

PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Lytgobi Prior Authorization Policy

- Lytgobi® (futibatinib tablets – Taiho Oncology)

REVIEW DATE: 11/13/2024

OVERVIEW

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

Guidelines

Lytgobi is addressed in National Comprehensive Cancer Network (NCCN) guidelines:

- **Biliary Tract Cancers:** NCCN guidelines (version 4.2024 – August 29, 2024) recommend Lytgobi for disease progression on or following systemic therapy for patients with unresectable, resected gross residual, or metastatic intrahepatic or extrahepatic cholangiocarcinoma with *FGFR2* fusions or rearrangements.^{2,3} NCCN guidelines also recommend Pemazyre® (pemigatinib tablets) for the same indication.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Lytgobi. All approvals are provided for the duration noted below.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Lytgobi is recommended in those who meet the following criteria:

FDA-Approved Indication

1. **Cholangiocarcinoma.** Approve for 1 year if the patient meets ALL of the following (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.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Lytgobi is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

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REFERENCES

1. Lytgobi® tablets [prescribing information.]. Princeton, NJ: Taiho Oncology; April 2024.
2. The NCCN Drugs & Biologics Compendium. © 2024 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on November 7, 2024. Search term: futibatiniib.
3. The NCCN Biliary Tract Cancers Clinical Practice Guidelines in Oncology (version 4.2024 – August 29, 2024). © 2024 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on November 7, 2024.