PRIOR AUTHORIZATION POLICY

POLICY: Oncology (Oral – Fibroblast Growth Factor Receptor Agent) – Pemazyre Prior Authorization Policy
- Pemazyre® (pemigatinib tablets – Incyte)

REVIEW DATE: 05/07/2025

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT WHERE APPROPRIATE AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. WHERE COVERAGE FOR CARE OR SERVICES DOES NOT DEPEND ON SPECIFIC CIRCUMSTANCES, REIMBURSEMENT WILL ONLY BE PROVIDED IF A REQUESTED SERVICE(S) IS SUBMITTED IN ACCORDANCE WITH THE RELEVANT CRITERIA OUTLINED IN THE APPLICABLE COVERAGE POLICY, INCLUDING COVERED DIAGNOSIS AND/OR PROCEDURE CODE(S). REIMBURSEMENT IS NOT ALLOWED FOR SERVICES WHEN BILLED FOR CONDITIONS OR DIAGNOSES THAT ARE NOT COVERED UNDER THIS COVERAGE POLICY (SEE "CODING INFORMATION" BELOW). WHEN BILLING, PROVIDERS MUST USE THE MOST APPROPRIATE CODES AS OF THE EFFECTIVE DATE OF THE SUBMISSION. CLAIMS SUBMITTED FOR SERVICES THAT ARE NOT ACCOMPANIED BY COVERED CODE(S) UNDER THE APPLICABLE COVERAGE POLICY WILL BE DENIED AS NOT COVERED. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

Pemazyre, a kinase inhibitor, is indicated in adults for the following uses:[1]
- Previously treated, unresectable locally advanced or metastatic **cholangiocarcinoma** with a fibroblast growth factor receptor 2 (*FGFR2*) fusions or other rearrangements.
- Relapsed or refractory **myeloid/lymphoid neoplasms** with fibroblast growth factor receptor 1 (*FGFR1*) rearrangement.

The indication of cholangiocarcinoma 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.

Guidelines

Pemazyre is addressed in National Comprehensive Cancer Network (NCCN) guidelines:[2]

- **Biliary Tract Cancers**: Guidelines (version 1.2025 – March 20, 2025) recommend Pemazyre for disease progression on or following systemic treatment for patients with unresectable, gross residual, or metastatic cholangiocarcinoma with *FGFR2* fusion or rearrangement, as a single agent (category 2A).[3]
- **Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Fusion Genes**: Guidelines (version 2.2025 – April 4, 2025) recommend Pemazyre for the treatment of myeloid/lymphoid neoplasms with eosinophilia and *FGFR1* rearrangement (category 2A).[2,4]

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Pemazyre. All approvals are provided for the duration noted below.

- **Pemazyre® (pemigatinib tablets - Incyte)**

is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

FDA-Approved Indications

1. **Cholangiocarcinoma.** Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has unresectable locally advanced, gross residual, or metastatic disease; AND
   - **C)** Tumor has fibroblast growth factor receptor 2 (*FGFR2*) gene fusion or other rearrangement, as detected by an approved test; AND
   - **D)** Patient has been previously treated with at least one systemic regimen.
     Note: Examples of systemic regimens include gemcitabine + cisplatin, 5-fluorouracil + oxaliplatin or cisplatin, capecitabine + cisplatin or oxaliplatin, gemcitabine + Abraxane (albumin-bound paclitaxel) or capecitabine or oxaliplatin, gemcitabine + Abraxane + cisplatin.

2. **Myeloid/Lymphoid Neoplasms.** Approve for 1 year if the patient meets ALL of the following (A, B, and C):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has eosinophilia; AND
   - **C)** The cancer has fibroblast growth factor receptor 1 (*FGFR1*) rearrangement, as detected by an approved test.

CONDITIONS NOT COVERED

- **Pemazyre® (pemigatinib tablets - Incyte)**

is(are) considered not medically necessary for ANY other use(s); criteria will be updated as new published data are available.

REFERENCES

1. Pemazyre® tablets [prescribing information]. Wilmington, DE: Incyte; August 2022.
2. The NCCN Drugs & Biologics Compendium. © 2025 National Comprehensive Cancer Network. Available at: http://www.ncc.org. Accessed on April 9, 2025. Search term: pemigatinib.
3. The NCCN Biliary Tract Cancers Clinical Practice Guidelines in Oncology (version 1.2025 – March 20, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on April 9, 2025.
4. The NCCN Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Fusion Genes Clinical Practice Guidelines in Oncology (version 2.2025 – April 4, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.ncc.org. Accessed on April 9, 2025.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	05/10/2023
Annual Revision	No criteria changes.	05/08/2024
Update	04/21/2025: Policy name was changed from "Oncology – Pemazyre PA Policy" to "Oncology (Oral – Fibroblast Growth Factor Receptor Agent) – Pemazyre PA Policy".	NA
Annual Revision	**Cholangiocarinoma: "**Gross residual disease" was added as an option for approval. For the requirement that tumor has fibroblast growth factor receptor (*FGFR2*) fusion or rearrangement, added "gene" as a descriptor. The following examples of systemic regimens, "FOLFOX (5-fluorouracil, leucovorin, and oxaliplatin), FOLFIRI (5-fluorouracil, leucovorin, irinotecan), Stivarga (regorafenib tablets)" were removed from the note. **Myeloid/Lymphoid Neoplasms:** The requirement that "the cancer is in chronic phase or blast phase" was removed.	05/07/2025