Medical Policy:
Pemfexy™ (pemetrexed) injection for intravenous use

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.319	January 23, 2024	September 17, 2020

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

PEMFEXY is a folate analog metabolic inhibitor that exerts its action by disrupting folate-dependent metabolic processes essential for cell replication.

Length of Authorization

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

Dosing Limits [Medical Benefit]

Max Units (per dose and over time):

- 500 mg/m^2 every 21 days for up to 6 cycles

Guideline

I. Initial Approval Criteria

Coverage is provided in the following conditions:

1. **Non-squamous Non-small cell lung cancer (NSCLC)†**
   A. Patient must be 18 years of age; **AND**
   B. Patient is diagnosed with locally advanced or metastatic non-squamous, non-small cell lung cancer (NSCLC) and one of the following (i or ii);
      i. Patient will be using Pemfexy in combination with cisplatin as initial treatment; **OR**
      ii. As a single agent for the maintenance treatment of patients with locally advanced or metastatic non-squamous NSCLC whose disease has not progressed after four cycles of platinum-based first-line chemotherapy; **OR**
   C. Patient is diagnosed with recurrent, metastatic non-squamous NSCLC, and Pemfexy is being used as a single agent after prior chemotherapy; **OR**
   D. Patient will be using Pemfexy in combination with pembrolizumab and platinum chemotherapy, for the initial treatment of metastatic non-squamous non-small cell lung cancer (NSCLC), with no EGFR or ALK genomic tumor aberrations

2. **Mesothelioma†**
   A. Patient must be 18 years of age or older; **AND**
   B. Patient is diagnosed with malignant pleural mesothelioma; **AND**
   C. Pemfexy is being used in combination with cisplatin for initial treatment; **AND**
   D. Patent's disease is unresectable or who are otherwise not candidates for curative surgery.

† FDA Approved Indication(s)

II. RENEWAL CRITERIA

Coverage can be renewed based upon the following criteria:

1. Tumor response with stabilization of disease or decrease in size of tumor or tumor spread; **AND**
2. Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: bone marrow suppression, renal impairment, bullous and exfoliative skin toxicity, interstitial pneumonitis and radiation recall.

Limitations/Exclusions

1. Pemfexy is not indicated for the treatment of patients with squamous cell non-small cell lung cancer.
2. History of severe hypersensitivity reaction to pemetrexed.

Applicable Procedure Codes

Code	Description
J9304	Injection: 500 mg/20 mL (25 mg/mL) in a multi-dose vial
J9314	Injection, pemetrexed (teva) not therapeutically equivalent to J9305, 10 mg
J9294	Injection, pemetrexed (2ospira) not therapeutically equivalent to j9305, 10 mg
J9296	Injection, pemetrexed (accord) not therapeutically equivalent to j9305, 10 mg
J9297	Injection, pemetrexed (sandoz), not therapeutically equivalent to j9305, 10 mg

Applicable NDCs

Code	Description

42367-0531-33	PEMFEXY, multi-dose vial of 500 mg/20 mL (25 mg/mL)

ICD-10 Diagnoses

Code	Description
C34.90	Malignant neoplasm of unspecified part of unspecified bronchus or lung
C33	Malignant neoplasm of trachea
C34.00	Malignant neoplasm of unspecified main bronchus
C34.01	Malignant neoplasm of right main bronchus
C34.02	Malignant neoplasm of left main bronchus
C34.10	Malignant neoplasm of upper lobe, unspecified bronchus or lung
C34.11	Malignant neoplasm of upper lobe, right bronchus or lung
C34.12	Malignant neoplasm of upper lobe, left bronchus or lung
C34.2	Malignant neoplasm of middle lobe, bronchus or lung
C34.30	Malignant neoplasm of lower lobe, unspecified bronchus or lung
C34.31	Malignant neoplasm of lower lobe, right bronchus or lung
C34.32	Malignant neoplasm of lower lobe, left bronchus or lung
C34.80	Malignant neoplasm of overlapping sites of unspecified bronchus or lung
C34.81	Malignant neoplasm of overlapping sites of right bronchus and lung
C34.82	Malignant neoplasm of overlapping sites of left bronchus and lung
C34.91	Malignant neoplasm of unspecified part of right bronchus or lung
C34.92	Malignant neoplasm of unspecified part of left bronchus or lung
C45.0	Mesothelioma of pleura
C38.4	Malignant neoplasm of pleura

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	1/23/2024	Annual Review: No criteria changes
EmblemHealth & ConnectiCare	5/30/2023	Added JCODES – J9314 -Injection, pemetrexed (teva) not therapeutically equivalent to J9305, 10 mg J9294 - Injection, pemetrexed (ospira) not therapeutically equivalent to j9305, 10 mg J9296 - Injection, pemetrexed (accord) not therapeutically equivalent to j9305, 10 mg J9297 - Injection, pemetrexed (sandoz), not therapeutically equivalent to j9305, 10 mg
EmblemHealth & ConnectiCare	05/23/2023	Annual Review: NSCLC: Added: “Patient will be using Pemfexy in combination with pembrolizumab and platinum chemotherapy, for the initial treatment of metastatic non-squamous non-small cell lung cancer (NSCLC), with no EGFR or ALK genomic tumor aberrations”
EmblemHealth & ConnectiCare	09/20/2022	Transferred policy to new template
EmblemHealth & ConnectiCare	02/16/2021	Updated J-Code and NDC Pemfexy description from single-dose vial to multi-dose vial

EmblemHealth & ConnectiCare	09/17/2020	New Policy

References

1. Pemfexy [package insert]. Woodcliff Lake, NJ: Eagle Pharmaceuticals, Inc. February 2022.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed September 2020.