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
A. Unresectable advanced or metastatic colorectal cancer that was not previously treated with Stivarga
B. 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 locally advanced, unresectable or metastatic 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.

IV. REFERENCES

1. Stivarga [package insert]. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc; April 2017.
2. The NCCN Drugs & Biologics Compendium™ © 2016 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed August 3, 2016.
3. National Comprehensive Cancer Network. NCCN clinical practice guidelines in oncology: colon cancer. Version 2.2016. http://www.nccn.org/professionals/physician_gls/PDF/colon.pdf. Accessed August 9, 2016.
4. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in oncology: rectal cancer. Version 2.2016. http://www.nccn.org/professionals/physician_gls/PDF/rectal.pdf. Accessed August 9, 2016.
5. National Comprehensive Cancer Network. NCCN clinical practice guidelines in oncology: soft tissue sarcoma. Version 2.2016. http://www.nccn.org/professionals/physician_gls/pdf/sarcoma.pdf. Accessed August 10, 2016.