

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**
 - A. Individual is using as monotherapy; **AND**
 - B. Individual has confirmed disease progression after one or more prior lines of systemic therapy; **AND**
 - C. Individual has fibroblast growth factor receptor 2 (FGFR2) fusion or non-fusion rearrangement with test results confirmed;

OR

- II. Individual has a diagnosis of relapsed or refractory myeloid/lymphoid neoplasms (MLNs) with fibroblast growth factor receptor 1 (FGFR1) rearrangement.

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2022. 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: July 8, 2022.
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
5. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2022; Updated periodically.
6. NCCN Clinical Practice Guidelines in Oncology™. © 2021 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on July 8, 2022.
 - a. Hepatobiliary Cancers. V1.2022. Revised March 29, 2022.
 - b. Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Fusion Genes. V1.2022. Revised April 14, 2022
7. Verstovsek S, Vanucchi AM, Rambaldi A, et al. Interim results from Fight-203, a phase 2, open-label, multicenter study evaluating the efficacy and safety of pemigatinib (INCB054828) in patients with myeloid/lymphoid neoplasms with

rearrangement of fibroblast growth factor receptor 1 (FGFR1) [abstract]. Blood 2018;132:Abstract 690. Available at: <https://ashpublications.org/blood/article/132/Supplement%201/690/266005/Interim-Results-from-Fight-203-a-Phase-2-Open>. Accessed July 8, 2022.

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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