PATIENT ACCESS GUIDE

LYTGOBI® (futibatinib) tablets

Patient Access and Dosing Information Guide

INDICATION

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.

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).

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

- **Ocular Toxicity:** LYTGOBI can cause Retinal Pigment Epithelial Detachment (RPED), which may cause symptoms such as blurred vision. RPED occurred in 9% of 318 patients who received LYTGOBI across clinical trials. The median time to first onset of RPED was 40 days. RPED led to dose interruption of LYTGOBI in 1.3% of patients, dose reduction in 1.6% of patients, and permanent discontinuation in 0.3% of patients. Perform a comprehensive ophthalmological examination, including optical coherence tomography (OCT) of the macula, prior to initiation of therapy, every 2 months for the first 6 months, and every 3 months thereafter. For onset of visual symptoms, refer patients for ophthalmologic evaluation urgently, with follow-up every 3 weeks until resolution or discontinuation of LYTGOBI. Withhold or reduce the dose of LYTGOBI as recommended. Dry Eye/Corneal Keratitis: Among 318 patients who received LYTGOBI across clinical trials, dry eye occurred in 15% of patients. Treat patients with ocular demulcents as needed.

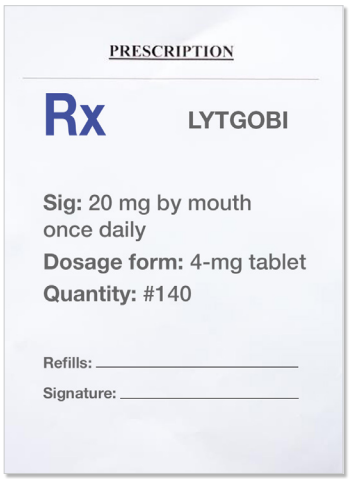
The information in this guide is valid as of November 2024 and is subject to change.

Please see Important Safety Information on pages 7 and 8, and full Prescribing Information.

LYTGOBI®
(futibatinib) tablets 4 mg

DOSING INFORMATION FOR LYTGOBI®[1]

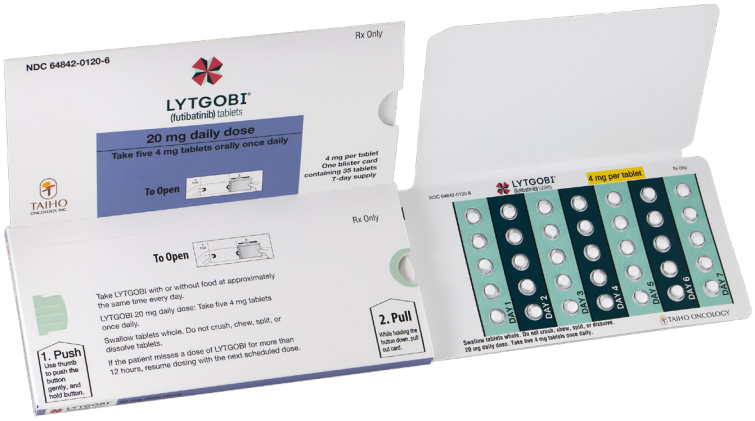
The recommended starting dose of LYTGOBI is 20 mg (five 4-mg tablets) taken orally once daily until disease progression or unacceptable toxicity occurs.



20 mg (five 4-mg tablets) taken orally once daily.

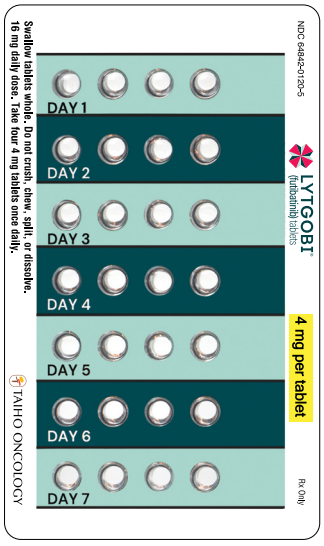
A 28-day supply of the starting dose is 140 tablets.

Tablets shown are not actual size.

