

**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"/> Peripheral 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): _____	
	<input type="checkbox"/> Acknowledgement that prior to administration of Folotyn, the patient should demonstrate the following: <ul style="list-style-type: none"> <li>• ANC count <math>\geq 1,000/\text{mcL}</math> prior to each dose</li> <li>• Platelet count <math>\geq 100,000/\text{mcL}</math> prior to the 1<sup>st</sup> dose and <math>\geq 50,000/\text{mcL}</math> prior to subsequent doses</li> </ul> Mucositis at a grade 1 or less prior to each dose	
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: Folotyn <sup>®</sup> (pralatrexate) Strength _____ Sig _____ Qty _____ Refills _____	
	<p style="text-align: center;"><i>*Please attach all relevant medical records and test results*</i></p> <p style="text-align: center;"><b>We will not process incomplete forms.</b></p> <p style="text-align: center;"><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></p>	

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:**

This facsimile transmission (and/or documents accompanying it) may contain confidential information. This information is intended only for the use of the individual(s) named above. If you have received this transmission in error, or cannot identify the recipient for distribution purposes, please notify us immediately at 970-244-7760. Plans underwritten by Rocky Mountain HMO or Rocky Mountain HealthCare Options. 01/05/11

## RMHP Formulary Coverage Policy

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

# Folotyn (pralatrexate)

## CLASSIFICATION

- Antimetabolite (Antifolate)

## DESCRIPTION

- First agent specifically approved for peripheral T-cell lymphoma (PTCL)
- Structurally related to methotrexate, but with stronger affinity for dihydrofolate reductase
- Competitively inhibits dihydrofolate reductase. Additionally, it is a competitive inhibitor for polyglutamylation via the folylpolyglutamyl synthetase enzyme. This results in thymidine and other biological molecule depletion of which the synthesis depends on single carbon transfer.
- Pralatrexate injection was given accelerated approval for the treatment of patients with relapsed or refractory peripheral T-cell lymphoma (PTCL). Approval was based on overall response rate in an open-label, single-arm, multicenter study. Treatment with pralatrexate produced a response rate of 27% (complete response, complete response unconfirmed, and partial response) in patients with relapsed or refractory peripheral T-cell lymphoma (n=109). Improvement in progression free survival or overall survival has not yet been demonstrated.

## FORMULARY COVERAGE

Prior authorization:	Required
Good Health Formulary:	T6
Commercial Formulary:	T6
Medicare Part D coverage:	Medical benefit

## COVERAGE CRITERIA

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

- Peripheral T-cell lymphoma, relapsed or refractory following at least one prior therapy

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

- First line therapy of 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)

- All patients should receive oral folic acid 1 mg to 1.25 mg orally daily for 10 days prior to treatment with pralatrexate, during, and for 30 days after the last dose. Patients should also receive a vitamin B12 1000 mcg IM injection no more than 10 weeks prior to the first dose of pralatrexate and then every 8 to 10 weeks thereafter. Vitamin B12 injections may be given the same day as treatment with pralatrexate

- Peripheral T-cell lymphoma, relapsed or refractory following at least one prior systemic therapy: 30 mg/m<sup>2</sup> IV push over 3 to 5 minutes via the side port of a free flowing 0.9% Sodium Chloride Injection, USP IV line once weekly for 6 weeks in 7-week cycles until progressive disease or unacceptable toxicity
- Prior to administering pralatrexate:
  - ANC count should be  $\geq 1,000/\text{mcL}$  prior to each dose
  - Platelet count should be  $\geq 100,000/\text{mcL}$  for first dose and  $\geq 50,000/\text{mcL}$  for all subsequent doses
  - Mucositis should be at a grade 1 or less

Dosing adjustments:

- Doses may be omitted or reduced based on patient tolerance regarding hematologic toxicity, mucositis, or other adverse events. See package insert for dosing recommendations
- No dose adjustment necessary in geriatric patients with normal renal function
- Pralatrexate has not been studied in patients with renal or hepatic impairment. Caution is advised.

**PRECAUTIONS:**

- Specific contraindications have not been determined
- Anemia may occur; monitoring and possible dose modification
- Bone marrow suppression may occur; dose modification recommended; folic acid and vitamin B12 supplementation recommended to reduce treatment-related hematological toxicity
- Liver function test abnormalities have been observed and may be indicators of liver toxicity; monitoring and possible dose modification recommended
- Mucositis may occur; grade 2 or greater requires dose modification; folic acid and vitamin B12 supplementation recommended to reduce treatment-related mucositis
- Neutropenia may occur; monitoring and possible dose modification
- Renal impairment, severe or moderate; monitoring recommended
- Thrombocytopenia may occur; monitoring and possible dose modification recommended

**Billing/Coding information**

**Associated HCPCS Codes:**

C9259	Injection, pralatrexate, 1 mg

**Associated CPT Coding:**


**Associated ICD-9 Coding:**

202.7	Peripheral T-cell lymphoma

**COST**

- AWP (July 2010): Folutyn 20mg vial for IV administration (1): \$3,750.00

## COMMITTEE APPROVAL:

- July 28, 2010

## GUIDELINE UPDATE INFORMATION:

July 2010	Policy created

## REFERENCES:

- DRUGDEX®, accessed 07/20/2010
- Product Information: FOLOTYN(TM) solution for IV injection, pralatrexate solution for IV injection. Allos Therapeutics, Inc., Westminister, CO, 2009.