Clinical Policy: Futibatinib (Lytgobi)

Reference Number: CP.PHAR.604
Effective Date: 03.01.23
Last Review Date: 02.26
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 ≥ 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 for examples*);
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. Dose of Lytgobi is ≥ 12 mg per day;
10. Request meets one of the following (a or b):*
    a. Dose does not exceed both of the following (i and ii):
        i. 20 mg per day;
        ii. 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: 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 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. Dose of Lytgobi is ≥ 12 mg per day;
5. If request is for a dose increase, request meets one of the following (a or b):*
   a. New dose does not exceed both of the following (i and ii):
      i. 20 mg per day;
      ii. 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
Examples of prior systemic cancer therapy: • durvalumab (Imfinzi®)+ gemcitabine + cisplatin • pembrolizumab (Keytruda®) + gemcitabine + cisplatin • gemcitabine ± [cisplatin, oxaliplatin, Abraxane® (albumin-bound paclitaxel), or capecitabine (Xeloda®)] • 5-fluorouracil ± (oxaliplatin or cisplatin) • capecitabine (Xeloda®) ± oxaliplatin • 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

Tablets: 4 mg, 16 mg

VII. References

1. Lytgobi Prescribing Information. Princeton, NJ: Taiho Oncology, Inc.; October 2025. Available at: www.lytogobi.com. Accessed November 6, 2025.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed November 6, 2025.
3. National Comprehensive Cancer Network. Biliary Tract Cancers Version 2.2025. Available at: https://www.nccn.org/professionals/physician_gls/pdf/btc.pdf. Accessed November 6, 2025.

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
1Q 2026 annual review: added 16 mg tablet strength; added minimum dose of 12 mg per day per PI; extended initial approval duration from 6 months to 12 months for this maintenance medication for a chronic condition; references reviewed and updated.	11.06.25	02.26

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.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members, and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

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.