Medical Policy:

Folotyn® (pralatrexate) injection, Intravenous

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.146	April 8, 2025	

Definitions

Folotyn (pralatrexate): is a novel 10-deazaaminopterin antifolate, structurally similar to methotrexate. It is a competitive inhibitor of dihydrofolate reductase. Compared to other antifolates, pralatrexate was designed to have a greater affinity for the reduced folate carrier and folylpolyglutamyl synthetase, enhancing intracellular accumulation and polyglutamylation in tumor cells.

Length of Authorization

Coverage will be provided for 6 months and may be renewed.

Dosing Limits

Max Units (per dose and over time) [HCPCS Unit]:
80 billable units weekly x 6 doses in a 7-week cycle

Guideline

I. Initial Approval Criteria

Folotyn *may be considered medically necessary if any of the following selection criteria is met:*

1. **Peripheral T-Cell Lymphoma (PTCL)**
    A. The member has relapsed or refractory PTCL (*i.e. angioimmunoblastic T-cell lymphoma, peripheral T-cell lymphoma not otherwise specified, anaplastic large cell lymphoma, enteropathy-associated T-cell lymphoma, or monomorphic epitheliotropic intestinal T-cell lymphoma, Nodal peripheral T-Cell lymphoma with TFH phenotype or Follicular T-Cell lymphoma)*; **AND**
    B. Used as single agent therapy

Limitations/Exclusions

Folotyn is not considered medically necessary for when any of the following selection criteria is met:

1. Folotyn (pralatrexate) is being used after disease progression with the same regimen.
2. Concurrent use with other anti-cancer therapy.
3. Dosing exceeds single dose limit of Folotyn (pralatrexate) 30 mg/m^2.
4. Indications not supported by CMS recognized compendia or acceptable peer reviewed literature may be deemed as not approvable and therefore not reimbursable.

II. Renewal Criteria

1. Patient continues to meet INITIAL APPROVAL CRITERIA; **AND**
2. Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
3. Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: myelosuppression suppression (e.g., neutropenia, anemia, and/or thrombocytopenia), mucositis, severe dermatologic reactions, tumor lysis syndrome (TLS), increased risk of toxicity (e.g., toxic epidermal necrolysis, mucositis, etc.) in patients with severe renal impairment, hepatic toxicity, etc

Dosage/Administration

Indication	Dose
Peripheral T-Cell Lymphoma (PTCL)	30 mg/m^2 IV once weekly for 6 weeks in 7-week cycles until disease progression or unacceptable toxicity.

Applicable Procedure Codes

Code	Description
J9307	Injection, pralatrexate, 1 mg, 1 billable unit = 1 mg

Applicable NDCs

Code	Description
72893-0003-xx	Folotyn 20 mg/ml single use vial
72893-0005-xx	Folotyn 20 mg/ml single use vial
48818-0001-xx	Folotyn 20 mg/mL

ICD-10 Diagnoses

Code	Description
C82.50 - C82.59	Diffuse follicle center lymphoma
C84.00 - C84.09	Mycosis fungoides

C84.10 - C84.19	Sezary disease
C84.40 - C84.49	Peripheral T-hyphencell lymphoma, not classified [adult]
C84.60 - C84.79	Anaplastic large cell lymphoma
C84.A0 - C86.6	Cutaneous T-hyphencell lymphoma unspecified, other mature T/NK-hyphencell lymphomas, mature T/NK-hyphencell lymphomas, other specified and unspecified types of non-hyphenHodgkin lymphoma and other specified types of T/NK-hyphencell lymphoma [relapsed or refractory monomorphic epitheliotropic]
C91.50	Adult T-hyphencell lymphoma/leukemia (HTLV-hyphen1-hyphenassociated) not having achieved remission
C91.51	Adult T-hyphencell lymphoma/leukemia (HTLV-hyphen1-hyphenassociated), in remission
C91.52	Adult T-hyphencell lymphoma/leukemia (HTLV-hyphen1-hyphenassociated), in relapse
C91.Z0	Other lymphoid leukemia not having achieved remission [adult T-hyphencell lymphoma]
C91.Z2	Other lymphoid leukemia, in relapse [adult T-hyphencell lymphoma]

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	04/08/2025	Annual Review: updated NDC. No criteria changes.
EmblemHealth & ConnectiCare	3/1/2024	Annual Review: Added dosing limits Initial Criteria: Peripheral T-Cell Lymphoma (PTCL):Added: "Nodal peripheral T-Cell lymphoma with TFH phenotype or Follicular T-Cell lymphoma(as types); AND Used as single agent therapy; AND" Removed: "Folotyn (pralatrexate is being used as second line or subsequent therapy)" Renewal Criteria: Added: "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: myelosuppression suppression (e.g., neutropenia, anemia, and/or thrombocytopenia), mucositis, severe dermatologic reactions, tumor lysis syndrome (TLS), increased risk of toxicity (e.g., toxic epidermal necrolysis, mucositis, etc.) in patients with severe renal impairment, hepatic toxicity, etc"
EmblemHealth & ConnectiCare	6/29/2023	Annual Review: NDCs removed: 48818-0001-xx, added 72893-0003-xx
EmblemHealth & ConnectiCare	6/15/2022	Transferred policy to new template.
EmblemHealth & ConnectiCare	7/15/2019	Annual review

References

1. Folotyn PI prescribing information. Allos Therapeutics, Inc. Westminster, CO 2016.
2. Clinical Pharmacology Elsevier Gold Standard. 2018.
3. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, Co. 2018.
4. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium. 2018
5. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs. Bethesda, MD. 2018.