PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 06/12/2024

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.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Truseltiq is recommended in those who meet the following criteria:

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 RECOMMENDED FOR APPROVAL

Coverage of Truseltiq is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. 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.