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:** 12/6/17

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 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:

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- 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. 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	
12/6/2017	1. **Changed** “I. A. 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)” **to** “I. A. 3. Prior treatment with an anti-EGFR therapy (i.e. Erbitux®, Vectibix®) has been ineffective, contraindicated, or not tolerated if RAS wild-type” **under Prior Authorization Criteria**. 2. **Added** “I. C. Hepatocellular carcinoma (HCC) and criterion 1 is met: 1. Prior treatment with Nexavar® (sorafenib) has been ineffective, contraindicated, or not tolerated” **under Prior Authorization Criteria**.
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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