

Futibatinib (LYTGOBI)

Criteria for Use

November 2023

VA Pharmacy Benefits Management Services, Medical Advisory Panel, and VISN Pharmacist Executives

The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. THE CLINICIAN SHOULD USE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.

The Product Information should be consulted for detailed prescribing information.

See the VA National PBM-MAP-VPE Monograph on this drug at the [PBM INTRAnet](#) site for further information.

Exclusion Criteria

If the answer to ANY item below is met, then the patient should NOT receive Futibatinib.

- Unmanageable CYP3A inhibitor/inducer interaction identified
- Clinically significant corneal or retinal disorder identified by ophthalmologic examination
- Serum phosphate greater than upper limit of normal
- Untreated, clinically unstable brain and/or central nervous system metastases
- Pregnancy
- Breastfeeding

Inclusion Criteria

All of the following criteria must be met.

- Care provided by a VA or VA Community Care provider of Hematology/Oncology services
- Diagnosis of advanced/metastatic or surgically unresectable cholangiocarcinoma
- Documented disease progression after at least one platinum-based chemotherapy regimen
- Confirmed tumor expression of Fibroblast Growth Factor Receptor 2 (FGFR2) fusion or select rearrangement by FDA-approved next generation sequencing
- Baseline ophthalmology exam, including optical coherence tomography (OCT) has been performed
- Goals of care and role of palliative care consult have been discussed and documented
- Eastern Cooperative Oncology Group Performance Status 0 or 1

Additional Criteria (if applicable)

For women of childbearing potential

- Pregnancy should be excluded prior to receiving futibatinib and the patient provided contraceptive counseling on potential risks vs. benefits of taking futibatinib if patient were to become pregnant.
- Advise women not to breastfeed during treatment with futibatinib and for 1 week after the last dose.