

**Complete Patient and Physician information (PLEASE PRINT)**

STEP  
1

Member Name:	Physician Name:
Address:	Address:
Member ID:	Phone #:
Member DOB:	Fax #:
	Tax ID or NPI Number:

**If Applicable:** Pharmacy Name: \_\_\_\_\_  
 Pharmacy Phone: \_\_\_\_\_

**Complete the Clinical Assessment:**

STEP  
2

Diagnosis	<input type="checkbox"/> Primary cutaneous T-cell lymphoma	<input type="checkbox"/> Other (please state): _____ _____
Clinical Consideration	<input type="checkbox"/> Patient has failed at least one prior systemic therapy (please state failed therapy and date mo/year): _____ _____	
Physician Specialty	Diagnosis made by: <input type="checkbox"/> Oncology <input type="checkbox"/> Other (please state): _____	
Supporting Documentation	Diagnosis: ICD-9/10 Code #/ Description / J Code (required):	
	Please attach a copy of the prescription or provide ALL of the information below: Istodax <sup>®</sup> (romidepsin) Strength _____ Sig _____ Qty _____ Refills _____	
	<i>*Please attach all relevant medical records and test results*</i> <b>We will not process incomplete forms.</b> <b>If we do not receive the completed form &amp; all relevant medical records &amp; test results within 10 calendar days of this request, it will be denied.</b>	

STEP  
3

**I certify that the above is correct and accurate to the best of my knowledge and that the form is complete.  
 (please sign and date)**

\_\_\_\_\_  
 Prescriber Signature

\_\_\_\_\_  
 Date

STEP  
4

**Fax completed form to the Rocky Mountain Health Plans Pharmacy Help Desk:  
 970-248-5034**

Name of Person filling out form: \_\_\_\_\_

Pharmacy Technician initials \_\_\_\_\_ Date Initiated \_\_\_\_\_

**Confidentiality Notice:**

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## RMHP Formulary Coverage Policy

THIS INFORMATION IS NOT ALL-INCLUSIVE AND IS PROVIDED FOR INFORMATIONAL PURPOSES ONLY

### Istodax (romidepsin)

#### CLASSIFICATION

- Histone Deacetylase Inhibitor

#### DESCRIPTION

- Romidepsin inhibits histone deacetylase (HDAC), resulting in an accumulation of acetylated histones. It induces cell cycle arrest and apoptosis of some cancer cell lines
- The mechanism of the antineoplastic effect in clinical studies has not been fully characterized
- Romidepsin was studied in patients who have received at least one prior systemic therapy and produced an overall response rate of 34% in patients with cutaneous T-cell lymphoma in 2 multicenter studies (n=167)

#### FORMULARY COVERAGE

Prior authorization:	Required
Good Health Formulary:	Medical Benefit
Commercial Formulary:	Medical Benefit
Medicare Part D coverage:	Part B if incident to a physician's service, Part D if obtained at a pharmacy

#### COVERAGE CRITERIA

Istodax (romidepsin) meets the definition of **medical necessity** for the following:

- Primary cutaneous T-cell lymphoma, Following at least one prior systemic therapy

Istodax (romidepsin) is considered **experimental** for the following:

- First line therapy of primary cutaneous T-cell lymphoma

Required Provider Specialty:

- Approval is limited to Oncology

#### DOSAGE/ADMINISTRATION:

Adult Dosing (safety and efficacy in pediatric patients has not been established)

- Primary cutaneous T-cell lymphoma, Following at least one prior systemic therapy: 14 mg/m<sup>2</sup> IV over 4 hr on days 1, 8, 15 repeated in 28-day cycles

Dosing adjustments:

- Refer to package insert/ prescribing information

## PRECAUTIONS:

- A concomitant use of potent CYP3A4 inducers (eg, dexamethasone, carbamazepine, phenytoin, rifampin, rifabutin, rifapentine, phenobarbital, St. Johns Wort) should be avoided
- Concomitant use of strong CYP3A4 inhibitors (eg, ketoconazole, itraconazole, clarithromycin, atazanavir, indinavir, nefazodone, nelfinavir, ritonavir, saquinavir, telithromycin, voriconazole) should be avoided
- ECG alterations, including T-wave and ST-segment changes, have been reported; patients with congenital long QT syndrome, significant cardiovascular disease, and/or receiving anti-arrhythmic drugs or products associated with QT prolongation may be at increased risk; consider ECG and electrolyte monitoring in patients at increased risk
- Hematologic toxicities, including thrombocytopenia, leukopenia (neutropenia and lymphopenia), and anemia have been reported; monitoring recommended; dose modification may be necessary
- QT prolongation has been reported; ensure potassium and magnesium levels are within the normal range prior to administration
- Women of childbearing potential; may cause fetal harm and may decrease the efficacy of estrogen-containing contraceptives

## Billing/Coding information

### Associated HCPCS Codes:

J9315	Injection, romidepsin, 1 mg

### Associated CPT Coding:


### Associated ICD-9 Coding:

202.1, 202.2	Mycosis fungoides or Sezary's disease (forms of cutaneous T-cell lymphoma)

## COST

- AWP (April 2010): Istodax 10mg vial for IV administration (1): \$2,533.33

## COMMITTEE APPROVAL:

- January 26, 2011

## GUIDELINE UPDATE INFORMATION:

April 2010	Policy created

## REFERENCES:

- DRUGDEX®, accessed 04/06/2010
- Product Information: ISTODAX(R) IV injection, romidepsin IV injection. Gloucester Pharmaceuticals, Inc., Cambridge, MA, 2009.