SmartHealth

Ascension

Pralatrexate

(Folotyn®) J9316 (1 mg)

Covered with prior authorization

Pralatrexate (Folotyn®) may be authorized when the following criteria are met:

- Individual is 18 years or older; **AND**
- Medication is prescribed by an oncologist or hematologist; **AND**
- Medication is being prescribed as a single-agent therapy.
- Individual has one of the following diagnosis:
    - Peripheral T-Cell Lymphoma; **AND**
        - Medication is being prescribed as a single-agent therapy; **AND**
            - Failure of at least one prior therapy (either a first or second line therapy per NCCN guidelines); **OR**
            - Medication is initial therapy for palliative care; **OR**
    - Mycosis fungoides or Sézary syndrome; **OR**
    - Primary cutaneous anaplastic large cell lymphoma (ALCL); **OR**
    - Adult T-cell leukemia/lymphoma (ATLL); **AND**
        - Failure of first line therapy; **OR**
    - Extranodal NK/T-cell lymphoma (NKTL); **AND**
        - Failure of asparaginase-based therapy; **OR**
        - Failure of first line therapy; **OR**
    - Hepatosplenic gamma-delta T-cell lymphoma (HGTL); **AND**
        - Failure of 2 prior treatment regimens; **OR**
    - Breast implant-associated anaplastic large cell lymphoma (BI-ALCL); **AND**
        - Failure of first line therapy.

Exclusion criteria:

- Product use for non-FDA approved indications or indications not supported by industry-accepted guidelines;
- Doses, durations, or dosing intervals that exceed FDA maximum limits for any FDA-approved indication or are not supported by industry-accepted practice guidelines or peer-reviewed literature for the relevant off-label use;
- Individuals with significant known risk factors unless the record provides an assessment of clinical benefit that outweighs the risk.

Initial authorization for approved indications is up to 12 months.

Continuation requests may be approved if there is confirmation of clinically significant improvement or stabilization in clinical signs and symptoms of the disease. Clinical documentation provided must be from within the most recent 12 months.

Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

U.S. Food and Drug Administration:

This section is to be used for informational purposes. FDA approval alone is not a basis for coverage.

Folotyn® is a folate analog metabolic inhibitor. The inhibition results in depleting thymidine and other biological molecules that depend on the single carbon transfer that competitively inhibits dihydrofolate reductase.

- Pralatrexate is indicated for treatment of refractory or relapsed Peripheral T-Cell Lymphoma.

References:

1. National Comprehensive Cancer Network, Inc. (Copyright © National Comprehensive Cancer Network, Inc). *NCCN Guidelines: Treatment by Cancer Type*. NCCN Clinical Practice Guidelines in Oncology. Retrieved April 25, 2022, from https://www.nccn.org/guidelines/category_1
2. *Folotyn® (Pralatrexate) Label*. (2009, September). Accessdata.fda.gov. Retrieved January 23, 2023, from https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/022468lbl.pdf

Date	Summary of Changes
September 2021	Criteria for use summary developed by the Ascension Ambulatory Care Expert Review Panel.
January 2023	Criteria for use summary revised by the Ascension Medical Specialty Prior Authorization Team.
February 2023	Criteria for use summary approved by the Ascension Hematology/Oncology Expert Review Panel.
March 2023	Criteria for use summary approved by the Ascension Therapeutic Affinity Group.

If you have questions, call 833-980-2352 to speak to a member of the Ascension Rx prior authorization team or email your questions to smarthealthspecialty@ascension.org.