



UnitedHealthcare Pharmacy  
Clinical Pharmacy Programs

Program Number	2021 P 1363-1
Program	Prior Authorization/Notification
Medication	Truseltiq™ (infigratinib)
P&T Approval Date	7/2021
Effective Date	10/1/2021; Oxford only: 10/1/2021

**1. Background:**

Truseltiq (infigratinib) is a kinase inhibitor indicated for the treatment of adults with previously treated, unresectable locally advanced or metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement.<sup>1</sup>

**Coverage Information:**

Members will be required to meet the criteria below for coverage. For members under the age of 19 years, the prescription will automatically process without a coverage review.

Some states mandate benefit coverage for off-label use of medications for some diagnoses or under some circumstances. Some states also mandate usage of other Compendium references. Where such mandates apply, they supersede language in the benefit document or in the notification criteria.

**2. Coverage Criteria:**

**A. Patients less than 19 years of age**

**1. Truseltiq** will be approved based on the following criterion:

- a. Patient is less than 19 years of age

**Authorization will be issued for 12 months.**

**B. Cholangiocarcinoma**

**1. Initial Authorization**

**a. Truseltiq** will be approved based on the following criteria:

- (1) Diagnosis of cholangiocarcinoma

**-AND-**

- (2) Disease is **one** of the following:

- i. Unresectable locally advanced
- ii. Metastatic

**-AND-**

- (3) Disease has presence of a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement

**-AND-**

- (4) Patient has been previously treated

**Authorization will be issued for 12 months.**

## **2. Reauthorization**

- a. **Truseltiq** will be approved based on the following criterion:

- (1) Patient does not show evidence of progressive disease while on Truseltiq therapy

**Authorization will be issued for 12 months.**

## **B. NCCN Recommended Regimens**

The drug has been recognized for treatment of the cancer indication by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B

**Authorization will be issued for 12 months.**

## **3. Additional Clinical Rules:**

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits and/or step therapy may be in place.

## **4. References:**

1. Truseltiq [package insert]. Brisbane, CA: QED Therapeutics, Inc. May 2021.

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<b>Change Control</b>	
7/2021	New program.