

PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Truseltiq Prior Authorization Policy

- Truseltiq[™] (infigratinib capsules – QED Therapeutics)

REVIEW DATE: 06/09/2021

OVERVIEW

Truseltiq, a kinase inhibitor, is indicated for the treatment of adults with 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.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.

Guidelines

The National Comprehensive Cancer Network Hepatobiliary Cancers (version 3.2021 – June 15, 2021) clinical practice guidelines 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.^{2,3}

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 Indications

1. **Cholangiocarcinoma.** Approve for 3 years if the patient meets the following criteria (A, B, C, and D):
 - A) Patient is ≥ 18 years of age; AND
 - B) Patient has unresectable locally advanced or metastatic disease; AND
 - C) Patient has fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement, as detected by an approved test; AND
 - D) 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 Hepatobiliary Cancers Clinical Practice Guidelines in Oncology (Version 3.2021 – June 15, 2021). © 2021 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed June 24, 2021.
3. The NCCN Drugs & Biologics Compendium. © 2021 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed June 24, 2021. Search term: infigratinib.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	06/09/2021
Update	6/24/2021: No criteria changes. Updated guidelines in Overview section.	NA