

# **STIVARGA** (regorafenib)

#### Pre - PA Allowance

None

#### **Prior-Approval Requirements**

Age 18 years of age and older

**Diagnoses** 

Patient must have **ONE** of the following:

- 1. Metastatic colorectal cancer (CRC)
  - a. Previously treated with fluoropyrimidine-, oxaliplatin-and irinotecanbased chemotherapy and if RAS wild type, an anti-EGFR therapy
- 2. Gastrointestinal stromal tumor (GIST)
  - a. Unresectable OR metastatic OR locally advanced
  - b. Previously treated with Gleevec (imatinib) and Sutent (sunitinib)
- 3. Hepatocellular carcinoma (HCC)
  - a. Previously treated with sorafenib (Nexavar)
- 4. Cholangiocarcinoma

#### **AND ALL** of the following for **ALL** indications:

- 1. Assessment of ALT, AST, and bilirubin tests before initiation of therapy
  - Agreement to monitor levels every 2 weeks during the first 2 months of treatment, then monitored at least monthly
- 2. **NO** signs or symptoms of severe hemorrhage

### **Prior - Approval Limits**

Quantity 252 tablets per 84 days

**Duration** 12 months

## Prior – Approval Renewal Requirements

Age 18 years of age and older

**Diagnoses** 

Patient must have **ONE** of the following:

- 1. Metastatic colorectal cancer (CRC)
- 2. Gastrointestinal stromal tumor (GIST)
  - a. Unresectable **OR** metastatic **OR** locally advanced



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- 3. Hepatocellular Carcinoma (HCC)
- 4. Cholangiocarcinoma

#### **AND ALL** of the following for **ALL** indications:

- 1. Liver function tests are < 3 times the upper limit of normal (ULN) or baseline
- 2. NO signs or symptoms of severe hemorrhage
- 3. NO signs or symptoms of gastrointestinal perforation or fistula
- 4. **NO** development of Reversible Posterior Leukoencephalopathy Syndrome (RPLS)

### **Prior - Approval Limits**

Same as above