PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 04/28/2021

OVERVIEW

Pemazyre, a kinase inhibitor, 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

The National Comprehensive Cancer Network (NCCN) hepatobiliary cancers guidelines (version 1.2021 – March 5, 2021) note Pemazyre as a useful therapy for the treatment of patients with cholangiocarcinoma with FGFR2 fusion or rearrangement. NCCN notes gemcitabine + cisplatin as the preferred regimen (category 1) for the primary treatment of unresectable and metastatic biliary tract cancer. Other recommended regimens include 5-fluorouracil (5-FU) + oxaliplatin or cisplatin; capecitabine + cisplatin or oxaliplatin, gemcitabine + Abraxane® (albumin-bound paclitaxel intravenous injection) or capecitabine or oxaliplatin, and gemcitabine + Abraxane + cisplatin. Upon disease progression, the preferred regimen (category 2A) is FOLFOX (5-FU, folinic acid [leucovorin], and oxaliplatin). Other regimens include FOLFIRI (folinic acid [leucovorin], 5-FU, irinotecan [category 2B]), and Stivarga® (regorafenib tablets) [category 2B]. NCCN lists other regimens that are useful in patients with specific cases: Neurotrophic receptor tyrosine kinase gene fusion-positive tumors: Rozlytrek™ (entrecitinb capsules) and Vitrakvi® (larotrectinib capsules); microsatellite instability high/mismatch repair-deficient/tumor mutational burden-high tumors: Keytruda® (pembrolizumab intravenous injection); cholangiocarcinoma with isocitrate dehydrogenase 1 mutations: Tibsovo® (ivosidenib tablets); BRAF-V600E mutated tumors: Tafinlar® (dabrafenib capsules) + Mekinist® (trametinib tablets). Opdivo® (nivolumab intravenous injection) and Lenvima® (lenvatinib capsules) + Keytruda are also listed as useful regimens.

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)** 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)** 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).

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 Corporation; February 2021.
2. The NCCN Hepatobiliary Cancers Clinical Practice Guidelines in Oncology (Version 1.2021 – March 5, 2021). © 2021 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on April 16, 2021.