



PHARMACY COVERAGE GUIDELINES
SECTION: DRUGS

ORIGINAL EFFECTIVE DATE: 5/21/2020
LAST REVIEW DATE:
LAST CRITERIA REVISION DATE:
ARCHIVE DATE:

PEMAZYRE™ (pemigatinib)

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Pharmacy Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Pharmacy Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "**Description**" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "**Criteria**" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Pharmacy Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Pharmacy Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

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This Pharmacy Coverage Guideline does not apply to FEP or other states' Blues Plans.

Information about medications that require precertification is available at www.azblue.com/pharmacy.

Some large (100+) benefit plan groups may customize certain benefits, including adding or deleting precertification requirements.

All applicable benefit plan provisions apply, e.g., waiting periods, limitations, exclusions, waivers and benefit maximums.

Precertification for medication(s) or product(s) indicated in this guideline requires completion of the [request form](#) in its entirety with the chart notes as documentation. **All requested data must be provided.** Once completed the form must be signed by the prescribing provider and faxed back to BCBSAZ Pharmacy Management at (602) 864-3126 or emailed to Pharmacyprecert@azblue.com. **Incomplete forms or forms without the chart notes will be returned.**



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Criteria:

- **Criteria for initial therapy:** Pemazyre (pemigatinib) is considered *medically necessary* and will be approved when **ALL** of the following criteria are met:
1. Prescriber is a physician specializing in the patient's diagnosis or is in consultation with an Oncologist
 2. Individual is 18 years of age or older
 3. A confirmed diagnosis of **ONE** of the following:
 - Previously treated, unresectable locally advanced or metastatic cholangiocarcinoma with a fibroblast growth factor receptor (FGFR) 2 fusion or other rearrangement
 - Other request for a specific oncologic direct treatment use that is found and listed in the National Comprehensive Cancer Network (NCCN) Guidelines with Categories of Evidence and Consensus of 1 and 2A
 4. **ALL** of the following **baseline tests** have been completed before initiation of treatment with continued monitoring as clinically appropriate:
 - Confirm presence of an FGFR2 fusion or rearrangement
 - Ophthalmological examination including optical coherence tomography (OCT)
 - Serum phosphate level
 - Negative pregnancy test in a woman of child bearing potential
 - Eastern Cooperative Oncology Group (ECOG) performance 0-1
 5. Individual does not have severe renal impairment (GFR < 30 mL/min) or on dialysis
 6. Individual does not have severe hepatic impairment (total bilirubin >3x UKN with any AST)

Initial approval duration: 6 months

- **Criteria for continuation of coverage (renewal request):** Pemazyre (pemigatinib) is considered *medically necessary* and will be approved when **ALL** of the following criteria are met:
1. Individual continues to be seen by a physician specializing in the patient's diagnosis or is in consultation with an Oncologist
 2. Individual's condition responded while on therapy
 - Response is defined as:
 - No evidence of disease progression
 - Functionality retained in most activities of daily living
 3. Individual has been adherent with the medication

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4. Dose is at least 4.5 mg once daily
5. Individual does not have severe renal impairment (GFR < 30 mL/min) or on dialysis
6. Individual does not have severe hepatic impairment (total bilirubin >3x UKN with any AST)
7. Individual has not developed any significant level 4 adverse drug effects that may exclude continued use
 - Significant adverse effect such as:
 - Retinal Pigment Epithelial Detachment (RPED)
 - Recurrence of serum phosphate > 10 mg/dL after 2 dose reductions
 - Any severe adverse reaction that recurs after 2 dose reduction or any life-threatening adverse reaction
8. There are no significant interacting drugs

Renewal duration: 12 months

Description:

Pemazyre (pemigatinib) is 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. Select patients for the treatment of locally advanced or metastatic cholangiocarcinoma with Pemazyre (pemigatinib) based on the presence of an FGFR2 fusion or 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).

