PRIOR AUTHORIZATION POLICY

POLICY: Oncology (Injectable) – Pralatrexate Products Prior Authorization Policy
- Folotyn® (pralatrexate intravenous infusion – Spectrum, generic)

REVIEW DATE: 06/05/2024

OVERVIEW

Folotyn, a dihydrofolate reductase inhibitor, is indicated for the treatment of relapsed or refractory **peripheral T-cell lymphoma**.[1] This indication is based on overall response rate. Continued approval for this indication may be contingent on verification and description of clinical benefit in a confirmatory trial.

Guidelines

Pralatexate is addressed in National Comprehensive Cancer Network (NCCN) guidelines:

- **Primary Cutaneous Lymphomas:** The NCCN clinical practice guidelines (version 2.2024 – May 6, 2024) recommend pralatrexate as systemic therapy for mycosis fungoides/Sezary syndrome with or without skin-directed therapy and as a single agent for primary cutaneous CD30+ T-cell lymphoproliferative disorders.[2,3]
- **T-Cell Lymphomas:** The NCCN clinical practice guidelines (version 4.2024 – May 28, 2024) recommend pralatrexate as a single agent for the second-line or subsequent therapy of relapsed or refractory peripheral T-cell lymphomas including anaplastic large cell lymphoma, peripheral T-cell lymphoma not otherwise specified, angioimmunoblastic T-cell lymphoma, enteropathy-associated T-cell lymphoma, monomorphic epitheliotropic intestinal T-cell lymphoma, and nodal peripheral T-cell lymphoma with T-follicular helper phenotype; breast implant-associated anaplastic large cell lymphoma; adult T-cell leukemia/lymphoma; extranodal NK/T-cell lymphoma; and hepatosplenic T-cell lymphoma.[3,4]

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of pralatrexate. All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with pralatrexate as well as the monitoring required for adverse events and long-term efficacy, approval requires pralatrexate to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of pralatrexate is recommended in those who meet one of the following criteria:

FDA-Approved Indication

1. **T-Cell Lymphoma.** Approve for 1 year if the patient meets ALL of the following (A, B, C, D, and E):
   Note: Examples of peripheral T-cell lymphoma include anaplastic large cell lymphoma, enteropathy-associated T-cell lymphoma, monomorphic epitheliotropic intestinal T-cell lymphoma, angioimmunoblastic T-cell lymphoma, peripheral T-cell lymphoma not otherwise specified.
   A) Patient is ≥ 18 years of age; AND

B) Patient has peripheral disease; AND
C) Patient has relapsed or refractory disease; AND
D) The medication is used as a single agent; AND
E) The medication is prescribed by or in consultation with an oncologist.

Other Uses with Supportive Evidence

2. **Adult T-Cell Leukemia/Lymphoma**. Approve for 1 year if the patient meets ALL of the following (A, B, C, D, and E):
   A) Patient is ≥ 18 years of age; AND
   B) Patient has acute or lymphoma subtype; AND
   C) The medication is used as second-line or subsequent therapy; AND
   D) The medication is used as a single agent; AND
   E) The medication is prescribed by or in consultation with an oncologist.

3. **Breast Implant-Associated Anaplastic Large Cell Lymphoma.** Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):
   A) Patient is ≥ 18 years of age; AND
   B) Patient has relapsed or refractory disease; AND
   C) The medication is used as a single agent; AND
   D) The medication is prescribed by or in consultation with an oncologist.

4. **Cutaneous CD30+ T-Cell Lymphoproliferative Disorders**. Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):
   A) Patient is ≥ 18 years of age; AND
   B) Patient has ONE of the following diagnoses (i or ii):
      i. Primary cutaneous anaplastic large cell lymphoma with multifocal lesions; OR
      ii. Cutaneous anaplastic large cell lymphoma with regional nodes; AND
   C) The medication is used as a single agent; AND
   D) The medication is prescribed by or in consultation with an oncologist.

5. **Extranodal NK/T-Cell Lymphoma**. Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):
   A) Patient is ≥ 18 years of age; AND
   B) Patient has relapsed/refractory disease following combination, asparaginase-based chemotherapy; AND
   C) The medication is used as a single agent; AND
   D) The medication is prescribed by or in consultation with an oncologist.

6. **Hepatosplenic T-Cell Lymphoma**. Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):
   A) Patient is ≥ 18 years of age; AND
   B) The medication is used as second-line or subsequent therapy; AND
   C) The medication is used as a single agent; AND
   D) The medication is prescribed by or in consultation with an oncologist.

7. **Mycosis Fungoides/Sezary Syndrome**. Approve for 1 year if the patient meets BOTH of the following (A and B):
   A) Patient is ≥ 18 years of age; AND
   B) The medication is prescribed by or in consultation with an oncologist or dermatologist.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of pralatrexate is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Folotyn® injection [prescribing information]. East Windsor, NJ: Acrotech Biopharma; October 2020.
2. The NCCN Primary Cutaneous Lymphomas Clinical Practice Guidelines in Oncology (version 2.2024 – May 6, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed May 31, 2024.
3. The NCCN Drugs and Biologics Compendium. © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on May 31, 2024. Search term: pralatrexate.
4. The NCCN T-Cell Lymphomas Clinical Practice Guidelines in Oncology (version 4.2024 – May 28, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed May 31, 2024.