

Medical Policy:

Folotyn® (pralatrexate) injection, Intravenous

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.146	March 1, 2024	

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The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as “EmblemHealth”), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

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 folypolyglutamyl 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/m².
- 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

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	3/1/2024	Annual Review: Added dosing limits Initial Criteria: <u>Peripheral T-Cell Lymphoma (PTCL)</u> :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.