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Section:	Prescription Drugs	**Effective Date:**	April 1, 2024
Subsection:	Antineoplastic Agents	**Original Policy Date:**	October 28, 2022
Subject:	Lytgobi	**Page:**	1 of 5

Last Review Date: March 8, 2024

Lytgobi

Description

Lytgobi (futibatinib)

Background
Lytgobi (futibatinib) is a small molecule kinase inhibitor that targets fibroblast growth factor receptors (FGFR): FGFR1, 2, 3, and 4. Lytgobi inhibits FGFR phosphorylation and signaling and decreases cell viability in cancer cell lines with activating FGFR fusions/rearrangements, amplifications, and mutations that resulted in constitutive activation of FGFR signaling. Constitutive FGFR signaling can support the proliferation and survival of malignant cells (1).

Regulatory Status
FDA-approved indication: Lytgobi 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 (1).

Lytgobi can cause retinal pigment epithelial detachment (RPED). A comprehensive ophthalmological examination should be performed prior to the initiation of Lytgobi and every 2 months for the first 6 months and every 3 months thereafter during treatment and urgently at any time for visual symptoms (1).

Increases in phosphate levels are a pharmacodynamic effect of Lytgobi. Patients should be monitored for hyperphosphatemia and a low phosphate diet should be initiated when serum phosphate level is > 5.5 mg/dL. For serum phosphate levels > 7mg/dL, phosphate lowering

therapy should be initiated and Lytgobi should be withheld, reduced, or permanently discontinued based on duration and severity of the hyperphosphatemia (1).

Lytgobi can cause fetal harm when administered to a pregnant woman. Female patients of reproductive potential should be advised to use effective contraception during treatment with Lytgobi and for 1 week after the final dose. Male patients with female partners of reproductive potential should be advised to use effective contraception during treatment with Lytgobi and for 1 week after the final dose (1).

The safety and efficacy of Lytgobi in pediatric patients less than 18 years of age have not been established (1).

Related policies
Pemazyre, Truseltiq

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Lytgobi may be considered **medically necessary** if the conditions indicated below are met.

Lytgobi may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

1. Unresectable locally advanced or metastatic cholangiocarcinoma
    a. Fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement
    b. Patient has had at least one prior therapy

AND ALL of the following:

a. Baseline ophthalmological examination has been done and patient will be monitored for retinal pigment epithelial detachment (RPED)
b. Prescriber agrees to monitor for hyperphosphatemia and agrees to initiate a low phosphate diet or phosphate lowering therapy, as clinically indicated
c. Females of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Lytgobi and for 1 week after the last dose
d. Males with female partners of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Lytgobi and for 1 week after the last dose

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

1. Unresectable locally advanced or metastatic cholangiocarcinoma

AND ALL of the following:

a. **NO** disease progression or unacceptable toxicity
b. Patient will be monitored for retinal pigment epithelial detachment (RPED)
c. Prescriber agrees to monitor for hyperphosphatemia and agrees to initiate a low phosphate diet or phosphate lowering therapy, as clinically indicated
d. Females of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Lytgobi and for 1 week after the last dose
e. Males with female partners of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Lytgobi and for 1 week after the last dose

Policy Guidelines

Pre - PA Allowance
None

Prior - Approval Limits

Quantity 420 tablets per 84 days

Duration 12 months

Prior – Approval *Renewal* Limits
Same as above

Rationale

Summary
Lytgobi (futibatinib) is a small molecule kinase inhibitor that targets fibroblast growth factor receptors (FGFR): FGFR1, 2, 3, and 4. Lytgobi is 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 safety and effectiveness of Lytgobi in pediatric patients less than 18 years of age have not been established (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Lytgobi while maintaining optimal therapeutic outcomes.

References
1. Lytgobi [package insert]. Princeton, NJ: Taiho Oncology; September 2022.
2. NCCN Drugs & Biologics Compendium® Futibatinib 2024. National Comprehensive Cancer Network, Inc. Accessed on January 24, 2024.

Policy History

Date	Action
October 2022	Addition to PA
December 2022	Annual review
March 2023	Annual review and reference update
March 2024	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 8, 2024 and is effective on April 1, 2024.