PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Pemazyre Prior Authorization Policy
- Pemazyre® (pemigatinib tablets – Incyte)

REVIEW DATE: 05/08/2024

OVERVIEW
Pemazyre, a kinase inhibitor, is indicated in adults for the following uses:[1]
- Previously treated, unresectable locally advanced or metastatic **cholangiocarcinoma** with a fibroblast growth factor receptor 2 (*FGFR2*) fusion or other rearrangement as detected by an FDA-approved test.
- Relapsed or refractory **myeloid/lymphoid neoplasms** with fibroblast growth factor receptor 1 (*FGFR1*) rearrangement.

Guidelines
Pemazyre is addressed in National Comprehensive Cancer Network (NCCN) guidelines:[2]
- **Biliary tract cancers**: Guidelines (version 2.2024 – April 19, 2024) recommend Pemazyre for disease progression on or following systemic treatment for patients with unresectable or metastatic cholangiocarcinoma with *FGFR2* fusion or rearrangement, as a single agent (category 2A).[3]
- **Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Fusion Genes**: Guidelines (version 1.2024 – December 21, 2023) recommend Pemazyre for the treatment of myeloid/lymphoid neoplasms with eosinophilia and *FGFR1* rearrangement in chronic phase or blast phase (category 2A).[2,4]

POLICY STATEMENT
Prior Authorization is recommended for prescription benefit coverage of Pemazyre. All approvals are provided for the duration noted below.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA
Coverage of Pemazyre is recommended in those who meet one of the following criteria:

FDA-Approved Indications

1. **Cholangiocarcinoma.** Approve for 1 year if the patient meets ALL of the following criteria (A, B, C, and D):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has unresectable locally advanced or metastatic disease; AND
   - **C)** Tumor has fibroblast growth factor receptor 2 (*FGFR2*) fusion or other rearrangement, as detected by an approved test; AND
   - **D)** Patient has been previously treated with at least one systemic regimen.
     Note: Examples of systemic regimens are gemcitabine + cisplatin, 5-fluorouracil + oxaliplatin or cisplatin, capecitabine + cisplatin or oxaliplatin, gemcitabine + Abraxane (albumin-bound paclitaxel) or capecitabine or oxaliplatin, gemcitabine + Abraxane + cisplatin, FOLFOX (5-

fluorouracil, leucovorin, and oxaliplatin), FOLFIRI (5-fluorouracil, leucovorin, irinotecan), Stivarga (regorafenib tablets).

2. Myeloid/Lymphoid Neoplasms. Approve for 1 year if the patient meets ALL of the following criteria (A, B, C, and D):
- **A)** Patient is ≥ 18 years of age; AND
- **B)** Patient has eosinophilia; AND
- **C)** The cancer has fibroblast growth factor receptor 1 (*FGFR1*) rearrangement, as detected by an approved test; AND
- **D)** The cancer is in chronic phase or blast phase.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Pemazyre is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Pemazyre® tablets [prescribing information]. Wilmington, DE: Incyte; August 2022.
2. The NCCN Drugs & Biologics Compendium. © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on May 2, 2024. Search term: pemigatinib.
3. The NCCN Biliary Tract Cancers Clinical Practice Guidelines in Oncology (version 2.2024 – April 19, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on May 2, 2024.
4. The NCCN Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Fusion Genes Clinical Practice Guidelines in Oncology (version 1.2024 – December 21, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on May 2, 2024.