POLICY: Oncology – Folotyn® (pralatrexate injection – Spectrum Pharmaceuticals)

DATE REVIEWED: 06/03/2020

OVERVIEW

Folotyn is an antineoplastic folate analog which competitively inhibits dihydrofolate reductase.[1]

Folotyn is indicated for the treatment of patients with 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

The National Comprehensive Cancer Network (NCCN) Primary Cutaneous Lymphomas clinical practice guidelines (version 2.2020 – April 10, 2020) recommend Folotyn 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]

The NCCN T-Cell Lymphomas clinical practice guidelines (version 1.2020 – January 6, 2020) recommend Folotyn 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 (TFH) phenotype; follicular T-cell lymphoma; adult T-cell leukemia/lymphoma; extranodal NK/T-cell lymphoma – nasal type; and hepatosplenic gamma-delta T-cell lymphoma.[3,4]

POLICY STATEMENT

Prior authorization is recommended for medical benefit coverage of Folotyn. Approval is recommended for those who meet the Criteria and Dosing for the listed indication(s). Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). All approvals are provided for the duration noted below.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Folotyn as well as the monitoring required for adverse events and long-term efficacy, approval requires Folotyn to be prescribed by or in consultation with a physician who specializes in the condition being treated.

RECOMMENDED AUTHORIZATION CRITERIA

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

FDA-Approved Indications

1. **T-Cell Lymphoma, Peripheral.** Approve for 1 year if the patient meets the following criteria (A, B, and C):
   - **A)** The patient has relapsed or refractory disease; AND
   - **B)** Folotyn is used as a single agent; AND

C) Folotyn is prescribed by or in consultation with an oncologist.

Dosing. Approve the following dosing regimens (A and B):
A) Each individual dose must not exceed 30 mg/m^2 administered intravenously; AND
B) The dose is administered once weekly for 6 weeks in each 7 week cycle.[1]

Other Uses with Supportive Evidence

2. Mycosis Fungoides/Sezary Syndrome. Approve for 1 year if Folotyn is prescribed by or in consultation with an oncologist or dermatologist.

Dosing. Approve the following dosing regimens (A and B):
A) Each individual dose must not exceed 30 mg/m^2 administered intravenously; AND
B) The dose is administered once weekly for 6 weeks in each 7 week cycle.[1]

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3. Cutaneous CD30+ T-Cell Lymphoproliferative Disorders. Approve for 1 year if the patient meets the following criteria (A, B, and C):
A) The 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
B) Folotyn is used as a single agent; AND
C) Folotyn is prescribed by or in consultation with an oncologist.

Dosing. Approve the following dosing regimens (A and B):
A) Each individual dose must not exceed 30 mg/m^2 administered intravenously; AND
B) The dose is administered once weekly for 6 weeks in each 7 week cycle.[1]

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4. Adult T-Cell Leukemia/Lymphoma, Acute or Lymphoma Subtype. Approve for 1 year if the patient meets the following criteria (A, B, and C):
A) Folotyn is used as second-line or subsequent therapy; AND
B) Folotyn is used as a single agent; AND
C) Folotyn is prescribed by or in consultation with an oncologist.

Dosing. Approve the following dosing regimens (A and B):
A) Each individual dose must not exceed 30 mg/m^2 administered intravenously; AND
B) The dose is administered once weekly for 6 weeks in each 7 week cycle.[1]

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5. Extranodal NK/T-Cell Lymphoma, Nasal Type. Approve for 1 year if the patient meets the following criteria (A, B, and C):
A) The patient has relapsed/refractory disease following combination, asparaginase-based chemotherapy; AND
B) Folotyn is used as a single agent; AND
C) Folotyn is prescribed by or in consultation with an oncologist.

Dosing. Approve the following dosing regimens (A and B):

A) Each individual dose must not exceed 30 mg/m^2 administered intravenously; AND
B) The dose is administered once weekly for 6 weeks in each 7 week cycle.[1]

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6. Hepatosplenic Gamma-Delta T-Cell Lymphoma. Approve for 1 year if the patient meets the following criteria (A, B, and C):
A) Folotyn is used as second-line or subsequent therapy; AND
B) Folotyn is used as a single agent; AND
C) Folotyn is prescribed by or in consultation with an oncologist.

Dosing. Approve the following dosing regimens (A and B):
A) Each individual dose must not exceed 30 mg/m^2 administered intravenously; AND
B) The dose is administered once weekly for 6 weeks in each 7 week cycle.[1]

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Folotyn has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions.

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; May 2020.
2. The NCCN Primary Cutaneous Lymphomas Clinical Practice Guidelines in Oncology (Version 2.2020 – April 10, 2020). © 2020 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed May 26, 2020.
3. The NCCN Drugs and Biologics Compendium. © 2020 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on May 26, 2020. Search term: pralatrexate.
4. The NCCN T-Cell Lymphomas Clinical Practice Guidelines in Oncology (Version 1.2020 – January 6, 2020). © 2020 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed May 26, 2020.

HISTORY

Type of Revision	Summary of Changes	Date Reviewed
New Policy	--	06/05/2019
Annual Revision	Hepatosplenic Gamma-Delta T-Cell Lymphoma: added use as "second-line" therapy to criteria and removed "after two primary treatment regimens" from the criteria.	06/03/2020