

## PRIOR AUTHORIZATION POLICY

**POLICY:** Oncology – Pemazyre Prior Authorization Policy

- Pemazyre® (pemigatinib tablets – Incyte)

**REVIEW DATE:** 05/08/2024

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### OVERVIEW

Pemazyre, a kinase inhibitor, is indicated in adults for the following uses:<sup>1</sup>

- 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:<sup>2</sup>

- **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).<sup>3</sup>
- **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).<sup>2,4</sup>

### 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  $\geq 18$  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-

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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  $\geq$  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.