

SPECIALTY GUIDELINE MANAGEMENT

PEMAZYRE (pemigatinib)

POLICY

I. 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.

A. FDA-Approved Indication

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

B. Compendial Uses

1. Cholangiocarcinoma
2. 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.

II. 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)

III. CRITERIA FOR INITIAL APPROVAL

A. **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.

B. **Myeloid/Lymphoid Neoplasms**

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

IV. CONTINUATION OF THERAPY

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

Reference number(s)
3822-A

V. REFERENCES

1. Pemazyre [package insert]. Wilmington, DE: Incyte Corporation; June 2023.
2. The NCCN Drugs & Biologics Compendium® © 2023 National Comprehensive Cancer Network, Inc. <https://www.nccn.org>. Accessed July 10, 2023.