OVERVIEW
Stivarga, a kinase inhibitor, is FDA approved for the treatment of patients with the following conditions:
1. 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;
2. Locally advanced, unresectable or metastatic gastrointestinal stromal tumor (GIST) who have been previously treatment with Gleevec (imatinib mesylate tablets) and Sutent (sunitinib malate capsules);
3. Hepatocellular carcinoma (HCC) who have been previously treated with Nexavar (sorafenib tablets).

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.

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:

1. Metastatic or Unresectable advanced Colon Cancer. Approve if the patient meets the following criteria (a, b, or c):
   a) First progression (KRAS/NRAS mutant only) or second progression and patient was previously treated with fluorouracil, leucovorin, oxaliplatin, and irinotecan regimen; OR
   b) Second progression and patient as previously treated with irinotecan and oxaliplatin. OR
   c) Patient has progressed through all available regimens.

2. Metastatic or Unresectable advanced Rectal Cancer. Approve if the patient meets the following criteria (a, b, or c):
   a) First progression (KRAS/NRAS mutant only) or second progression and patient was previously treated with fluorouracil, leucovorin, oxaliplatin, and irinotecan regimen; OR
   b) Second progression and patient as previously treated with irinotecan and oxaliplatin. OR
   c) Patient has progressed through all available regimens, including trifluridine and tipiracil.
3. **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.

4. **Hepatocellular Carcinoma.** Approve if the patient meets the following criteria (a and b):
   a) Patient has previously tried Nexavar (sorafenib tablets); AND
   b) Patient meets one of the following conditions (i, ii, or iii):
      i. Patient is a nontransplant candidate with unresectable disease; OR
      ii. Patient is inoperable by performance status or comorbidity (local disease or local disease with minimal extrahepatic disease only); OR
      iii. Patient has extensive liver tumor burden or metastatic disease.

5. **Patient has been started on Stivarga.** Approve for an indication or condition addressed as an approval in this document.

6. **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**