

Clinical Policy: Pralatrexate (Folotyn)

Reference Number: PA.CP.PHAR.313

Effective Date: 01/18

Last Review Date: 10/18

[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/m² 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/m² 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.		

References

1. Folutyn Prescribing Information. Westminster, CO: Spectrum Pharmaceuticals, Inc.; November 2016. Available at: 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. Accessed July 24, 2018.