

---

# 5.21.015

---

<b>Section:</b>	Prescription Drugs	<b>Effective Date:</b>	April 1, 2025
<b>Subsection:</b>	Antineoplastic Agents	<b>Original Policy Date:</b>	September 8, 2011
<b>Subject:</b>	Zolinza	<b>Page:</b>	1 of 4

---

**Last Review Date:** March 7, 2025

---

## 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

---

<b>Section:</b>	Prescription Drugs	<b>Effective Date:</b>	April 1, 2025
<b>Subsection:</b>	Antineoplastic Agents	<b>Original Policy Date:</b>	September 8, 2011
<b>Subject:</b>	Zolinza	<b>Page:</b>	2 of 4

---

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

---

<b>Section:</b>	Prescription Drugs	<b>Effective Date:</b>	April 1, 2025
<b>Subsection:</b>	Antineoplastic Agents	<b>Original Policy Date:</b>	September 8, 2011
<b>Subject:</b>	Zolinza	<b>Page:</b>	3 of 4

---

## Pre – PA Allowance

None

## Prior - Approval Limits

<b>Quantity</b>	100 mg	360 capsules per 90 days
<b>Duration</b>	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<sup>®</sup> Vorinostat 2025. National Comprehensive Cancer Network, Inc. Accessed on January 14, 2025.

## Policy History

# 5.21.015

---

<b>Section:</b>	Prescription Drugs	<b>Effective Date:</b>	April 1, 2025
<b>Subsection:</b>	Antineoplastic Agents	<b>Original Policy Date:</b>	September 8, 2011
<b>Subject:</b>	Zolozinza	<b>Page:</b>	4 of 4

---

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 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 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
March 2025	Annual review and reference update

## Keywords

---

**This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 7, 2025 and is effective on April 1, 2025.**