Custom Criteria for
BlueCross Blue Shield of Rhode Island Commercial

Stivarga® (regorafenib)

GPI CODING:

21533050000320

DESCRIPTION:

Stivarga is indicated for the treatment of patients with metastatic colorectal cancer who have been previously treated with fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy, an anti-VEGF therapy, and, if KRAS wild type, an anti-EGFR therapy. Stivarga is an inhibitor of multiple kinases including, but not limited to VEGF receptors 1-3, platelet derived growth factor receptors (PDGFRα and PDGFRβ), fibroblast growth factor receptor (FGFR1-2), receptor kinase inhibitors (RET and KIT), and tyrosine kinase with immunoglobulin and epidermal growth factor homology domain 2 (TIE2). These kinases are involved in normal cellular functions and in pathologic processes such as oncogenesis, tumor angiogenesis, and maintenance of the tumor microenvironment. Stivarga demonstrated anti-angiogenic activity, inhibition of tumor growth, as well as anti-metastatic activity in several animal models.

APPROVAL DURATION:

Approval duration: 24 months

CRITERIA FOR STIVARGA

I. Patient has a diagnosis of metastatic colorectal cancer **AND**
II. Patient has been previously treated with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy **AND**
III. Patient has been previously treated with an anti-VEGF agent (eg, bevacizumab) **AND**
IV. *KRAS* mutation testing was performed on either the primary tumor or metastases **AND**
V. If tumor was *KRAS* wild-type, patient has been previously treated with an anti-EGFR agent (eg, cetuximab, panitumumab)

OR

VI. Off label uses for oncology drugs are approvable if considered medically acceptable in one or more of the following compendia (i.e., Micromedex DrugDex, AHFS, Clinical Pharmacology, and NCCN.)) A use is identified by a compendium as medically accepted if the:
   A. Indication is a Category 1 or 2A in NCCN,
   B. Indication is a Class I, Class IIa or Class IIb in DrugDex,
   C. Narrative text in AHFS or Clinical Pharmacology is supportive; or
   D. The use is supported by clinical research in 2 or more peer-reviewed medical journals