PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Qinlock Prior Authorization Policy
- Qinlock® (ripretinib tablets – Deciphera Pharmaceuticals)

REVIEW DATE: 04/19/2024

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

Qinlock, a kinase inhibitor, is indicated for the treatment of advanced **gastrointestinal stromal tumor** in adults who have received prior treatment with three or more kinase inhibitors, including imatinib.[1]

Guidelines

Qinlock is discussed in guidelines from the National Comprehensive Cancer Network (NCCN):

- **Gastrointestinal Stromal Tumor**: NCCN guidelines (version 1.2024 – March 8, 2024) recommend Qinlock for unresectable, progressive, or metastatic disease in the following situations: Qinlock 150 mg daily as second-line therapy for patients who are intolerant of second-line sunitinib as a "Preferred Regimen" (category 2A); Qinlock 150 mg daily as fourth-line therapy after therapy with imatinib, sunitinib, and Stivarga® (regorafenib tablets) if not previously received as a "Preferred Regimen" (category 1); Qinlock dose escalation to 150 mg twice daily if patient has previously treated with Qinlock 150 mg daily as additional options after progression on approved therapies as "Useful in Certain Circumstances"(category 2A); and Qinlock 150 mg daily or Qinlock 150 mg twice daily (if previously treated with Qinlock 150 mg daily) after progression with Ayvakit® (avapritinib tablets) and Sprycel® (dasatinib tablets).[2,3]

- **Melanoma: Cutaneous**: NCCN guidelines (version 2.2024 –April 3, 2024) recommend Qinlock as "Useful in Certain Circumstances" for metastatic or unresectable disease with an activating *KIT* mutation as second-line or subsequent therapy for disease progression, intolerance, and/or projected risk of progression with *BRAF*-targeted therapy (category 2A).[2,4]

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Qinlock. All approvals are provided for the duration noted below.

- **Qinlock® (ripretinib tablets (Deciphera Pharmaceuticals)**

is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

FDA-Approved Indication

1. **Gastrointestinal Stromal Tumor.** Approve for 1 year if the patient meets ALL of the following (A, B and C):
   A) Patient is ≥ 18 years of age; AND
   B) Patient has tried imatinib or Ayvakit (avapritinib tablets); AND
   C) Patient meets ONE of the following (i, ii, or iii):
      i. Patient has tried sunitinib and Stivarga (regorafenib tablets); OR
      ii. Patient has tried Sprycel (dasatinib tablets); OR
      iii. Patient is intolerant of sunitinib.

Other Uses with Supportive Evidence

2. **Melanoma, Cutaneous.** Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):
   A) Patient is ≥ 18 years of age; AND
   B) Patient has metastatic or unresectable disease; AND
   C) Patient has an activating *KIT* mutation; AND
   D) Patient has tried at least ONE systemic regimen.
   Note: Examples of a systemic regimen include: Opdivo (nivolumab intravenous infusion) + Yervoy (ipilimumab intravenous infusion), Opdivo + Opdualag (nivolumab/relatlimab-rmbw intravenous infusion), Keytruda (pembrolizumab intravenous infusion), Opdivo, Tafinlar (dabrafenib capsules and oral tablets for suspension) + Mekinist (trametinib tablets), Zelboraf (vemurafenib tablets) + Cotellic (cobimetinib tablets), Braftovi (encorafenib capsules) + Mektovi (binimetinib tablets).

CONDITIONS NOT COVERED

- **Qinlock® (ripretinib tablets (Deciphera Pharmaceuticals)**

is(are) considered experimental, investigational or unproven for ANY other use(s); criteria will be updated as new published data are available.

REFERENCES

1. Qinlock™ tablets [prescribing information]. Waltham, MA: Deciphera Pharmaceuticals; October 2023.
2. The NCCN Drugs & Biologics Compendium. © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org/. Accessed on April 15, 2024.
3. The NCCN Gastrointestinal Stromal Tumor (GIST) Clinical Practice Guidelines in Oncology (version 1.2024 – March 8, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org/. Accessed on April 15, 2024.
4. The NCCN Melanoma: Cutaneous Clinical Practice Guidelines in Oncology (version 2.2024 – April 3, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org/. Accessed on April 15, 2024.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	**Gastrointestinal Stromal Tumor:** The requirement that the patient has tried imatinib; and one of Sutent (sunitinib capsules) or Sprycel (dasatinib tablets); and Stivarga (regorafenib tablets) OR patient has tried Ayvakit (avapritinib tablets) and Sprycel (dasatinib tablets) was changed to patient has tried imatinib or Ayvakit (avapritinib tablets) AND patient has tried one of the following: sunitinib capsules and Stivarga (regorafenib tablets); OR Sprycel (dasatinib capsules); OR patient is intolerant to sunitinib. **Melanoma, Cutaneous:** Indication and criteria were added to Other Uses with Supportive Evidence based on NCCN guideline recommendations.	04/19/2023
Annual Revision	No criteria changes.	04/19/2024