Clinical Policy: Pralatrexate (Folotyn)

Reference Number: PA.CP.PHAR.313
Effective Date: 01/18
Last Review Date: 02/17

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®).

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 relapsed or refractory peripheral T-cell lymphoma (PTCL) (see Appendix B for examples of PTCL subtypes).

Approval duration: 3 months

B. Other diagnoses/indications: Refer to CP.PHAR.57 - Global Biopharm Policy.

1. The following NCCN recommended uses for Folotyn, meeting NCCN categories 1, 2a, or 2b, are approved per the CP.PHAR.57 Global Biopharm Policy:
   a. Non-Hodgkin lymphoma:
      i. Adult T-cell leukemia/lymphoma;
      ii. Mycosis fungoides (MF)/Sezary syndrome (SS);
      iii. Primary cutaneous CD30+ T-cell lymphoproliferative disorders.

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. Member has none of the following reasons to discontinue:
   a. Disease progression or unacceptable toxicity;
   b. Mucositis: On day of treatment, Grade 4* (life-threatening);
   c. Hematologic toxicities: On day of treatment, any of the following:
      i. Platelet < 50,000/mcL lasting 3 weeks;
      ii. Absolute neutrophil count (ANC) characterized as any of the following:
         a) ANC 500-1,000/mcL with fever;
         b) ANC < 500/mcL lasting 3 weeks;
         c) ANC < 500/mcL if a second occurrence;
   d. Non-hematologic toxicities: Recurrence of CTCAE Grade 3* (severe) or 4* (life-threatening) toxicities after two dosage reductions;
   e. Any treatment-related toxicity: Grade 4* (life-threatening);

**Grading is based on the Common Terminology Criteria for Adverse Events (CTCAE).*

Approval duration: 6 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.PHAR.57 - Global Biopharm Policy**.**

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)

FDA Approved Indications:

Folotyn is a folate analog metabolic inhibitor/intravenous formulation indicated for:

- Treatment of patients with relapsed or refractory peripheral T-cell lymphoma (PTCL).
  - This indication is based on overall response rate. Clinical benefit such as improvement in progression-free survival or overall survival has not been demonstrated.

Appendices

Appendix A: Abbreviation Key

AITL: Angioimmunoblastic T-cell lymphoma
ALCL: Anaplastic large cell lymphoma
ANC: Absolute neutrophil count
CTCAE: Common Terminology Criteria for Adverse Events
EATL: Enteropathy-associated T-cell lymphoma
MEITL: Monomorphic epitheliotropic intestinal T-cell lymphoma
MF: Mycosis fungoides
PTCL-NOS: Peripheral T-cell lymphoma, not otherwise specified
SS: Sezary syndrome

Appendix B: Peripheral T-cell lymphomas* (PTCL) subtypes[3]

- Peripheral T-cell lymphoma (PTCL), not otherwise specified (NOS)
- Angioimmunoblastic T-cell lymphoma (AITL)
- Anaplastic large cell lymphoma (ALCL), ALK positive or negative
- Enteropathy-associated T-cell lymphoma (EATL)

- Monomorphic epitheliotropic intestinal T-cell lymphoma (MEITL)

**PTLC is classified as a non-Hodgkin T-cell lymphoma. PTCL classification schemes are periodically advanced as new information becomes available; therefore, the above list is provided as general guidance. For additional information, see WHO's 2016 updated classification of hematological malignancies for a complete list of lymphoid neoplasms, including PTCL.*[4]

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

References

1. Folotyn prescribing information. Westminster, CO: Spectrum Pharmaceuticals Inc.; May 2016. Available at http://www.folotyn.com/downloads/2016_05_folotyn_FPI.pdf. Accessed January 17, 2017.
2. Pralatrexate. In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at NCCN.org. Accessed January 17, 2017.
3. T-cell lymphomas (Version 1.2017). In: National Comprehensive Cancer Network Guidelines. Available at NCCN.org. Accessed January 17, 2017.
4. Swerdlow SH, Campo E, Pileri SA, et al. The 2016 revision of the World Health Organization classification of lymphoid neoplasms. *Blood.* 2016; 127: 2375-2390.