UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 1399-3
Program	Prior Authorization/Notification
Medication	Lytgobi® (futibatinib)
P&T Approval Date	11/2022, 11/2023, 11/2024
Effective Date	2/15/2025

1. Background:

Lytgobi (futibatinib) is a kinase inhibitor indicated for the 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.

The National Cancer Comprehensive Network (NCCN) also recommends the use of Lytgobi in extrahepatic cholangiocarcinoma for subsequent treatment for progression on or after systemic treatment for unresectable or resected gross residual (R2) disease, or metastatic disease with fibroblast growth factor receptor 2 (FGFR2) fusions or rearrangements.

This indication is approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

Coverage Information:
Members will be required to meet the criteria below for coverage. For members under the age of 19 years, the prescription will automatically process without a coverage review.

Some states mandate benefit coverage for off-label use of medications for some diagnoses or under some circumstances. Some states also mandate usage of other Compendium references. Where such mandates apply, they supersede language in the benefit document or in the notification criteria.

2. Coverage Criteria[a]:

A. <u>Patients less than 19 years of age</u>

1. **Lytgobi** will be approved based on the following criterion:

   a. Patient is less than 19 years of age

   Authorization will be issued for 12 months.

B. <u>Cholangiocarcinoma</u>

1. **<u>Initial Authorization</u>**

   a. **Lytgobi** will be approved based on **<u>all</u>** of the following criteria:

      (1) Diagnosis of cholangiocarcinoma (intrahepatic or extrahepatic)

-AND-

(2) Disease is **one** of the following:

i. Unresectable
ii. Resected gross residual (R2)
iii. Metastatic

-AND-

(3) Positive for fibroblast growth factor receptor 2 (FGFR2) fusions or rearrangements

-AND-

(4) Used as second line or subsequent treatment

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Lytgobi** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Lytgobi therapy

Authorization will be issued for 12 months.

C. NCCN Recommended Regimens

The drug has been recognized for treatment of the cancer indication by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits and/or step therapy may be in place.

4. References:

1. Lytgobi [package insert]. Princeton, NJ: Taiho Pharmaceutical Co., Ltd. April 2024.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org. Accessed September 21, 2024.

Program	Prior Authorization/Notification – Lytgobi® (futibatinib)
Change Control	
11/2022	New program.
11/2023	Annual review. Updated cholangiocarcinoma criteria to include NCCN recommendations. Updated background. Added reference.
11/2024	Annual review. Modified criteria for disease type in cholangiocarcinoma. Updated references.