects, including pulmonary embolism, deep vein thrombosis, and gastrointestinal disturbances. Zolinza may cause dose-related thrombocytopenia and anemia, which could require dose reduction or discontinuation. Patients receiving Zolinza may experience hyperglycemia, especially patients with diabetes. Zolinza requires careful monitoring of blood cell counts, electrolytes, glucose and serum creatinine. Testing should be repeated every two weeks during the first two months of therapy and monthly thereafter. Baseline and periodic ECG are also recommended since QT prolongation has been observed. Hypokalemia and hypomagnesemia should be corrected prior to starting Zolinza. It is

important that adequate hydration be maintained during treatment. Any pre-existing nausea, vomiting and diarrhea should be adequately controlled before implementation of therapy (3-4).

The safety and effectiveness of Zolinza has not been established in patients less than 18 years of age (3).

**Related policies**
Beleodaq, Istodax

## Policy

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

Zolinza may be considered **medically necessary** if the conditions indicated below are met.

Zolinza may be considered **investigational** for all other indications.

## Prior-Approval Requirements

**Age** 18 years of age or older

**Diagnosis**

Patient must have the following:

Cutaneous T-Cell Lymphoma (CTCL)

**AND ALL** of the following:

1. Previous or concurrent treatment with two **systemic** therapies
2. Baseline ECG, blood cell counts, electrolytes, serum glucose and serum creatinine
3. Able to maintain adequate hydration (at least 2 L/day)

## Prior-Approval *Renewal* Requirements

Same as above

## Policy Guidelines

## Pre – PA Allowance
None

## Prior - Approval Limits

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|---|---|---|
| **Quantity** | 100 mg | 360 capsules per 90 days |
| **Duration** | 12 months | |

## Prior – Approval *Renewal* Limits
Same as above

## Rationale

**Summary**
Zolinza (vorinostat) is considered medically necessary for the treatment of cutaneous T-cell lymphoma (CTCL) in patients who have progressive, persistent or recurrent disease during or following treatment with two systemic therapies. The drug has the potential for serious side effects, including pulmonary embolism, deep vein thrombosis, gastrointestinal disturbances, hyperglycemia, hypokalemia, hypomagnesemia, and dose-related thrombocytopenia and anemia, which could require dose reduction or discontinuation. Zolinza requires careful monitoring of blood cell counts, electrolytes, glucose, and serum creatinine. Testing should be repeated every two weeks during the first two months of therapy and monthly thereafter. It is important that adequate hydration be maintained during treatment (1-4).

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

**References**
1. Willemze R, Jaffe ES, Burg G, et al. WHO-EORTC classification for cutaneous lymphomas. Blood. May 2005; 105(10):3768-85.
2. Jaffe ES, Krenacs L, Raffeld M. Classification of cytotoxic T-cell and natural killer cell lymphomas. Semin Hematol. 2003; 40(3):175-84.
3. Zolinza [package insert]. Whitehouse Station, NJ: Merck & Co., Inc.; July 2022.
4. NCCN Drugs & Biologics Compendium® Vorinostat 2024. National Comprehensive Cancer Network, Inc. Accessed on January 24, 2024.

## Policy History

| Date | Action |
|---|---|
| September 2011 | New Policy |
| September 2012 | Annual editorial and reference update |
| March 2013 | Annual editorial and reference update |
| March 2014 | Annual review and reference update. Addition of baseline serum creatinine levels. |
| December 2014 | Annual editorial review and reference update |
| December 2015 | Annual editorial review |
| June 2016 | Annual review and reference update<br>Policy number changed from 5.04.15 to 5.21.15 |
| June 2017 | Annual review and reference update |
| June 2018 | Annual editorial review and reference update<br>Addition of quantity limits to criteria |
| June 2019 | Annual review and reference update |
| June 2020 | Annual review and reference update |
| December 2021 | Annual review and reference update |
| December 2022 | Annual review and reference update. Changed policy number to 5.21.015 |
| March 2023 | Annual review and reference update |
| 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.**