

**Generic Name:** Regorafenib

**Preferred:** N/A

**Therapeutic Class or Brand Name:** N/A

**Non-preferred:** N/A

**Applicable Drugs (if Therapeutic Class):** N/A

**Date of Origin:** 2/1/2013

**GPI Code:** 2153305000

**Date Last Reviewed / Revised:** 9/30/2020

## PRIOR AUTHORIZATION CRITERIA

(may be considered medically necessary when criteria I through III 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. Prescriber is an oncologist.

## 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. National Comprehensive Cancer Network (NCCN). Colon Cancer. Version 4.2020. Updated June 15, 2020. Available at: [https://www.nccn.org/professionals/physician\\_gls/pdf/colon.pdf](https://www.nccn.org/professionals/physician_gls/pdf/colon.pdf)
2. National Comprehensive Cancer Network (NCCN). Hepatobiliary Cancers. Version 5.2020. Updated August 4, 2020. Available at: [https://www.nccn.org/professionals/physician\\_gls/pdf/hepatobiliary.pdf](https://www.nccn.org/professionals/physician_gls/pdf/hepatobiliary.pdf).
3. Medi-Span®.
4. Stivarga® [Package Insert]. Whippany, NJ: Bayer; June 2020. Available at: [http://labeling.bayerhealthcare.com/html/products/pi/Stivarga\\_PI.pdf](http://labeling.bayerhealthcare.com/html/products/pi/Stivarga_PI.pdf).