BlueCross BlueShield
Federal Employee Program

LYTGOBI
(futibatinib)

RATIONALE FOR INCLUSION IN PA PROGRAM

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).

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; April 2024.
2. NCCN Drugs & Biologics Compendium® Futibatinib 2025. National Comprehensive Cancer Network, Inc. Accessed on January 9, 2025.