Clinical Policy: Pemigatinib (Pemazyre)

Reference Number: ERX.SPA.399
Effective Date: 09.01.20
Last Review Date: 08.21
Line of Business: Commercial, Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Pemigatinib (Pemazyre™) is a small molecule kinase inhibitor that inhibits fibroblast growth factor receptor (FGFR).

FDA Approved Indication(s)
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).

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

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ that Pemazyre is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Cholangiocarcinoma (must meet all)**:**

1. Diagnosis of unresectable locally advanced or metastatic cholangiocarcinoma;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Documentation of FGFR2 fusion or rearrangement;
5. Member has not previously received a selective FGFR inhibitor (e.g., Stivarga®);
6. Failure of at least one previous systemic cancer therapy (*see Appendix B*);
7. Request meets one of the following (a or b):*
   a. Dose does not exceed 13.5 mg (1 tablet) per day;
   b. Dose is supported by practice guideline or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration:
Commercial – Length of Benefit
Medicaid – 6 months

B. Myeloid/Lymphoid Neoplasms with Eosinophilia (off-label) (must meet all)**:**

1. Diagnosis of myeloid/lymphoid neoplasms with eosinophilia;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Confirmation of FGFR1 rearrangement;
5. Member is unable to enroll in a Pemazyre clinical trial;
6. Request meets one of the following (a or b):*

a. Dose does not exceed 13.5 mg (1 tablet) per day;
b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration:
Commercial – Length of Benefit
Medicaid – 6 months

C. Other diagnoses/indications

1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

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

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions, 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;
3. If request is for a dose increase, request meets one of the following (a or b):*
   a. New dose does not exceed 13.5 mg (1 tablet) per day;
   b. New dose is supported by practice guideline or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration:
Commercial – Length of Benefit
Medicaid –12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – ERX.PA.01 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
FGFR: fibroblast growth factor receptor

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
gemcitabine (Gemzar®) + cisplatin	Gemcitabine 1,000 mg/m^2 IV in combination with cisplatin 25 mg/m^2 IV, both on days 1 and 8 every 21 days for 8 cycles	Varies
5-fluorouracil + oxaliplatin	Varies	Varies
5-fluorouracil + cisplatin	Varies	Varies

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
capecitabine (Xeloda®) + cisplatin	Varies	Varies
capecitabine (Xeloda®) + oxaliplatin	Varies	Varies
gemcitabine + Abraxane®	Varies	Varies
gemcitabine (Gemzar®) + capecitabine (Xeloda®)	Varies	Varies
gemcitabine (Gemzar®) + oxaliplatin	Varies	Varies
5-fluorouracil	Varies	Varies
capecitabine (Xeloda®)	Varies	Varies
gemcitabine (Gemzar®)	Varies	Varies
FOLFOX (5-fluorouracil, leucovorin, oxaliplatin)	Varies	Varies

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings
None reported

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Cholangiocarcinoma	13.5 mg PO QD for 14 days followed by 7 days off therapy, in 21-day cycles	13.5 mg/day

VI. Product Availability
Tablets: 4.5 mg, 9 mg, 13.5 mg

VII. References
1. Pemazyre Prescribing Information. Wilmington, DE: Incyte Corporation; February 2021. Available at: https://www.pemazyre.com/pdf/prescribing-information.pdf. Accessed March 25, 2021.
2. 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. Lancet Oncol 2020 Marc 20;S1470-2045(20)30109-1.
3. Ghassan A, Sahai V, Hollebecque A, et al. Pemigatinib for previously treated, locally advanced or metastatic cholangiocarcinoma: a multicentre, open-label, phase 2 study. Lancet Oncol 2020 May; 21(5):671-684.
4. National Comprehensive Cancer Network. Hepatobiliary Cancers v1.2021. Available at: https://www.nccn.org/professionals/physician_gls/pdf/hepatobiliary.pdf. Accessed March 25, 2021.
5. National Comprehensive Cancer Network. Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Fusion Genes v3.2021. Available at: https://www.nccn.org/professionals/physician_gls/pdf/mlne.pdf. Accessed March 25, 2021.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	05.26.20	08.20
3Q 2021 annual review: added NCCN compendium supported off-label use in myeloid/lymphoid neoplasms with eosinophilia and tyrosine kinase fusion genes; for cholangiocarcinoma remove language allowing for first-line use if other alternatives are not suitable, as Pemazyre is only indicated as second-line therapy; references reviewed and updated.	03.25.21	08.21

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.