Clinical Policy: Infigratinib (Truseltiq)

Reference Number: CP.PHAR.547
Effective Date: 09.01.21
Last Review Date: 08.24
Line of Business: Commercial, HIM, 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).

***Helsinn Therapuetics., the manufacturer of Truseltiq, voluntarily withdrew Truseltiq due to difficulties in recruiting and enrolling study participants for the required confirmatory trial and the FDA withdrew its approval for the product** *(see Appendix D).*

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.

It is the policy of health plans affiliated with Centene Corporation® that Truseltiq is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Cholangiocarcinoma (must meet all)**:**

1. Authorization is not permitted. Member may not initiate therapy with Truseltiq. If member is currently using Truseltiq proceed to Section II (*see Appendix D)*;

Approval duration: Not applicable

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

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or

b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or

2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. Cholangiocarcinoma (must meet all)**:**

1. Currently receiving medication via Centene benefit, 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 guidelines 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: 12 months

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

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

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 policies – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid, or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
FGFR: fibroblast growth factor receptor
NCCN: National Comprehensive Cancer Network

Appendix B: Therapeutic Alternatives
Not applicable

Appendix C: Contraindications/Boxed Warnings
None reported

Appendix D: General Information

- On October 14, 2022, Helsinn Therapeutics decided to withdraw its New Drug Application (NDA) of Truseltiq and permanently discontinue Truseltiq because of difficulties in recruiting and enrolling study participants for the required confirmatory trial. The discontinuation is not due to safety or efficacy reasons. Helsinn Therapeutics will discontinue distribution of the capsules in the first quarter of 2023 and is now ending all promotional and educational activities. Product will be available until March 31, 2023. It is strongly recommended against healthcare providers starting new patients on Truseltiq.
- NCCN no longer supports usage of Truseltiq for unresectable and metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement (biliary tract cancers version 2.2024).
- On May 16, 2024, the FDA announced the final withdrawal of the approval of infigratinib (Truseltiq) for previously treated, unresectable locally advanced or metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement.

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.accessdata.fda.gov/drugsatfda_docs/label/2021/214622s000lbl.pdf. Accessed May 6, 2024.
2. National Comprehensive Cancer Network. hepatocellular carcinoma v1.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/hcc.pdf. Accessed May 6, 2024.
3. National Comprehensive Cancer Network. Biliary Tract Cancers v2.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/btc.pdf. Accessed May 6. 2024.
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.
5. Helsinn Healthcare SA; Withdrawal of approval of new drug application for Truseqliq (infigratinib phosphate) capsules, 25 milligrams and 100 milligrams. Food and Drug Administration, HHS. May 16, 2024. Available at: https://www.federalregister.gov/documents/2024/05/16/2024-10714/helsinn-healthcare-sa-withdrawal-of-approval-of-new-drug-application-for-truseltiq-infigratinib. Accessed May 23, 2024.

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
Template changes applied to other diagnoses/indications.	10.06.22	
3Q 2023 annual review: removed initial approval criteria for cholangiocarcinoma; added Appendix D with product discontinuation information; references reviewed and updated.	04.14.23	08.23
3Q2024 annual review: updated Appendix D and disclaimer added about FDA and manufacturer withdrawal; removed therapeutic alternatives in Appendix B; references reviewed and updated.	05.06.24	08.24

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. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. 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. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members, and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.