VENTURA COUNTY
HEALTH CARE PLAN

# PRIOR AUTHORIZATION POLICY

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

**REVIEW DATE:** 05/04/2022; selected revision 06/22/2022 and 09/14/2022

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## 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]

- **Hepatobiliary cancers**: NCCN guidelines (version 1.2022 – March 29, 2022) 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**: NCCN guidelines (version 1.2022 – April 14, 2022) recommend Pemazyre for the treatment of myeloid/lymphoid neoplasms with eosinophilia and *FGFR1* rearrangement in chronic phase or blast phase (category 2A).[4] Treatment in a clinical trial is preferred, if available, rather than off-label use.

## 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. © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed September 6, 2022. Search term: pemigatinib.
3. The NCCN Hepatobiliary Cancers Clinical Practice Guidelines in Oncology (version 1.2022 – March 29, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on May 2, 2022.
4. The NCCN Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Fusion Genes Clinical Practice Guidelines in Oncology (version 1.2022 – April 14, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on September 6, 2022.

## HISTORY

| Type of Revision | Summary of Changes | Review Date |
|---|---|---|
| Annual Revision | No criteria changes.<br>Revised the Note regarding examples of systemic regimens: Added FOLFIRI (5-fluorouracil, leucovorin, irinotecan), Stivarga (regorafenib tablets). | 04/28/2021 |
| Annual Revision | **Cholangiocarcinoma.** Added requirement that the patient is ≥ 18 years of age.<br>**Myeloid/Lymphoid Neoplasms.** Added new condition of approval. | 05/04/2022 |
| Selected Revision | **Cholangiocarcinoma.** Changed approval duration from 3 years to 1 year.<br>**Myeloid/Lymphoid Neoplasms.** Changed approval duration from 3 years to 1 year. | 06/22/2022 |
| Selected Revision | **Myeloid/Lymphoid Neoplasms:** Moved indication to FDA-Approved Indications. | 09/14/2022 |