UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2021 P 1316-2
Program	Prior Authorization/Notification
Medication	Pemazyre® (pemigatinib)
P&T Approval Date	6/2020, 6/2021
Effective Date	9/1/2021; Oxford only: 9/1/2021

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]

The National Cancer Comprehensive Network (NCCN) also recommends use of Pemazyre for the treatment of myeloid/lymphoid neoplasms with eosinophilia and FGFR1 rearrangement.

Coverage Information:

Members will be required to meet the criteria below for coverage. For members under the age of 19 years, the prescription will automatically process without a coverage review.

Some states mandate benefit coverage for off-label use of medications for some diagnoses or under some circumstances. Some states also mandate usage of other Compendium references. Where such mandates apply, they supersede language in the benefit document or in the notification criteria.

2. Coverage Criteria:

A. <u>Patients less than 19 years of age</u>

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

   a. Patient is less than 19 years of age

Authorization will be issued for 12 months.

B. <u>Cholangiocarcinoma</u>

1. **<u>Initial Authorization</u>**

   a. **Pemazyre** will be approved based on **<u>all</u>** of the following criteria:

      (1) Diagnosis of cholangiocarcinoma

-AND-

(2) Disease is **one** of the following:
   a. Unresectable locally advanced
   b. Metastatic

-AND-

(3) Disease has presence of a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement

-AND-

(4) Patient has been previously treated

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.

C. Myeloid/Lymphoid Neoplasms

1. Initial Authorization

a. Pemazyre will be approved based on **all** of the following criteria:

(1) Diagnosis of myeloid/lymphoid/mixed lineage neoplasms with eosinophilia

-AND-

(2) Presence FGFR1 rearrangement

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.

C. NCCN Recommended Regimens

The drug has been recognized for treatment of the cancer indication by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B

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. February 2021.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at www.nccn.org. Accessed April 14, 2021.

Program	Prior Authorization/Notification – Pemazyre (pemigatinib)
Change Control	
6/2020	New program.
6/2021	Annual review. Addition of coverage criteria for myeloid/lymphoid neoplasms according to NCCN. Updated background and references.