Market Applicability						
Market	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X

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); **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 after monotherapy with imatinib, sunitinib, and regorafenib (NCCN 2A);

OR

VI. Individual has a diagnosis of Soft Tissue Sarcoma (cancers of the extremity/superficial trunk, head/neck or retroperitoneal/Intra-abdominal; angiosarcoma; rhabdomyosarcoma; pleomorphic; solitary fibrous) and using as palliative monotherapy;

OR

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

OR

~~IX.~~ Individual has a diagnosis of recurrent Glioblastoma (NCCN 2A); **AND**

Market Applicability						
Market	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X

~~X.~~ Individual has progressed on radiation therapy;

OR

~~XI.~~ 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:

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7. NCCN Clinical Practice Guidelines in Oncology™. © 2019 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Accessed on June 16, 2020.
    a. Colon Cancer. V4.2020. Revised June 15, 2020.
    b. Soft Tissue Sarcoma. V2.2020. Revised May 28, 2020.
    c. Hepatobiliary Cancers. V3.2020. Revised June 1, 2020.
    d. Central Nervous System Cancers. V2.2020. Revised April 30, 2020.
    e. Bone Cancer. V1.2020. Revised August 12, 2019.