Clinical Policy Title:	futibatinib
Policy Number:	RxA.779
Drug(s) Applied:	Lytgobi®
Original Policy Date:	01/17/2023
Last Review Date:	10/19/2023
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. 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. Accessed December 08, 2022.

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