BlueCross BlueShield
Federal Employee Program

PEMAZYRE
(pemigatinib)

RATIONALE FOR INCLUSION IN PA PROGRAM

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

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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).

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 2025. National Comprehensive Cancer Network, Inc. Accessed on January 9, 2025.