# Clinical Policy: Pralatrexate (Folotyn)

Reference Number: PA.CP.PHAR.313
Effective Date: 01/18
Last Review Date: 10/30/2019

Coding Implications
Revision Log

**Description**
The intent of the criteria is to ensure that patients follow selection elements established by Pennsylvania Health and Wellness ® clinical policy for pralatrexate injection (Folotyn®).

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

**Policy/Criteria**
It is the policy of Pennsylvania Health and Wellness ® 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. Request meets one of the following (a or b):
   a. PTCL: dose does not exceed 30 mg/m$^2$ 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. 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:** Refer to PA.CP.PMN.53

**II. Continued Approval**

**A. Peripheral T-Cell Lymphoma** (must meet all)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
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$^2$ 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 Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies; or
2. Refer to PA.CP.PMN.53

**Background**

*Description/Mechanism of Action:*

Pralatrexate is a folate analog metabolic inhibitor that competitively inhibits dihydrofolate reductase. It is also a competitive inhibitor for polyglutamylation by the enzyme folylpolyglutamyl synthetase. This inhibition results in the depletion of thymidine and other biological molecules the synthesis of which depends on single carbon transfer.

*Formulations:*

Folotyn is available in single-dose clear glass vials containing pralatrexate at a concentration of 20 mg/mL as a preservative-free, sterile, clear yellow solution individually packaged for intravenous use in the following presentations:

- 20 mg of pralatrexate in 1 mL solution in a vial (20 mg / 1 mL)
- 40 mg of pralatrexate in 2 mL solution in a vial (40 mg / 2 mL)

**Appendices**

*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

**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 | Approval Date |
|---|---|---|
| 4Q 2018 annual review: no significant changes; summarized NCCN and FDA-approved uses for improved clarity; added specialist involvement in care; added COC; references reviewed and updated. | | |
| 4Q 2019 annual review: No changes per Statewide PDL implementation 01-01-2020 | 10/30/19 | |

**References**
1. Folotyn Prescribing Information. Westminster, CO: Spectrum Pharmaceuticals, Inc.; November 2016. Available at: http://www.folotyn.com/HCP/downloads/folotyn-pi_Nov2016.pdf. Accessed July 24, 2018.
2. Pralatrexate. In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at nccn.org. Accessed July 24, 2018.