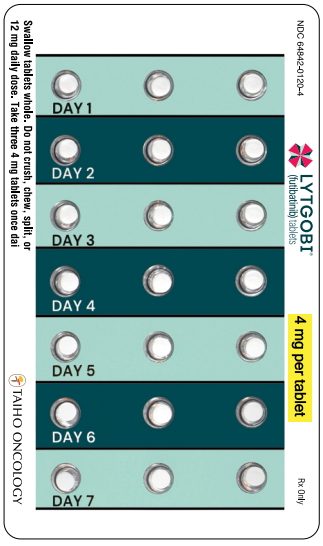


- Take LYTGOBI with or without food at approximately the same time each day
- Advise patients to avoid grapefruit products during treatment with LYTGOBI
- If the patient misses a dose of LYTGOBI for more than 12 hours, or if vomiting occurs, resume dosing with the next scheduled dose

IN THE EVENT THAT DOSE MODIFICATIONS ARE REQUIRED, ALTERNATIVE BLISTER CARDS ARE AVAILABLE



- First dose reduction: 16 mg (four 4-mg tablets) once daily



- Second dose reduction: 12 mg (three 4-mg tablets) once daily

Recommended dose adjustments and management guidelines for adverse reactions are provided in Table 2 of the Prescribing Information.

If the patient is unable to tolerate 12 mg once daily, permanently discontinue LYTGOBI.

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PACKAGING INFORMATION FOR LYTGOBI[1]

LYTGOBI tablets are packaged in blister cards and supplied in a child-resistant Dosepak® as follows:

REGIMEN/DAILY DOSE	PACKAGE SIZE CONTAINING 4-MG TABLETS	11-DIGIT NDC
Starting dose (20 mg)	35 tablets; blister card containing 7-day supply	64842-0120-06
First dose reduction (16 mg)	28 tablets; blister card containing 7-day supply	64842-0120-05
Second dose reduction (12 mg)	21 tablets; blister card containing 7-day supply	64842-0120-04

The red zero converts the 10-digit NDC to the 11-digit NDC. Payer requirements regarding the use of NDCs may vary. Electronic data exchange generally requires use of the 11-digit NDC.

A 28-day supply of the starting dose is 140 tablets.

Store LYTGOBI tablets at room temperature 20°C to 25°C (68°F to 77°F); excursions permitted between 15°C and 30°C (59°F to 86°F).

SPECIALTY PHARMACY AND DISTRIBUTORS

SPECIALTY PHARMACY	WEBSITE	TELEPHONE	FAX
Onco360	www.onco360.com	(877) 662-6633	(877) 662-6355

Onco360 is the only specialty pharmacy with the ability to fill prescriptions for LYTGOBI.

SPECIALTY DISTRIBUTOR	WEBSITE	TELEPHONE	FAX
Cencora Oncology Supply	www.oncologysupply.com	(800) 633-7555	(800) 248-8205
Cencora Specialty Distribution	www.asdhealthcare.com	(800) 746-6273	(800) 547-9413
Cardinal Health SPD Hospital	orderexpress.cardinalhealth.com	(866) 677-4844	(614) 553-6301
Cardinal Health SPD Physician Office and Clinic	specialtyonline.cardinalhealth.com	(877) 453-3972	(877) 274-9897
McKesson Plasma and Biologics	connect.mckesson.com	(877) 625-2566	(888) 752-7626
McKesson Specialty Health	mscs.mckesson.com	(800) 482-6700	(800) 289-9285

NDC=National Drug Code.

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DIAGNOSIS CODES FOR CHOLANGIOCARCINOMA[2,3]

ICD-10-CM DIAGNOSIS CODE	DESCRIPTION
C22.1	Intrahepatic bile duct carcinoma • Cholangiocarcinoma
C24.8	Malignant neoplasm of overlapping sites of biliary tract • Malignant neoplasm involving both intrahepatic and extrahepatic bile ducts • Primary malignant neoplasm of two or more contiguous sites of biliary tract
C24.9	• Malignant neoplasm of biliary tract, unspecified

The 2025 version of the ICD-10-CM took effect on October 1, 2024.

This information is not intended as coverage or coding advice and does not guarantee reimbursement. You should verify the appropriate reimbursement information for services or items you provide. Each healthcare professional is responsible for ensuring all coding is accurate and appropriate.

