



Prior Authorization Approval Criteria

Istodax (romidepsin)

Generic name: Romidepsin

Brand name: Istodax

Medication class: Histone deacetylase inhibitor

FDA-approved uses: Treatment of cutaneous T-cell lymphoma (CTCL) in patients that have tried at least one prior systemic therapy

Available dosage forms: 10mg vial

Usual dose: 14mg/m² IV infusion over a 4-hour period on days 1, 8, and 15 of a 28-day cycle

Approximate monthly cost: \$22,800 per month (Based on a BMI of 2m²; \$2533 per 10mg vial) (based on AWP 2010)

Duration of therapy: Until disease progression or unacceptable toxicity

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

- The indicated diagnosis (including any applicable labs and /or tests) and medication usage must be supported by documentation from the patient's medical records.
- Clinically diagnosed cutaneous T-cell lymphoma
- At least one previous systemic therapy
- No evidence of systemic disease

Criteria for continuation of therapy:

- Disease is in remission
- No evidence of systemic disease

Caution:

- Risk of QT prolongation
- Risk of thrombocytopenia, leukopenia, and anemia
- May reduce the effectiveness of estrogen-containing contraceptives
- Pregnancy category D

Monitoring:

- Potassium and magnesium levels
- CBC
- ECG changes

Not approved if:

- Patient does not meet the above stated criteria
- Disease has progressed
- Patient has systemic disease

Special considerations:

- Median time to first response is 2 months

FCHP Pharmacy and Therapeutics Committee approval: _____

Date: _____

Adopted: 09/08/10