Stivarga (regorafenib)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Stivarga (regorafenib)	May be subject to quantity limit

APPROVAL CRITERIA

Requests for Stivarga (regorafenib) may be approved if the following criteria are met:

I. Individual has a diagnosis of unresectable, advanced or metastatic colorectal cancer (mCRC) including appendiceal adenocarcinoma; **AND**
II. Confirmation of progression through all various available regimens besides regorafenib or trifluridine and tipiracil (Lonsurf) (NCCN 2A);

OR

III. Individual has a diagnosis of locally advanced, unresectable, or metastatic gastrointestinal stromal tumors (GIST); **AND**
IV. Individual has had progression after monotherapy with imatinib (Gleevec) and sunitinib (Sutent);
OR
V. Individual is receiving in combination with everolimus for disease progression on approved therapies (such as imatinib, sunitinib, regorafenib, and ripretinib) (NCCN 2A);

OR

VI. Individual has a diagnosis of succinate-dehydrogenase (SDH)- deficient gastrointestinal stromal tumor (GIST) (NCCN 2A);

OR

VII. Individual has a diagnosis of Soft Tissue Sarcoma (cancers of the extremity/body wall, head/neck or retroperitoneal/Intra-abdominal; angiosarcoma; rhabdomyosarcoma) and using as palliative therapy or for advanced/metastatic disease;

OR

VIII. Individual has a diagnosis of Hepatocellular cancer (HCC); **AND**
IX. Individual has been previously treated with sorafenib (Nexavar)

OR

X. Individual has a diagnosis of recurrent Glioblastoma (NCCN 2A); **AND**
XI. Individual has progressed on radiation therapy (Lombardi 2019);

OR

XII. Individual has a diagnosis of relapsed or refractory or metastatic Osteosarcoma (NCCN 2A).

Note:
Stivarga (regorafenib) has a black box warning for hepatotoxicity. Severe and sometimes fatal hepatotoxicity has been observed in clinical trials. Monitor hepatic function prior to and during treatment. Interrupt and then reduce or discontinue depending on severity and persistence.

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2022. URL: http://www.clinicalpharmacology.com. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: June 30, 2022.
3. Davis LE, Bolejack V, Ryan CW, et al. Randomized Double-Blind Phase II Study of Regorafenib in Patients with Metastatic Osteosarcoma. J Clin Oncol. 2019;37(16):1424-1431.
4. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
5. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2022; Updated periodically.
6. Lombardi G, De Salvo GL, Brandes AA, et al. Regorafenib compared with lomustine in patients with relapsed glioblastoma (REGOMA): a multicentre, open-label, randomised, controlled, phase 2 trial. Lancet Oncol. 2019;20(1):110-119.
7. NCCN Clinical Practice Guidelines in Oncology™. © 2022 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Accessed on June 30, 2022.
    a. Hepatobiliary Cancers. V1.2022. Revised March 29, 2022.
    b. Bone Cancer. V2.2022. Revised October 8, 2021.
    c. Soft Tissue Sarcoma. V2.2022. Revised May 17, 2022.
    d. Gastrointestinal Stromal Tumors (GISTs). V1.2022. Revised January 21, 2022.
    e. Central Nervous System Cancers. V1.2022. Revised June 2, 2022.
    f. Colon Cancer. V1.2022. Revised February 25, 2022.
    g. Rectal Cancer. V1.2022. Revised February 25, 2022.