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

☐ **Urgent**[1] ☐ **Non-Urgent**

Requested Drug Name: Istodax® (romidepsin)

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: ☐ New Request ☐ Reauthorization

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:

Istodax® (romidepsin)

Diagnosis (documentation supportive of diagnosis is required)

☐ Primary cutaneous T-cell lymphoma (CTCL)
☐ Peripheral T-cell lymphoma (PTCL)
☐ Other (please state): _____

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

☐ Diagnosis of CTCL
☐ Patient has failed at least one prior multi-agent chemotherapy regimen (e.g. CHOP, CHOEP, EPOCH, HyperCVAD).
List failed therapy: _____

☐ Diagnosis of PTCL:

☐ Patient has failed at least one prior systemic therapy (e.g. extracorporeal photopheresis, systemic retinoids, interferons, vorinostat).

List failed therapy: _____

Physician Specialty (diagnosis made by)

☐ 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. 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

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)
- In two phase 2 trials (n=131; n=47), single-agent therapy with romidepsin provided a complete response rate of 15% and 18% and an overall response rate of 25% and 38%, respectively, in patients who previously received at least one prior systemic therapy for peripheral T-cell lymphoma.

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 in patients who have received at least one prior systemic therapy
- Peripheral T-cell lymphoma in patients who have received at least one prior systemic therapy

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

- Any condition or diagnosis not FDA approved or Compendia supported.
- First line therapy for either primary cutaneous T-cell lymphoma or peripheral 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)

- **Peripheral T-cell lymphoma (clinical) following at least one prior systemic therapy**: recommended dosage regimen of romidepsin is 14 mg/m(2) IV over 4 hours on day 1, 8, and 15 every 28 days. Additional cycles every 28 days should be provided based on response and tolerance.
- **Primary cutaneous T-cell lymphoma following at least one prior systemic therapy:** recommended dosage of romidepsin is 14 mg/m(2) IV over 4 hour on days 1, 8, 15. Treatment cycles may be repeated every 28 days while the patient continues to have benefit and tolerates therapy.

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:

96413	Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug
96415	Chemotherapy administration, intravenous infusion technique; each additional hour (List separately in addition to code for primary procedure) (Use 96415 in conjunction with 96413)

COST

- AWP (April 2010): Istodax 10mg vial for IV administration (1): $2,533.33
- AWP (May 2013): Istodax 10mg vial for IV administration (1): $2,878.80

COMMITTEE APPROVAL:

- January 26, 2011

GUIDELINE UPDATE INFORMATION:

April 2010	Policy created
May 2013	Policy updated
September 2013	Policy updated

REFERENCES:

- DRUGDEX®, accessed 04/06/2010, 5/20/2013, 9/24/2013
- Product Information: ISTODAX®IV injection, romidepsin IV injection. Gloucester Pharmaceuticals, Inc., Cambridge, MA, 2009.
- Product Information: ISTODAX®IV injection, romidepsin IV injection. Celgene Corporation, Summit, NJ, 06/2013.