Pharmacy Policy Bulletin: J-0107 Zolinza (vorinostat) - Commercial and Healthcare Reform	
Number: J-0107	**Category:** Prior Authorization
Line(s) of Business: ☒ Commercial ☒ Healthcare Reform ☐ Medicare	**Benefit(s):** **Commercial:** **Prior Authorization (1.):** **1.** Miscellaneous Specialty Drugs Oral = Yes w/ Prior Authorization **Healthcare Reform:** Not Applicable
Region(s): ☒ All ☐ Delaware ☐ New York ☐ Pennsylvania ☐ West Virginia	**Additional Restriction(s):** None
Version: J-0107-020	**Original Date:** 12/06/2006
Effective Date: 10/28/2024	**Review Date:** 10/02/2024

Drugs Product(s):	• Zolinza (vorinostat)
FDA-Approved Indication(s):	• 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.

Background:	• Zolinza inhibits the enzymatic activity of histone deacetylases (HDAC) HDAC1, HDAC2, HDAC3 (Class I), and HDAC6 (Class II). In some cancer cells there is an overexpression of HDACs or an aberrant recruitment of HDACs to oncogenic transcription factors. HDACs are involved in remodeling of chromatin, regulating gene expression without altering DNA sequence. Histone deacetylation is believed to be a key mechanism by which cancer cells inactivate tumor-suppressor genes resulting in uncontrolled proliferation of tumor cells.
	• Prescribing Considerations
	  ○ Zolinza should be prescribed under the supervision of an oncologist/hematologist.
	  ○ The safety and effectiveness of Zolinza have not been established in pediatric patients.

Approval Criteria

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).

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.
2. 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.