Clinical Policy Title:	infigratinib
Policy Number:	RxA.691
Drug(s) Applied:	Truseltiq™
Original Policy Date:	08/16/2021
Last Review Date:	09/14/2021
Line of Business Policy Applies to:	All lines of business

Background

Infigratinib (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.

This indication is 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 confirmatory trial(s).

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
infigratinib (Truseltiq™)	Previously treated, unresectable, locally advanced or metastatic cholangiocarcinoma	125 mg orally once daily for 21 consecutive days followed by 7 days off therapy, in 28-day cycles. Mild and Moderate Renal Impairment: 100 mg orally once daily for 21 consecutive days followed by 7 days off therapy, in 28-day cycles. Mild Hepatic Impairment: is 100 mg orally once daily for 21 consecutive days followed by 7 days off therapy, in 28-day cycles. Moderate Hepatic Impairment: 75 mg orally once daily for 21 consecutive days followed by 7 days off therapy, in 28- day cycles	125 mg orally once daily

Dosage Forms

- Capsules: 25 mg and 100 mg

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria. The provision of provider samples does not guarantee coverage under the terms of the pharmacy benefit administered by RxAdvance. All criteria for initial approval must be met in order to obtain coverage.

I. Initial Approval Criteria

A. Cholangiocarcinoma (must meet all):

1. Diagnosis of unresectable locally advanced or metastatic cholangiocarcinoma;
2. Member must have positive result of FDA-approved test to determine fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement;
3. Prescribed by or in consultation with an oncologist;
4. Age ≥ 18 years;
5. Member must have received at least one prior line of systemic therapy recommended by NCCN (e.g. gemcitabine + cisplatin, gemcitabine + oxaliplatin, 5-fluorouracil, capecitabine, gemcitabine and others);
6. Dose does not exceed 125 mg orally once daily.

Approval Duration
Commercial: 3 months
Medicaid: 3 months

II. Continued Therapy Approval

A. Cholangiocarcinoma (must meet all):

1. Member is currently receiving medication that has been authorized by RxAdvance or the member has met initial approval criteria listed in this policy;
2. Member is responding positively to therapy;
3. If request is for a dose increase, dose does not exceed 125 mg orally once daily.

Approval Duration
Commercial: 3 months
Medicaid: 3 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
FGFR2: fibroblast growth factor receptor 2
RPED: retinal pigment epithelial detachment
OCT: optical coherence tomography
NCCN: National Comprehensive Cancer Network

APPENDIX B: Therapeutic Alternatives
Not applicable.

APPENDIX C: Contraindications/Boxed Warnings

- Contraindication(s):
  - None reported.

- Boxed Warning(s):
  - None reported.

APPENDIX D: General Information

- Ocular Toxicity: Truseltiq™ can cause retinal pigment epithelial detachment (RPED). Perform comprehensive ophthalmic examination including optical coherence tomography (OCT) prior to initiation of Truseltiq™ and again at 1 month, at 3 months, and every 3 months thereafter during treatment. Withhold as recommended.
- Hyperphosphatemia and Soft Tissue Mineralization: Increases in phosphate levels can cause hyperphosphatemia leading to soft tissue mineralization, cutaneous calcinosis, non-uremic calciphylaxis, vascular calcification, and myocardial calcification. Withhold, dose reduce, or permanently discontinue as recommended.
- Embryo-Fetal Toxicity: Can cause fetal harm; Advise patients of reproductive potential of the potential risk to the fetus and to use effective contraception.

References

1. Truseltiq™ Prescribing Information. Brisbane, CA: QED Therapeutics, Inc.; May 2021. Available at: https://www.truseltiq.com/pdfs/prescribing-information.pdf . Accessed August 16, 2021.
2. Clinical Pharmacology [database online] powered by ClinicalKey. Tampa, FL: Elsevier, 2021. Accessed with subscription at: http://www.clinicalkey.com. Updated June 03, 2021. Accessed August 16, 2021.
3. IPD Analytics Rx Insights_New Drug Approval Review_ Truseltiq™_05 2021. Accessed with subscription at: https://secure.ipdanalytics.com/User/Pharma/RxStrategy/Search?q=Truseltiq . Accessed August 16, 2021.
4. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: https://www.nccn.org/professionals/drug_compendium/content/ . Accessed August 16, 2021.
5. National Comprehensive Cancer Network. Hepatobiliary Cancers Version 3.2021. Available at: https://www.nccn.org/professionals/physician_gls/pdf/hepatobiliary.pdf . Accessed August 16, 2021.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	08/16/2021	09/14/2021