Pralatrexate (Folotyn®)	Place of Service Office Administration Home Infusion Outpatient Facility Infusion Administration Infusion Center Administration HCPCS: **J9307** per 1 mg

Condition(s) listed in policy (*see criteria for details*)
Adult T-cell leukemia/lymphoma
Cutaneous anaplastic large cell lymphoma
Extranodal NK / T-cell lymphoma, nasal type
Hepatosplenic gamma-delta T-cell lymphoma
Mycosis fungoides / Sézary syndrome
Peripheral T-cell lymphoma (PTCL)

AHFS therapeutic class: Antineoplastic Agent

Mechanism of action: Pralatrexate is a folate analogue metabolic inhibitor that competitively inhibits dihydrofolate reductase

(1) Special Instructions and pertinent Information

Covered under the Medical Benefit, please submit clinical information for prior authorization review.

(2) Prior Authorization/Medical Review is required for the following condition(s)

All requests for Folotyn® (pralatrexate) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

Adult T-Cell leukemia/lymphoma

1. Patient has received at least one previous chemotherapy regimen or stem cell transplant

Covered Doses
Up to 60 mg weekly for 6 out of 7 weeks

ICD-10:
C91.50, C91.52

Cutaneous anaplastic large cell lymphoma (ALCL)

1. Single agent therapy for either of the following diagnoses:
    a. Primary cutaneous anaplastic large cell lymphoma (ALCL) with multifocal lesions, OR

b. Cutaneous ALCL with regional nodes (excludes systemic ALCL)

Covered Doses
Up to 30 mg/m^2 mg weekly for 6 out of 7 weeks

ICD-10:
C86.6

Extranodal NK/T-cell lymphoma, nasal type

Covered Doses
Up to 30 mg/m^2 weekly for 6 out of 7 weeks

ICD-10:
C84.90-C84.99, C84.Z0, C84.Z1, C84.Z2, C84.Z3, C84.Z4, C84.Z5, C84.Z6, C84.Z7, C84.Z8, C84.Z9, C86.0

Hepatosplenic gamma-delta T-cell lymphoma

Covered Doses
Up to 30 mg/m^2 weekly for 6 out of 7 weeks

ICD-10:
C84.90-C84.99, C84.Z0, C84.Z1, C84.Z2, C84.Z3, C84.Z4, C84.Z5, C84.Z6, C84.Z7, C84.Z8, C84.Z9, C86.1

Mycosis Fungoides/Sezary Syndrome
1. Not being used in combination with other systemic therapies

Covered Doses
Up to 30 mg/m^2 weekly for 6 out of 7 weeks

ICD-10:
C84.00-C84.09, C84.10-C84.19

Peripheral T-cell lymphomas (PTCL)
1. Patient has received at least one previous chemotherapy regimen or stem cell transplant

Covered Doses
Up to 30 mg/m^2 weekly for 6 out of 7 weeks

ICD-10:
C84.40-C84.49, C84.60-C84.69, C84.70-C84.79, C86.2, C86.5

(3) The following condition(s) DO NOT require Prior Authorization/Preservice

All requests for Folotyn® (pralatrexate) must be sent for clinical review and receive authorization prior to drug administration or claim payment

(4) This Medication is NOT medically necessary for the following condition(s)

The Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

(5) Additional Information

How supplied:

Sterile, single-use vials containing pralatrexate at a concentration of 20 mg/mL in the following preservative-free 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)

(6) References

- AHFS®. Available by subscription at http://www.lexi.com
- DrugDex®. Available by subscription at http://www.micromedexsolutions.com
- Folotyn® (pralatrexante) [Prescribing Information]. East Windsor, NJ: Acrotech Biopharma LLC; 9/2020.
- National Comprehensive Cancer Network. Primary Cutaneous Lymphomas (Version 2.2021). Available at: www.nccn.org/
- National Comprehensive Cancer Network. T-Cell Lymphomas (Version 1.2021). Available at: www.nccn.org/

(7) Policy Update

Date of initial review: 4Q2022
Date of next review: 1Q2023
Changes from previous policy version:

- New policy

BSC Drug Coverage Criteria to Determine Medical Necessity
Reviewed by P&T Committee