Clinical Policy Title:	ripretinib
Policy Number:	RxA.646
Drug(s) Applied:	Qinlock®
Original Policy Date:	09/14/2020
Last Review Date:	10/19/2023
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

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

1. Diagnosis of locally advanced, unresectable, recurrent, progressive or metastatic GIST;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Trial and failure of at least three (3) prior kinase inhibitor therapies, including imatinib, unless contraindicated or clinically significant adverse effects experienced;
5. Member has an ECOG performance status of 0-2;
6. Member does not have active central nervous system metastases;
7. Request meets one of the following (a or b):
   a. Dose does not exceed 150 mg orally once daily or 150 mg twice daily when co-administered with moderate CYP3A inducers.
   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
Commercial: 6 months
Medicaid: 6 months

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. Age ≥ 18 years;
4. Qinlock® will be used as single agent for second-line or subsequent therapy;
5. 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
Commercial: 6 months
Medicaid: 6 months

II. Continued Therapy Approval

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

1. Member is 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;
3. If request is for a dose increase, request meets one of the following (a or b):
   a. New dose does not exceed 150 mg orally once daily or 150 mg twice daily when co-administered with moderate CYP3A inducers.
   b. 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
Commercial: 12 months
Medicaid: 12 months

References

1. National Comprehensive Cancer Network. Gastrointestinal Stromal Tumors. Version 1.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/gist.pdf. Accessed May 29, 2023.
2. National Comprehensive Cancer Network. Cutaneous Melanoma. Version 2.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/cutaneous_melanoma.pdf. Accessed May 29, 2023.
3. ECOG Performance status. Available at: https://ecog-acrin.org/resources/ecog-performance-status. Accessed May 29, 2023.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	08/2020	09/14/2020
Policy was reviewed: 1. Initial Approval Criteria I.A.5 was updated to include “Member has an ECOG performance status of 0- 2”. 2. Continued Therapy Approval Criteria II.A was updated from “All Indications in Section I” to “Advanced Gastrointestinal Stromal Tumor”. 3. Continued Therapy Approval Criteria II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...". 4. References were reviewed and updated.	07/09/2021	09/14/2021
Policy was reviewed: 1. Initial Approval Criteria, I.A.1: Updated indication from “Diagnosis of advanced GIST” to “Diagnosis of locally advanced, unresectable or metastatic GIST”. 2. Initial Approval Criteria, I.A.4: Updated trial and failure criteria from “Member has received 3 or more prior kinase inhibitor therapies, including imatinib unless contraindicated or clinically significant	06/30/2022	07/18/2022

adverse effects experienced" to "Trial and failure of at least three (3) prior kinase inhibitor therapies, including imatinib, unless contraindicated or clinically significant adverse effects experienced". 3. References were reviewed and updated.		
Policy was reviewed: 1. Initial Approval Criteria, I.A.1: Updated diagnosis criteria to include "recurrent, progressive" disease state. 2. Initial Approval Criteria, I.A.6: Updated to include new criteria pertaining to indication Advanced GIST, Member does not have active central nervous system metastases. 3. Initial Approval Criteria, I.B: Updated to include off label approval criteria for indication, Cutaneous Melanoma (off-label). 4. References were reviewed and updated.	05/29/2023	07/13/2023
Policy was reviewed.	10/19/2023	10/19/2023