

Applicable Drugs: Lytgobi (futibatinib)

Preferred: N/A

Non-preferred: N/A

Date of Origin: 8/26/2024

Date Last Reviewed / Revised: 2/20/2026

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I to V are met)

- I. Documentation of the following FDA-approved diagnosis AND must meet all criteria listed under the applicable diagnosis:
FDA-Approved Indication(s)
 - A. Cholangiocarcinoma (CCA)
 - i. Documentation of metastatic or locally advanced surgically unresectable disease
 - ii. Documented disease progression after at least one systemic regimen
 - iii. Documented presence of fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement
- II. Minimum age requirement: 18 years old.
- III. Treatment must be prescribed by or in consultation with an oncologist or hematologist.
- IV. Request is for a medication with the appropriate FDA labeling, or its use is supported by current National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1 or 2A.
- V. Refer to the plan document for the list of preferred products. If the requested agent is not listed as a preferred product, must have documented treatment failure or contraindication to the preferred product(s).

EXCLUSION CRITERIA

- None

OTHER CRITERIA

- N/A

QUANTITY / DAYS SUPPLY RESTRICTIONS

- 140 tablets/28 days

APPROVAL LENGTH

- **Authorization:** 6 months
- **Re-Authorization:** 6 months with an updated letter of medical necessity or progress notes showing current medical necessity criteria are met and does not show evidence of progressive disease.

APPENDIX

N/A

REFERENCES

1. Lytgobi. Prescribing information. Taiho Oncology, Inc. 2026. Accessed February 20, 2026. taihocorporate-media-release.s3.us-west-2.amazonaws.com/documents/LYTGOBI_Prescribing_Information.pdf
2. Goyal L, Meric-Bernstam F, Hollebecque A, et al.; FOENIX-CCA2 Study Investigators. Futibatinib for FGFR2-Rearranged Intrahepatic Cholangiocarcinoma. *N Engl J Med*. 2023;388(3):228-239. doi: 10.1056/NEJMoa2206834
3. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Biliary Tract Cancers Version 2.2025. Updated July 2, 2025. Accessed February 20, 2026. www.nccn.org/professionals/physician_gls/pdf/btc.pdf

DISCLAIMER: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.