

Clinical Pharmacy Program Guidelines for Pemazyre

Program	Prior Authorization
Medication	Pemazyre™ (pemigatinib)
Markets in Scope	Arizona, California, Hawaii, Nevada, Maryland, New Jersey, New York, New York EPP, Pennsylvania- CHIP, Rhode Island, South Carolina
Issue Date	06/2020
Pharmacy and Therapeutics Approval Date	06/2020
Effective Date	08/2020

1. Background:

Pemazyre™ (pemigatinib) 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.¹

2. Coverage Criteria:

<p><u>A. Cholangiocarcinoma</u></p> <p>1. <u>Initial Authorization</u></p> <p style="margin-left: 20px;">a. Pemazyre will be approved based on <u>all</u> of the following criteria:</p> <p style="margin-left: 40px;">(1) Diagnosis of cholangiocarcinoma</p> <p style="margin-left: 80px; text-align: center;">-AND-</p> <p style="margin-left: 40px;">(2) Disease is <u>one</u> of the following:</p> <p style="margin-left: 60px;">a. Unresectable locally advanced</p> <p style="margin-left: 60px;">b. Metastatic</p> <p style="margin-left: 80px; text-align: center;">-AND-</p> <p style="margin-left: 40px;">(3) Disease has presence of a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement</p> <p style="margin-left: 80px; text-align: center;">-AND-</p> <p style="margin-left: 40px;">(4) Patient has been previously treated</p>

Authorization will be issued for 12 months.

2. Reauthorization

a. **Pemazyre** will be approved based on the following criterion:

- (1) Patient does not show evidence of progressive disease while on **Pemazyre** therapy

Authorization will be issued for 12 months.

B. NCCN Recommended Regimens

1. Initial Authorization

a. **Pemazyre** will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium.

Authorization will be issued for 12 months.

2. Reauthorization

a. **Pemazyre** will be approved based on the following criterion:

- (1) Documentation of positive clinical response to Pemazyre therapy

Authorization will be issued for 12 months.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Pemazyre™ [package insert]. Wilmington, DE: Incyte Corporation. April 2020.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at www.nccn.org. Accessed May 12, 2020

Program	Program type – Prior Authorization
Change Control	
Date	Change
6/2020	New program.