RXADVANCE
2 Park Central Drive
Southborough, MA 01772

Clinical Policy Title:	ripretinib
Policy Number:	RxA.646
Drug(s) Applied:	Qinlock®
Original Policy Date:	09/14/2020
Last Review Date:	09/14/2020
Line of Business Policy Applies to:	All lines of business

Background

QINLOCK™ (ripretinib) is a kinase inhibitor 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.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
Qinlock® (ripretinib)	4th Line Treatment of Advanced Gastrointestinal Stromal Tumors (GIST)	150 mg PO once daily until disease progression	150 mg daily

Dosage Forms

Drug Name	Availability
Qinlock® (ripretinib)	50 mg tablets

Clinical Policy

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

I. Initial Approval Criteria

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

1. Diagnosis of advanced GIST;
2. Prescribed by or in consultation with an oncologist;
3. Age 18 years of age or older;

4. Member has received 3 or more prior kinase inhibitor therapies, including imatinib unless contraindicated or clinically significant adverse effects experienced;

Approval duration
Commercial: 6 months
Medicaid: 6 months

II. Continued Therapy Approval

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

1. Currently receiving medication that has been authorized by RxAdvance, 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;

Approval duration
Commercial: 12 months
Medicaid: 12 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key
GIST: Gastrointestinal stromal tumor

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
Examples of Tyrosine Kinase Inhibitors		
imatinib (Gleevec®)	400 mg PO once daily with food	800 mg per day
Ayvakit® (avapritinib)	300 mg PO once daily on an empty stomach	300 mg per day
Sutent® (sunitinib)	50 mg PA once daily for 4 weeks on-treatment, followed by 2 weeks off-treatment	87.5 mg per day
Stivarga® (regorafenib)	160 mg PO once daily with a low-fat breakfast on days 1 to 21 of each 28-day cycle	160 mg per 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

- Contraindication(s): none reported
- Boxed warning(s): none reported

Appendix D: General Information

National Comprehensive Cancer Network®

NCCN Guidelines Version 2.2020
Gastrointestinal Stromal Tumors (GIST)

NCCN Guidelines Index
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Discussion

SYSTEMIC THERAPY AGENTS AND REGIMENS FOR UNRESECTABLE OR METASTATIC GIST

	Preferred Regimens	Other Recommended Regimens	Useful in Certain Circumstances
First-line therapy for unresectable recurrent or metastatic disease	• Imatinib[a,1,2] (category 1) • Avapritinib[a,b,3] (for GIST with *PDGFRA* exon 18 mutation, including *PDGFRA* D842V mutations)		
Second-line therapy for unresectable or metastatic disease (progressive disease after imatinib)	• Sunitinib[a,4] (category 1)		
Third-line therapy for unresectable or metastatic disease (progressive disease after imatinib and sunitinib)	• Regorafenib[a,5] (category 1)		
Fourth-line therapy for unresectable or metastatic disease (progressive disease after imatinib, sunitinib, and regorafenib)	• Ripretinib[a,6]		• Sorafenib[7-9] • Nilotinib[10-11] • Dasatinib[12] (for patients with *PDGFRA* D842V mutation) • Pazopanib[13] • Everolimus + TKI[c,14] • Avapritinib[a,b,3]

References

1. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed August 14, 2019.
2. Clinical Pharmacology [database online] powered by ClinicalKey. Tampa, FL: Elsevier, 2020. Accessed with subscription at: http://www.clinicalkey.com. Updated January 14, 2020. Accessed July 31, 2020.
3. Qinlock [prescribing information]. Waltham, MA: Deciphera Pharmaceuticals, LLC; May 2020. Available at qinlock.com. Accessed August 3,2020.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	08/2020	