Pemigatinib is a small molecule kinase inhibitor that targets FGFR1, 2, and 3. FGFR phosphorylation inhibition results in decreased FGFR-related signaling and decreased cell viability in cell lines expressing FGFR genetic alterations, leading to decreased proliferation and survival of malignant cells.

Definitions:

Optical coherence tomography:

A noninvasive imaging technology used to obtain high resolution cross-sectional images of the retina. The layers within the retina can be differentiated and retinal thickness can be measured to aid in the early detection and diagnosis of retinal diseases and conditions.

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Activities of daily living (ADL):

Instrumental ADL:

Prepare meals, shop for groceries or clothes, use the telephone, manage money, etc.

Self-care ADL:

Bathe, dress and undress, feed self, use the toilet, take medications, not bedridden

Common Terminology Criteria for Adverse Events (CTCAE) Version 4.0:

Grade 1	Mild; asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated
Grade 2	Moderate; minimal, local or noninvasive intervention indicated; limiting age-appropriate instrumental ADL*
Grade 3	Severe or medically significant but not immediately life-threatening; hospitalization or prolongation of hospitalization indicated; disabling; limiting self-care ADL**
Grade 4	Life-threatening consequences; urgent intervention indicated
Grade 5	Death related to AE
U.S. department of Health and Human Services, National Institutes of Health, and National Cancer Institute	

The Child-Pugh classification system:

The Child-Pugh classification is a scoring system used to determine the prognosis of individuals with cirrhosis. Scoring is based upon several factors: albumin, ascites, total bilirubin, prothrombin time, and encephalopathy, as follows:

	Score: 1 point	Score: 2 points	Score: 3 points
Serum Albumin (g/dL)	> 3.5	3.0 - 3.5	< 3.0
Serum Bilirubin (mg/dL)	< 2.0	2.0 - 3.0	> 3.0
Prothrombin time (seconds)	1 - 4	4 - 6	> 6
Ascites	none	moderate	severe
Encephalopathy	none	mild	severe

The three classes and their scores are:

- **Class A** is score 5 – 6: Well compensated
- **Class B** is score 7 – 9: Significant functional compromise
- **Class C** is score > 9: Decompensated disease

Child-Pugh Classification of severity of liver disease			
Child-Pugh Classification	Points		
A: Well compensated	5-6		
B: Significant functional compromise	7-9		
C: Decompensated	10-15		
Parameter/Factor	1 point each	2 points each	3 points each
Total Bilirubin, mg/dL (or μmol/L)	< 2 (or < 34)	2-3 (or 34-50)	>3 or (> 50)
Albumin, g/dL (or g/L)	>3.5 (or > 35)	2.8-3.5 (or 28-35)	< 2.8 (or < 28)
Prothrombin time prolongation			
Seconds over control	1-3	4-6	> 6



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	INR	< 1.7	1.71-2.3	> 2.3
Ascites		Absent	Slight/Mild	Moderate to severe
Encephalopathy		None	Grade 1-2 (or suppressed with medication)	Grade 3-4 (or refractory)

ECOG Performance status:

Eastern Co-operative Oncology Group (ECOG) Performance Status	
Grade	ECOG description
0	Fully active, able to carry on all pre-disease performance without restriction
1	Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light house work, office work
2	Ambulatory and capable of all selfcare but unable to carry out any work activities. Up and about more than 50% of waking hours
3	Capable of only limited selfcare, confined to bed or chair more than 50% of waking hours
4	Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair
5	Dead

Oken, M.M., Creech, R.H., Tormey, D.C., Horton, J., Davis, T.E., McFadden, E.T., Carbone, P.P.: Toxicity And Response Criteria Of The Eastern Cooperative Oncology Group. Am J Clin Oncol 5:649-655, 1982

Resources:

Pemazyre (pemigatinib) product information accessed 04-28-20 at DailyMed

Off Label Use of Cancer Medications: A.R.S. §§ 20-826(R) & (S). Subscription contracts; definitions.

Off Label Use of Cancer Medications: A.R.S. §§ 20-1057(V) & (W). Evidence of coverage by health care service organizations; renewability; definitions.