PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Pemazyre™ (pemigatinib tablets – Incyte Corporation)

DATE REVIEWED: 04/22/2020

OVERVIEW

Pemazyre is indicated for the treatment of adults with 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.[1] This indication is approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

Guidelines

Pemazyre is not addressed in the guidelines. According to the National Comprehensive Cancer Network (NCCN) hepatobiliary guidelines (version 1.2020 – March 23, 2020), for primary treatment of unresectable and metastatic disease, gemcitabine + cisplatin is the category 1 preferred regimen. Upon disease progression, FOLFOX is the preferred subsequent therapy regimen (category 2A). Other recommended regimens are FOLFIRI (category 2B) or Stivarga (regorafenib tablets) [category 2B]. For neurotrophic receptor tyrosine kinase (*NTRK*) gene fusion-positive tumors, Vitrakvi (larotrectinib capsules) and Rozlytrek (entrectinib capsules) are recommended (both category 2A); Keytruda (pembrolizumab for injection) is recommended for microsatellite instability high (MSI-H) and mismatch repair-deficient (dMMR) tumors (category 2A).

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 the following criteria:

FDA-Approved Indications

1. **Cholangiocarcinoma.** Approve for 3 years if the patient meets the following criteria (A and B):
   - **A)** The patient has unresectable locally advanced or metastatic disease with a fibroblast growth factor receptor 2 (*FGFR2*) fusion or other rearrangement, as detected by an approved test; AND
   - **B)** The patient has been previously treated with at least one systemic therapy regimen.
     Note: Examples are gemcitabine + cisplatin, 5-fluorouracil + oxaliplatin or cisplatin, capecitabine + oxaliplatin or cisplatin, gemcitabine + Abraxane or capecitabine or oxaliplatin, FOLFOX (5-fluorouracil, leucovorin, and oxaliplatin).

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Pemazyre has not been shown to be effective or there are limited or preliminary data that are not supportive of general approval for the following conditions.

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 Corporation; April 2020.
2. The NCCN Hepatobiliary Cancers Clinical Practice Guidelines in Oncology (Version 1.2020 – March 23, 2020). © 2020 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on April 19, 2020.