

Applicable Drugs: Stivarga (regorafenib)

Preferred: N/A

Non-preferred: N/A

Date of Origin: 2/1/2013

Date Last Reviewed / Revised: 11/14/2025

PRIOR AUTHORIZATION CRITERIA

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

- I. Documentation of one of the following diagnoses A through C AND must meet all criteria listed under the applicable diagnosis:

FDA-Approved Indication(s)

A. Metastatic colorectal cancer (CRC)

- i. Prior treatment with fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy has been ineffective, contraindicated, or not tolerated.
- ii. Prior treatment with an anti-VEGF therapy (i.e. bevacizumab, ramucirumab, or zivafibercept) has been ineffective, contraindicated, or not tolerated.
- iii. Prior treatment with an anti-EGFR therapy (i.e. cetuximab, panitumumab) has been ineffective, contraindicated, or not tolerated if RAS wild-type.

B. Locally advanced, unresectable, or metastatic gastrointestinal stromal tumor (GIST)

- i. Prior treatment with imatinib and sunitinib have been ineffective, contraindicated, or not tolerated.

C. Hepatocellular carcinoma (HCC)

- i. Prior treatment with sorafenib has been ineffective, contraindicated, or not tolerated.

Other Uses With Supportive Evidence

D. Angiosarcoma

E. Appendiceal Adenocarcinoma

F. Ewing Sarcoma

G. Osteosarcoma

H. Rectal Cancer

I. Soft Tissue Sarcoma

J. Uterine Sarcoma

- II. Minimum age requirement: 18 years old.

- III. Treatment must be prescribed by or in consultation with an oncologist or hematologist.
- IV. Request is for a medication with the appropriate FDA labeling, or its use is supported by current National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1 or 2A.
- V. Refer to the plan document for the list of preferred products. If the requested agent is not listed as a preferred product, must have documented treatment failure 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 does not show evidence of progressive disease.

REFERENCES

1. Stivarga. Prescribing information. Bayer HealthCare Pharmaceuticals Inc; 2025. Accessed August 11, 2025. https://labeling.bayerhealthcare.com/html/products/pi/Stivarga_PI.pdf
2. National Comprehensive Cancer Network (NCCN). Colon Cancer. Version 4.2025. Updated June 27, 2025. Accessed August 11, 2025. https://www.nccn.org/professionals/physician_gls/pdf/colon.pdf
3. National Comprehensive Cancer Network (NCCN). Gastrointestinal Stromal Tumors. Version 1.2025. Updated April 17, 2025. Accessed August 11, 2025. https://www.nccn.org/professionals/physician_gls/pdf/gist.pdf
4. National Comprehensive Cancer Network (NCCN). Hepatobiliary Cancers. Version 1.2025. Updated March 20, 2025. Accessed August 11, 2025. https://www.nccn.org/professionals/physician_gls/pdf/hcc.pdf

5. National Comprehensive Cancer Network (NCCN). Bone Cancer. Version 2.2025, February 28, 2025. Accessed August 11, 2025.
https://www.nccn.org/professionals/physician_gls/pdf/bone.pdf
6. National Comprehensive Cancer Network (NCCN). Central Nervous System Cancers. Version 1.2025, June 3, 2025. Accessed August 11, 2025.
www.nccn.org/professionals/physician_gls/pdf/cns.pdf
7. National Comprehensive Cancer Network (NCCN). Rectal Cancer. Version 2.2025, March 31, 2025. Accessed August 11, 2025.
https://www.nccn.org/professionals/physician_gls/pdf/rectal.pdf
8. National Comprehensive Cancer Network (NCCN). Soft Tissue Sarcoma. Version 1.2025, May 2, 2025. Accessed August 11, 2025.
https://www.nccn.org/professionals/physician_gls/pdf/sarcoma.pdf
9. National Comprehensive Cancer Network (NCCN). Uterine Neoplasms. Version 3.2025, March 7, 2025. Accessed August 11, 2025.
https://www.nccn.org/professionals/physician_gls/pdf/uterine.pdf

DISCLAIMER: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.