

# Specialty Guideline Management

## Pemazyre

### Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Pemazyre	pemigatinib

### Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

#### FDA-approved Indications

- 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.
- Treatment of adults with relapsed or refractory myeloid/lymphoid neoplasms (MLNs) with fibroblast growth factor receptor 1 (FGFR1) rearrangement.

#### Compendial Uses

- Cholangiocarcinoma
- Myeloid/lymphoid neoplasms with eosinophilia and FGFR1 rearrangement in chronic phase or blast phase

All other indications are considered experimental/investigational and not medically necessary.

Reference number(s)
3822-A

## Documentation

Submission of the following information is necessary to initiate the prior authorization review:  
Documentation of FGFR2 fusion or rearrangement or FGFR1 rearrangement (where applicable)

## Coverage Criteria

### Cholangiocarcinoma

Authorization of 12 months may be granted for subsequent treatment of progressive, unresectable, resected gross residual (R2) disease or metastatic cholangiocarcinoma with a FGFR2 fusion or rearrangement, when used as a single agent.

### Myeloid/Lymphoid Neoplasms

Authorization of 12 months may be granted for treatment of myeloid/lymphoid neoplasms with FGFR1 rearrangement.

## Continuation of Therapy

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in the coverage criteria section when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

## References

1. Pemazyre [package insert]. Wilmington, DE: Incyte Corporation; June 2023.
2. The NCCN Drugs & Biologics Compendium® © 2024 National Comprehensive Cancer Network, Inc. <https://www.nccn.org>. Accessed July 9, 2024.