Drug Policy:

Truseltiq™ (infigratinib)

POLICY NUMBER UM ONC_1442	SUBJECT Truseltiq™ (infigratinib)		DEPT/PROGRAM UM Dept	PAGE 1 of 3
DATES COMMITTEE REVIEWED 07/14/21, 11/15/21, 05/11/22, 06/08/22, 12/14/22, 12/13/2023	APPROVAL DATE December 13, 2023	EFFECTIVE DATE December 22, 2023	COMMITTEE APPROVAL DATES 07/14/21, 11/15/21, 05/11/22, 06/08/22, 12/14/22, 12/13/2023	
PRIMARY BUSINESS OWNER: UM		COMMITTEE/BOARD APPROVAL Utilization Management 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 Truseltiq (infigratinib) usage in the treatment of cancer, including FDA approved indications, and off-label indications.

New Century Health (NCH) is responsible for processing all medication requests from network ordering providers. Medications not authorized by NCH 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 member has not experienced disease progression on the requested medication, AND
2. The requested medication was used within the last year without a lapse of more than 30 days of having an active authorization, AND
3. Additional medication(s) are not being added to the continuation request.

B. Cholangiocarcinoma

1. Truseltiq (infigratinib) may be used as monotherapy following disease progression on or after at least one prior systemic treatment for FGFR2 positive (fibroblast growth factor receptor 2 fusion positive), unresectable/metastatic cholangiocarcinoma. Please note that the above only applies to continuation requests for this agent for members who are experiencing documented clinical benefit from the drug. On October 2022, the manufacturer withdrew its New Drug Application for the FDA and decided to permanently discontinue US distribution of the drug.

III. EXCLUSION CRITERIA

A. Disease progression while taking Truseltiq (infigratinib) or another FGFR inhibitor (e.g., pemigatinib).

B. Lack of molecular testing confirming the presence of an FGFR2 fusion/other rearrangement in the member's cancer.

C. Concurrent use with other anti-cancer therapies.

D. Dosing exceeds single dose limit of Truseltiq (infigratinib) 125 mg.

E. Treatment exceeds the maximum limit of 21 (25 mg) and 21 (100mg) tablets/month.

F. Investigational use of Truseltiq (infigratinib) 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. Javle M, et al. Infigratinib (BGJ398) in previously treated patients with advanced or metastatic cholangiocarcinoma with FGFR2 fusions or rearrangements: mature results from a multicentre, open-label, single-arm, phase 2 study. Lancet Gastroenterol Hepatol. 2021 Oct;6(10):803-815.

B. Truseltiq prescribing information. QED Therapeutics, Inc. Brisbane, CA 2022.

C. Clinical Pharmacology Elsevier Gold Standard 2022.

D. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, CO 2022.

E. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium 2022.

F. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs Bethesda, MD 2022.

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.

I. Current and Resolved Drug Shortages and Discontinuations Reported to the FDA: http://www.accessdata.fda.gov/scripts/drugshortages/default.cfm.

J. NCQA UM 2022 Standards and Elements.