Drug Policy:

Pemazyre™ (pemigatinib)

POLICY NUMBER UM ONC_1398	SUBJECT Pemazyre™ (pemigatinib)		DEPT/PROGRAM UM Dept	PAGE 1 OF 3
DATES COMMITTEE REVIEWED 05/13/20, 04/14/21, 11/15/21, 04/13/22, 05/11/22, 10/12/22, 07/12/23, 07/10/24	**APPROVAL DATE** July 10, 2024	**EFFECTIVE DATE** July 26, 2024	**COMMITTEE APPROVAL DATES** 05/13/20, 04/14/21, 11/15/21, 04/13/22, 05/11/22, 10/12/22, 07/12/23, 07/10/24	
PRIMARY BUSINESS OWNER: UM		**COMMITTEE/BOARD APPROVAL** Utilization Management Committee		
NCQA STANDARDS UM 2		**ADDITIONAL AREAS OF IMPACT**		
CMS REQUIREMENTS	**STATE/FEDERAL REQUIREMENTS**		**APPLICABLE LINES OF BUSINESS** Commercial, Exchange, Medicaid	

I. PURPOSE

To define and describe the accepted indications for Pemazyre (pemigatinib) usage in the treatment of cancer, including FDA approved indications, and off-label indications.

Evolent is responsible for processing all medication requests from network ordering providers. Medications not authorized by Evolent may be deemed as not approvable and therefore not reimbursable.

The use of this drug must be supported by one of the following: FDA approved product labeling, CMS-approved compendia, National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO) clinical guidelines, or peer-reviewed literature that meets the requirements of the CMS Medicare Benefit Policy Manual Chapter 15.

II. INDICATIONS FOR USE/INCLUSION CRITERIA

A. Continuation requests for a not-approvable medication shall be exempt from this Evolent policy provided:

1. The requested medication was used within the last year, AND
2. The member has not experienced disease progression and/or no intolerance to the requested medication, AND
3. Additional medication(s) are not being added to the continuation request.

B. Cholangiocarcinoma

1. Pemazyre (pemigatinib) use as a single agent is supported when ALL of the following criteria are met:
   a. The member has unresectable or metastatic cholangiocarcinoma with disease progression on or after one prior therapy AND

b. A positive test for FGFR2- fibroblast growth factor receptor 2-gene fusion or rearrangement is confirmed in the tumor cell by an approved test (Foundation One CDX test or another gene sequencing test).

C. Myeloid/Lymphoid Neoplasms (MLNs)

1. Pemazyre (pemigatinib) may be used as monotherapy in a member who has relapsed after stem cell transplantation and/or after disease modifying therapies (e.g., chemotherapy) for the treatment of MLNs and the tumor is positive for fibroblast growth factor receptor-1 (FGFR-1) rearrangement.

III. EXCLUSION CRITERIA

A. Disease progression while receiving Pemazyre (pemigatinib) or on prior FGFR2 inhibitor therapy [e.g., Lytgobi (futibatinib)].

B. No confirmatory test is available to confirm the presence of an FGFR-2 (for cholangiocarcinoma) or FGFR-1 (for MLNs) gene fusion/gene rearrangement.

C. Dosing exceeds single dose limit of Pemazyre (pemigatinib) 13.5 mg.

D. For Cholangiocarcinoma: Treatment exceeds the maximum limit of 42 (4.5 mg), 28 (9 mg), 14 (13.5 mg) tablets/month.

E. For MLNs: Treatment exceeds the maximum limit of 90 (4.5 mg), 60 (9 mg), 30 (13.5 mg) tablets/month.

F. Investigational use of Pemazyre (pemigatinib) with an off-label indication that is not sufficient in evidence or is not generally accepted by the medical community. Sufficient evidence that is not supported by CMS recognized compendia or acceptable peer reviewed literature is defined as any of the following:

1. Whether the clinical characteristics of the patient and the cancer are adequately represented in the published evidence.
2. Whether the administered chemotherapy/biologic therapy/immune therapy/targeted therapy/other oncologic therapy regimen is adequately represented in the published evidence.
3. Whether the reported study outcomes represent clinically meaningful outcomes experienced by patients. Generally, the definitions of Clinically Meaningful outcomes are those recommended by ASCO, e.g., Hazard Ratio of less than 0.80 and the recommended survival benefit for OS and PFS should be at least 3 months.
4. Whether the experimental design, considering the drugs and conditions under investigation, is appropriate to address the investigative question. (For example, in some clinical studies, it may be unnecessary or not feasible to use randomization, double blind trials, placebos, or crossover).
5. That non-randomized clinical trials with a significant number of subjects may be a basis for supportive clinical evidence for determining accepted uses of drugs.
6. That case reports are generally considered uncontrolled and anecdotal information and do not provide adequate supportive clinical evidence for determining accepted uses of drugs.
7. That abstracts (including meeting abstracts) without the full article from the approved peer-reviewed journals lack supporting clinical evidence for determining accepted uses of drugs.

IV. MEDICATION MANAGEMENT

A. Please refer to the FDA label/package insert for details regarding these topics.

V. APPROVAL AUTHORITY

A. Review – Utilization Management Department

B. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

A. None

VII. REFERENCES

A. Abou-Alfa GK, et al. Pemigatinib for previously treated, locally advanced or metastatic cholangiocarcinoma: a multicentre, open-label, phase 2 study. Lancet Oncol. 2020 May;21(5):671-684.

B. Gotlib, J et al. A Phase 2 Study of Pemigatinib (FIGHT-203; INCB054828) in Patients with Myeloid/Lymphoid Neoplasms (MLNs) with Fibroblast Growth Factor Receptor 1. Blood (2021) 138 (Supplement 1): 385.

C. Pemazyre prescribing information. Incyte Corporation, Wilmington, DE 2023.

D. Clinical Pharmacology Elsevier Gold Standard 2024.

E. Micromedex® Healthcare Series: Micromedex Drugdex Ann Arbor, Michigan 2024.

F. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium 2024.

G. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs. Bethesda, MD 2024.

H. Ellis LM, et al. American Society of Clinical Oncology perspective: Raising the bar for clinical trials by defining clinically meaningful outcomes. J Clin Oncol. 2014 Apr 20;32(12):1277-80.

I. Medicare Benefit Policy Manual Chapter 15 Covered Medical and Other Health Services: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf.