Stivarga (regorafenib) Prior Approval Criteria
September 2016

OVERVIEW: Stivarga, a kinase inhibitor, is indicated for the treatment of patients with metastatic colorectal cancer (mCRC) who have been previously treated with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy, and, if KRAS wild-type, an anti-epidermal growth factor receptor (EGFR) therapy. Stivarga is also indicated for the treatment of patients with locally advanced, unresectable or metastatic gastrointestinal stromal tumor (GIST) who have been previously treatment with Gleevec (imatinib mesylate tablets) and Sutent (sunitinib malate capsules). Stivarga is a small molecule inhibitor of multiple membrane-bound and intracellular kinases involved in normal cellular functions and in pathologic processes such as oncogenesis, tumor angiogenesis, and maintenance of the tumor microenvironment. Stivarga treatment should continue until disease progression or unacceptable toxicity.

POLICY STATEMENT
Prior authorization is recommended for prescription benefit coverage of Stivarga. All approvals are provided for 1 year in duration unless otherwise noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days.

Automation: None.

Please Note: In order to be considered for coverage, this drug must be prescribed by or in consultation with a hematologist or oncologist.

RECOMMENDED AUTHORIZATION CRITERIA
Coverage of Stivarga is recommended in those who meet the following criteria:

Food and Drug Administration (FDA)-Approved Indications

1. Metastatic Colorectal Cancer (mCRC). Approve if the patient meets the following criteria (a, b, c, and d):
   a) Patient has been previously treated with a fluoropyrimidine (e.g., capecitabine, 5-FU); AND
   b) Patient has been previously treated with oxaliplatin; AND
   c) Patient has been previously treated with irinotecan; AND
   d) Patient’s tumor or metastases are wild-type KRAS and/or NRAS (that is, the tumors or metastases are KRAS and/or NRAS mutation negative),) and has been treated with anti-EGFR therapy (e.g., Erbitux, Vectibix).

2. Metastatic and/or Unresectable Gastrointestinal Stromal Tumor (GIST). Approve if the patient meets the following criteria (a and b):
   a) Patient has previously tried Gleevec; AND
   b) Patient has previously tried Sutent.
3. Patient has been started on Stivarga. Approve for an indication or condition addressed as an approval in this document.

Other Uses with Supportive Evidence

4. Patients with another indication that is not listed but is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. Prescriber will provide specific diagnosis for documentation. Approve.

REFERENCES