PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Truseltiq Prior Authorization Policy
- Truseltiq™ (infigratinib capsules – QED Therapeutics)

REVIEW DATE: 06/12/2024

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

Truseltiq, a kinase inhibitor, is indicated for the treatment of previously treated, unresectable locally advanced or metastatic **cholangiocarcinoma** with a fibroblast growth factor 2 (FGFR2) fusion or other rearrangement as detected by an FDA-approved test in adults.[1]

This indication was 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.

In October 2022, Helsinn, the manufacturer, announced the discontinuation of distribution of Truseltiq on March 31, 2023.[3] Helsinn stated that this was not for safety reason and they recommend that no new patients be started on Truseltiq.

Guidelines

The National Comprehensive Cancer Network Biliary Tract Cancers (version 2.2024 – April 19, 2024) clinical practice guidelines no longer recommend Truseltiq for the subsequent treatment of unresectable or metastatic cholangiocarcinoma with FGFR2 fusions or rearrangements, as a single agent for progression on or after systemic treatment.[2]

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Truseltiq. All approvals are provided for the duration noted below.

- **Truseltiq™ (infigratinib capsules – QED Therapeutics)**

is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

FDA-Approved Indication

1. **Cholangiocarcinoma.** Approve for 1 year if the patient meets the following (A, B, C, D, and E):
   - **A)** Patient is currently receiving Truseltiq; AND
   - **B)** Patient is ≥ 18 years of age; AND
   - **C)** Patient has unresectable locally advanced or metastatic disease; AND
   - **D)** Patient has fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement, as detected by an approved test; AND
   - **E)** Truseltiq is used as subsequent therapy.

CONDITIONS NOT COVERED

- **Truseltiq™ (infigratinib capsules – QED Therapeutics)**

is(are) considered experimental, investigational or unproven for ANY other use(s); criteria will be updated as new published data are available.

REFERENCES

1. Truseltiq™ capsules [prescribing information]. Brisbane, CA: QED Therapeutics; May 2021.
2. The NCCN Biliary Tract Cancers Clinical Practice Guidelines in Oncology (version 2.2024 – April 19, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on June 4, 2024.
3. Important information: Truseltiq® (infigratinib) capsules notice of permanent discontinuation of distribution [press release]. Iselin, NJ: Helsinn Therapeutics; October 2022. Available at: https://www.ccanewsonline.com/web-exclusives/press-releases/october-10-2022-truseltiq. Accessed on June 12, 2023.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	**Cholangiocarcinoma:** Added patient is currently receiving Truseltiq as an additional requirement.	06/14/2023
Annual Revision	No criteria changes.	06/12/2024