

Reference number(s)
3822-A

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

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.

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).

B. Compendial Uses

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 treatment of members with previously treated, unresectable locally advanced or metastatic cholangiocarcinoma with a FGFR2 fusion or rearrangement.

B. **Myeloid/Lymphoid Neoplasms with Eosinophilia**

Authorization of 12 months may be granted for treatment of myeloid and/or lymphoid neoplasms with eosinophilia and FGFR1 rearrangement in the chronic phase or blast phase.

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.

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V. REFERENCES

1. Pemazyre [package insert]. Incyte Corporation: Wilmington, DE; April 2020.
2. The NCCN Drugs & Biologics Compendium® © 2020 National Comprehensive Cancer Network, Inc. <https://www.nccn.org>. Accessed August 18, 2020.