

Clinical Policy: Futibatinib (Lytgobi)

Reference Number: CP.PHAR.604

Effective Date: 03.01.23

Last Review Date: 02.25

Line of Business: Commercial, HIM, Medicaid

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

Description

Futibatinib (Lytgobi[®]) is a small molecule kinase inhibitor that inhibits fibroblast growth factor receptor (FGFR).

FDA Approved Indication(s)

Lytgobi is indicated for the treatment of adult patients with previously treated, unresectable, locally advanced, or metastatic intrahepatic cholangiocarcinoma harboring fibroblast growth factor 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).

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation[®] that Lytgobi is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria**A. Cholangiocarcinoma (must meet all):**

1. Diagnosis of unresectable locally advanced or metastatic cholangiocarcinoma;
2. Prescribed by or in consultation with an oncologist;
3. Age \geq 18 years;
4. Documentation of FGFR2 fusion or rearrangement;
5. Member has not previously received a selective FGFR inhibitor (e.g., Pemazyre[®]);
6. Failure of at least one prior systemic cancer therapy (*See Appendix B*);
7. Prescribed as a single agent;
8. For Lytgobi requests, member must use futibatinib, if available, unless contraindicated or clinically significant adverse effects are experienced;
9. Request meets one of the following (a or b):*
 - a. Dose does not exceed 20 mg (5 tablets) per day;
 - b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration: 6 months

B. Other diagnoses/indications (must meet 1 or 2):

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
 - a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
 - b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. Cholangiocarcinoma (must meet all):

1. Currently receiving medication via Centene benefit, or documentation supports that member is currently receiving Lytgobi for a covered indication and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. For Lytgobi requests, member must use futibatinib, if available, unless contraindicated or clinically significant adverse effects are experienced;
4. If request is for a dose increase, request meets one of the following (a or b):*
 - a. New dose does not exceed 20 mg (5 tablets) per day;
 - b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2):

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
 - a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
 - b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or

2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 2 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

- A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid, or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

FDA: Food and Drug Administration

FGFR: fibroblast growth factor receptor

FGFR2: fibroblast growth factor receptor 2

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
durvalumab + gemcitabine + cisplatin	Varies	Varies
pembrolizumab + gemcitabine + cisplatin	Varies	Varies
gemcitabine (Gemzar [®]) + cisplatin	Gemcitabine 1000 mg/m ² IV in combination with cisplatin 25 mg/m ² IV, both on days 1 and 8 every 21 days for 8 cycles	Varies
5-fluorouracil + oxaliplatin	Varies	Varies
5-fluorouracil + cisplatin	Varies	Varies
capecitabine (Xeloda [®]) + cisplatin	Varies	Varies
capecitabine (Xeloda [®]) + oxaliplatin	Varies	Varies
gemcitabine + Abraxane [®]	Varies	Varies
gemcitabine (Gemzar [®]) + capecitabine (Xeloda [®])	Varies	Varies
gemcitabine (Gemzar [®]) + oxaliplatin	Varies	Varies
5-fluorouracil	Varies	Varies
capecitabine (Xeloda [®])	Varies	Varies
gemcitabine (Gemzar [®])	Varies	Varies

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
FOLFOX (5-fluorouracil, leucovorin, oxaliplatin)	Varies	Varies

Therapeutic alternatives are listed as Brand name[®] (generic) when the drug is available by brand name only and generic (Brand name[®]) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings
None reported

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Cholangiocarcinoma	20 mg orally once daily	20 mg/day

VI. Product Availability

Tablet: 4 mg

VII. References

1. Lytgobi Prescribing Information. Princeton, NJ: Taiho Oncology, Inc.; April 2024. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/214801s0021bl.pdf. Accessed October 21, 2024.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed November 21, 2024.
3. National Comprehensive Cancer Network. Biliary Tract Cancers Version 4.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/btc.pdf. Accessed November 21, 2024.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	10.25.22	02.23
1Q 2024 annual review: no significant changes; references reviewed and updated.	11.01.23	02.24
1Q 2025 annual review: removed “intrahepatic” for diagnosis of cholangiocarcinoma criteria as NCCN supports both intrahepatic and extrahepatic cholangiocarcinoma use; removed Truseltiq as a FGFR inhibitor example as product is discontinued; updated Appendix B with examples of primary treatment regimens as supported by NCCN guidelines; references reviewed and updated.	10.21.24	02.25

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical

policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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Note:

For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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