SPECIALTY GUIDELINE MANAGEMENT

LYTGOBI (futibatinib)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indication

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.

B. <u>Compendial Use</u> Extrahepatic cholangiocarcinoma

All other indications are considered experimental/investigational and not medically necessary.

II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review: Documentation of FGFR2 gene fusions or rearrangements.

III. CRITERIA FOR INITIAL APPROVAL

Cholangiocarcinoma

Authorization of 12 months may be granted as a single agent for subsequent treatment of unresectable, resected gross residual (R2) disease, locally advanced, or metastatic cholangiocarcinoma with FGFR2 gene fusions or rearrangements.

IV. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section III when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

V. REFERENCES

- 1. Lytgobi [package insert]. Princeton, NJ: Taiho Pharmaceutical Co., Ltd.; September 2022.
- 2. The NCCN Drugs & Biologics Compendium[®] © 2023 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed July 7, 2023.

Lytgobi 5638-A SGM P2023.docx

© 2023 CVS Caremark. All rights reserved.

This document contains confidential and proprietary information of CVS Caremark and cannot be reproduced, distributed or printed without written permission from CVS Caremark. This document contains prescription brand name drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with CVS Caremark.



Reference	number(s)
5638-A	

Lytgobi 5638-A SGM P2023.docx

 $\ensuremath{\textcircled{\sc 0}}$ 2023 CVS Caremark. All rights reserved.

This document contains confidential and proprietary information of CVS Caremark and cannot be reproduced, distributed or printed without written permission from CVS Caremark. This document contains prescription brand name drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with CVS Caremark.

