

Clinical Policy Title:	pemigatinib
Policy Number:	RxA.635
Drug(s) Applied:	Pemazyre®
Original Policy Date:	07/05/2020
Last Review Date:	09/14/2021
Line of Business Policy Applies to:	All lines of business

Background

Pemigatinib (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	Indication	Dosing Regimen	Maximum Dose
pemigatinib (Pemazyre®)	Unresectable locally advanced or metastatic cholangiocarcinoma	13.5 mg orally once daily for 14 consecutive days followed by 7 days off therapy in 21-day cycles. Continue treatment until disease progression or unacceptable toxicity occurs Severe renal impairment and Hepatic Impairment: 9 mg orally once daily for 14 consecutive days followed by 7 days off therapy in 21-day cycles.	13.5 mg/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. The provision of provider samples does not guarantee coverage under the terms of the pharmacy benefit administered by RxAdvance. All criteria for initial approval must be met in order to obtain coverage.

I. Initial Approval Criteria

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

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.

1. Diagnosis of unresectable locally advanced or metastatic 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 \geq 18 years;
5. Patient must have tried and failed at least 1 regimen as recommended by NCCN.
6. Maximum dose does not exceed 13.5 mg/day.

Approval Duration

Commercial: 6 months

Medicaid: 6 months

B. Myeloid/Lymphoid Neoplasms with Eosinophilia & Tyrosine Kinase Fusion Gene (off-label) (must meet all):

1. Diagnosis of Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Fusion Gene;
2. Prescribed by or in consultation with an oncologist;
3. Age \geq 18 years;
4. Positive result of FDA-approved test to determine fibroblast growth factor receptor 1 (FGFR1) in chronic phase or blast phase;
5. Request meets one of the following (a or b):
 - a. Treatment with a preferred clinical trial rather than off-label use;
 - b. Treatment in combination with ALL- or AML-type induction chemotherapy followed by allogeneic HCT (if eligible) for lymphoid, myeloid or mixed lineage neoplasms with eosinophilia and FGFR1 rearrangement in blast phase;
6. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (Prescriber must submit supporting evidence).

Approval Duration

Commercial: 6 months

Medicaid: 6 months

II. Continued Therapy Approval

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

1. Member is 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;
3. Maximum dose does not exceed (a or b):
 - a. Cholangiocarcinoma: 13.5 mg/day;
 - b. Myeloid/Lymphoid Neoplasms: Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).

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

NCCN: National Comprehensive Cancer Network

ALL: Acute lymphoblastic leukemia

AML: Acute myeloid leukemia
 HCT: Hematopoietic cell transplantation
 OCT: Optical coherence tomography
 PFS: Progression free survival

APPENDIX B: Therapeutic Alternatives

Not Applicable.

APPENDIX C: Contraindications/Boxed Warnings

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

APPENDIX D: General Information

- Ocular Toxicity: Pemazyre® can cause retinal pigment epithelial detachment. Perform ophthalmological examination including optical coherence tomography (OCT) prior to initiation of therapy, every 2 months for the first 6 months of treatment and every 3 months thereafter, and urgently at any time for visual symptoms.
- Hyperphosphatemia and Soft Tissue Mineralization: Pemazyre® can cause hyperphosphatemia leading to soft tissue mineralization, cutaneous calcification, calcinosis, and non-uremic calciphylaxis. Monitor for hyperphosphatemia and withhold, reduce the dose, or permanently discontinue based on duration and severity of hyperphosphatemia.
- Embryo-Fetal Toxicity: Can cause fetal harm. Advise patients of reproductive potential of the potential risk to the fetus and use effective contraception.
- Renal impairment (severe, estimated GFR 15 to 29 mL/min/1.73 m(2), estimated by Modification of Diet in Renal Disease (MDRD))
- Hepatic impairment (severe, total bilirubin greater than 3x ULN with any AST)

References

1. Pemazyre® (pemigatinib) [prescribing information]. Wilmington, DE: Incyte Corporation; February 2021. Available at: <https://www.pemazyre.com/> . Accessed July 2, 2021.
2. Pemigatinib. Lexi-Drugs. Hudson, OH: Lexicomp, 2020. <http://online.lexi.com/> . Updated June 5, 2021. Accessed July 2, 2021.
3. National Comprehensive Cancer Network Guidelines. Hepatobiliary Cancers Version 3.2021. Available at: https://www.nccn.org/professionals/physician_gls/pdf/hepatobiliary.pdf. Published June 15, 2021. Accessed July 2, 2021.
4. National Comprehensive Cancer Network Guidelines. Myeloid/Lymphoid Neoplasms with Eosinophilia & Tyrosine Kinase Fusion Gene Version 3.2021. Available at: https://www.nccn.org/professionals/physician_gls/pdf/mlne.pdf . Published August 21,2020. Accessed July 2, 2021.
5. 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. Available at: <https://pubmed.ncbi.nlm.nih.gov/32203698/>. Accessed July 2, 2021.

Review/Revision History	Review/Revised Date	P&T Approval Date

Policy established.	07/05/2020	09/14/2020
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> 1. Clinical Policy Title was updated to include Last Review Date. 2. Dosing Information was updated to include indication “Unresectable locally advanced or metastatic cholangiocarcinoma”. 3. Dosing Information dosing regimen was updated to include renal and hepatic impairment dosing “Severe renal impairment and Hepatic Impairment: 9 mg orally once daily...”. 4. Statement about provider sample “The provision of provider samples does not guarantee coverage...” was added to Clinical Policy. 5. Initial Approval Criteria I.A.6 was updated to include “Maximum dose does not exceed 13.5 mg/day”. 6. Initial Approval Criteria I.B was updated to include off-label indication “Myeloid/Lymphoid Neoplasms with Eosinophilia & Tyrosine Kinase Fusion Gene (off-label)”. 7. Continued Therapy Approval Criteria II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...". 8. Continued Therapy Approval Criteria II.A.3 was updated to include “Maximum dose does not exceed (a or b)...”. 9. Continued Therapy Approval Criteria II.A.3.a was updated to include “Cholangiocarcinoma: 13.5 mg/day”. 10. Continued Therapy Approval Criteria II.A.3.b was updated to include “Myeloid/Lymphoid Neoplasms: Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence)”. 11. Appendix A was updated to include abbreviations NCCN, ALL, AML, HCT, OCT, and PFS. 12. Appendix B: Therapeutic Alternatives was updated from “There are no FDA approved medications for previously treated...” to “Not Applicable”. 13. Appendix D: General Information was updated to include “Ocular Toxicity: Pemazyre® can cause retinal pigment epithelial detachment...”, 	07/02/2021	09/14/2021

<p>“Hyperphosphatemia and Soft Tissue Mineralization: Pemazyre® can cause hyperphosphatemia...”, “Embryo-Fetal Toxicity: Can cause fetal harm. Advise patients...”, “Renal impairment (severe, estimated GFR 15 to 29 mL/min/1.73 m(2), estimated...”, and “Hepatic impairment (severe, total bilirubin greater than 3x ULN with any AST)”.</p> <p>14. References were reviewed and updated.</p> <p>15.</p>		
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