

Criteria for Use of Vorinostat in Cutaneous T-cell Lymphoma (CTCL)

VHA Pharmacy Benefits Management-Strategic Healthcare Group and Medical Advisory Panel

The following recommendations are based on current medical evidence and expert opinion from clinicians. The content of the document is dynamic and will be revised as new clinical data becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. The clinician should utilize this guidance and interpret it in the clinical context of individual patient situations.

Refer to the National PBM Drug Monograph for Vorinostat (Zolinza™) at:

Inclusion Criteria	#1
<input type="checkbox"/> Stage histological diagnosis of CTCL with advanced disease documented as Stage IIb or higher including Sézary syndrome. <input type="checkbox"/> Documented contraindication or treatment failure of radiotherapy, total skin electron beam therapy, PUVA, or extracorporeal photopheresis <input type="checkbox"/> Documented current or prior treatment or treatment failure of interferon-alpha and oral bexarotene <input type="checkbox"/> Age > 18 years <input type="checkbox"/> Ability to swallow capsules. <input type="checkbox"/> Adequate hepatic, renal, and hematological function at baseline. <input type="checkbox"/> Prior chemotherapy has been discontinued for at least 3 weeks and the patient has recovered from toxicities of prior therapy; exception in patients with rapidly progressing disease who should be considered for therapy on an individual basis.	<input type="checkbox"/> yes (to all criterion) <input type="checkbox"/> no
Exclusion Criteria	#2
<input type="checkbox"/> Hypersensitivity to vorinostat <input type="checkbox"/> Pregnant women or women intending to become pregnant (Pregnancy Category D) <input type="checkbox"/> Use for other indications (such as for colorectal cancer) or in combination with other chemotherapeutic agents is not recommended at this time due to insufficient evidence	<input type="checkbox"/> yes <input type="checkbox"/> no (to all criterion)
Dosing	
<input type="checkbox"/> Vorinostat is dosed at 400mg orally once daily with food. If necessary, for those intolerant to therapy, the dose can be reduced to 300 mg daily or further to 300 mg for 5 consecutive days each week.	
Monitoring	
<input type="checkbox"/> Severe thrombocytopenia and gastrointestinal bleeding: Reported with concomitant use of vorinostat and other HDAC inhibitors (e.g., valproic acid). Monitor platelet count every 2 weeks during the first 2 months <input type="checkbox"/> Thrombocytopenia and anemia: Doses should be modified or therapy discontinued according to any reductions platelet counts and/or hemoglobin. <input type="checkbox"/> Discuss appropriate methods of contraception <input type="checkbox"/> Pre-existing nausea, vomiting, and diarrhea should be adequately controlled before beginning therapy with vorinostat. Hypokalemia or hypomagnesemia should be corrected prior to administration, and potassium and magnesium should be considered in patients with nausea, vomiting, diarrhea, fluid imbalance or cardiac symptoms. <input type="checkbox"/> QTc prolongation has been reported; close monitoring should occur particularly among patients taking drugs known to prolong the QTc interval. <input type="checkbox"/> Pulmonary embolism and deep vein thrombosis has been reported; physicians should be alert to the signs and symptoms of these events, particularly in patients with a prior history of thromboembolic events. <input type="checkbox"/> Prolongation of prothrombin time and increased INR has occurred among some patients taking vorinostat and warfarin concomitantly. <input type="checkbox"/> Serum glucose should be monitored, especially in diabetic patients. Adjustment of diet and/or therapy may be necessary	
Discontinuation	
<input type="checkbox"/> Vorinostat is given until disease progression or intolerance to therapy occurs.	

Approved by Physician: _____

Date/Time: _____

2/2007

Updated versions may be found at <http://www.vapbm.org> or <http://vaww.pbm.med.va.gov>

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