

Market Applicability							
Market	DC	GA	KY	MD	NJ	NY	WA
Applicable	X	X	X	X	X	X	X

Pemazyre (pemigatinib)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Pemazyre (pemigatinib)	May be subject to quantity limit

APPROVAL CRITERIA

Requests for Pemazyre (pemigatinib) may be approved if the following criteria are met (Label, NCCN 2A):

- I. Individual has a diagnosis of previously treated, unresectable locally advanced, or metastatic cholangiocarcinoma; **AND**
- II. Individual is using as monotherapy; **AND**
- III. Individual has confirmed disease progression after one or more prior lines of systemic therapy; **AND**
- IV. Individual has confirmation of fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement as detected by an FDA-approved test.

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2020. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: May 19, 2020.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. FDA Approves First Targeted Treatment for Patients with Cholangiocarcinoma, a Cancer of Bile Ducts. U.S. Food & Drug Administration. April 17, 2020. Available at: https://www.fda.gov/news-events/press-announcements/fda-approves-first-targeted-treatment-patients-cholangiocarcinoma-cancer-bile-ducts?utm_campaign=FDA%20approves%20new%20treatment%20for%20cholangiocarcinoma&utm_medium=email&utm_source=Eloqua Accessed May 19, 2020.
5. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2020; Updated periodically.
6. NCCN Clinical Practice Guidelines in Oncology™. © 2020 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on May 19, 2020.
 - a. Hepatobiliary Cancers. V2.2020. Revised May 8, 2020.

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PAGE 1 of 2 08/19/2020
New Program Date 06/09/2020

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

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Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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