Commercial/Healthcare Exchange PA Criteria

Effective: December 12, 2022

Prior Authorization: Lytgobi

Products Affected: Lytgobi (futibatinib) oral tablets

Medication Description: Lytgobi, a fibroblast growth factor receptor 2 (FGFR2) inhibitor, is indicated for the treatment of adults with previously treated, unresectable, locally advanced or metastatic intrahepatic cholangiocarcinoma harboring FGFR2 gene fusions or other rearrangements.

Covered Uses:

1. Treatment of adults with previously treated unresectable, locally advanced or metastatic intrahepatic cholangiocarcinoma

Exclusion Criteria: None

Required Medical Information:

1. Diagnosis
2. Previous therapies tried and failed

Prescriber Restriction: Medication must be prescribed by, or in consultation with, an oncologist

Age Restriction: Patient must be 18 years of age or older

Coverage Duration: 12 months

Other Criteria:

Initial Approval Criteria

1. **Cholangiocarcinoma** Approve for 1 year if the patient meets ALL of the following criteria (A, B, C, and D):
   A. Patient is ≥ 18 years of age; **AND**
   B. Patient has unresectable locally advanced or metastatic disease; **AND**
   C. Tumor has fibroblast growth factor receptor 2 (*FGFR2*) gene fusions or other rearrangements, as detected by an approved test; **AND**
   D. Patient has been previously treated with at least one systemic regimen.
   Note: Examples of systemic regimens include gemcitabine + cisplatin, 5-fluorouracil + oxaliplatin or cisplatin, capecitabine + cisplatin or oxaliplatin, gemcitabine + Abraxane (albumin-bound paclitaxel) or capecitabine or oxaliplatin, and gemcitabine + cisplatin + Abraxane.

References:

1. Product Information: LYTGOBI® oral tablets, futibatinib oral tablets. Taiho Oncology Inc (per FDA), Princeton, NJ, 2022.

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	12/15/2022