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. Advanced or metastatic colorectal cancer
2. Gastrointestinal stromal tumors (GIST)
3. Soft tissue sarcoma
   a. Non-adipocytic sarcoma
   b. Retroperitoneal/Intra-abdominal
   c. Rhabdomyosarcoma
   d. Angiosarcoma
   e. Solitary fibrous tumor
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 treatment of 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 treatment of progressive GIST when either of the following criteria are met:

1. Stivarga will be used following disease progression after single-agent therapy with imatinib and sunitinib; or
2. Stivarga will be used in combination with everolimus for members who have failed at least four FDA-approved therapies (e.g., imatinib, sunitinib, ripretinib, avapritinib)

C. Hepatocellular carcinoma

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

D. Soft tissue sarcomas

Authorization of 12 months may be granted for treatment of angiosarcoma, solitary fibrous tumor, retroperitoneal/intra-abdominal soft tissue sarcoma, rhabdomyosarcoma, and non-adipocytic sarcoma, as a single agent.

E. Osteosarcoma

Authorization of 12 months may be granted for second-line treatment of relapsed/refractory or metastatic 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 when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

IV. REFERENCES

1. Stivarga [package insert]. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc.; December 2020.
2. The NCCN Drugs & Biologics Compendium 2021 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed July 7, 2021.
3. Lexicomp [database online]. Hudson, OH: Lexi-Comp, Inc.; http://online.lexi.com/lco/action/index/dataset/complete_ashp [available with subscription]. Accessed July 7, 2021.