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Section:	Prescription Drugs	**Effective Date:**	April 1, 2024
Subsection:	Antineoplastic Agents	**Original Policy Date:**	May 15, 2020
Subject:	Pemazyre	**Page:**	1 of 5

Last Review Date: March 8, 2024

Pemazyre

Description

Pemazyre (pemigatinib)

Background
Pemazyre (pemigatinib) is a small molecule kinase inhibitor that targets fibroblast growth factor receptors (FGFR): FGFR1, 2, and 3. Pemazyre inhibits FGFR1-3 phosphorylation and signaling and decreases cell viability in cancer cell lines with activating FGFR amplifications and fusions that resulted in constitutive activation of FGFR signaling. Constitutive FGFR signaling can support the proliferation and survival of malignant cells (1).

Regulatory Status
FDA-approved indications: Pemazyre is a kinase inhibitor indicated: (1)

- 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.
- For the treatment of adults with relapsed or refractory myeloid/lymphoid neoplasms (MLNs) with FGFR1 rearrangement.

Pemazyre can cause retinal pigment epithelial detachment (RPED). A comprehensive ophthalmological examination should be performed prior to the initiation of Pemazyre and every 2 months for the first 6 months and every 3 months thereafter during treatment. For onset of visual symptoms, patients should be referred for ophthalmologic evaluations urgently, with follow-up every 3 weeks until resolution or discontinuation of Pemazyre (1).

Increases in phosphate levels are a pharmacodynamic effect of Pemazyre. Patients should be monitored for hyperphosphatemia and a low phosphate diet should be initiated when serum phosphate level is > 5.5 mg/dL. For serum phosphate levels > 7mg/dL, phosphate lowering therapy should be initiated and Pemazyre should be withheld, reduced, or permanently discontinued based on duration and severity of the hyperphosphatemia (1).

Pemazyre can cause fetal harm when administered to a pregnant woman. Female patients of reproductive potential should be advised to use effective contraception during treatment with Pemazyre and for 1 week after the final dose. Male patients with female partners of reproductive potential should be advised to use effective contraception during treatment with Pemazyre and for 1 week after the final dose (1).

For cholangiocarcinoma, Pemazyre is given orally once daily for 14 consecutive days followed by 7 days off therapy, in 21-day cycles. For myeloid/lymphoid neoplasms, Pemazyre is given orally once daily on a continuous basis (1).

The safety and efficacy of Pemazyre in pediatric patients less than 18 years of age have not been established (1).

Related policies
Truseltiq

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Pemazyre may be considered **medically necessary** if the conditions indicated below are met.

Pemazyre may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnoses

Patient must have **ONE** of the following:

1. Unresectable locally advanced or metastatic cholangiocarcinoma

a. Fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement, as detected by an FDA-approved test
b. Patient has had at least one prior therapy

2. Relapsed or refractory myeloid/lymphoid neoplasms (MLNs)
   a. Fibroblast growth factor receptor 1 (FGFR1) rearrangement

AND ALL of the following:

a. Baseline ophthalmological examination has been done and patient will be monitored for retinal pigment epithelial detachment (RPED)
b. Prescriber agrees to monitor for hyperphosphatemia and agrees to initiate a low phosphate diet or phosphate lowering therapy, as clinically indicated
c. Females of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Pemazyre and for 1 week after the last dose
d. Males with female partners of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Pemazyre and for 1 week after the last dose

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnoses

Patient must have **ONE** of the following:

1. Unresectable locally advanced or metastatic cholangiocarcinoma
2. Relapsed or refractory myeloid/lymphoid neoplasms (MLNs)

AND ALL of the following:

a. **NO** disease progression or unacceptable toxicity
b. Patient will be monitored for retinal pigment epithelial detachment (RPED)
c. Prescriber agrees to monitor for hyperphosphatemia and agrees to initiate a low phosphate diet or phosphate lowering therapy, as clinically indicated

d. Females of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Pemazyre and for 1 week after the last dose
e. Males with female partners of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Pemazyre and for 1 week after the last dose

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity

Diagnosis	Quantity
Cholangiocarcinoma	56 tablets per 84 days **OR**
Myeloid/Lymphoid Neoplasms	84 tablets per 84 days

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Pemazyre (pemigatinib) is a small molecule kinase inhibitor that targets fibroblast growth factor receptors (FGFR): FGFR1, 2, and 3. Pemazyre inhibits FGFR1-3 phosphorylation and signaling and decreases cell viability in cancer cell lines with activating FGFR amplifications and fusions that resulted in constitutive activation of FGFR signaling. Constitutive FGFR signaling can support the proliferation and survival of malignant cells. The safety and efficacy of Pemazyre in pediatric patients less than 18 years of age have not been established (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Pemazyre while maintaining optimal therapeutic outcomes.

References

1. Pemazyre [package insert]. Wilmington, DE: Incyte Corporation; June 2023.

2. NCCN Drugs & Biologics Compendium® Pemigatinib 2024. National Comprehensive Cancer Network, Inc. Accessed on January 24, 2024.

Policy History

Date	Action
May 2020	Addition to PA
June 2020	Annual review
September 2020	Annual review
September 2021	Annual review and reference update
September 2022	Annual review and reference update. Per PI update, addition of indication: myeloid/lymphoid neoplasms (MLNs)
March 2023	Annual review and reference update
March 2024	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 8, 2024 and is effective on April 1, 2024.