**Pralatrexate (Folotyn®); Pralatrexate**

**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 or government program (e.g., TennCare), the express terms of the health plan or government program will govern.

**The proposal is to add text/statements in red and to delete text/statements with strikethrough:**
**POLICY**

**INDICATIONS**

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications
Indicated for the treatment of patients with relapsed or refractory peripheral T-cell lymphoma (PTCL).

Compendial Uses
- Adult T-cell leukemia/lymphoma (ATLL)
- Mycosis fungoides/Sezary syndrome (MF/SS)
- Cutaneous anaplastic large cell lymphoma (ALCL)
- Subcutaneous panniculitis-like T-cell lymphoma
- Extranodal NK/T-cell lymphoma
- Hepatosplenic T-cell lymphoma
- 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
- Breast implant associated anaplastic large cell lymphoma (ALCL)

All other indications are considered experimental/investigational and not medically necessary.

**COVERAGE CRITERIA ~~FOR INITIAL APPROVAL~~**

**Peripheral T-cell lymphoma (PTCL)**

Authorization of 12 months may be granted for treatment of PTCL (including the following subtypes: 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, or follicular T-cell lymphoma) when both of the following criteria are met:
- The requested medication will be used as a single agent.
- The requested medication will be used to treat relapsed or refractory disease or for initial palliative therapy.

**Adult T-cell leukemia/lymphoma (ATLL)**
Authorization of 12 months may be granted for treatment of ATLL when both of the following criteria are met:

- The requested medication is used as a single agent.
- The requested medication is used as subsequent therapy.

**Mycosis fungoides/Sezary syndrome (MF/SS)**

Authorization of 12 months may be granted for treatment of MF or SS.

**Cutaneous anaplastic large cell lymphoma**

Authorization of 12 months may be granted for treatment of cutaneous anaplastic large cell lymphoma (ALCL) when the requested medication is used as a single agent.

**Subcutaneous panniculitis-like T-cell lymphoma**

Authorization of 12 months may be granted for treatment of subcutaneous panniculitis-like T-cell lymphoma when the requested medication is used as a single agent or in combination with prednisone.

**Extranodal NK/T-cell lymphoma**

Authorization of 12 months may be granted for treatment of extranodal NK/T-cell lymphoma when all of the following criteria are met:

- The requested medication will be used as a single agent.
- The member has relapsed or refractory disease.
- The member has had an inadequate response or contraindication to asparaginase-based therapy (e.g., pegaspargase).

**Hepatosplenic T-cell lymphoma**

Authorization of 12 months may be granted for treatment of hepatosplenic T-cell lymphoma when both of the following criteria are met:

- The requested medication will be used as a single agent.
- The member has had two or more previous lines of chemotherapy.

**Breast implant-associated anaplastic large cell lymphoma (ALCL)**

Authorization of 12 months may be granted for treatment of breast implant associated ALCL when both of the following criteria are met:

- The requested medication will be used as a single agent.
- The requested medication will be used as subsequent therapy.

**CONTINUATION OF THERAPY**

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in the coverage criteria section ~~II~~ when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

## 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.

## 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).

## REFERENCES

1. Folotyn [package insert]. East Windsor, NJ: Acrotech Biopharma Inc.; September 2020.
2. Pralatrexate [package insert]. Lake Zurich, IL: Fresenius Kabi; September 2022.
3. The NCCN Drugs & Biologics Compendium® © 2025 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed April, 9 2025.

## EFFECTIVE DATE

ID_CHS