Applicable Drugs: Stivarga (regorafenib)

Preferred: N/A

Non-preferred: N/A

Date of Origin: 2/1/2013

Date Last Reviewed / Revised: 10/16/2026

PRIOR AUTHORIZATION CRITERIA

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

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

FDA-Approved Indication(s)

A. Colorectal cancer (CRC)
   i. Disease is locally advanced, unresectable, or metastatic
   ii. Prior treatment with fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy has been ineffective, contraindicated, or not tolerated.
   iii. Prior treatment with an anti-VEGF therapy (i.e. bevacizumab, ramucirumab, or zivaflibercept) has been ineffective, contraindicated, or not tolerated.
   iv. Prior treatment with an anti-EGFR therapy (i.e. cetuximab, panitumumab) has been ineffective, contraindicated, or not tolerated if RAS wild-type.
   v. Minimum age requirement: 18 years old

B. Gastrointestinal stromal tumor (GIST)
   i. Disease is locally advanced, unresectable, or metastatic
   ii. Prior treatment with imatinib and sunitinib has been ineffective, contraindicated, or not tolerated.
   iii. Minimum age requirement: 18 years old

C. Hepatocellular carcinoma (HCC)
   i. Prior treatment with sorafenib has been ineffective, contraindicated, or not tolerated.
   ii. Minimum age requirement: 18 years old

Other Uses With Supportive Evidence

D. Angiosarcoma

E. Appendiceal Adenocarcinoma

F. Ewing Sarcoma

G. Osteosarcoma
H. Pediatric Sarcoma (Bone and Soft Tissue)
I. Rectal Cancer
J. Soft Tissue Sarcoma
K. Uterine Sarcoma

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

III. 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.

IV. 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; 2026. Accessed October 16, 2026. https://labeling.bayerhealthcare.com/html/products/pi/Stivarga_PI.pdf
2. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Colon Colon Cancer. Version 2.2026. Updated April 7, 2026. Accessed October 16, 2026. https://www.nccn.org/professionals/physician_gls/pdf/colon.pdf
3. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Gastrointestinal Stromal Tumors. Version 1.2026. Updated January 13, 2026. Accessed October 16, 2026. https://www.nccn.org/professionals/physician_gls/pdf/gist.pdf

4. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Hepatobiliary Cancers. Version 2.2026. Updated August 14, 2026. Accessed October 16, 2026. https://www.nccn.org/professionals/physician_gls/pdf/hcc.pdf

   National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Bone Cancer. Version 1.2027. Updated July 21, 2026. Accessed October 16, 2026. https://www.nccn.org/professionals/physician_gls/pdf/bone.pdf
5. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Rectal Cancer. Version 2.2026. Updated April 7, 2026. Accessed October 16, 2026. https://www.nccn.org/professionals/physician_gls/pdf/rectal.pdf
6. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Soft Tissue Sarcoma. Version 5.2026. Updated July 23, 2026. Accessed October 16, 2026. https://www.nccn.org/professionals/physician_gls/pdf/sarcoma.pdf
7. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Uterine Neoplasms. Version 3.2026. Updated June 16, 2026. Accessed October 16, 2026. https://www.nccn.org/professionals/physician_gls/pdf/uterine.pdf
8. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Pediatric Soft Tissue Sarcoma. Version 1.2026. Updated February 17, 2026. Accessed October 16, 2026. https://www.nccn.org/professionals/physician_gls/pdf/ped_sts.pdf
9. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Pediatric Bone Sarcoma. Version 1.2027. Updated October 1, 2026. Accessed October 16, 2026. https://www.nccn.org/professionals/physician_gls/pdf/ped_bone.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.