RxAdvance

Clinical Policy Title:	futibatinib
Policy Number:	RxA.779
Drug(s) Applied:	Lytgobi®
Original Policy Date:	01/17/2023
Last Review Date:	12/11/2025
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. **Initial Approval Criteria**
   A. **Unresectable, locally advanced, or metastatic intrahepatic cholangiocarcinoma** (must meet all):
      1. Diagnosis of unresectable locally advanced or metastatic intrahepatic cholangiocarcinoma;
      2. Positive result of FDA-approved test to determine FGFR2 fusion or other rearrangement;
      3. Member must have been treated with at least one prior systemic therapy;
      4. Documentation of radiographic progression of disease on prior systemic therapy;
      5. Member must not have experienced disease progression on an FGFR inhibitor (e.g., Pemazyre®, Truseltiq™);
      6. Lytgobi® will be used as a single agent for subsequent therapy.

      Approval Duration
      All Lines of Business (except Medicare): 3 months

II. **Continued Therapy Approval**
   A. **Unresectable, locally advanced, or metastatic intrahepatic cholangiocarcinoma** (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): 3 months

References

1. National Comprehensive Cancer Network. Biliary tract cancers. Version 1.2025. Available at: https://www.nccn.org/professionals/physician_gls/pdf/hepatobiliary.pdf. Accessed March 24, 2025.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	12/08/2022	01/17/2023
Policy was reviewed.	10/19/2023	10/19/2023
Policy was reviewed: 1. Removed prescriber criteria. 2. Removed age criteria. 3. Removed dosing criteria. 4. Updated approval duration verbiage.	03/24/2025	04/10/2025

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

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5. Removed reauthorization requirement for positive response to therapy. 6. Updated continuation of therapy language.		
Policy reviewed.	12/11/2025	12/11/2025

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