



Prior Authorization Approval Criteria
Department of Pharmacy Services

Generic Name: vorinostat

Brand Name: Zolinza

Medication Class: antineoplastic agent

FDA Approved Uses: 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.

Available Dosage Forms: 100mg capsules

Usual Dose: 400mg once daily. If the patient is intolerant to treatment the dose may be reduced to 300mg daily or further reduced to 300mg for 5 consecutive days each week.

Duration of Therapy: Until there is no evidence of progressive disease or unacceptable toxicity.

Approximate monthly cost (based on AWP 2006): \$8640.00

Criteria for Use: *(bullet points below are all inclusive unless otherwise noted)*

- Patient must have a medical oncology consult.
- Clinically diagnosed cutaneous T-cell lymphoma (CTCL).
- Strict diagnostic criteria and demonstration of a T cell clonality or mutation.
- Progressive, persistent or recurrent disease on or following two systemic therapies.
- Approved for 3 months at a time and can receive a 1 month supply at a time.

Criteria for Continuation of Therapy:

- Patient must have a follow up with medical oncology.
- Must have a clinical response* to treatment within 3 to 6 months of beginning treatment.
- Approved for 3 months initially,
 - If a response* is seen, Zolinza will be approved each time for an additional 3 months.
 - If no response** is seen, may be approved for an additional 3 months. Zolinza will not be re-approved if no response** after 6 months of treatment.

*Response- Objective measures for disease activity may include pruritis or decrease plaques or erythema.

**No response-Disabling pruritis and diffuse erythema may warrant a treatment change.

Cautions:

- Pulmonary Embolism and deep vein thrombosis have been reported.
- Dose related thrombocytopenia have occurred and may require dose modification or discontinuation.
- Gastrointestinal disturbances (nausea, vomiting, and diarrhea). Patients may require antiemetics, antidiarrheals and fluid and electrolyte replacement to prevent dehydration.



Monitoring:

- Blood cell counts and chemistry tests, including electrolytes, glucose and serum creatinine, every 2 weeks during the first 2 months of therapy and monthly thereafter.

Contraindications:

- None at this time.

Not Approved if:

- Does not meet the above stated criteria.

Special Considerations:

Until more data are available, use should be reserved for patients with disease progressing or recurring on or following 2 systemic therapies.

-other treatment options:

PUVA

UVB therapy

Radiotherapy

Chemotherapy

Bexarotene

Interferon

Photopheresis

-Clinical trials- 45% BSA involved, mean pruritis score was 8 (0-10)

-Median time to response was about 55 days. Rare cases took up to 6 months.

-Median time to progression was about 5 months.

-Response rates in studies were about 24%-30%.

-Zolinza will be made accessible to patients through Mercks Accessing Coverage Today (ACT) program. Act is a three part program specifically designed to assist patients in obtaining Zolinza, help with insurance reimbursement issues, and provide support for those qualified individuals lacking insurance coverage for Zolinza. To enroll in Act program patients should call 1-866-363-6379.

P&T Approval: _____ Date: _____