Reference number(s)
1809-A

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. Colorectal cancer
   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. Gastrointestinal stromal tumors
   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. Hepatocellular carcinoma
   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
2. Gastrointestinal stromal tumors (GIST)
3. Soft tissue sarcoma
   a. Extremity/superficial trunk, head/neck
   b. Retroperitoneal/Intra-Abdominal
   c. Rhabdomyosarcoma
4. Hepatocellular Carcinoma
5. Osteosarcoma
6. Glioblastoma

All other indications are considered experimental/investigational and not medically necessary.

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 as a single agent when the member has progressed on previous treatment with all the following regimens unless the member has a contraindication or intolerance:
1. Fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy; and

2. An anti-vascular endothelial growth factor (VEGF) therapy; and
3. If RAS wild type, an anti-epidermal growth factor receptor (EGFR) therapy, such as Erbitux (cetuximab) or Vectibix (panitumumab)

B. Gastrointestinal stromal tumor (GIST)
Authorization of 12 months may be granted for the treatment of progressive disease in members when either of the following criteria are met:
1. Stivarga will be used following disease progression while previously treated with single-agent therapy with imatinib or sunitinib; or
2. Stivarga will be used in combination with everolimus following disease progression with imatinib, sunitinib, and regorafenib.

C. Hepatocellular carcinoma
Authorization of 12 months may be granted for the treatment of hepatocellular carcinoma as subsequent treatment as a single agent.

D. Soft tissue sarcomas
Authorization of 12 months may be for the treatment of retroperitoneal/intra-abdominal soft tissue sarcoma, rhabdomyosarcoma, and soft tissue sarcomas of the extremities, superficial trunk, or head and neck, as single agent palliative therapy.

E. Osteosarcoma
Authorization of 12 months may be granted for second-line treatment of osteosarcoma as a single agent.

F. Glioblastoma
Authorization of 12 months may be granted for treatment of recurrent glioblastoma as a single agent.

III. CONTINUATION OF THERAPY
Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in section II who have not experienced disease progression or an unacceptable toxicity.

IV. REFERENCES
1. Stivarga [package insert]. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc; June 2019.
2. The NCCN Drugs & Biologics Compendium 2020 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed March 13, 2020.