ICD-10-CM=*International Classification of Diseases, 10th Revision, Clinical Modification.*

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

- **Hyperphosphatemia and Soft Tissue Mineralization:** LYTGOBI can cause hyperphosphatemia leading to soft tissue mineralization, calcinosis, nonuremic calciphylaxis, and vascular calcification. Hyperphosphatemia was reported in 88% of 318 patients treated with LYTGOBI across clinical trials with a median time of onset of 5 days (range 3-117). Phosphate binders were received by 77% of patients who received LYTGOBI. Monitor for hyperphosphatemia throughout treatment. Initiate a low-phosphate diet and phosphate-lowering therapy when serum phosphate level is ≥5.5 mg/dL; initiate or intensify phosphate-lowering therapy when >7 mg/dL; reduce dose, withhold, or permanently discontinue LYTGOBI based on duration and severity of hyperphosphatemia.

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TAIHO ONCOLOGY CO-PAY ASSISTANCE PROGRAM

Making Access Easier for Patients

TAIHO ONCOLOGY PATIENT SUPPORT
Supporting your treatment journey

CO-PAY ASSISTANCE PROGRAM

Potential

$0 CO-PAY*

If you are eligible, the Taiho Oncology Co-Pay Program may help reduce your co-pay responsibility to $0

TAIHO ONCOLOGY

TAIHO ONCOLOGY PATIENT SUPPORT
Supporting your treatment journey

TO DETERMINE PATIENT ELIGIBILITY

GO TO: **TaihoOncologyCopay.com**

OR CALL: **844-824-4648**

Eligible patients may pay $0 per treatment cycle

PATIENTS MAY BE ELIGIBLE IF THEY:

- Have commercial prescription insurance coverage
- Use a specialty pharmacy
- Use a hospital outpatient pharmacy
- Receive medicine from a doctor's office

PATIENTS MAY NOT BE ELIGIBLE IF THEY:

- Are reimbursed under Medicaid, a Medicare drug benefit program, TRICARE, or other state or federal programs
- Reside outside of the US, Puerto Rico, or US territories

LYTGOBI QUICKSTART

Your patients may be eligible for the LYTGOBI QuickStart Program. If your patient's insurance coverage determination is delayed by 5 or more days, Taiho Oncology may provide a free 28-day supply of LYTGOBI. To learn more, call 1-844-TAIHO-4U (1-844-824-4648).

*Restrictions and eligibility: Offer valid in the US, Puerto Rico, and US territories only. Only valid for patients with private insurance. Offer not valid for prescriptions reimbursed under Medicaid, a Medicare drug benefit plan, TRICARE, or other federal or state programs (such as medical assistance programs). If the patient is eligible for drug benefits under any such program, this offer is not valid and the patient cannot use this offer. By presenting or accepting this benefit, patient and pharmacist agree not to submit claim for reimbursement under the above programs. Patient further agrees to comply with any and all terms of his or her health insurance contract requiring notification to his or her payer of the existence and/or value of this offer. It is illegal to or offer to sell, purchase, or trade this benefit. Maximum reimbursement limits apply; patient out-of-pocket expense may vary. Taiho Oncology, Inc., reserves the right to rescind, revoke, or amend this offer at any time without notice.

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TAIHO ONCOLOGY PATIENT SUPPORT™

TAIHO ONCOLOGY PATIENT SUPPORT
Supporting your treatment journey

Taiho Oncology Patient Support offers personalized services to help patients, caregivers, and healthcare professionals access Taiho Oncology products. This includes insurance coverage determination and help with medication affordability.

HOW TO ENROLL

We offer 3 convenient ways to enroll in Taiho Oncology Patient Support Services:

Via the HCP Portal

- **Enroll online,** directly through our HCP portal

taihopatientsupport.com

NOTE: Login required. Please register prior to enrolling.

OR

Download, Print, and Fax

- Download and fill in the **Enrollment Form** and print it out to complete
- Fax the completed form to **1-844-287-2559**

OR

By Phone

- Call **1-844-TAIHO-4U** (1-844-824-4648) for help with enrollment

TAIHO ONCOLOGY PATIENT SUPPORT CAN ASSIST WITH:

Insurance Coverage Support

- Benefits investigation
- Prior authorization assistance
- Appeals assistance
- Coordination of prescriptions with pharmacies

Patient Affordability Assistance*

- $0 co-pay program enrollment for eligible commercially insured patients
- Patient assistance program designed to provide free medication to eligible patients who are uninsured or underinsured
- Referrals to third-party foundations for co-pay or other assistance based on eligibility and additional criteria
- Referrals to Medicare Part D Low-Income Subsidy (LIS)/Extra Help Program

Personalized Nurse Support†

- One-on-one nurse educational support for patients, available via opt-in

*Visit TaihoPatientSupport.com to see full eligibility criteria.
†If this option is selected on the Patient Enrollment Form, a Nurse Navigator will be assigned to provide telephone support and will address general inquiries about LYTGOBI treatment.

