Clinical Policy Title:	pemigatinib
Policy Number:	RxA.635
Drug(s) Applied:	Pemazyre®
Original Policy Date:	07/05/2020
Last Review Date:	08/28/2024
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Unresectable locally advanced or metastatic cholangiocarcinoma (must meet all):

1. Diagnosis of unresectable locally advanced or metastatic cholangiocarcinoma;
2. Positive result of FDA-approved test to determine fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement;
3. Member has tried and failed at least 1 regimen recommended by NCCN.

Approval Duration

All Lines of Business (except Medicare): 12 months

B. Myeloid/Lymphoid Neoplasms with Eosinophilia & Tyrosine Kinase Fusion Gene (must meet all):

1. Diagnosis of Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Fusion Gene;
2. Positive result of FDA-approved test to determine fibroblast growth factor receptor 1 (FGFR1) in chronic phase or blast phase.

Approval Duration

All Lines of Business (except Medicare): 12 months

II. Continued Therapy Approval

A. All Indications in Section I (must meet all):

1. Auto-approval based on lookback functionality within the past 120 days as a proxy for member responding positively to therapy.

Approval Duration

All Lines of Business (except Medicare): 12 months

References

1. National Comprehensive Cancer Network Guidelines. Hepatocellular Carcinoma Version 2.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/hcc.pdf. Accessed August 28, 2024.
2. National Comprehensive Cancer Network Guidelines. Myeloid/Lymphoid Neoplasms with Eosinophilia & Tyrosine Kinase Fusion Gene Version 2.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/mlne.pdf. Accessed August 28, 2024.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	07/05/2020	09/14/2020

Policy was reviewed: 1. Clinical Policy Title was updated to include Last Review Date. 2. Initial Approval Criteria I.B was updated to include off-label indication “Myeloid/Lymphoid Neoplasms with Eosinophilia & Tyrosine Kinase Fusion Gene (off-label)”. 3. Continued Therapy Approval Criteria II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...". 4. Continued Therapy Approval Criteria II.A.3.a was updated to include “Cholangiocarcinoma: 13.5 mg/day”. 5. Continued Therapy Approval Criteria II.A.3.b was updated to include “Myeloid/Lymphoid Neoplasms: Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence)”. 6. References were reviewed and updated.	07/02/2021	09/14/2021
Policy was reviewed: 1. References were reviewed and updated.	04/07/2022	07/18/2022
Policy was reviewed: 1. Initial Approval Criteria, I.B: Indication Myeloid/Lymphoid Neoplasms with Eosinophilia & Tyrosine Kinase Fusion Gene Updated from Off label indication to Labelled indication. 2. Initial Approval Criteria, I.B.5: Updated to remove prior requesting criteria "Request meets one of the following (a or b): a. Treatment with a preferred clinical trial rather than off-label use; b. Treatment in combination with ALL- or AML-type induction chemotherapy followed by allogeneic HCT (if eligible) for lymphoid, myeloid or mixed lineage neoplasms with eosinophilia and FGFR1 rearrangement in blast phase". 3. Initial Approval Criteria I.A and I.B: Approval duration for Commercial and Medicaid updated from 6 months to 12 months. 4. References were reviewed and updated.	04/28/2023	07/13/2023
Policy was reviewed.	10/19/2023	10/19/2023
Policy was reviewed: 1. Removed age restrictions. 2. Removed prescriber restrictions.	8/28/2024	9/13/2024

3. Removed dose restrictions. 4. Updated Continued therapy approval with auto-approval based on lookback functionality within the past 120 days. 5. Removed reauthorization requirement for positive response to therapy. 6. Updated approval duration verbiage. 7. References were reviewed and updated.		