VENTURA COUNTY
HEALTH CARE PLAN

UTILIZATION MANAGEMENT MEDICAL POLICY

POLICY: Oncology (Injectable) – Folotyn Utilization Management Medical Policy
- Folotyn® (pralatrexate injection – Spectrum)

REVIEW DATE: 05/18/2022

OVERVIEW

Folotyn, a dihydrofolate reductase inhibitor, 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

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

- **Primary Cutaneous Lymphomas:** The NCCN clinical practice guidelines (version 1.2022 – January 26, 2022) 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]
- **T-Cell Lymphomas:** The NCCN clinical practice guidelines (version 2.2022 – March 7, 2022) 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 phenotype; follicular T-cell lymphoma; 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 medical benefit coverage of Folotyn. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indications. 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.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

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

FDA-Approved Indication

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1. T-Cell Lymphoma. Approve for 1 year if the patient meets ALL of the following criteria (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, anhioimmunoblastic 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) Folotyn is used as a single agent; AND
E) Folotyn is prescribed by or in consultation with an oncologist.

Dosing. Approve up to 30 mg/m^2 administered intravenously once weekly for 6 weeks in each 7 week cycle.

Other Uses with Supportive Evidence

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

Dosing. Approve up to 30 mg/m^2 administered intravenously once weekly for 6 weeks in each 7 week cycle.

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

Dosing. Approve up to 30 mg/m^2 administered intravenously once weekly for 6 weeks in each 7 week cycle.

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4. Cutaneous CD30+ T-Cell Lymphoproliferative Disorders. Approve for 1 year if the patient meets ALL of the following criteria (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) Folotyn is used as a single agent; AND
D) Folotyn is prescribed by or in consultation with an oncologist.

Dosing. Approve up to exceed 30 mg/m^2 administered intravenously once weekly for 6 weeks in each 7 week cycle.

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5. Extranodal NK/T-Cell Lymphoma. Approve for 1 year if the patient meets ALL of the following criteria (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)** Folotyn is used as a single agent; AND
- **D)** Folotyn is prescribed by or in consultation with an oncologist.

Dosing. Approve up to 30 mg/m^2 administered intravenously once weekly for 6 weeks in each 7 week cycle.

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

Dosing. Approve up to 30 mg/m^2 administered intravenously once weekly for 6 weeks in each 7 week cycle.

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

Dosing. Approve up to 30 mg/m^2 administered intravenously once weekly for 6 weeks in each 7 week cycle.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Folotyn 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 1.2022 – January 26, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed May 13, 2022.
3. The NCCN Drugs and Biologics Compendium. © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on May 13, 2022. Search term: pralatrexate.

4. The NCCN T-Cell Lymphomas Clinical Practice Guidelines in Oncology (Version 2.2022 – March 7, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed May 13, 2022.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	**Breast Implant-Associated Anaplastic Large Cell Lymphoma:** Added criteria for new indication recommended by the National Comprehensive Cancer Network. **Hepatosplenic T-cell Lymphoma:** The qualifier of "Gamma-Delta" was removed from the condition of approval.	06/02/2021
Annual Revision	**T-Cell Lymphoma:** Changed condition to as listed (removed "Peripheral" from the conditional of approval). Added requirement that the patient is ≥ 18 years of age and patient has peripheral disease. Added Note with examples of peripheral T-cell lymphomas. **Adult T-Cell Leukemia/Lymphoma:** Removed Acute or Lymphoma Subtype from the condition of approval. Added requirement that the patient is ≥ 18 years of age and patient has acute or lymphoma subtype. **Breast Implant-Associated Anaplastic Large Cell Lymphoma:** Added requirement that the patient is ≥ 18 years of age. **Cutaneous CD30+ T-Cell Lymphoproliferative Disorders:** Added requirement that the patient is ≥ 18 years of age. **Extranodal NK/T-Cell Lymphoma:** Removed Nasal Type from the condition of approval. Added requirement that the patient is ≥ 18 years of age. **Hepatosplenic T-Cell Lymphoma:** Added requirement that the patient is ≥ 18 years of age. **Mycosis Fungoides/Sezary Syndrome:** Added requirement that the patient is ≥ 18 years of age.	05/18/2022