

Specialty Guideline Management

Lytgobi

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Lytgobi	futibatinib

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indication

Treatment of adult patients with previously treated, unresectable, locally advanced or metastatic intrahepatic cholangiocarcinoma harboring fibroblast growth factor receptor 2 (FGFR2) gene fusions or other rearrangements.

Compendial Use

Extrahepatic cholangiocarcinoma

All other indications are considered experimental/investigational and not medically necessary.

Documentation

Submission of the following information is necessary to initiate the prior authorization review:
Documentation of FGFR2 gene fusions or rearrangements.

Coverage Criteria

Cholangiocarcinoma

Authorization of 12 months may be granted as a single agent for subsequent treatment of unresectable, resected gross residual (R2) disease, locally advanced, or metastatic cholangiocarcinoma with FGFR2 gene fusions or rearrangements.

Continuation of Therapy

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in the coverage criteria section when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

References

1. Lytgobi [package insert]. Princeton, NJ: Taiho Oncology, Inc.; April 2024.
2. The NCCN Drugs & Biologics Compendium® © 2024 National Comprehensive Cancer Network, Inc. <http://www.nccn.org>. Accessed July 7, 2024.