

Generic Name: futibatinib

Preferred: N/A

Therapeutic Class or Brand Name: Lytgobi

Non-preferred: N/A

Applicable Drugs: N/A

Date of Origin: 8/26/2024

Date Last Reviewed / Revised: N/A

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria ____ are met)

- I. Patient aged \geq 18 years old.
- II. Chart notes documenting diagnosis of metastatic or locally advanced surgically unresectable cholangiocarcinoma (CCA).
- III. Documented disease progression on one gemcitabine and cisplatin-containing regimen.
- IV. Documented presence of Fibroblast Growth Factor Receptor 2 (FGFR2) fusion or select rearrangement.
- V. Documented Eastern Cooperative Oncology Group (ECOG) performance status of 0–2.
- VI. Documented baseline comprehensive ophthalmological examination, including optical coherence tomography (OCT) of the macula.
- VII. Must be prescribed by a board-certified hematologist or oncologist.
- VIII. Prescribed according to FDA labeling, or its use is supported by current clinical practice guidelines.

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 documentation of absence of disease progression while on therapy.

APPENDIX

N/A

REFERENCES

1. Lytgobi. Prescribing information. Taiho Oncology, Inc; April 2024. Accessed July 17, 2024. https://taihocorp-media-release.s3.us-west-2.amazonaws.com/documents/LYTGObI_Prescribing_Information.pdf
2. U.S. Food & Drug Administration. FDA grants accelerated approval to futibatinib for cholangiocarcinoma. FDA.gov. September 30, 2022. Accessed July 13, 2024. <https://www.fda.gov/drugs/resources-information-approved-drugs/fda-grants-accelerated-approval-futibatinib-cholangiocarcinoma#:~:text=On%20September%2030%2C%202022%2C%20the%20Food%20and%20Drug,receptor%202%20%28FGFR2%29%20gene%20fusions%20or%20other%20rearrangements.>
3. 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
4. Biliary Tract Cancers 3.2024. © National Comprehensive Cancer Network, Inc. 2024. All rights reserved. Accessed July 13, 2024

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.