HCP=healthcare professional.

Please see Important Safety Information on pages 7 and 8, and full Prescribing Information for complete details.

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- **Embryo-fetal Toxicity:** Based on findings in an animal study and its mechanism of action, LYTGOBI can cause fetal harm when administered to a pregnant woman. Advise pregnant women of the potential risk to the fetus. Advise female patients of reproductive potential, and males with female partners of reproductive potential, to use effective contraception during treatment with LYTGOBI and for 1 week after the last dose.

ADVERSE REACTIONS

- **Serious adverse reactions** occurred in 39% of patients receiving LYTGOBI, and in ≥2% of patients included pyrexia (3.9%), gastrointestinal hemorrhage (3.9%), ascites (2.9%), musculoskeletal pain (2.9%), and bile duct obstruction (2.9%).
- **The most common adverse reactions** (≥20%) were nail toxicity (47%), musculoskeletal pain (43%), constipation (39%), diarrhea (39%), fatigue (37%), dry mouth (35%), alopecia (34%), stomatitis (30%), abdominal pain (30%), dry skin (29%), arthralgia (25%), dysgeusia (25%), dry eye (25%), nausea (24%), decreased appetite (23%), urinary tract infection (23%), palmar-plantar erythrodysesthesia syndrome (21%), and vomiting (20%).

Please see full Prescribing Information for complete details.

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IMPORTANT SAFETY INFORMATION (cont'd)

ADVERSE REACTIONS (cont'd)

- **The most common laboratory abnormalities** (≥20%) were increased phosphate (97%), increased creatinine (58%), decreased hemoglobin (52%), increased glucose (52%), increased calcium (51%), decreased sodium (51%), decreased phosphate (50%), increased alanine aminotransferase (50%), increased alkaline phosphatase (47%), decreased lymphocytes (46%), increased aspartate aminotransferase (46%), decreased platelets (42%), increased activated partial thromboplastin time (36%), decreased leukocytes (33%), decreased albumin (31%), decreased neutrophils (31%), increased creatine kinase (31%), increased bilirubin (28%), decreased glucose (25%), increased prothrombin international normalized ratio (25%), and decreased potassium (22%).

DRUG INTERACTIONS

- **Dual P-gp and Strong CYP3A Inhibitors:** Avoid concomitant use of drugs that are dual P-gp and strong CYP3A inhibitors.
- **Dual P-gp and Strong CYP3A Inducers:** Avoid concomitant use of drugs that are dual P-gp and strong CYP3A inducers.

USE IN SPECIFIC POPULATIONS

- **Lactation:** Because of the potential for serious adverse reactions from LYTGOBI in breastfed children, advise women not to breastfeed during treatment and for 1 week after the last dose.
- **Hepatic Impairment:** Patients with hepatic impairment may have the potential for increased adverse reactions compared to patients with normal hepatic function.

Please see full Prescribing Information for complete details.

NCCN Category 2A

National Comprehensive Cancer Network® (NCCN®) recommends futibatinib (LYTGOBI) as a Category 2A, useful in certain circumstances subsequent-line systemic therapy option for unresectable or metastatic CCA with *FGFR2* fusions or rearrangements if disease progression[4]

REFERENCES

1. LYTGOBI. Package insert. Taiho Oncology Inc; 2022. **2.** Billing and coding: hepatic (liver) function panel (A57802). Centers for Medicare & Medicaid Services. Updated October 1, 2022. Accessed October 30, 2024. https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleId=57802&ver=13 **3.** ICD10Data.com. 2023 ICD-10-CM codes. ICD10Data.com website. Updated October 1, 2024. Accessed October 30, 2024. https://www.icd10data.com/ **4.** Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Biliary Tract Cancers. V.4.2024. © National Comprehensive Cancer Network, Inc. 2024. All rights reserved. Accessed October 28, 2024. To view the most recent and complete version of the guideline, go online to NCCN.org. NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way.

CCA=cholangiocarcinoma; FGFR=fibroblast growth factor receptor; NCCN=National Comprehensive Cancer Network.

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