

Qinlock™ (ripretinib) (Oral)

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I. Length of Authorization

Coverage is provided for six months and may be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

- 50 mg tablets: 3 tablets per day

B. Max Units (per dose and over time) [HCPCS Unit]:

- 150 mg per day

III. Initial Approval Criteria^{1,2,3,4,5}

Coverage is provided in the following conditions:

- Patient is 18 years or older; **AND**

Universal Criteria

- Patient will avoid concomitant therapy with any of the following:
 - Coadministration with strong CYP3A inhibitors (e.g., fluconazole, itraconazole, etc.), if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications; **OR**
 - Coadministration with strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.); **AND**
- Left ventricular ejection fraction (LVEF) is within normal limits prior to initiating therapy and will be assessed at regular intervals during treatment; **AND**
- Patient will have a dermatologic evaluation prior to initiating therapy and routinely during treatment; **AND**
- Patient does not have uncontrolled hypertension; **AND**
- Patient must not have had a surgical procedure within the preceding 14 days or have a surgical wound that has not fully healed; **AND**
- Patient does not have active CNS metastases; **AND**

Gastrointestinal stromal tumors (GIST) †/Φ

- Patient has unresectable, locally advanced or metastatic disease; **AND**
- Patient's disease progressed after an adequate trial or intolerance to three or more prior therapies (e.g., imatinib, sunitinib, regorafenib, etc.), with one being imatinib

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Φ Orphan Drug

IV. Renewal Criteria¹

- Patient continues to meet universal and other indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in section III; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include palmar-plantar erythrodysesthesia syndrome, new primary cutaneous malignancies (*Note: suspicious skin lesions are managed with excision and dermato-pathologic evaluation with continuation of Qinlock therapy*), uncontrolled hypertension, severe arthralgia or myalgia, impaired wound healing and complications, etc.; **AND**
 - Patient does not have Grade 3 or 4 left-ventricular systolic dysfunction (i.e., symptomatic due to a resting ejection fraction $\leq 39\%$ or $> 20\%$ decrease from baseline); **AND**
- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread

V. Dosage/Administration

Indication	Dose
Gastrointestinal stromal tumors (GIST)	Administer 150 mg orally once daily with or without food until disease progression or unacceptable toxicity. Refer to the package insert regarding dose reductions and dosage modifications for adverse reactions. <ul style="list-style-type: none">– Avoid use with strong CYP3A inducers– Refer to the package insert for concomitant use with strong CYP3A inhibitors.

VI. Billing Code/Availability Information

HCPCS code:

- J8999: Prescription drug, oral, chemotherapeutic, NOS

NDC:

- 50 mg tablets: 73207-0101-xx

VII. References

1. Qinlock [package insert]. Waltham, MA; Deciphera Pharma, LLC.; May 2020. Accessed May 2020.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) ripretinib. National Comprehensive Cancer Network, 2020. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed May 2020.
3. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Soft Tissue Sarcoma version 4.2019. National Comprehensive Cancer Network, 2020. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Guidelines, go online to NCCN.org. Accessed May 2020.
4. ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). Date: 11/27/17. Identifier NCT03353753: A Phase 3, INterVentional, Double-Blind, Placebo-Controlled Study to Assess the Safety and Efficacy of DCC-2618 In Patients With AdvanCed Gastrointestinal Stromal TUmorS Who Have Received Treatment With Prior Anticancer Therapies; [Accessed 5/12/20]; [about 4 screens]. Available from: <https://clinicaltrials.gov/ct2/show/NCT03157128?term=NCT03157128&draw=2&rank=1>.
5. von Mehren M, Serrano C, Bauer S, et al. LBA87 - INVICTUS: A phase III, interventional, double-blind, placebo-controlled study to assess the safety and efficacy of ripretinib as ≥ 4th-line therapy in patients with advanced gastrointestinal stromal tumors (GIST) who have received treatment with prior anticancer therapies (NCT03353753). Annals of Oncology Volume 30, Supplement 5, October 2019, Pages v925-v926.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C49.A0	Gastrointestinal stromal tumor unspecified site
C49.A1	Gastrointestinal stromal tumor of esophagus
C49.A2	Gastrointestinal stromal tumor of stomach
C49.A3	Gastrointestinal stromal tumor of small intestine
C49.A4	Gastrointestinal stromal tumor of large intestine
C49.A5	Gastrointestinal stromal tumor of rectum
C49.A9	Gastrointestinal stromal tumor of other sites
C49.4	Malignant neoplasm of connective and soft tissue of abdomen
C49.8	Malignant neoplasm of overlapping sites of connective and soft tissue
C49.9	Malignant neoplasm of connective and soft tissue, unspecified
Z85.831	Personal history of malignant neoplasm of soft tissue

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD), Local Coverage Article (LCAs) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at:

<http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx>. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCA/LCD): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC