UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 1316-6
Program	Prior Authorization/Notification
Medication	Pemazyre® (pemigatinib)
P&T Approval Date	6/2020, 6/2021, 6/2022, 10/2022, 10/2023, 10/2024
Effective Date	1/1/2025

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 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). Pemazyre is also indicated for the treatment of adults with relapsed or refractory myeloid/lymphoid neoplasms (MLNs) with FGFR1 rearrangement.

The National Cancer Comprehensive Network (NCCN) also recommends use of Pemazyre for the treatment of myeloid/lymphoid/mixed lineage 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]:

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. Resected gross residual (R2)
c. 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 **both** of the following criteria:

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

-AND-

(2) Presence of an 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.

D. 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.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

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. June 2023.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at www.nccn.org. Accessed August 28, 2024.

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.
6/2022	Annual review. Revised grammar in criteria with no changes to clinical intent. Updated background with conditional approval language per prescribing information. Updated references.
10/2022	Updated criteria and background based on newly approved indication for myeloid/lymphoid neoplasms. Updated reference. Added state mandate footnote.
10/2023	Annual review. Updated criteria for Myeloid/Lymphoid Neoplasms. Updated references.
10/2024	Annual review. Updated criteria for cholangiocarcinoma.