Pemazyre™ (pemigatinib)
(Oral)

Document Number: IC-0534

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Dates Reviewed: 05/2020, 05/2021, 05/2022

I. Length of Authorization

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

II. Dosing Limits

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

- Pemazyre 4.5 mg tablet: 14 tablets per each 21-day cycle
- Pemazyre 9 mg tablet: 14 tablets per each 21-day cycle
- Pemazyre 13.5 mg tablet: 14 tablets per each 21-day cycle

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

- 13.5 mg daily for 14 days of each 21-day cycle

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**
- Patient will not be on concomitant therapy with any of the following:
  - Strong or moderate CYP3A Inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.); **AND**
  - Strong or moderate CYP3A4 Inhibitors (e.g., fluconazole, itraconazole, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications; **AND**

Cholangiocarcinoma † Φ [1,2]

- Must be used as a single agent; **AND**
- 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 with Eosinophilia ‡ [6,7]

- Patient has FGFR1 rearrangement; **AND**
    - Patient has chronic or blast phase disease; **AND**
        - Treatment with a clinical trial is unavailable; **OR**
    - Patient has lymphoid, myeloid, or mixed lineage neoplasms; **AND**
        - Used in combination with ALL- or AML-type induction chemotherapy followed by allogeneic HCT (if eligible)

§ *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

Coverage can 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 central serous retinopathy/retinal pigment epithelial detachment (CSR/RPED), severe hyperphosphatemia, etc.; **AND**
- Patient serum phosphate level is < 7.0 mg/dL

V. Dosage/Administration

Indication	Dose
Cholangiocarcinoma/ Myeloid/Lymphoid Neoplasms with Eosinophilia	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.

VI. Billing Code/Availability Information

HCPCS code:

- J8999 – Prescription drug, oral, chemotherapeutic, not otherwise specified

NDC:

- 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.; June 2021. Accessed March 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 March 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 4.2021. 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.

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). https://doi.org/10.1182/blood-2018-99-110388

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)

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
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