Reference number(s)
1702-A

SPECIALTY GUIDELINE MANAGEMENT

FOLOTYN (pralatrexate)

POLICY

I. 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.

A. FDA-Approved Indications
Treatment of patients with relapsed or refractory peripheral T-cell lymphoma (PTCL)

B. Compendial Uses
1. Adult T-cell leukemia/lymphoma (ATLL)
2. Mycosis fungoides/Sezary syndrome (MF/SS)
3. Cutaneous anaplastic large cell lymphoma (ALCL)
4. Extranodal NK/T-cell lymphoma, nasal type
5. Hepatosplenic T-cell lymphoma
6. Anaplastic large cell lymphoma
7. Peripheral T-cell lymphoma not otherwise specified
8. Angioimmunoblastic T-cell lymphoma
9. Enteropathy associated T-cell lymphoma
10. Monomorphic epitheliotropic intestinal T-cell lymphoma
11. Nodal peripheral T-cell lymphoma with TFH phenotype
12. Follicular T-cell lymphoma
13. Breast implant associated anaplastic large cell lymphoma (ALCL)
14. Refer to Section II, Criteria for Initial Approval, for additional approvable regimens

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

II. CRITERIA FOR INITIAL APPROVAL

A. 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 the member has relapsed or refractory disease or when used for initial palliative intent.

B. 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:
1. The requested medication is used as a single agent.
2. The requested medication is used as second-line or subsequent therapy.

C. Mycosis fungoides/Sezary syndrome (MF/SS)
Authorization of 12 months may be granted for treatment of MF or SS.

D. 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.

E. Extranodal NK/T-cell lymphoma, nasal type
Authorization of 12 months may be granted for treatment of extranodal NK/T-cell lymphoma, nasal type when all of the following criteria are met:
1. The requested medication will be used as a single agent.
2. The member has relapsed or refractory disease.
3. The member has had an inadequate response or contraindication to asparaginase-based therapy (e.g., pegaspargase).

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

G. 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:
1. The requested medication will be used as a single agent.
2. The requested medication will be used as subsequent therapy.

III. CONTINUATION OF THERAPY

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

IV. REFERENCES

1. Folotyn [package insert]. East Windsor, NJ: Acrotech Biopharma LLC; September 2020.
2. The NCCN Drugs & Biologics Compendium® © 2021 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed April 14, 2021.