

<b>Clinical Policy Title:</b>	pemigatinib
<b>Policy Number:</b>	RxA.635
<b>Drug(s) Applied:</b>	Pemazyre®
<b>Original Policy Date:</b>	07/05/2020
<b>Line of Business Policy Applies to:</b>	All lines of business

## Background

Pemazyre is a kinase inhibitor 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.

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).

## Dosing Information

Drug Name	Dosing Regimen	Maximum Dose
pemigatinib (Pemazyre®)	13.5mg once daily PO on days 1 to 14 of a 21-day cycle; continue until disease progression or unacceptable toxicity	13.5mg/day

## Dosage Forms

- Oral Tablets: 4.5 mg, 9 mg, and 13.5 mg.

## Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

### I. Initial Approval Criteria

#### A. Unresectable locally advanced or metastatic cholangiocarcinoma (must meet all):

1. Diagnosis of cholangiocarcinoma;
2. Positive result of FDA-approved test to determine fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement;
3. Prescribed by or in consultation with an oncologist;
4. Age ≥ 18 years;
5. Patient must have tried and failed at least 1 regimen as recommended by NCCN.

#### Approval Duration:

**Commercial:** 6 months

**Medicaid:** 6 months

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

**II. Continued Therapy Approval**

**A. All Indications in Section I (must meet all):**

1. Currently receiving medication that has been authorized by RxAdvance, or documentation supports that member is currently receiving Pemazyre® for a covered indication and has received this medication for at least 30 days;
2. Member is responding positively to therapy;

**Approval Duration**

**Commercial:** 12 months

**Medicaid:** 12 months

**III. Appendices**

**APPENDIX A: Abbreviation/Acronym Key**

FGFR2: fibroblast growth factor receptor 2

FDA: Food and Drug Administration

PO: by mouth

**APPENDIX B: Therapeutic Alternatives**

There are no FDA-approved medications for previously treated, unresectable locally advanced or metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement. Standard therapy has been combination of chemotherapy agents that might include gemcitabine, paclitaxel, oxaliplatin, cisplatin, fluorouracil, capecitabine, and/or epirubicin. Outcome data from these studies have shown PFS ranging from 2.6 to 3.2 months, with a median OS of 6.2 to 7.2 months.

**APPENDIX C: Contraindications/Boxed Warnings**

- Contraindication(s):
  - None.
- Boxed Warning(s):
  - None.

**References**

1. Pemazyre (pemigatinib) [prescribing information]. Wilmington, DE: Incyte Corporation; April 2020. Available at: [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2020/213736s000lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/213736s000lbl.pdf). Accessed on July 5, 2020.
2. Pemigatinib. Lexi-Drugs. Hudson, OH: Lexicomp, 2020. <http://online.lexi.com/>. Updated June 24, 2020. Accessed July 5, 2020.
3. National Comprehensive Cancer Network Guidelines. Hepatobiliary Cancers Version 4.2020. Available at: [https://www.nccn.org/professionals/physician\\_gls/pdf/hepatobiliary.pdf](https://www.nccn.org/professionals/physician_gls/pdf/hepatobiliary.pdf). Published June 19, 2020. Accessed July 5, 2020.
4. Abou-Alfa GK, Sahai V, Hollebecque A, et al. Pemigatinib for previously treated, locally advanced or metastatic cholangiocarcinoma: a multicentre, open-label, phase 2 study [published online March 20, 2020]. *Lancet Oncol*. doi:10.1016/S1470-2045(20)30109-1. Accessed on July 5, 2020.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	07/05/2020	09/14/2020