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Section:	Prescription Drugs	**Effective Date:**	April 1, 2024
Subsection:	Antineoplastic Agents	**Original Policy Date:**	June 25, 2021
Subject:	Truseltiq	**Page:**	1 of 5

Last Review Date: March 8, 2024

Truseltiq

Description

Truseltiq (infigratinib)

Background
Truseltiq (infigratinib) is a small molecule kinase inhibitor of fibroblast growth factor receptor (FGFR): FGFR1, FGFR2, FGFR3, and FGFR4. Truseltiq inhibits FGFR signaling and decreases cell proliferation in cancer cell lines with activating FGFR amplifications, mutations, or fusions. Constitutive FGFR signaling can support the proliferation and survival of malignant cells (1).

Regulatory Status
FDA-approved indication: Truseltiq 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 as detected by an FDA-approved test (1).

Truseltiq has warnings regarding ocular toxicity, hyperphosphatemia and soft tissue mineralization, and embryo-fetal toxicity (1).

Truseltiq can cause retinal pigment epithelial detachment (RPED). A comprehensive ophthalmological examination should be performed prior to the initiation of Truseltiq, at 1 month, at 3 months, and then every 3 months thereafter during treatment. For onset of visual symptoms, patients should be referred for ophthalmologic evaluations urgently, with follow-up every 3 weeks until resolution or discontinuation of Truseltiq (1).

Increases in phosphate levels are a pharmacodynamic effect of Truseltiq. Patients should be monitored for hyperphosphatemia. When serum phosphate level is > 5.5 mg/dL, phosphate lowering therapy should be initiated. For serum phosphate level > 7.5 mg/dL, Truseltiq should be withheld and phosphate lowering therapy should be initiated. Truseltiq should be withheld, reduced, or permanently discontinued based on duration and severity of the hyperphosphatemia (1).

Truseltiq can cause fetal harm when administered to a pregnant woman. Female patients of reproductive potential should be advised to use effective contraception during treatment with Truseltiq and for 1 month after the final dose. Male patients with female partners of reproductive potential should be advised to use effective contraception during treatment with Truseltiq and for 1 month after the final dose (1).

Truseltiq is given orally (125 mg) once daily for 21 consecutive days followed by 7 days off therapy, in 28-day cycles (1).

The safety and effectiveness of Truseltiq in pediatric patients less than 18 years of age have not been established (1).

Related policies
Pemazyre

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Truseltiq may be considered **medically necessary** if the conditions indicated below are met.

Truseltiq may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Unresectable locally advanced or metastatic cholangiocarcinoma

AND ALL of the following:

a. Patient has had at least one prior therapy
b. Fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement, as detected by an FDA-approved test
c. Baseline ophthalmological examination has been done and patient will be monitored for retinal pigment epithelial detachment (RPED)
d. Prescriber agrees to monitor for hyperphosphatemia and agrees to withhold Truseltiq and initiate phosphate lowering therapy as clinically indicated
e. Females of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Truseltiq and for 1 month after the final dose
f. Males with female partners of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Truseltiq and for 1 month after the final dose

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Unresectable locally advanced or metastatic cholangiocarcinoma

AND ALL of the following:

a. **NO** disease progression or unacceptable toxicity
b. Patient will be monitored for retinal pigment epithelial detachment (RPED)
c. Prescriber agrees to monitor for hyperphosphatemia and agrees to withhold Truseltiq and initiate phosphate lowering therapy as clinically indicated
d. Females of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Truseltiq and for 1 month after the final dose

e. Males with female partners of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Truseltiq and for 1 month after the final dose

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity

Medication	Daily Dosing Limits
Truseltiq 25 mg, 100 mg	125 mg per day

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

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. Truseltiq has warnings regarding ocular toxicity, hyperphosphatemia and soft tissue mineralization, and embryo-fetal toxicity. The safety and effectiveness of Truseltiq in pediatric patients less than 18 years of age have not been established (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Truseltiq while maintaining optimal therapeutic outcomes.

References

1. Truseltiq [package insert]. Brisbane, CA: QED Therapeutics, Inc.; May 2021.
2. NCCN Drugs & Biologics Compendium® Infigratinib 2024. National Comprehensive Cancer Network, Inc. Accessed on January 24, 2024.

Policy History

Date	Action
June 2021	Addition to PA
September 2021	Annual review and reference update
December 2022	Annual review and reference update
March 2023	Annual review and reference update
March 2024	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy Medical Policy Committee on March 8, 2024 and is effective on April 1, 2024.