

SPECIALTY GUIDELINE MANAGEMENT

STIVARGA (regorafenib)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indications

1. Stivarga is indicated for the treatment of patients with metastatic colorectal cancer (CRC) who have been previously treated with fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy, an anti-vascular endothelial growth factor (VEGF) therapy, and, if *RAS* wild type, an anti-epidermal growth factor receptor (EGFR) therapy.
2. Stivarga is indicated for the treatment of patients with locally advanced, unresectable or metastatic gastrointestinal stromal tumor (GIST) who have been previously treated with imatinib mesylate and sunitinib malate.
3. Stivarga is indicated for the treatment of patients with hepatocellular carcinoma (HCC) who have been previously treated with sorafenib.

B. Compendial Uses

1. Unresectable advanced or metastatic colorectal cancer that was not previously treated with Stivarga
2. Progressive GIST

All other indications are considered experimental/investigational and are not a covered benefit.

II. CRITERIA FOR INITIAL APPROVAL

A. **Colorectal Cancer (CRC)**

Authorization of 12 months may be granted for the treatment of unresectable advanced or metastatic colorectal cancer when the member has progressed on treatment with either of the following:

1. FOLFOXIRI (fluorouracil, leucovorin, oxaliplatin, and irinotecan) regimen, OR
2. Irinotecan- AND oxaliplatin-based regimens

B. **Gastrointestinal stromal tumor (GIST)**

Authorization of 12 months may be granted for the treatment of progressive disease in members who have been previously treated with imatinib or sunitinib.

C. **Hepatocellular carcinoma**

Authorization of 12 months may be granted for the treatment of hepatocellular carcinoma in members who have been previously treated with sorafenib.

III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet ALL initial authorization criteria.

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IV. REFERENCES

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