Pharmacy Policy Bulletin: J-0107 Zolinza (vorinostat) - Commercial and		
Healthcare Reform		
Number: J-01		Category: Prior Authorization
Line(s) of Business:		Benefit(s):
□ Commercial		Commercial:
		Prior Authorization (1.):
☐ Medicare		 Miscellaneous Specialty Drugs Oral =
		Yes w/ Prior Authorization
		Healthcare Reform: Not Applicable
Region(s):		Additional Restriction(s):
⊠ AII		None
☐ Delaware		
☐ New York		
☐ Pennsylvania		
☐ West Virginia		
Version: J-0107-020		Original Date: 12/06/2006
Effective Date: 10/28/2024		Review Date: 10/02/2024
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Drugs	Zolinza (vorinostat)	
Drugs Product(s):	Zolinza (vorinostat)	
Product(s): FDA-	Treatment of cutaneous	manifestations in patients with cutaneous T-cell
Product(s): FDA- Approved	Treatment of cutaneous lymphoma (CTCL) who	have progressive, persistent, or recurrent disease on or
Product(s): FDA-	Treatment of cutaneous	have progressive, persistent, or recurrent disease on or
Product(s): FDA- Approved Indication(s):	Treatment of cutaneous lymphoma (CTCL) who following two systemic the company of the cutaneous systemic sys	have progressive, persistent, or recurrent disease on or nerapies.
Product(s): FDA- Approved	Treatment of cutaneous lymphoma (CTCL) who following two systemic the Zolinza inhibits the enzy Zolinza inhibits the enzy	have progressive, persistent, or recurrent disease on or nerapies. matic activity of histone deacetylases (HDAC) HDAC1,
Product(s): FDA- Approved Indication(s):	 Treatment of cutaneous lymphoma (CTCL) who following two systemic the systemic than the system of the	have progressive, persistent, or recurrent disease on or nerapies. matic activity of histone deacetylases (HDAC) HDAC1, I), and HDAC6 (Class II). In some cancer cells there is DACs or an aberrant recruitment of HDACs to oncogenic
Product(s): FDA- Approved Indication(s):	Treatment of cutaneous lymphoma (CTCL) who following two systemic the Zolinza inhibits the enzy HDAC2, HDAC3 (Class an overexpression of HE transcription factors. HD	have progressive, persistent, or recurrent disease on or nerapies. matic activity of histone deacetylases (HDAC) HDAC1, I), and HDAC6 (Class II). In some cancer cells there is DACs or an aberrant recruitment of HDACs to oncogenic ACs are involved in remodeling of chromatin, regulating
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Approval Criteria

The safety and effectiveness of Zolinza have not been established in

I. Initial Authorization

When a benefit, coverage Zolinza may be approved when all of the following criteria are met (A., B., and C.):

- **A.** The member is 18 years of age or older.
- B. The member is being treated for cutaneous manifestations of CTCL (ICD-10: C84.A).

oncologist/hematologist.

pediatric patients.

C. The member has progressive, persistent, or recurrent disease on or following two (2) systemic therapies (e.g., bexarotene (Targretin), interferon-α, extracorporeal photochemotherapy, PUVA, single agent or combination chemotherapies).

II. Reauthorization

When a benefit, reauthorization of Zolinza may be approved when the following criterion is met (A.):

- **A.** The prescriber attests that the member is tolerating therapy and has experienced a therapeutic response defined as one (1) of the following **(1. or 2.)**:
 - 1. Disease improvement
 - 2. Delayed disease progression
- **III.** An exception to some or all of the criteria above may be granted for select members and/or circumstances based on state and/or federal regulations.
- **IV.** Coverage of oncology drug(s) listed in this policy may be approved on a case-by-case basis per indications supported in the most current NCCN guidelines.

Limitations of Coverage

- I. Coverage of drug(s) addressed in this policy for disease states outside of the FDA-approved indications should be denied based on the lack of clinical data to support effectiveness and safety in other conditions unless otherwise noted in the approval criteria.
- **II.** For Commercial or HCR members with a closed formulary, a non-formulary product will only be approved if the member meets the criteria for a formulary exception in addition to the criteria outlined within this policy.

Authorization Duration

Commercial and HCR Plans: If approved, up to a 12 month authorization may be granted.

Automatic Approval Criteria

None

References:

- 1. Zolinza [package insert]. Whitehouse Station, NJ: Merck & Co., Inc.: December 2018.
- NCCN Guidelines. Primary Cutaneous Lymphomas. v.2.2024. National Comprehensive Cancer Network. Available at:
 - https://www.nccn.org/professionals/physician_gls/pdf/primary_cutaneous.pdf. Accessed August 8, 2024.

Pharmacy policies do not constitute medical advice, nor are they intended to govern physicians' prescribing or the practice of medicine. They are intended to reflect the plan's coverage and reimbursement guidelines. Coverage may vary for individual members, based on the terms of the benefit contract.

The plan retains the right to review and update its pharmacy policy at its sole discretion. These guidelines are the proprietary information of the plan. Any sale, copying or dissemination of the pharmacy policies is prohibited; however, limited copying of pharmacy policies is permitted for individual use.