ROCKY MOUNTAIN HEALTH PLANS®
We understand Colorado. We understand you.

UNIFORM PHARMACY PRIOR AUTHORIZATION REQUEST FORM

CONTAINS CONFIDENTIAL PATIENT INFORMATION

Complete this form in its entirety and send to Rocky Mountain Health Plans at 858-357-2538

☐ **Initial Request** ☐ **Renewal** ☐ **Appeal/Redetermination**[1]

☐ **Urgent**[2] ☐ **Non-Urgent**

Requested Drug Name: Zolinza® (vorinostat) – Medicare Part D

Patient Information:	**Prescribing Provider Information:**
Patient Name:	Prescriber Name:
Member/Subscriber Number:	Prescriber Fax:
Policy/Group Number:	Prescriber Phone:
Patient Date of Birth (MM/DD/YYYY):	Prescriber Pager:
Patient Address:	Prescriber Address:
Patient Phone:	Prescriber Office Contact:
Patient Email Address:	Prescriber NPI:
	Prescriber DEA:
Prescription Date:	Prescriber Tax ID:
	Specialty/Facility Name (If applicable):
	Prescriber Email Address:

Prior Authorization Request for Drug Benefit:

Patient Diagnosis and ICD Diagnostic Code(s):

Drug(s) Requested (with J-Code, if applicable):

Strength/Route/Frequency:

Unit/Volume of Named Drug(s):

Start Date and Length of Therapy:

Location of Treatment: (e.g. provider office, facility, home health, etc.) including name, Type 2 NPI (if applicable), address and tax ID:

Clinical Criteria for Approval, Including other Pertinent Information to Support the Request, other Medications Tried, Their Name(s), Duration, and Patient Response:

Zolinza® (vorinostat)

Diagnosis (documentation supportive of diagnosis is required)

☐ Cutaneous T Cell Lymphoma (CTCL) **CTCL Type:** _____

☐ Other (please state): _____

Clinical Consideration (for approval, please indicate and provide documentation of the following):

☐ ≥ 2 Prior Systemic Therapies for CTCL ***(approval requires 2 prior systemic therapies.***
Examples: **Targretin, Ontak, Campath, interferon alpha, various chemotherapy regimens)**

Specific Therapies Used:

1. _____

2. _____

3. _____

Physician Specialty

☐ Oncology

☐ Other (please state):_____

☐ For use in clinical trial? (If yes, provide trial name and registration number):

Drug Name (Brand Name and Scientific Name)/Strength:

Dose:	Route:	Frequency:
Quantity:	Number of Refills:	

Product will be delivered to: ☐ Patient's Home ☐Physician Office Other:

Prescriber or Authorized Signature: Date:

Dispensing Pharmacy Name and Phone Number:

☐ **Approved** ☐ **Denied**

If denied, provide reason for denial, and include other potential alternative medications, if applicable, that are found in the formulary of the carrier:

1. Appeal/redetermination requests can be made for this medication within 60 calendar days from the date on the faxed/written denial notice you received at the time of the original request.

2. A request for prior authorization that if determined in the time allowed for non-urgent requests could seriously jeopardize the life or health of the covered person or the ability of the covered person to regain maximum function, or subject the person to severe pain that cannot be adequately managed without the drug benefit contained in the prior authorization request.

ZOLINZA® (vorinostat)

CLASSIFICATION

- Antineoplastic Agent

DESCRIPTION

- The antineoplastic mechanism of vorinostat has not been fully characterized.
- Vorinostat is a histone deacetylase (HDAC) inhibitor and inhibits the enzymatic activity of histone deacetylases HDAC1, HDAC2 and HDAC3 (Class I) and HDAC6 (Class II). These enzymes catalyze the removal of acetyl groups from the lysine residues of protein, such as transcription factors and histones. In some cancer cells, there is an overexpression of HDACs or an aberrant recruitment of HDACs to oncogenic transcription factors. Inhibition of HDAC activity allows for the accumulation of acetylated histones, resulting in cell cycle arrest induction or apoptosis of some transformed cells.
- Vorinostat is approved by the FDA for the treatment of cutaneous manifestations in patients with cutaneous T-cell lymphoma who have progressive, persistent, or recurrent disease on or following 2 systemic therapies. Its approval was based on results from 2 single-arm, open-label trials.
- In an open-label, single-arm, multicenter, nonrandomized trial among 74 patients (median age, 61 years) with advanced refractory cutaneous T-cell lymphoma, nearly 30% treated with vorinostat 400 mg daily achieved an objective clinical response for at least 4 weeks. The 82.4% patients had stage IIB and higher cutaneous T-cell lymphoma, and had previously failed a median of 3 prior systemic therapies (range, 1 to 12). Treatment of oral vorinostat 400 mg daily continued until disease progression or intolerable toxicity. The primary efficacy endpoint was measured as either a complete clinical response (i.e., no evidence of disease) or partial response (i.e., 50% or greater decrease in a modified severity weighted assessment tool (SWAT) score from baseline). Twenty-two (29.7%) patients receiving vorinostat achieved overall objective response (95% CI, 19.7 to 41.5%) of whom 18 had stage IIB and higher cutaneous T-cell lymphoma. The median times to response for the overall population and individuals with stage IIB and higher cutaneous T-cell lymphoma was 55 days and 56 days (range, 28 to 171 days), respectively. The estimated median response duration was 168 days and the median time to tumor progression (50% increase in the SWAT score from the nadir) was 202 days. Response to previous systemic therapy was not a response predictor to vorinostat.
- In a phase 2, open-label, single-center, nonrandomized trial (n=33, median age, 67 years), vorinostat provided clinical improvement among previously-treated patients with relapsed or refractory cutaneous T-cell lymphoma. The 85% of patients had stage IIB and higher cutaneous T-cell lymphoma, refractory to or intolerant to prior systemic therapies (median, 5; range, 1 to 15). They were assigned to one of the 3 groups: group 1 received vorinostat 400 mg daily (n=13); group 2 received vorinostat 300 mg twice daily for 3 days with 4 days rest (n=11); and group 3 received vorinostat 300 mg twice daily for 14 days with 7 days rest, followed by 200 mg twice daily (n=9). Treatment continued until disease progression or intolerable toxicity. Oral retinoids, vitamin A or alternative medicines were not allowed. Based on the intent-to-treat analysis, the overall response rates were 31%, 9%, and 33% in group 1, group 2, and group 3, respectively. The objective response rates were 24.2% (8 of 33) in the overall population, 25% (7 of 28) in individuals with stage IIB or higher disease, and 36.4% (4 of 11) in patients with Sezary syndrome. Relative to vorinostat 400 mg once daily, the 300 mg twice daily regimen had higher toxicity and offered no additional clinical benefits (p values not provided).

