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. Primary cutaneous CD30+ T-cell lymphoproliferative disorders: cutaneous anaplastic large cell lymphoma (ALCL)
4. Extranodal NK/T-cell lymphoma, nasal type
5. Hepatosplenic gamma-delta T-cell lymphoma

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 when used for relapsed or refractory disease.

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. Folotyn is used as a single agent.
2. Folotyn 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. Primary cutaneous CD30+ T-cell lymphoproliferative disorders
Authorization of 12 months may be granted for treatment of cutaneous anaplastic large cell lymphoma (ALCL) when Folotyn 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. Folotyn will be used as a single agent.

2. Patient has relapsed or refractory disease.
3. Patient has had an inadequate response or contraindication to asparaginase-based therapy (e.g., pegaspargase).

F. Hepatosplenic Gamma-Delta T-cell lymphoma

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

1. Folotyn will be used a single agent.
2. The patient has had two or more previous lines of chemotherapy.

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 who have not experienced disease progression or an unacceptable toxicity.

IV. REFERENCES

1. Folotyn [package insert]. Westminster, CO: Allos Therapeutics, Inc.; May 2016.
2. The NCCN Drugs & Biologics Compendium® © 2019 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed April 28, 2019.