Clinical Policy: Ripretinib (Qinlock)

Reference Number: ERX.SPA.400
Effective Date: 09.01.20
Last Review Date: 08.22
Line of Business: Commercial, 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.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ 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 or b):
   a. Failure of all of the following, unless clinically significant adverse effects are experienced or all are contraindicated: imatinib, Sutent® or Sprycel®, and Stivarga®;*
      **Prior authorization is required for imatinib, Sutent, Sprycel, and Stivarga.*
   b. For members with PDGFRA exon 18 mutation, one of the following (i or ii):*
      i. If D842V mutation positive, failure of Ayvakit™ and Sprycel, unless clinically significant adverse effects are experienced or both are contraindicated;
      ii. If positive for mutation other than D842V, failure of Ayvakit, unless contraindicated or clinically significant adverse effects are experienced;
      **Prior authorization is required for Ayvakit and Sprycel*
5. Member does not have active central nervous system metastases;
6. 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 – 6 months
Commercial – Length of Benefit

B. Other diagnoses/indications

1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

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

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions, 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. 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. 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 – 12 months
Commercial – Length of Benefit

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

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

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 policy – ERX.PA.01 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 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

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)

VI. Product Availability

Tablet: 50 mg

VII. References

1. Qinlock Prescribing Information. Waltham, MA: Deciphera Pharmaceuticals, LLC; June 2021. Available at: www.qinlock.com. Accessed May 2, 2022.
2. NCCN Clinical Practice Guidelines in Oncology: Gastrointestinal Stromal Tumors Version 1.2022. Available at: https://www.nccn.org/professionals/physician_gls/pdf/gist.pdf. Accessed May 2, 2022.

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; references reviewed and updated.	03.25.21	08.21
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; references reviewed and updated.	05.02.22	08.22

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.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. 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.