UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2023 P 1319-4
Program	Prior Authorization/Notification
Medication	Qinlock™ (ripretinib)
P&T Approval Date	7/2020, 7/2021, 7/2022, 7/2023
Effective Date	10/1/2023; Oxford only: 10/1/2023

1. Background:

Qinlock (ripretinib) is a kinase inhibitor 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.

The National Cancer Comprehensive Network (NCCN) recommends Qinlock in GIST as the preferred fourth-line therapy for unresectable, recurrent, or metastatic disease with generalized progression after single agent therapy with imatinib, sunitinib, and regorafenib. NCCN also recommends Qinlock as single-agent therapy (preferred) with standard dosing for gross residual disease (R2 resection), unresectable primary disease, tumor rupture or recurrent/metastatic disease with generalized (widespread, systemic) progression in patients with performance status 0-2 who are intolerant to sunitinib as second-line therapy after imatinib; for gross residual disease (R2 resection), unresectable primary disease, tumor rupture or recurrent/ metastatic disease as an additional option after progression on avapritinib and dasatinib. NCCN also recommends Qinlock in cutaneous melanoma for metastatic or unresectable tumors with activating mutations of KIT as second-line or subsequent therapy for disease progression, intolerance, and/or projected risk of progression with BRAF-targeted therapy.

Coverage Information:

Members will be required to meet the criteria below for coverage. For members under the age of 19 years, the prescription will automatically process without a coverage review.

Some states mandate benefit coverage for off-label use of medications for some diagnoses or under some circumstances. Some states also mandate usage of other Compendium references. Where such mandates apply, they supersede language in the benefit document or in the notification criteria.

2. Coverage Criteria[a]:

A. <u>Patients less than 19 years of age</u>

1. **Qinlock** will be approved based on the following criterion:

   a. Patient is less than 19 years of age

Authorization will be issued for 12 months.

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B. Gastrointestinal Stromal Tumor (GIST)

1. **Initial Authorization**

a. **Qinlock** will be approved based on the following criteria:

(1) **All** of the following:

(a) Diagnosis of gastrointestinal stromal tumor (GIST)

-AND-

(b) Disease is **one** of the following:
i. Advanced
ii. Unresectable
iii. Recurrent
iv. Metastatic

-AND-

(c) **One** of the following:

i. History of failure to **all** of the following:
- Imatinib (Gleevec)
- Sunitinib (Sutent)
- Regorafenib (Stivarga)

-OR-

ii. **All** of the following:
- Performance status 0-2
- History of progression on imatinib (Gleevec)
- History of intolerance to sunitinib (Sutent)

-OR-

iii. **All** of the following:
- PDGFRA exon 18 mutations that are insensitive to imatinib (Gleevec) (including PDGFRA D842V)
- History of progression on avapritinib (Ayvakit)
- History of progression on dasatinib (Sprycel)

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Qinlock** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Qinlock therapy

Authorization will be issued for 12 months.

C. Cutaneous Melanoma

1. **Initial Authorization**

   a. **Qinlock** will be approved based on **all** the following criteria:

      (1) Diagnosis of cutaneous melanoma

      -AND-

      (2) Disease is unresectable or metastatic

      -AND-

      (3) Disease progression, intolerance, and/or projected risk of progression with BRAF-targeted therapy

      -AND-

      (4) Positive for activating mutations of KIT

   Authorization will be issued for 12 months.

2. **Reauthorization**

   a. **Qinlock** will be approved based on the following criterion:

      (1) Patient does not show evidence of progressive disease while on Qinlock therapy

   Authorization will be issued for 12 months.

D. NCCN Recommended Regimens

The drug has been recognized for treatment of the cancer indication by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.

- Supply limits may be in place.

4. References:

1. Qinlock [package insert]. Waltham, MA: Deciphera Pharmaceuticals, LLC; December 2022.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at www.nccn.org. Accessed June 6, 2023.

Program	Prior Authorization/Notification – Qinlock™ (ripretinib)
Change Control	
7/2020	New program.
7/2021	Annual review. Updated criteria per NCCN guidelines. Updated references.
7/2022	Annual review with no changes to criteria. Added state mandate disclaimer and updated references.
7/2023	Annual review. Updated background and criteria for GIST tumors and added background and criteria for cutaneous melanoma per NCCN guidelines. Updated references.