MEDICATION POLICY

Generic Name: Regorafenib

Therapeutic Class or Brand Name: Stivarga®

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

Date of Origin: 2/1/13 **Date Last Reviewed/Revised:** 9/24/16

GPI Code: 2153305000

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 B 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 when no KRAS mutation is present (for use with KRAS wild type tumors only).
   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.

II. Minimum age requirement: 18 years old.

III. Prescriber is an oncologist.

Exclusion Criteria:

- N/A

Other Criteria:

- N/A

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 judgment in providing the most appropriate care for their patients.

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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. http://blue.regence.com/trgmedpol/drugs/dru284.pdf.
2. Medi-Span.
3. http://labeling.bayerhealthcare.com/html/products/pi/Stivarga_PI.pdf.

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Historical Tracking Of Changes Made To Policy	
9/24/2016	1. **Changed** "I. A. Metastatic colorectal cancer (CRC) and criteria 1 and 2 are met: 1. Prior treatment with bevacizumab (Avastin®) has been ineffective, contraindicated, or not tolerated; 2. Prior treatment with an anti-EGFR therapy [i.e. cetuximab (Erbitux®) or panitumumab (Vectibix®)] has been ineffective, contraindicated, or not tolerated when no KRAS mutation is present (for use with KRAS wild type tumors only)" **to** "I. 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 when no KRAS mutation is present (for use with KRAS wild type tumors only)" **under Prior Authorization Criteria**. 2. **Changed** "I. B. 1. Prior treatment with imatinib (Gleevec®) and sunitinib (Sutent®) have been ineffective, contraindicated, or not tolerated" **to** "I. B. 1. Prior treatment with Gleevec® and Sutent® have been ineffective, contraindicated, or not tolerated" **under Prior Authorization Criteria**.
3/26/2015	1. Policy reviewed: no changes made.
12/21/2013	1. **Adapted policy to new format.** 2. **Added GPI code**. 3. **Changed Prior Authorization Criteria from:** "Documented diagnosis of Metastatic Colorectal Cancer; Prior treatment with bevacizumab (Avastin®) has been ineffective, contraindicated, or not tolerated; Prior treatment with cetuximab (Erbitux®) has been ineffective, contraindicated, or not tolerated when no KRAS mutation is present (for use with KRAS wild type tumors only)" **to:** **"**Documented diagnosis of one of the following conditions A through B AND must meet criteria listed under applicable diagnosis: A. Metastatic colorectal cancer (CRC) and criteria 1 and 2 are met: 1. Prior treatment with bevacizumab (Avastin®) has been ineffective, contraindicated, or not tolerated, 2. Prior treatment with an anti-EGFR therapy [i.e. cetuximab (Erbitux®) or panitumumab (Vectibix®)] has been ineffective, contraindicated, or not tolerated when no KRAS mutation is present (for use with KRAS wild type tumors only); B. Locally advanced, unresectable, or metastatic gastrointestinal stromal tumor (GIST) and criterion 1 is met: 1. Prior treatment with imatinib (Gleevec®) and sunitinib (Sutent®) have been ineffective, contraindicated, or not tolerated". 4. **Updated references** to include Medi-Span.

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