

<b>Clinical Policy Title:</b>	futibatinib
<b>Policy Number:</b>	RxA.779
<b>Drug(s) Applied:</b>	Lytgobi®
<b>Original Policy Date:</b>	01/17/2023
<b>Last Review Date:</b>	10/19/2023
<b>Line of Business Policy Applies to:</b>	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. Prescribed by or in consultation with an oncologist;
4. Age ≥ 18 years;
5. Member must have been treated with at least one prior systemic therapy;
6. Documentation of radiographic progression of disease on prior systemic therapy;
7. Member must not have experienced disease progression on an FGFR inhibitor (e.g., Pemazyre®, Truseltiq™);
8. Lytgobi® will be used as a single agent for subsequent therapy;
9. Dose does not exceed 20 mg/day.

#### Approval Duration

**Commercial:** 3 months

**Medicaid:** 3 months

### II. Continued Therapy Approval

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

1. Member is currently receiving medication that has been authorized by RxAdvance or the member has met initial approval criteria listed in this policy;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 20 mg/day.

#### Approval Duration

**Commercial:** 3 months

**Medicaid:** 3 months

## References

1. National Comprehensive Cancer Network. Hepatobiliary Cancers Version 3.2022. Available at: [https://www.nccn.org/professionals/physician\\_gls/pdf/hepatobiliary.pdf](https://www.nccn.org/professionals/physician_gls/pdf/hepatobiliary.pdf). Accessed December 08, 2022.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	12/08/2022	01/17/2023

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.

Policy was reviewed.	10/19/2023	10/19/2023
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