

Clinical Policy: Infigratinib (Truseltiq)

Reference Number: ERX.SPA.445

Effective Date: 09.01.21

Last Review Date: 08.22

Line of Business: Commercial, Medicaid

[Revision Log](#)

See **Important Reminder** at the end of this policy for important regulatory and legal information.

Description

Infigratinib (Truseltiq™) is a small molecule kinase inhibitor that inhibits fibroblast growth factor receptor (FGFR).

FDA Approved Indication(s)

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.

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 a confirmatory trial(s).

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ that Truseltiq is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Cholangiocarcinoma (must meet all):

1. Diagnosis of unresectable locally advanced or metastatic cholangiocarcinoma;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Documentation of FGFR2 fusion or rearrangement;
5. Member has not previously received a selective FGFR inhibitor (e.g., Stivarga®, Pemazyre™);
6. Failure of at least one previous systemic cancer therapy (*see Appendix B*);
7. Prescribed as a single agent;
8. Request meets one of the following (a or b):*
 - a. Dose does not exceed 125 mg (2 capsules) per day for 21 days per 28-day cycle;
 - b. Dose is supported by practice guideline or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration:

Commercial – Length of Benefit

Medicaid – 6 months

B. Other diagnoses/indications

1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. Cholangiocarcinoma (must meet all):

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions, or documentation supports that member is currently receiving Truseltiq for a covered indication and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. If request is for a dose increase, request meets one of the following (a or b):*
 - a. New dose does not exceed 125 mg (2 capsules) per day for 21 days per 28-day cycle;
 - b. New dose is supported by practice guideline or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration:

Commercial – Length of Benefit

Medicaid –12 months

B. Other diagnoses/indications (must meet 1 or 2):

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.

Approval duration: Duration of request or 6 months (whichever is less); or

2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:

- A.** Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – ERX.PA.01 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

FDA: Food and Drug Administration

FGFR: fibroblast growth factor receptor

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria.

The drugs listed here may not be a formulary agent and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
gemcitabine (Gemzar®) + cisplatin	Gemcitabine 1000 mg/m ² IV in combination with cisplatin 25 mg/m ² IV, both on days 1 and 8 every 21 days for 8 cycles	Varies
5-fluorouracil + oxaliplatin	Varies	Varies
5-fluorouracil + cisplatin	Varies	Varies
capecitabine (Xeloda®) + cisplatin	Varies	Varies
capecitabine (Xeloda®) + oxaliplatin	Varies	Varies
gemcitabine + Abraxane®	Varies	Varies
gemcitabine (Gemzar®) + capecitabine (Xeloda®)	Varies	Varies
gemcitabine (Gemzar®) + oxaliplatin	Varies	Varies
5-fluorouracil	Varies	Varies
capecitabine (Xeloda®)	Varies	Varies
gemcitabine (Gemzar®)	Varies	Varies
FOLFOX (5-fluorouracil, leucovorin, oxaliplatin)		

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings
None reported

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Cholangiocarcinoma	125 mg PO QD for 21 days followed by 7 days off therapy, in 28-day cycles	125 mg/day

VI. Product Availability

Capsules: 25 mg, 100 mg

VII. References

1. Truseltiq Prescribing Information. Brisbane, CA: QED Therapeutics, Inc.; May 2021. Available at: <https://www.truseltiq.com/pdfs/prescribing-information.pdf>. Accessed April 4, 2022.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed April 4, 2022.
3. National Comprehensive Cancer Network. Hepatobiliary Cancers v1.2022. Available at: https://www.nccn.org/professionals/physician_gls/pdf/hepatobiliary.pdf. Accessed April 4, 2022.
4. Javle M, Lowery M, Shroff RT, et al. Phase II Study of BGJ398 in Patients With FGFR-Altered Advanced Cholangiocarcinoma. J Clin Oncol. 2018 Jan 20;36(3):276-282.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	06.08.21	08.21
3Q 2022 annual review: added requirement for use as a single agent per NCCN; modified max dose requirement to specify treatment is for 21 days per every 28-day cycle per PI; references reviewed and updated.	04.04.22	08.22

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.

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