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
4. Hepatocellular carcinoma
5. Osteosarcoma
6. Glioblastoma
7. Ewing sarcoma

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, including appendiceal adenocarcinoma and anal adenocarcinoma, 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 (with or without bevacizumab); and
2. If RAS wild type, an anti-epidermal growth factor receptor (EGFR) therapy, such as Erbitux (cetuximab) or Vectibix (panitumumab), for rectal cancer, appendiceal adenocarcinoma, anal adenocarcinoma, or left-sided colon cancer.

B. Gastrointestinal stromal tumor (GIST)

Authorization of 12 months may be granted for treatment of GIST when any of the following criteria are met:

1. The requested medication will be used as a single agent for locally advanced, residual, unresectable, tumor rupture, or recurrent/metastatic GIST following disease progression on imatinib and either sunitinib or ripretinib
2. The requested medication will be used for treatment of residual, unresectable, tumor rupture or recurrent/metastatic GIST in combination with everolimus for disease progression after the member has failed at least four FDA-approved therapies (e.g., imatinib, sunitinib, ripretinib, avapritinib)
3. The requested medication will be used for treatment of residual, unresectable, tumor rupture or recurrent/metastatic succinate dehydrogenase (SDH)-deficient GIST as a single agent.

C. Hepatocellular carcinoma

Authorization of 12 months may be granted for treatment of unresectable/inoperable, metastatic, or extensive liver tumor burden hepatocellular carcinoma as subsequent treatment as a single agent.

D. Soft tissue sarcomas

Authorization of 12 months may be granted for treatment of angiosarcoma, 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 or progressive glioblastoma as a single agent.

G. Ewing sarcoma

Authorization of 12 months may be granted for subsequent treatment of relapsed (with or without radiation), progressive or metastatic Ewing sarcoma 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 2023 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed November 24, 2023.

3. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines): Anal Carcinoma. Version 2.2023. Accessed July 6, 2023. https://www.nccn.org/professionals/physician_gls/pdf/anal.pdf
4. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines): Colon Cancer. Version 4.2023. Accessed November 24, 2023. https://www.nccn.org/professionals/physician_gls/pdf/colon.pdf