Pemazyre® (pemigatinib)
(Oral)

Document Number: IC-0534

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I. Length of Authorization

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

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

- Pemazyre 4.5 mg tablet: 1 tablet per day
- Pemazyre 9 mg tablet: 1 tablet per day
- Pemazyre 13.5 mg tablet: 1 tablet per day

B. Max Units (per dose and over time) [HCPCS Unit]:

- Cholangiocarcinoma: 13.5 mg daily for 14 days of each 21-day cycle
- Myeloid/Lymphoid Neoplasms: 13.5 mg daily

III. Initial Approval Criteria [1]

Coverage is provided in the following conditions:

- Patient is at least 18 years of age; **AND**

Universal Criteria [1]

- Patient has received ophthalmological examinations (i.e., assessment of visual acuity, slit lamp examination, fundoscopy, and optical coherence tomography) at baseline and periodically throughout therapy; **AND**
- Patient serum phosphate level is measured at baseline and periodically throughout therapy; **AND**
- Therapy will not be used concomitantly with other selective FGFR-inhibitors (e.g., erdafitinib, etc.); **AND**
- Used as single agent therapy; **AND**
- Patient will avoid concomitant therapy with all of the following:

- Coadministration with strong or moderate CYP3A Inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.); **AND**
- Coadministration with strong or moderate CYP3A Inhibitors (e.g., fluconazole, itraconazole, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**

Cholangiocarcinoma † Φ [1,2]

- Patient has unresectable locally advanced or metastatic disease; **AND**
- Patient has a susceptible gene mutation rearrangement or fusion in the fibroblast growth factor receptor 2 (FGFR2) gene, as determined by an FDA-approved or CLIA-compliant test §; **AND**
- Used as subsequent therapy after systemic treatment

Myeloid/Lymphoid Neoplasms † ‡ [1,2,6]

- Patient has fibroblast growth factor receptor 1 (FGFR1) rearrangement; **AND**
  - Patient has relapsed or refractory disease †; **OR**
  - Patient has chronic or blast phase disease ‡; **AND**
    - Patient has eosinophilia; **AND**
    - Treatment with a clinical trial is unavailable

§ *If confirmed using an FDA approved assay* - http://www.fda.gov/companiondiagnostics

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Φ Orphan Drug

IV. Renewal Criteria [1]

Coverage may be renewed based upon the following criteria:

- Patient continues to meet the universal and indication specific criteria as identified in section III; **AND**
- Disease response with treatment 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: retinal pigment epithelial detachment (RPED), severe hyperphosphatemia and soft tissue mineralization, etc.; **AND**
- Patient serum phosphate level is < 7.0 mg/dL

V. Dosage/Administration [1]

Indication	Dose

Cholangiocarcinoma	Administer 13.5 mg orally once daily for 14 consecutive days followed by 7 days off therapy, in 21-day cycles. Continue treatment until disease progression or unacceptable toxicity occurs.
Myeloid/Lymphoid Neoplasms	Administer 13.5 mg orally once daily on a continuous basis. Continue treatment until disease progression or unacceptable toxicity occurs.

VI. Billing Code/Availability Information

HCPCS Code:

- J8999 – Prescription drug, oral, chemotherapeutic, not otherwise specified
- C9399 – Unclassified drugs or biologicals *(Hospital Outpatient Use ONLY)*

NDC(s):

- Pemazyre 4.5 mg tablet: 50881-0026-xx
- Pemazyre 9 mg tablet: 50881-0027-xx
- Pemazyre 13.5 mg tablet: 50881-0028-xx

VII. References

1. Pemazyre [package insert]. Wilmington, DE; Incyte, Corp.; August 2022. Accessed August 2022.
2. Referenced with permission from the NCCN Drugs and Biologics Compendium (NCCN Compendium®) pemigatinib. National Comprehensive Cancer Network, 2022. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed August 2022.
3. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Hepatobiliary Cancers. Version 5.2021. National Comprehensive Cancer Network, 2022. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed March 2022.
4. Qiagen. therascreen® FGFR RGQ RT-PCR Kit Companion Diagnostic Test. www.qiagen.com/fgfr-lab-finder. Accessed April 2020
5. Abou-Alfa GK, Sahai V, Hollebecque A, et al. Pemigatinib for previously treated, locally advanced or metastatic cholangiocarcinoma: a multicentre, open-label, phase 2 study. Lancet Oncol. 2020 Mar 20. pii: S1470-2045(20)30109-1. doi: 10.1016/S1470-2045(20)30109-1. [Epub ahead of print]

6. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Fusion Genes. Version 1.2022. National Comprehensive Cancer Network, 2022. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed August 2022.
7. Verstovsek S, Vannucchi A, Rambaldi A, et al. Interim Results from Fight-203, a Phase 2, Open-Label, Multicenter Study Evaluating the Efficacy and Safety of Pemigatinib (INCB054828) in Patients with Myeloid/Lymphoid Neoplasms with Rearrangement of Fibroblast Growth Factor Receptor 1 (FGFR1). Blood 2018; 132 (Supplement 1): 690. doi: https://doi.org/10.1182/blood-2018-99-110388.
8. Gotlib J, Kiladjian JJ, Vannucchi A, et al. A Phase 2 Study of Pemigatinib (FIGHT-203; INCB054828) in Patients with Myeloid/Lymphoid Neoplasms (MLNs) with Fibroblast Growth Factor Receptor 1 (FGFR1) Rearrangement (MLN FGFR1). Blood 2021; 138 (Supplement 1): 385. Doi: https://doi.org/10.1182/blood-2021-148103.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C22.1	Intrahepatic bile duct carcinoma
C24.0	Malignant neoplasm of extrahepatic bile duct
C24.8	Malignant neoplasm of overlapping sites of biliary tract
C24.9	Malignant neoplasm of biliary tract, unspecified
C94.8	Other specified leukemias
C94.80	Other specified leukemias not having achieved remission
C94.81	Other specified leukemias not having achieved remission
C94.82	Other specified leukemias, in relapse
C95.1	Other specified leukemias, in relapse
C95.10	Chronic leukemia of unspecified cell type not having achieved remission
C95.11	Chronic leukemia of unspecified cell type, in remission
C95.12	Chronic leukemia of unspecified cell type, in relapse
C96.Z	Other specified malignant neoplasms of lymphoid, hematopoietic and related tissue
C96.9	Malignant neoplasm of lymphoid, hematopoietic and related tissue, unspecified

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage

Determination (NCD), Local Coverage Determinations (LCDs) and Local Coverage Articles (LCAs) may exist and compliance with these policies is required where applicable. They can be found at: http://www.cms.gov/medicare-coverage-database/ search.aspx. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC