UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 1329-7
Program	Prior Authorization/Notification
Medication	Zolinza® (vorinostat)
P&T Approval Date	9/2020, 9/2021, 10/2021, 10/2022, 10/2023, 10/2024, 10/2025
Effective Date	1/1/2026

1. Background:

Zolinza® (vorinostat) is a histone deacetylase (HDAC) inhibitor 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. The National Cancer Comprehensive Network (NCCN) also recommends the use of Zolinza as a systemic therapy as primary treatment or subsequent for cutaneous T-cell lymphoma (CTCL), Classic Hodgkin Lymphoma.

Coverage Information:

Members will be required to meet the criteria below for coverage. For members under the age of 19 years, the prescription will automatically process without a coverage review.

Some states mandate benefit coverage for off-label use of medications for some diagnoses or under some circumstances. Some states also mandate usage of other Compendium references. Where such mandates apply, they supersede language in the benefit document or in the notification criteria.

2. Coverage Criteria[a]:

A. Patients less than 19 years of age

1. **Zolinza** will be approved based on the following criterion:

   a. Patient is less than 19 years of age

   Authorization will be issued for 12 months.

B. Cutaneous T-cell Lymphoma (CTCL)

1. Initial Authorization

a. **Zolinza** will be approved based on **both** of the following criteria:

(1) Diagnosis of cutaneous T-cell Lymphoma (CTCL) [e.g., mycosis fungoides (MF) or Sezary syndrome)

-AND-

(2) **One** of the following:

(a) Used as primary treatment in **one** of the following settings:

i. Stage IB – IIA
ii. Stage IIB with limited tumor lesions
iii. Stage IIB with generalized tumor lesions, in combination with skin-directed therapy (e.g., phototherapy, topical corticosteroids, topical imiquimod)
iv. Stage III, in combination with skin-directed therapy (e.g., phototherapy, topical corticosteroids, topical imiquimod)
v. Stage IVA1 or IVA2 Sezary syndrome, in combination with skin-directed therapy (e.g., phototherapy, topical corticosteroids, topical imiquimod)

-OR-

(b) Used as subsequent treatment in progressive, persistent, or recurrent disease

Authorization will be issued for 12 months.

2. Reauthorization

a. **Zolinza** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Zolinza therapy

Authorization will be issued for 12 months.

C. Classic Hodgkin Lymphoma

1. Initial Authorization

a. **Zolinza** will be approved based on **all** of the following criteria:

(1) Diagnosis of Classic Hodgkin Lymphoma

-AND-

(2) Disease is refractory to at least 3 prior lines of subsequent therapy (e.g., rituximab, doxorubicin, cyclophosphamide, ifosfamide, carboplatin, etoposide, etc.)

-AND-

(3) Used in combination with Keytruda (pembrolizumab)

Authorization will be issued for 12 months.

2. Reauthorization

a. **Zolinza** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Zolinza therapy

Authorization will be issued for 12 months.

D. NCCN Recommended Regimens

The drug has been recognized for treatment of the cancer indication by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Zolinza [package insert]. Whitehouse Station, NJ: Merck & Co, Inc; July 2022.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed September 5, 2025.

Program	Prior Authorization/Notification – Zolinza® (vorinostat)
Change Control	
9/2020	New program.
9/2021	Annual review with no changes to coverage criteria. Updated references.
10/2021	Updated criteria to align with label. Updated references.
10/2022	Annual review with no changes to coverage criteria. Added state mandate footnote. Updated references.
10/2023	Annual review with no changes to coverage criteria. Updated references.
10/2024	Annual review with no changes to coverage criteria. Updated background and references.
10/2025	Annual review. Updated coverage criteria for cutaneous t-cell lymphoma per NCCN recommendation. Added new criteria for Classic Hodgkin Lymphoma per NCCN recommendation.