Qinlock™ (ripretinib)
(Oral)

Document Number: IC-0545

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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[1-5]

Coverage is provided in the following conditions:

- Patient is at least 18 years of age; **AND**

Universal Criteria

- Patient will avoid concomitant therapy with any of the following:
  - Coadministration with strong CYP3A inhibitors (e.g., fluconazole, itraconazole, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.); **AND**
  - Coadministration with moderate CYP3A inducers (e.g., bosentan, efavirenz, etravirine, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Patient's 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, recurrent, 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 Criteria [1]

Coverage can be renewed based upon the following criteria:

- 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**
- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: palmar-plantar erythrodysesthesia syndrome (≥ grade 3), new primary cutaneous malignancies *(Note: suspicious skin lesions are managed with excision and dermato-pathologic evaluation with continuation of Qinlock therapy)*, uncontrolled hypertension (≥ grade 4), severe arthralgia or myalgia, impaired wound healing and complications, left-ventricular systolic dysfunction (grade 3 or 4), etc.

V. Dosage/Administration[1]

Indication	Dose
Gastrointestinal stromal tumors (GIST)	Administer 150 mg orally once daily with or without food until disease progression or unacceptable toxicity.

VI. Billing Code/Availability Information

HCPCS code:

- J8999 -Prescription drug, oral, chemotherapeutic, Not Otherwise Specified
- C9399 - Unclassified drugs or biologicals (Hospital Outpatient Use ONLY)

NDC:

- Qinlock 50 mg tablets: 73207-0101-xx

VII. References

1. Qinlock [package insert]. Waltham, MA; Deciphera Pharma, LLC.; June 2021. Accessed June 2021.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) ripretinib. National Comprehensive Cancer Network, 2021. 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 June 2021.
3. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Gastrointestinal Stromal Tumors (GISTs). Version 1.2021. National Comprehensive Cancer Network, 2021. 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 June 2021.
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

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