BlueCross BlueShield
Federal Employee Program

TRUSELTIQ
(infigratinib)

RATIONALE FOR INCLUSION IN PA PROGRAM

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).

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 2025. National Comprehensive Cancer Network, Inc. Accessed on January 9, 2025.