

## SPECIALTY GUIDELINE MANAGEMENT

### TRUSELTIQ (infigratinib)

#### POLICY

##### I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

##### FDA-Approved Indications

Truseltiq is 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.

All other indications are considered experimental/investigational and not medically necessary.

##### II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review: Documentation of FGFR2 fusion or rearrangement

##### III. CRITERIA FOR INITIAL APPROVAL

##### **Cholangiocarcinoma**

Authorization of 12 months may be granted for treatment of members with previously treated, unresectable locally advanced or metastatic cholangiocarcinoma with a FGFR2 fusion or rearrangement when used as a single agent.

##### IV. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section III when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

##### V. REFERENCES

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