MEDICATION POLICY:
Stivarga®

Generic Name: Regorafenib

Therapeutic Class or Brand Name: N/A

Applicable Drugs (if Therapeutic Class): N/A

Preferred: N/A

Non-preferred: N/A

Date of Origin: 2/1/2013

Date Last Reviewed / Revised: 12/7/2022

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through V are met)

I. Documented diagnosis of one of the following conditions A through C AND must meet criteria listed under applicable diagnosis:
   A. Metastatic colorectal cancer (CRC) and criteria 1 through 3 are met:
      1. Prior treatment with fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy has been ineffective, contraindicated, or not tolerated.
      2. Prior treatment with an anti-VEGF therapy (i.e. Avastin®) has been ineffective, contraindicated, or not tolerated.
      3. Prior treatment with an anti-EGFR therapy (i.e. Erbitux®, Vectibix®) has been ineffective, contraindicated, or not tolerated if RAS wild-type.
   B. Locally advanced, unresectable, or metastatic gastrointestinal stromal tumor (GIST) and criterion 1 is met:
      1. Prior treatment with Gleevec® and Sutent® have been ineffective, contraindicated, or not tolerated.
   C. Hepatocellular carcinoma (HCC) and criterion 1 is met:
      1. Prior treatment with Nexavar® (sorafenib) has been ineffective, contraindicated, or not tolerated.

II. Minimum age requirement: 18 years old.

III. Treatment must be prescribed by or in consultation with an oncologist.

IV. Request is for a medication with the appropriate FDA labeling, or its use is supported by current clinical practice guidelines.

V. Refer to plan document for the list of preferred products. If requested agent is not listed as a preferred product, must have a documented failure, intolerance, or contraindication to the preferred product(s).

EXCLUSION CRITERIA

- N/A

Other Criteria

- N/A

Quantity / Days Supply Restrictions

- 84 tablets per 28 days.

Approval Length

- **Authorization:** 1 year.
- **Re-Authorization:** An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and that the medication is effective.

Appendix

N/A

References

1. Stivarga. Prescribing information. Bayer HealthCare Pharmaceuticals Inc; 2020. Accessed December 7, 2022. https://labeling.bayerhealthcare.com/html/products/pi/Stivarga_PI.pdf
2. National Comprehensive Cancer Network (NCCN). Colon Cancer. Version 2.2022. Updated September 10, 2021. Accessed December 7, 2022. https://www.nccn.org/professionals/physician_gls/pdf/colon.pdf.
3. National Comprehensive Cancer Network (NCCN). Hepatobiliary Cancers. Version 5.2021. Updated October 14, 2022. Accessed December 7, 2022. https://www.nccn.org/professionals/physician_gls/pdf/hepatobiliary.pdf.