- The most common adverse reactions (incidence ≥ 20%) are diarrhea, fatigue, nausea, thrombocytopenia, anorexia and dysgeusia.

FORMULARY COVERAGE

Prior authorization: Required
Good Health Formulary: Tier 3
Commercial Formulary: Tier 3
Medicare Part D coverage: Tier 5

COVERAGE CRITERIA

Zolinza® (vorinostat) meets the definition of **medical necessity** for all FDA approved indications not otherwise excluded from Part D including the following:

- Primary cutaneous t-cell lymphoma, progressive, persistent or recurrent on or following 2 systemic therapies. Documentation from the patient's medical record supportive of diagnosis and of prior systemic therapies is required.

Zolinza® (vorinostat) is considered **experimental** for the following:

- Any condition or diagnosis not FDA approved or Compendia supported.

Required Provider Specialty:

- Approval is limited to Oncology Specialist

DOSAGE/ADMINISTRATION

Adult Dosing (safety and efficacy has not been determined for pediatric patients):

PRIMARY CUTANEOUS T-CELL LYMPHOMA, PROGRESSIVE, PERSISTENT OR RECURRENT ON OR FOLLOWING 2 SYSTEMIC THERAPIES:

Normal Dosage: 400 mg orally once daily with food.
Dosage in Hepatic Insufficiency

- For patients with mild to moderate hepatic impairment (bilirubin 1 to 3 times ULN or AST > ULN), reduce the starting dose to 300 mg orally once daily with food.
- For patients with severe hepatic impairment (bilirubin > 3 times ULN), evidence is insufficient to recommend a starting dose; patients with severe hepatic impairment have not been treated at doses greater than 200 mg/day.

Dosage in Other Disease States

- Intolerable Adverse Drug Reactions: If intolerant to therapy, the dose of vorinostat may be reduced to 300 mg orally once daily with food. The dose may be further reduced to 300 mg once daily with food for 5 consecutive days each week, as necessary.

PRECAUTIONS

- Dose-related anemia and thrombocytopenia may occur. Monitoring recommended and dose adjustment or discontinuation of therapy may be necessary. Monitor blood counts every 2 weeks during the first 2 months of therapy and monthly thereafter.
- Severe thrombocytopenia with gastrointestinal bleeding has been reported with concomitant use of Zolinza and other HDAC inhibitors (e.g., valproic acid). Monitor platelet counts more frequently.

- DVT has been reported; monitoring recommended.
- Mild to moderate hepatic impairment: dose adjustment recommended.
- Hyperglycemia: Monitor blood glucose every 2 weeks during the first 2 months of therapy and monthly thereafter.
- Pregnancy (Category D – all trimesters): Fetal harm can occur when administered to a pregnant woman. Women should be apprised of the potential harm to the fetus.
- Pulmonary embolism has been reported; monitoring recommended.
- Gastrointestinal Toxicity: Nausea, vomiting and diarrhea; patients may require antiemetics, antidiarrheals, and fluid and electrolyte replacement to prevent dehydration.
- Clinical chemistry abnormalities: Measure and correct abnormal electrolytes, creatinine, magnesium and calcium at baseline. Monitor every 2 weeks during the first 2 months of therapy and at least monthly during treatment

Billing/Coding information

HCPCS Coding:

J8999	Prescription drug, oral, chemotherapeutic, Not Otherwise Specified

COST

- AWP (March 2011): Zolinza 100mg capsules (#120): $11,185
- AWP (January 2014): Zolinza 100mg capsules (#120): $13,284

COMMITTEE APPROVAL

- January 2007

GUIDELINE UPDATE INFORMATION

January 2007	Prior Authorization created
May 2014	Coverage Policy created

REFERENCES

- DRUGDEX®, accessed 05/05/2014.
- Product Information: Zolinza® (vorinostat), Capsule for oral administration. Merck and CO., Inc., Whitehouse Station, NJ, 4/2013.