Reference number(s)
5638-A

SPECIALTY GUIDELINE MANAGEMENT

LYTGOBI (futibatinib)

POLICY

I. 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.

A. 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.

B. Compendial Use
Extrahepatic cholangiocarcinoma

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

II. DOCUMENTATION

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

III. CRITERIA FOR INITIAL APPROVAL

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.

IV. CONTINUATION OF THERAPY

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

V. REFERENCES

1. Lytgobi [package insert]. Princeton, NJ: Taiho Pharmaceutical Co., Ltd.; September 2022.
2. The NCCN Drugs & Biologics Compendium® © 2023 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed July 7, 2023.

Reference number(s)
5638-A