BlueCross BlueShield Arizona

An Independent Licensee of the Blue Cross Blue Shield Association

PHARMACY COVERAGE GUIDELINE

TRUSELTIQ™ (infigratinib) oral

This Pharmacy Coverage Guideline (PCG):

- Provides information about the reasons, basis, and information sources we use for coverage decisions
- Is not an opinion that a drug (collectively "Service") is clinically appropriate or inappropriate for a patient
- Is not a substitute for a provider's judgment (Provider and patient are responsible for all decisions about appropriateness of care)
- Is subject to all provisions e.g. (benefit coverage, limits, and exclusions) in the member's benefit plan; and
- Is subject to change as new information becomes available.

Scope

- This PCG applies to Commercial and Marketplace plans
- This PCG does not apply to the Federal Employee Program, Medicare Advantage, Medicaid or members of out-of-state Blue Cross and/or Blue Shield Plans

Instructions & Guidance

- To determine whether a member is eligible for the Service, read the entire PCG.
- This PCG is used for FDA approved indications including, but not limited to, a diagnosis and/or treatment with dosing, frequency, and duration.
- Use of a drug outside the FDA approved guidelines, refer to the appropriate Off-Label Use policy.
- The "Criteria" section outlines the factors and information we use to decide if the Service is medically necessary as defined in the Member's benefit plan.
- The "Description" section describes the Service.
- The "Definition" section defines certain words, terms or items within the policy and may include tables and charts.
- The "Resources" section lists the information and materials we considered in developing this PCG
- **We do not accept patient use of samples as evidence of an initial course of treatment, justification for continuation of therapy, or evidence of adequate trial and failure.**
- Information about medications that require precertification is available at www.azblue.com/pharmacy. You must fully complete the request form and provide chart notes, lab workup and any other supporting documentation. The prescribing provider must sign the form. Fax the form to BCBSAZ Pharmacy Management at (602) 864-3126 or email it to Pharmacyprecert@azblue.com.

Criteria:

- **Criteria for initial therapy:** Truseltiq (infigratinib) is considered ***medically necessary*** and will be approved when **ALL** the following criteria are met:

  1. Prescriber is a physician specializing in the patient's diagnosis or is in consultation with an Oncologist.

  2. Individual is 18 years of age or older.

  3. Individual has a confirmed diagnosis of **ONE** of the following:
     a. Previously treated, unresectable locally advanced or metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 (FGFR2) fusion or other FGFR genetic alterations

b. Other request for a specific oncologic direct treatment use that is found and listed in the National Comprehensive Cancer Network (NCCN) Guidelines with Categories of Evidence and Consensus of 1 and 2A

4. The individual has received and completed **ALL** the following **baseline tests** before initiation of treatment and with continued monitoring of the individual as clinically appropriate:
    a. Ophthalmic examination including optical coherence tomography (OCT)
    b. There is a negative pregnancy test in a woman of childbearing potential
    c. Eastern Cooperative Oncology Group (ECOG) Performance Status of 0 or 1

5. Individual is not using any of the following interacting drugs:
    a. Strong or moderate CYP3A4 inducers (ex., carbamazepine, phenobarbital, phenytoin, rifampin, bosentan, dexamethasone, nafcillin, rifabutin, rifapentine, St. John's wort, others)
    b. Strong or moderate CYP3A4 inhibitors (ex., clarithromycin, itraconazole, ketoconazole, amiodarone, diltiazem, erythromycin fluconazole, verapamil, others)
    c. Proton pump inhibitors (ex., esomeprazole, lansoprazole, omeprazole, pantoprazole, others)

6. Individual has **NONE** of the following:
    a. Severe renal impairment (CrCl less than 30 mL/min) or end-stage renal disease receiving intermittent hemodialysis
    b. Severe hepatic impairment (total bilirubin greater than 3-times the upper limit of normal with any aspartate aminotransferase (AST)

Initial approval duration: 6 months

- **Criteria for continuation of coverage (renewal request):** Truseltiq (infigratinib) is considered ***medically necessary*** and will be approved when **ALL** the following criteria are met **(samples are not considered for continuation of therapy**):

1. Individual continues to be seen by a physician specializing in the patient's diagnosis or is in consultation with an Oncologist.

2. Individual's condition has responded while on therapy with response defined as the following:
    a. No evidence of disease progression
    b. No evidence individual has developed any significant unacceptable adverse drug reactions that may exclude continued use

3. Individual has been adherent with the medication

4. Individual has not developed any significant adverse drug effects that may exclude continued use such as:
    a. Ocular toxicity such as Retinal Pigment Epithelial Detachment (RPED)
    b. Hyperphosphatemia causing soft tissue mineralization, cutaneous calcinosis, non-uremic calciphylaxis, vascular calcification, and myocardial calcification
    c. Other serious adverse reaction that has not resolved in 14 days of dose adjustment
    d. Other life-threatening adverse reaction

5. Individual is not using any of the following interacting drugs:
    a. Strong or moderate CYP3A4 inducers (ex., carbamazepine, phenobarbital, phenytoin, rifampin, bosentan, dexamethasone, nafcillin, rifabutin, rifapentine, St. John's wort, others)
    b. Strong or moderate CYP3A4 inhibitors (ex., clarithromycin, itraconazole, ketoconazole, amiodarone, diltiazem, erythromycin fluconazole, verapamil, others)
    c. Proton pump inhibitors (ex., esomeprazole, lansoprazole, omeprazole, pantoprazole, others)

6. Individual has **NONE** of the following:
    a. Severe renal impairment (CrCl less than 30 mL/min) or end-stage renal disease receiving intermittent hemodialysis
    b. Severe hepatic impairment (total bilirubin greater than 3-times the upper limit of normal with any aspartate aminotransferase (AST)

Renewal duration: 12 months

- Criteria for a request for non-FDA use or indication, treatment with dosing, frequency, or duration outside the FDA-approved dosing, frequency, and duration, refer to one of the following Pharmacy Coverage Guideline:

1. **Off-Label Use of Non-Cancer Medications**

2. **Off-Label Use of Cancer Medications**

Description:

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 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).

Resources:

Truseltiq (infigratinib) product information, revised by QED Therapeutics, Inc. 05-2021. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed August 06, 2022.

National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology (NCCN Guidelines®): Hepatobiliary Cancers Version 2.2022 – Updated July 15, 2022. Available at https://www.nccn.org. Accessed August 06, 2022.

Off Label Use of Cancer Medications: A.R.S. §§ 20-826(R) & (S). Subscription contracts; definitions.

Off Label Use of Cancer Medications: A.R.S. §§ 20-1057(V) & (W). Evidence of coverage by health care service organizations; renewability; definitions.