

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](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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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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