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Section:	Prescription Drugs	**Effective Date:**	January 1, 2025
Subsection:	Antineoplastic Agents	**Original Policy Date:**	June 5, 2020
Subject:	Qinlock	**Page:**	1 of 5

Last Review Date: December 13, 2024

Qinlock

Description

Qinlock (ripretinib)

Background
Qinlock (ripretinib) is a tyrosine kinase inhibitor that inhibits KIT proto-oncogene receptor tyrosine kinase (KIT) and platelet derived growth factor receptor A (PDGFRA) kinase, including wild type, primary, and secondary mutations. Qinlock also inhibits other kinases in vitro, such as PDGFRB, TIE2, VEGFR2, and BRAF (1).

Regulatory Status
FDA-approved indication: Qinlock 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 (1).

Palmar-plantar erythrodysesthesia syndrome (PPES) has occurred in patients taking Qinlock. Based on severity, Qinlock should be withheld and then resumed at same or reduced dose (1).

Cutaneous squamous cell carcinoma (cuSCC) and melanoma has occurred in patients taking Qinlock. Dermatologic evaluations should be performed when initiating Qinlock and routinely during treatment. Suspicious skin lesions should be managed with excision and dermatopathologic evaluation and then Qinlock should be continued at the same dose (1).

Hypertension has occurred in patients taking Qinlock. Qinlock should not be initiated in patients with uncontrolled hypertension. Blood pressure should be monitored as clinically indicated during treatment with Qinlock, and antihypertensive therapy should be initiated or adjusted as appropriate.

Based on severity, Qinlock should be withheld and then resumed at same or reduced dose or permanently discontinued (1).

Cardiac dysfunction (including cardiac failure, acute left ventricular failure, diastolic dysfunction, and ventricular hypertrophy) has occurred in patients taking Qinlock. Ejection fraction should be assessed by echocardiogram or MUGA scan prior to initiating Qinlock and during treatment, as clinically indicated. Qinlock should be permanently discontinued for Grade 3 or 4 left ventricular systolic dysfunction (1).

Qinlock can cause fetal harm when administered to pregnant women. Females and males of reproductive potential should be advised to use effective contraception during treatment with Qinlock and for 1 week after the final dose (1).

The recommended dose of Qinlock is 150 mg orally once daily. If a moderate CYP3A inducer cannot be avoided, increase the Qinlock dosing frequency from 150 mg once daily to 150 mg twice daily during the co-administration period (1).

The safety and effectiveness of Qinlock in pediatric patients have not been established (1).

Related policies

Ayvakit, Nexavar, Sprycel, Stivarga, Sutent, Votrient

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Qinlock may be considered **medically necessary** if the conditions indicated below are met.

Qinlock may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age and older

Diagnosis

Patient must have the following:

1. Advanced gastrointestinal stromal tumor (GIST)

a. Patient has received prior treatment with 3 or more kinase inhibitors, including imatinib

AND ALL of the following:

a. Prescriber agrees to monitor for Palmar-Plantar Erythrodysesthesia Syndrome
b. Prescriber agrees to perform a dermatologic evaluation prior to initiating Qinlock and routinely during treatment
c. Ejection fraction has been assessed by echocardiogram or MUGA scan prior to initiating Qinlock
d. **NO** uncontrolled hypertension
e. Females of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Qinlock and for 1 week after the final dose
f. Males with female partners of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Qinlock and for 1 week after the final dose

Prior – Approval *Renewal* Requirements

Age 18 years of age and older

Diagnosis

Patient must have the following:

1. Advanced gastrointestinal stromal tumor (GIST)

AND ALL of the following:

a. **NO** disease progression or unacceptable toxicity
b. Prescriber agrees to monitor for Palmar-Plantar Erythrodysesthesia Syndrome
c. Prescriber agrees to perform a dermatologic evaluations routinely during treatment
d. Females of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Qinlock and for 1 week after the final dose
e. Males with female partners of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Qinlock and for 1 week after the final dose

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity 540 tablets per 90 days

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Qinlock (ripretinib) is a tyrosine kinase inhibitor that inhibits KIT proto-oncogene receptor tyrosine kinase (KIT) and platelet derived growth factor receptor A (PDGFRA) kinase, including wild type, primary, and secondary mutations. Qinlock also inhibits other kinases in vitro, such as PDGFRB, TIE2, VEGFR2, and BRAF (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Qinlock while maintaining optimal therapeutic outcomes.

References

1. Qinlock [package insert]. Waltham, MA; Diciphera Pharmaceuticals, LLC; October 2023.
2. NCCN Drugs & Biologics Compendium® Ripretinib 2024. National Comprehensive Cancer Network, Inc. Accessed on October 7, 2024.

Policy History

Date	Action
June 2020	Addition to PA
September 2020	Annual review
September 2021	Annual editorial review and reference update. Increased quantity limit to 540 tablets per 90 days per new package insert
September 2022	Annual review and reference update

September 2023	Annual review and reference update
March 2024	Annual review and reference update
September 2024	Annual review and reference update
December 2024	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 13, 2024 and is effective on January 1, 2025.