Pralatrexate (Folotyn®)

NDC CODE(S) 48818-0001-XX FOLOTYN 20MG/ML Solution (ACROTECH BIOPHARMA)

DESCRIPTION

Pralatrexate is folate analog metabolic inhibitor or antimetabolite with antineoplastic properties. It competitively inhibits dihydrofolate reductase and other enzymes causing depletion of thymidine and inhibiting the synthesis of other biological molecules leading to cell death.

POLICY

- Pralatrexate for the treatment of the following is considered ***medically necessary*** if the medical appropriateness criteria are met: **(See Medical Appropriateness below.)**
  - Adult T-cell leukemia/lymphoma
  - Breast Implant-Associated Anaplastic Large Cell Lymphoma (ALCL)
  - Extranodal NK/T-Cell Lymphoma
  - Hepatosplenic Gamma-Delta T-Cell Lymphoma
  - Mycosis fungoides (MF)/Sézary syndrome (SS)
  - Peripheral T-cell lymphoma (PTCL)
  - Primary cutaneous CD30-positive T-cell lymphoproliferative disorder (CD30+ CTCL)
- Pralatrexate for the treatment of other conditions/diseases is considered ***investigational.***

MEDICAL APPROPRIATENESS

INITIAL APPROVAL

- Patient is at least 18 years of age; **AND**

Adult T-Cell Leukemia/Lymphoma
- Used as a single agent in patients who have failed first line therapy for acute or lymphoma subtypes

Mycosis Fungoides/Sezary Syndrome
- Patient does NOT have stage IA-IIA disease with B1 blood involvement

Hepatosplenic Gamma-Delta T-Cell Lymphoma
- Used as a single agent as subsequent therapy; **AND**
- Used for disease that is refractory to two previous primary treatment regimens

Breast Implant-Associated Anaplastic Large Cell Lymphoma (ALCL)
- Used as subsequent therapy; **AND**
- Used as single agent therapy for relapsed or refractory disease

Extranodal NK/T-Cell Lymphoma
- Patient has nasal type disease; **AND**
- Used as single agent therapy for relapsed or refractory disease; **AND**
- Used as subsequent treatment following additional therapy with an alternate asparaginase-based combination chemotherapy regimen that was not previously used

Peripheral T-Cell Lymphoma (PTCL)
- Used as a single agent for relapsed or refractory disease; **AND**
- Patient has one of the following PTCL sub-types:
  - 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
  - Nodal peripheral T-Cell lymphoma with TFH phenotype
  - Follicular T-Cell lymphoma

Primary Cutaneous CD30+ T-Cell Lymphoproliferative Disorders
- Used as a single agent as primary treatment or for relapsed or refractory disease; **AND**
  - Patient has primary cutaneous anaplastic large cell lymphoma (ALCL) with multifocal lesions; **OR**
  - Patient has cutaneous ALCL with regional nodes (excluded systemic disease)

RENEWAL CRITERIA

- Patient continues to meet universal and other indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in Initial Approval Criteria; **AND**
- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: bone marrow suppression (e.g., neutropenia, anemia, and/or thrombocytopenia), mucositis, severe dermatologic reactions, tumor lysis syndrome (TLS), renal toxicity, hepatic toxicity, etc.

DOSAGE/ADMINISTRATION

INDICATION	DOSE
Primary Cutaneous T-cell lymphoma	30 mg/m² intravenously once weekly x 6 doses in 7 week cycles until progressive disease or unacceptable toxicity.
All Other Indications	15 mg/m² intravenously once weekly x 3 doses in 4 week cycles until progressive disease or unacceptable toxicity. -OR 30 mg/m² intravenously once weekly x 6 doses in 7 week cycles until progressive disease or unacceptable toxicity.

LENGTH OF AUTHORIZATION

Coverage will be provided for 6 months and may be renewed

DOSING LIMITS

Max Units (per dose and over time) [HCPC Unit]:

All indications

- 80 billable units weekly x 6 doses in a 7-week cycle

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the Medical Policy and a health plan, the express terms of the health plan will govern.

ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

SOURCES

1. Folotyn [package insert]. East Windsor, NJ; Acrotech Biopharma LLC, September 2020. Accessed December 2020.
2. Referenced with permission from the NCCN Drugs and Biologics Compendium (NCCN Compendium®) pralatrexate. National Comprehensive Cancer Network, 2020. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed December 2020.
3. O'Connor OA, Pro B, Pinter-Brown L, et al. Pralatrexate in patients with relapsed or refractory peripheral T-cell lymphoma: results from the pivotal PROPEL study. J Clin Oncol. 2011 Mar 20;29(9):1182-9. doi:10.1200/JCO.2010.29.9024. Epub 2011 Jan 18.
4. Foss F, Horwitz SM, Coiffier B, et al. Pralatrexate is an effective treatment for relapsed or refractory transformed mycosis fungoides: a subgroup efficacy analysis from the PROPEL study. Clin Lymphoma Myeloma Leuk. 2012 Aug;12(4):238-43. doi: 10.1016/j.clml.2012.01.010. Epub 2012 Apr 26.
5. Horwitz SM, Kim YH, Foss F, et al. Identification of an active, well-tolerated dose of pralatrexate in patients with relapsed or refractory cutaneous T-cell lymphoma. Blood. 2012 May 3;119(18):4115-22. doi: 10.1182/blood-2011-11-390211. Epub 2012 Mar 6.
6. Lunning MA, Gonsky J, Ruan J, et al. Pralatrexate in Relapsed/Refractory HTLV-1 Associated Adult T-Cell Lymphoma/Leukemia: A New York City Multi-Institutional Experience. Blood 120(21):2735-2735. November 2012.
7. Talpur R, Thompson A, Gangar P et al. Pralatrexate alone or in combination with bexarotene: long-term tolerability in relapsed/refractory mycosis fungoides. Clin Lymphoma Myeloma Leuk. 2014 Aug;14(4):297-304. doi: 10.1016/j.clml.2014.01.010. Epub 2014 Feb 4.
8. Lexi-Comp Online. (2020, March). AHFS DI. Pralatrexate. Retrieved December 29, 2020 from Lexi-Comp Online with AHFS.

9. MICROMEDEX Healthcare Series. Drugdex Evaluations. (2020, November). Pralatrexate. Retrieved December 29, 2020 from MICROMEDEX Healthcare Series.

EFFECTIVE DATE 6/2/2021

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