RXADVANCE
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Clinical Policy Title:	vorinostat
Policy Number:	RxA.578
Drug(s) Applied:	Zolinza®
Original Policy Date:	03/06/2020
Last Review Date:	12/07/2020
Line of Business Policy Applies to:	All lines of business

Background

Vorinostat (Zolinza®) is a histone deacetylase (HDAC) inhibitor. It 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.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
vorinostat (Zolinza®)	CTCL	400 mg PO once daily. If patient is intolerant to therapy, reduce the dose to 300 mg orally once daily. If necessary, reduce the dose further to 300 mg once daily for 5 consecutive days each week.	400 mg/day

Dosage Forms

- Capsules: 100 mg

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

I. Initial Approval Criteria

A. Cutaneous T-Cell Lymphoma (must meet all)**:**

1. Diagnosis of CTCL;
2. Prescribed by or in consultation with an oncologist;
3. Age 18 years of age or older;
4. Dose does not exceed 400 mg (4 capsules) per day.

Approval duration
Commercial: 6 months
Medicaid: 6 months

II. Continued Therapy Approval

A. Cutaneous T-Cell Lymphoma (must meet all)**:**

1. Currently receiving medication that has been authorized by RxAdvance, or documentation supports that member is currently receiving Zolinza for CTCL and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 400 mg (4 capsules) per day.

Approval duration
Commercial: 12 months
Medicaid: 12 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key

- CTCL: Cutaneous T-cell lymphoma
- FDA: Food and Drug Administration
- HDAC: Histone Deacetylase

APPENDIX B: Therapeutic Alternatives

- Not applicable

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APPENDIX C: Contraindications/Boxed Warnings

- None reported

APPENDIX D: General Information

World Health Organization-European Organization for Research and Treatment of Cancer Classification of CTCL* with Primary Cutaneous Manifestations:

- Mycosis fungoides (MF)
  - MF variants and subtypes
    - Folliculotropic MF
    - Pagetoid reticulosis
    - Granulomatous slack skin
- Sezary syndrome (SS)
- Adult T-cell leukemia/lymphoma (ATLL)
- Primary cutaneous CD30+ lymphoproliferative disorders
  - Primary cutaneous anaplastic large cell lymphoma (ALCL)
  - Lymphomatoid papulosis
- Subcutaneous panniculitis-like T-cell lymphoma
- Extranodal NK**/T-cell lymphoma, nasal type
- Primary cutaneous peripheral T-cell lymphoma, unspecified (PTCL-NOS)
  - Primary cutaneous aggressive epidermotropic CD8+ T-cell lymphoma
  - Cutaneous ϒ/δ (gamma/delta) T-cell lymphoma
  - Primary cutaneous CD4+ small/medium-sized pleomorphic T-cell lymphoma

**Non-Hodgkin's lymphomas (NHLs) include lymphoproliferative disorders originating in B-lymphocytes, T-lymphocytes, and natural killer cells. Cutaneous T-cell lymphomas (CTCLs) are a subset of NHLs characterized by skin involvement and the potential to progress to lymph nodes, blood, and visceral organs. Mycosis fungoides, the most common CTCL, is an extranodal NHL of mature T-cells with primary skin involvement. Sezary syndrome, a less common CTCL, is characterized by significant blood involvement and lymphadenopathy.*

***Extranodal NK-cell lymphoma is considered a CTCL subtype under the policy criteria.*

References

1. Zolinza Prescribing Information. Whitehouse Station, NJ: Merck and Company, Inc.; January 2020. Available from http://www.merck.com/product/usa/pi_circulars/z/zolinza/zolinza_pi.pdf. Accessed October 1, 2020.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed October 1, 2020.
3. National Comprehensive Cancer Network. Primary Cutaneous Version 2.2019. Available at: http://www.nccn.org. Accessed October 1, 2020.
4. National Comprehensive Cancer Network. T-Cell Lymphomas Version 2.2019. Available at: http://www.nccn.org. Accessed October 1, 2020.
5. Willemze R, Jaffe ES, Burg G, et al. WHO-EORTC classification for cutaneous lymphomas. Blood. May 2005; 105(10): 3768-85.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	01/2020	03/06/2020
Policy was reviewed: 1. Clinical Policy Title Table was updated. 2. Drug(s) Applied was updated. 3. Line of Business Policy Applies to was update to all lines of business. 4. Dosing information was updated to include the information for dose reduction. 5. Continued Therapy criteria II.A.1 was rephrased to "Currently receiving medication that has been authorized by RxAdvance..." 6. Initial Approval criteria: Commercial and Medicaid approval duration were updated from length of benefit to 6 months. 7. Continued Approval criteria: Commercial and Medicaid approval duration were updated from length of benefit to 12 months. 8. References were updated.	10/01/2020	12/07/2020