

**Clinical Policy: Pralatrexate (Folotyn)**

Reference Number: CP.PHAR.313

Effective Date: 02.01.17

Last Review Date: 11.18

Line of Business: Medicaid, HIM-Medical Benefit

[Coding Implications](#)[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

**Description**

Pralatrexate injection (Folotyn<sup>®</sup>) is a folate analog metabolic inhibitor.

**FDA Approved Indication(s)**

Folotyn is indicated for the treatment of patients with relapsed or refractory peripheral T-cell lymphoma (PTCL).

**Policy/Criteria**

*Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.*

It is the policy of health plans affiliated with Centene Corporation<sup>®</sup> that Folotyn is **medically necessary** when the following criteria are met:

**I. Initial Approval Criteria****A. Peripheral T-Cell Lymphoma (must meet all):**

1. Diagnosis of PTCL;
2. Prescribed by or in consultation with an oncologist or hematologist;
3. Age  $\geq$  18 years;
4. Request meets one of the following (a or b):
  - a. PTCL: dose does not exceed 30 mg/m<sup>2</sup> once weekly for 6 weeks in 7-week cycles;
  - b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Approval duration: 6 months**

**B. NCCN-Recommended Off-Label Indications (must meet all):**

1. Diagnosis of one of the following conditions:
  - a. Mycosis Fungoides or Sézary Syndrome;
  - b. Primary cutaneous anaplastic large cell lymphoma (ALCL) with multifocal lesions, or cutaneous ALCL with regional nodes;
  - c. Adult T-cell leukemia/lymphoma;
2. Prescribed by or in consultation with an oncologist or hematologist;
3. Age  $\geq$  18 years;
4. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Approval duration: 6 months**

**C. Other diagnoses/indications**

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.PMN.53 for Medicaid.

**II. Continued Therapy**

**A. All Indications in Section I (must meet all):**

1. Currently receiving medication via Centene benefit, or documentation supports that member is currently receiving Folutyn for a covered indication and has received this medication for at least 30 days;
2. Responding positively to therapy;
3. If request is for a dose increase, request meets one of the following (a or b):
  - a. New dose does not exceed 30 mg/m<sup>2</sup> once weekly for 6 weeks in 7-week cycles;
  - b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Approval duration: 12 months**

**B. Other diagnoses/indications (must meet 1 or 2):**

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.  
**Approval duration: Duration of request or 6 months (whichever is less);** or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.PMN.53 for Medicaid.

**III. Diagnoses/Indications for which coverage is NOT authorized**

- A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.PMN.53 for Medicaid or evidence of coverage documents.

**IV. Appendices/General Information**

*Appendix A: Abbreviation/Acronym Key*

ALCL: anaplastic large cell lymphoma

FDA: Food and Drug Administration

PTCL: peripheral T-cell lymphoma

*Appendix B: Therapeutic Alternatives*

Not applicable

*Appendix C: Contraindications/Boxed Warnings*

- Contraindication(s): none reported
- Boxed warning(s): none reported

**V. Dosage and Administration**

Indication	Dosing Regimen	Maximum Dose
PTCL	30 mg/m <sup>2</sup> IV once weekly for 6 weeks in 7-week cycles until progressive disease or unacceptable toxicity	30 mg/m <sup>2</sup> once weekly.

**VI. Product Availability**

Single-dose vial: 20 mg/1 mL, 40 mg/2 mL

**VII. References**

1. Folutyn Prescribing Information. Westminster, CO: Spectrum Pharmaceuticals, Inc.; November 2016. Available at: [http://www.folutyn.com/HCP/downloads/folutyn-pi\\_Nov2016.pdf](http://www.folutyn.com/HCP/downloads/folutyn-pi_Nov2016.pdf). Accessed July 24, 2018.
2. Pralatrexate. In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at [nccn.org](http://nccn.org). Accessed July 24, 2018.

**Coding Implications**

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J9307	Injection, pralatrexate, 1 mg

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy split from CP.PHAR.182.Excellus Oncology.	01.01.17	02.17
Age and dosing added. Safety information removed. NCCN recommended uses added separately.	09.05.17	11.17
4Q 2018 annual review: no significant changes; added HIM Medical Benefit line of business; summarized NCCN and FDA-approved uses for improved clarity; added specialist involvement in care; added COC; references reviewed and updated.	07.31.18	11.18

**Important Reminder**

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in

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This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

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**Note: For Medicaid members,** when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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