Qinlock®(ripretinib)
(Oral)

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I. Length of Authorization

Coverage is provided for 6 months and may be renewed.

II. Dosing Limits

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

- 50 mg tablets: 6 tablets per day

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

- 300 mg per day

III. Initial Approval Criteria [1]

Coverage is provided in the following conditions:

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

Universal Criteria [1]

- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with strong CYP3A inhibitors (e.g., ketoconazole, itraconazole, clarithromycin, 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**
- Used as single agent therapy; **AND**

Gastrointestinal Stromal Tumors (GIST) † ‡ Φ [1-3]

- Patient has gross residual (R2 resection), unresectable primary, recurrent, or metastatic disease OR tumor rupture; **AND**
    - Disease has progressed on prior treatment with three or more prior kinase inhibitors (e.g., imatinib, sunitinib, dasatinib, regorafenib, etc.), with one being imatinib; **OR**
    - Used as second-line therapy after imatinib for generalized (widespread, systemic) disease progression; **AND**
        - Patient is intolerant to sunitinib; **OR**
    - Disease has progressed on avapritinib and dasatinib

Cutaneous Melanoma ‡ [2]

- Used as subsequent therapy; **AND**
- Patient has metastatic or unresectable disease with activating mutations of KIT; **AND**
- Used for disease progression, intolerance, and/or projected risk of progression with BRAF-targeted therapy

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

IV. Renewal Criteria [1,3,6]

Coverage can be renewed based upon the following criteria:

- Patient continues to meet the 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: 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 (≥ grade 4), impaired wound healing complications, photosensitivity, etc.; **AND**
- Patient does not have Grade 3 or 4 left-ventricular systolic dysfunction (i.e., symptomatic due to a resting ejection fraction ≤ 39% or > 20% decrease from baseline); **AND**
- Dose escalation (up to the maximum dose and frequency specified below) may occur upon clinical review on a case by case basis if the patient has progressed on the standard daily dose.

V. Dosage/Administration [1,3,6,7,9]

Indication	Dose
Gastrointestinal Stromal Tumors (GIST)	Administer 150 mg orally once daily until disease progression or unacceptable toxicity. ***Note:*** *If the patient has progression on the 150 mg daily dose, increasing the dose to 150 mg twice daily may be considered.*
Cutaneous Melanoma	Administer 150 mg orally once daily (repeated in 28-day cycles) until disease progression or unacceptable toxicity. ***Note:*** *If the patient has progression on the 150 mg daily dose, increasing the dose to 150 mg twice daily may be considered after the completion of cycle 2.*

VI. Billing Code/Availability Information

HCPCS Code(s):

- J8999 – Prescription drug, oral, chemotherapeutic, Not Otherwise Specified
- C9399 – Unclassified drugs or biologicals

NDC:

- Qinlock 50 mg tablets: 73207-0101-xx

VII. References

1. Qinlock [package insert]. Waltham, MA; Deciphera Pharma, LLC.; October 2023. Accessed November 2023.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) ripretinib. National Comprehensive Cancer Network, 2023. 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 November 2023.
3. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Gastrointestinal Stromal Tumors. Version 1.2023. National Comprehensive Cancer Network, 2023. 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 November 2023.
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.
6. Zalcberg JR, Heinrich MC, George S, et al. Clinical Benefit of Ripretinib Dose Escalation After Disease Progression in Advanced Gastrointestinal Stromal Tumor: An Analysis of the INVICTUS Study, The Oncologist, Volume 26, Issue 11, November 2021, Pages e2053–e2060, https://doi.org/10.1002/onco.13917.
7. Janku F, Bauer S, Shoumariyeh K, et al. Efficacy and safety of ripretinib in patients with KIT-altered metastatic melanoma. ESMO Open. 2022 Aug;7(4):100520. doi: 10.1016/j.esmoop.2022.100520.
8. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Melanoma: Cutaneous. Version 3.2023. National Comprehensive Cancer Network, 2023. 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 November 2023.
9. George S, Chi P, Heinrich MC, et al. Ripretinib intrapatient dose escalation after disease progression provides clinically meaningful outcomes in advanced gastrointestinal stromal tumor. Eur J Cancer 2021;155:236-244

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C43.0	Malignant melanoma of lip
C43.111	Malignant melanoma of right upper eyelid, including canthus
C43.112	Malignant melanoma of right lower eyelid, including canthus
C43.121	Malignant melanoma of left upper eyelid, including canthus
C43.122	Malignant melanoma of left lower eyelid, including canthus
C43.20	Malignant melanoma of unspecified ear and external auricular canal
C43.21	Malignant melanoma of right ear and external auricular canal
C43.22	Malignant melanoma of left ear and external auricular canal
C43.30	Malignant melanoma of unspecified part of face
C43.31	Malignant melanoma of nose
C43.39	Malignant melanoma of other parts of face
C43.4	Malignant melanoma of scalp and neck
C43.51	Malignant melanoma of anal skin
C43.52	Malignant melanoma of skin of breast
C43.59	Malignant melanoma of other part of trunk
C43.60	Malignant melanoma of unspecified upper limb, including shoulder
C43.61	Malignant melanoma of right upper limb, including shoulder

C43.62	Malignant melanoma of left upper limb, including shoulder
C43.70	Malignant melanoma of unspecified lower limb, including hip
C43.71	Malignant melanoma of right lower limb, including hip
C43.72	Malignant melanoma of left lower limb, including hip
C43.8	Malignant melanoma of overlapping sites of skin
C43.9	Malignant melanoma of skin, unspecified
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
C49.5	Malignant neoplasm of connective and soft tissue of pelvis
C49.8	Malignant neoplasm of overlapping sites of connective and soft tissue
C49.9	Malignant neoplasm of connective and soft tissue, unspecified
Z85.820	Personal history of malignant melanoma of skin
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: https://www.cms.gov/medicare-coverage-database/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

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
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