Drug Policy:

Lytgobi™ (futibatinib)

POLICY NUMBER UM ONC_1466	SUBJECT Lytgobi™ (futibatinib)		DEPT/PROGRAM UM Dept	PAGE 1 of 3
DATES COMMITTEE REVIEWED 11/09/22, 11/08/23, 11/13/24	APPROVAL DATE November 13, 2024	EFFECTIVE DATE November 29, 2024	COMMITTEE APPROVAL DATES 11/09/22, 11/08/23, 11/13/24	
PRIMARY BUSINESS OWNER: UM		COMMITTEE/BOARD APPROVAL Evolent Specialty Services Clinical Guideline Review Committee		
NCQA STANDARDS UM 2		ADDITIONAL AREAS OF IMPACT		
CMS REQUIREMENTS	STATE/FEDERAL REQUIREMENTS		APPLICABLE LINES OF BUSINESS Commercial, Exchange, Medicaid	

I. PURPOSE

To define and describe the accepted indications for Lytgobi (futibatinib) usage in the treatment of cancer, including FDA approved indications, and off-label indications.

Evolent is responsible for processing all medication requests from network ordering providers. Medications not authorized by Evolent may be deemed as not approvable and therefore not reimbursable.

The use of this drug must be supported by one of the following: FDA approved product labeling, CMS-approved compendia, National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO) clinical guidelines, or peer-reviewed literature that meets the requirements of the CMS Medicare Benefit Policy Manual Chapter 15.

II. INDICATIONS FOR USE/INCLUSION CRITERIA

A. Continuation requests for a not-approvable medication shall be exempt from this Evolent policy provided:

1. The requested medication was used within the last year, AND
2. The member has not experienced disease progression and/or no intolerance to the requested medication, AND
3. Additional medication(s) are not being added to the continuation request.

B. Cholangiocarcinoma

1. Lytgobi (futibatinib) may be used as monotherapy for members with unresectable, advanced, or metastatic cholangiocarcinoma that is positive for FGFR2 rearrangement (e.g., gene fusion/activating mutations) as detected by an FDA approved test AND the member has disease progression on at least one prior systemic therapy.

III. EXCLUSION CRITERIA

A. Disease progression while taking Lytgobi (futibatinib) or on another FGFR inhibitor [e.g., Pemazyre (pemigatinib), Truseltiq (infigratinib)].

B. No documentation to confirm the presence of an FGFR2 rearrangement by an FDA approved test. A list for the FDA approved test is available at www.fda.gov/CompanionDiagnostics.

C. Concurrent use with other anti-cancer therapies.

D. Dosing exceeds single dose limit of Lytgobi (futibatinib) 20 mg.

E. Treatment with Lytgobi (futibatinib) exceeds the maximum limit of 140 (4 mg) tablets/month.

F. Investigational use of Lytgobi (futibatinib) with an off-label indication that is not sufficient in evidence or is not generally accepted by the medical community. Sufficient evidence that is not supported by CMS recognized compendia or acceptable peer reviewed literature is defined as any of the following:

1. Whether the clinical characteristics of the patient and the cancer are adequately represented in the published evidence.
2. Whether the administered chemotherapy/biologic therapy/immune therapy/targeted therapy/other oncologic therapy regimen is adequately represented in the published evidence.
3. Whether the reported study outcomes represent clinically meaningful outcomes experienced by patients. Generally, the definition of Clinically Meaningful outcomes are those recommended by ASCO, e.g., Hazard Ratio of less than 0.80 and the recommended survival benefit for OS and PFS should be at least 3 months.
4. Whether the experimental design, in light of the drugs and conditions under investigation, is appropriate to address the investigative question. (For example, in some clinical studies, it may be unnecessary or not feasible to use randomization, double blind trials, placebos, or crossover).
5. That non-randomized clinical trials with a significant number of subjects may be a basis for supportive clinical evidence for determining accepted uses of drugs.
6. That case reports are generally considered uncontrolled and anecdotal information and do not provide adequate supportive clinical evidence for determining accepted uses of drugs.
7. That abstracts (including meeting abstracts) without the full article from the approved peer-reviewed journals lack supporting clinical evidence for determining accepted uses of drugs.

IV. MEDICATION MANAGEMENT

A. Please refer to the FDA label/package insert for details regarding these topics.

V. APPROVAL AUTHORITY

A. Review – Utilization Management Department

B. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

A. None

VII. REFERENCES

A. Bahleda R, et al. FOENIX-101 Clinical Trial. Phase I, first-in-human study of futibatinib, a highly selective, irreversible FGFR1-4 inhibitor in patients with advanced solid tumors. Ann Oncol. 2020 Oct;31(10):1405-1412.

B. Lytgobi prescribing information. Taiho Oncology, Inc. Princeton, NJ 2024.

C. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs Bethesda, MD 2024.

D. Clinical Pharmacology Elsevier Gold Standard 2024.

E. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, CO 2024.

F. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium 2024.

G. Ellis LM, et al. American Society of Clinical Oncology perspective: Raising the bar for clinical trials by defining clinically meaningful outcomes. J Clin Oncol. 2014 Apr 20;32(12):1277-80.

H. Medicare Benefit Policy Manual Chapter 15 Covered Medical and Other Health Services: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf.