

Clinical Pharmacy Program Guidelines for Zolinza

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| Program | Prior Authorization |
| Medication | Zolinza® (vorinostat) |
| Markets in Scope | Arizona, California, Colorado, Hawaii, Maryland, Nevada, New York, New York EPP, Rhode Island, Pennsylvania- CHIP, New Jersey, South Carolina |
| Issue Date | 12/2014 |
| Pharmacy and Therapeutics Approval Date | 12/2020 |
| Effective Date | 1/2021 |

1. Background:

Zolinza 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.¹ The National Cancer Comprehensive Network (NCCN) also recommends the use of Zolinza as a systemic therapy as primary treatment for cutaneous T-cell lymphoma (CTCL).²

2. Coverage Criteria:

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| <p>A. <u>T-Cell Lymphoma</u></p> <p>1. <u>Initial Authorization</u></p> <p>a. Diagnosis of cutaneous T-cell lymphoma</p> <p>Authorization will be issued for 12 months.</p> <p>2. <u>Reauthorization</u></p> <p>a. Patient does not show evidence of progressive disease while on Zolinza therapy</p> <p>Authorization will be issued for 12 months.</p> <p>B. <u>NCCN Recommended Regimens</u></p> |
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1. Initial Authorization

a. **Zolinza** will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium.

Authorization will be issued for 12 months.

2. Reauthorization

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

(1) Documentation of positive clinical response to Zolinza therapy

Authorization will be issued for 12 months.

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., January 2020.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed August 5, 2020.

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| Program | Prior Authorization - Zolinza (vorinostat) |
| Change Control | |
| Date | Change |
| 12/2014 | New policy |
| 11/2016 | Annual review; updated policy template and added reauthorization criteria |
| 11/2017 | Annual review. Updated references. |
| 11/2018 | Annual review. Added NCCN Recommended Regimen review criteria. Updated references. |
| 11/2019 | Annual review. Added examples of systemic therapies. Updated background and references. |

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| 12/2020 | Annual review. Updated Coverage Criteria per NCCN recommendation. Updated references. Added Additional Clinical Rules section. |
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