DRUG QUANTITY MANAGEMENT POLICY – PER RX

POLICY: Oncology – Qinlock Drug Quantity Management Policy – Per Rx
- Qinlock® (ripretinib tablets – Deciphera)

REVIEW DATE: 05/02/2025

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT WHERE APPROPRIATE AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. WHERE COVERAGE FOR CARE OR SERVICES DOES NOT DEPEND ON SPECIFIC CIRCUMSTANCES, REIMBURSEMENT WILL ONLY BE PROVIDED IF A REQUESTED SERVICE(S) IS SUBMITTED IN ACCORDANCE WITH THE RELEVANT CRITERIA OUTLINED IN THE APPLICABLE COVERAGE POLICY, INCLUDING COVERED DIAGNOSIS AND/OR PROCEDURE CODE(S). REIMBURSEMENT IS NOT ALLOWED FOR SERVICES WHEN BILLED FOR CONDITIONS OR DIAGNOSES THAT ARE NOT COVERED UNDER THIS COVERAGE POLICY (SEE "CODING INFORMATION" BELOW). WHEN BILLING, PROVIDERS MUST USE THE MOST APPROPRIATE CODES AS OF THE EFFECTIVE DATE OF THE SUBMISSION. CLAIMS SUBMITTED FOR SERVICES THAT ARE NOT ACCOMPANIED BY COVERED CODE(S) UNDER THE APPLICABLE COVERAGE POLICY WILL BE DENIED AS NOT COVERED. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

Qinlock, a kinase inhibitor, is indicated for the treatment of adult patients with advanced **gastrointestinal stromal tumor** who have received prior treatment with three or more kinase inhibitors, including imatinib.[1]

Dosing

The recommended dose of Qinlock is 150 mg once daily (QD) with or without food until disease progression or unacceptable toxicity.[1] Tablets must be swallowed whole. If vomiting occurs after Qinlock, the patient should not take an additional dose, but continue with the next dose as scheduled. A dose reduction to 100 mg QD may be needed to manage adverse events. Patients taking Qinlock should avoid coadministration with moderate or severe cytochrome P450 (CYP)3A inducers. However, if coadministration with a moderate CYP3A inducer cannot be avoided, increase the dosing frequency of Qinlock to 150 mg twice daily (BID)_.

After the inducer has been discontinued for at least 14 days, the prior dose of Qinlock may be resumed.

Guidelines

Qinlock is discussed in the guidelines from the National Comprehensive Cancer Network (NCCN):

- **Gastrointestinal Stromal Tumor**: NCCN guidelines (version 1.2025 – April 17, 2025) recommend Qinlock for unresectable, progressive, or metastatic disease in the following situations: Qinlock 150 mg daily for second-line therapy for patients who are intolerant of second-line sunitinib as a "Preferred Regimen" (category 2A); Qinlock 150 mg QD as fourth-line therapy after therapy with imatinib, sunitinib, and Stivarga® (regorafenib tablets) if not previously received as a "Preferred Regimen" (category 1); Qinlock dose escalation to 150 mg BID if patient has previously been treated with Qinlock 150 mg QD as additional options after progression on approved therapies as "Useful in Certain Circumstances"(category 2A); and Qinlock 150 mg QD or Qinlock 150 mg BID (if previously treated with Qinlock 150 mg QD) after progression with Ayvakit® (avapritinib tablets) and Sprycel® (dasatinib tablets).[2,3]
- **Melanoma, Cutaneous**: NCCN guidelines (version 1.2025 – January 28, 2025) recommend Qinlock as "Useful in Certain Circumstances" for metastatic or unresectable disease with an activating *KIT* mutation as second-line or subsequent therapy for disease progression, intolerance, and/or projected risk of progression with *BRAF*-targeted therapy (category 2A).[2,4]

Availability

Qinlock is available as 50 mg tablets supplied in bottles of 90 tablets.[1]

POLICY STATEMENT

This Drug Quantity Management program has been developed to promote the safe, effective, and economic use of Qinlock. If the Drug Quantity Management rule is not met for the requested medication at the point of service, coverage will be determined by the Criteria below. All approvals are provided for 1 year in duration.

Drug Quantity Limits

Product	Strength and Dosage Form	Retail Maximum Quantity per Rx	Home Delivery Maximum Quantity Per Rx
Qinlock® (ripretinib tablets)	50 mg tablets	90 tablets	270 tablets

EXCEPTIONS TO THE QUANTITY LIMITS LISTED ABOVE ARE COVERED AS MEDICALLY NECESSARY WHEN THE FOLLOWING CRITERIA ARE MET. ANY OTHER EXCEPTION IS CONSIDERED NOT MEDICALLY NECESSARY.

CRITERIA

1. If the patient is taking a moderate cytochrome P450 (CYP)3A inducer, approve 180 tablets per dispensing at retail or 540 tablets per dispensing at home delivery.
Note: Moderate CYP3A inducers include, but are not limited to, bosentan, efavirenz, etravirine, phenobarbital, and primidone.

2. If the patient has a gastrointestinal stromal tumor and has experienced disease progression with Qinlock 150 mg once daily, approve 180 tablets per dispensing at retail or 540 tablets per dispensing at home delivery.

REFERENCES

1. Qinlock® tablets [prescribing information]. Waltham, MA: Deciphera; October 2023.
2. The NCCN Drugs & Biologics Compendium. © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org/. Accessed on April 18, 2025.
3. The NCCN Gastrointestinal Stromal Tumor (GIST) Clinical Practice Guidelines in Oncology (version 1.2025 – April 17, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org/. Accessed on April 18, 2025.
4. The NCCN Melanoma: Cutaneous Clinical Practice Guidelines in Oncology (version 1.2025 – January 28, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org/. Accessed on April 18, 2025.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	Policy was updated to reflect the existing quantity limits when a product is obtained via home delivery. **Qinlock 50 mg tablets:** New override added if a patient has a gastrointestinal stromal tumor and has experienced disease progression with Qinlock 150 mg once daily, to approve 180 tablets per dispensing at retail or 540 tablets per dispensing at home delivery.	05/17/2023
Annual Revision	No criteria changes.	05/15/2024
Annual Revision	No criteria changes.	05/02/2025