Clinical Policy: Ripretinib (Qinlock)

Reference Number: CP.PHAR.502
Effective Date: 09.01.20
Last Review Date: 08.24
Line of Business: Commercial, HIM, Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Ripretinib (Qinlock®) is a kinase inhibitor.

FDA Approved Indication(s)

Qinlock is 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.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Qinlock is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Gastrointestinal Stromal Tumor (must meet all)**:**

1. Diagnosis of unresectable, locally advanced, recurrent, progressive, or metastatic GIST;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Request meets one of the following (a, b, or c):
   a. Failure of all of the following, unless clinically significant adverse effects are experienced or all are contraindicated: imatinib, Sutent®, and Stivarga®;*
   b. Both of the following (i and ii):
      i. Failure of imatinib, unless contraindicated or clinically significant adverse effects are experienced;*
      ii. Member experienced clinically significant adverse effects to Sutent® used as second-line therapy;*
   c. For members with PDGFRA exon 18 mutations that are insensitive to imatinib (including D842V): Failure of Ayvakit™ and Sprycel®, unless clinically significant adverse effects are experienced or both are contraindicated;*

   **Prior authorization is required for imatinib, Sutent, Stivarga, Ayvakit, and Sprycel*
5. Prescribed as a single agent;
6. Member does not have active central nervous system metastases;
7. For Qinlock requests, member must use ripretinib, if available, unless contraindicated or clinically significant adverse effects are experienced;

8. Request meets one of the following (a or b):*
   a. Dose does not exceed 150 mg (3 tablets) per day;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

   **Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration:
Medicaid/HIM – 6 months
Commercial – 12 months or duration of request, whichever is less

B. Cutaneous Melanoma (off-label) (must meet all)**:**
1. Diagnosis of metastatic or unresectable cutaneous melanoma;
2. Prescribed by or in consultation with an oncologist;
3. Presence of KIT activating mutations;
4. Member has experienced disease progression, intolerance, and/or has projected risk of progression with BRAF-targeted therapy (*see Appendix B for examples*);
5. Prescribed as a single agent;
6. For Qinlock requests, member must use ripretinib, if available, unless contraindicated or clinically significant adverse effects are experienced;
7. Dose is within FDA maximum limit for any FDA-approved indication or is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).*

   **Prescribed regimen must be FDA-approved or recommended by NCCN.*

Approval duration:
Medicaid/HIM – 6 months
Commercial – 12 months or duration of request, whichever is less

C. Other diagnoses/indications (must meet 1 or 2)**:**
1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. All Indications in Section I (must meet all)**:**

1. Currently receiving medication via Centene benefit, or documentation supports that member is currently receiving Qinlock for a covered indication and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. For Qinlock requests, member must use ripretinib, if available, unless contraindicated or clinically significant adverse effects are experienced;
4. If request is for a dose increase, request meets one of the following (a, b, or c):*
   a. New dose does not exceed 150 mg (3 tablets) per day;
   b. For GIST only: New dose does not exceed 300 mg (6 tablets) per day, and member experienced disease progression with 150 mg per day dosing;
   c. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

   **Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration:
Medicaid/HIM– 12 months
Commercial – 12 months or duration of request, whichever is less

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid, or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

FDA: Food and Drug Administration
GIST: gastrointestinal stromal tumor

PDGFRA: platelet derived growth factor receptor α

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
imatinib (Gleevec®)	GIST: 400 mg PO QD	800 mg/day
Sutent® (sunitinib)	GIST: 50 mg PO QD 4 weeks on/2 weeks off	87.5 mg/day
Stivarga® (regorafenib)	GIST: 160 mg PO QD 21 days on/7 days off	160 mg/day
Ayvakit® (avapritinib)	GIST PDGFRA exon 18 mutation: 300 mg PO QD	300 mg/day
Sprycel® (dasatinib)	GIST PDGFRA exon 18 D842V mutation: 70 mg PO BID	140 mg/day
BRAF-targeted therapies: Tafinlar® (dabrafenib), Mekinist® (trametinib), Cotellic® (cobimetinib), Zelboraf® (vemurafenib), Braftovi® (encorafenib), Mektovi® (binimetinib)	Cutaneous melanoma: Varies	Varies

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings
None reported

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
GIST	150 mg PO QD	150 mg/day (300 mg/day* if disease progression with 150 mg/day dosing)

**Off-label per NCCN*

VI. Product Availability

Tablet: 50 mg

VII. References

1. Qinlock Prescribing Information. Waltham, MA: Deciphera Pharmaceuticals, LLC; October 2023. Available at: www.qinlock.com. Accessed May 8, 2024.
2. Ripretinib. In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed May 15, 2024.

3. National Comprehensive Cancer Network. Gastrointestinal Stromal Tumors Version 1.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/gist.pdf. Accessed May 16, 2024.
4. National Comprehensive Cancer Network. Melanoma; Cutaneous Version 2.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/cutaneous_melanoma.pdf. Accessed May 16, 2024.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created.	06.30.20	08.20
3Q 2021 annual review: added option for recurrent GIST per NCCN; modified HIM.PHAR.21 to reference HIM.PA.154; added legacy WellCare initial 12 month approval duration; retired WCG.CP.PHAR.502; references reviewed and updated.	03.25.21	08.21
Revised approval duration for Commercial line of business from length of benefit to 12 months or duration of request, whichever is less	01.20.22	05.22
3Q 2022 annual review: added additional option for progressive GIST; clarified criteria should require either that the request is following failure of 3 kinase inhibitors or member has a PDGFRA exon 18 mutation, not both; for continued therapy added dose escalation option to 300 mg per day if member experienced disease progression on 150 mg/day per NCCN; added generic oral oncology redirection language if available per template; references reviewed and updated.	05.02.22	08.22
Template changes applied to other diagnoses/indications.	10.03.22	
3Q 2023 annual review: per NCCN – added off-label criteria for cutaneous melanoma (category 2A); for GIST, removed Sprycel as a prior treatment option for fourth-line use, added pathway for second-line use following imatinib if Sutent-intolerant, removed specific criteria for non-D842V PDGFRA exon 18 mutations as the same approach is now recommended for both non-D842V and D842V mutations, and added requirement for use as a single agent; consolidated legacy WellCare approval durations with standard Medicaid approval durations; references reviewed and updated.	04.14.23	08.23
3Q 2024 annual review: no significant changes; references reviewed and updated.	05.08.24	08.24

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and

accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.