

PHARMACY COVERAGE GUIDELINE

QINLOCK™ (riporetinib) 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:** Qinlock (riporetinib) 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. Advanced gastrointestinal stromal tumor who have received prior treatment with 3 or more kinase inhibitors including imatinib

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- 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. Adequately controlled blood pressure
 - b. Ejection fraction is > 50% evaluation by either echocardiogram or MUGA
 - c. Negative pregnancy test in a woman of child-bearing potential
 - d. Eastern Cooperative Oncology Group (ECOG) Performance Status is ≤ 2
5. Individual does not have moderate or severe hepatic impairment (total bilirubin greater than 1.5-times the upper limit of normal and any aspartate aminotransferase (AST)).
6. Individual does not have severe renal impairment (creatinine clearance 15-29 mL/min).
7. Individual is not using strong 3A4 inducers (e.g., carbamazepine, phenobarbital, phenytoin, rifampin, and others).

Initial approval duration: 6 months

- **Criteria for continuation of coverage (renewal request):** Qinlock (ripretinib) 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 of the following:
 - a. Documented evidence disease stability
 - b. No evidence of disease progression
 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. Life-threatening hypertension that is not controlled by antihypertensive medications
 - b. LV systolic dysfunction that is severe or life-threatening
 - c. Any other adverse reaction that is severe or life-threatening that has recurred after dose adjustment
 5. Individual's dose is at least 100 mg once daily.
 6. Individual does not have moderate or severe hepatic impairment (total bilirubin greater than 1.5-times the upper limit of normal and any aspartate aminotransferase (AST)).
 7. Individual does not have severe renal impairment (creatinine clearance 15-29 mL/min).

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- 8. Individual is not using strong 3A4 inducers (e.g., carbamazepine, phenobarbital, phenytoin, rifampin, and others).

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:

Qinlock (riporetinib) is indicated for the treatment of adult patients with advanced gastrointestinal stromal tumor (GIST) who have received prior treatment with 3 or more kinase inhibitors, including imatinib.

Definitions:

Activities of daily living (ADL):

Instrumental ADL:

Prepare meals, shop for groceries or clothes, use the telephone, manage money, etc.

Self-care ADL:

Bathe, dress and undress, feed self, use the toilet, take medications, not bedridden

Common Terminology Criteria for Adverse Events (CTCAE) Version 4.0:

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|--|---|
| Grade 1 | Mild; asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated |
| Grade 2 | Moderate; minimal, local or noninvasive intervention indicated; limiting age-appropriate instrumental ADL* |
| Grade 3 | Severe or medically significant but not immediately life-threatening; hospitalization or prolongation of hospitalization indicated; disabling; limiting self-care ADL** |
| Grade 4 | Life-threatening consequences; urgent intervention indicated |
| Grade 5 | Death related to AE |
| U.S. Department of Health and Human Services, National Institutes of Health, and National Cancer Institute | |

ECOG Performance status:

| Eastern Co-operative Oncology Group (ECOG) Performance Status | |
|---|---|
| Grade | ECOG description |
| 0 | Fully active, able to carry on all pre-disease performance without restriction |
| 1 | Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light house work, office work |
| 2 | Ambulatory and capable of all selfcare but unable to carry out any work activities. Up and about more than 50% of waking hours |
| 3 | Capable of only limited selfcare, confined to bed or chair more than 50% of waking hours |
| 4 | Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair |



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| 5 | Dead |
| Oken, M.M., Creech, R.H., Tormey, D.C., Horton, J., Davis, T.E., McFadden, E.T., Carbone, P.P.: Toxicity And Response Criteria Of The Eastern Cooperative Oncology Group. Am J Clin Oncol 5:649-655, 1982 | |

Resources:

Qinlock (riporetinib) product information, revised by Deciphera Pharmaceuticals, LLC 06-2021. Available at DailyMed <http://dailymed.nlm.nih.gov>. Accessed August 05, 2022.

National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology (NCCN Guidelines®): Gastrointestinal Stromal Tumors (GISTs) Version 1.2022 – Updated January 21, 2022. Available at <https://www.nccn.org>. Accessed August 05, 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.