

Market Applicability														
Market	DC	FL & FHK	FL MMA	FL LTC	GA	KS	KY	MD	NJ	NV	NY	TN	TX	WA
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	X

*FHK- Florida Healthy Kids

Stivarga (regorafenib)

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

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** confirmation of prior therapy (or confirmed contraindications) with **ALL** of the following:
 - A. First progression after treatment with FOLFOXIRI; **AND**
 - B. Second progression after treatment with irinotecan and oxaliplatin based regimen; **AND**
 - C. Progression for disease that progressed through all various regimens besides trifluridine and tipiracil (Lonsurf) (NCCN 2A); **AND**
 - D. After anti-EGFR therapy such as panitumumab (Vectibix) or cetuximab (Erbix) if KRAS wild type mCRC;

OR

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

OR

- V. Individual has a diagnosis of Hepatocellular cancer (HCC); **AND**
- VI. Individual has been previously treated with sorafenib (Nexavar); **OR**
- VII. Individual is receiving as subsequent therapy for unresectable advanced or metastatic HCC disease in those who have progressed through all available regimens besides regorafenib or trifluridine/tipiracil (NCCN 2A).

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

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Note: Stivarga (regorafenib) has a black box warning for hepatotoxicity. Severe and sometimes fatal hepatotoxicity has been observed in clinical trials.

State Specific Mandates		
State name	Date effective	Mandate details (including specific bill if applicable)
N/A	N/A	N/A

Key References:

Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2017. URL: <http://www.clinicalpharmacology.com>. Updated periodically.

DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: 4/2018.

DrugPoints® System [Internet Database]. Greenwood Village, CO: Thomson Reuters (Healthcare) Inc. Updated periodically.

Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2018; Updated periodically.

The NCCN Drugs & Biologics Compendium (NCCN Compendium™) © 2018 National Comprehensive Cancer Network, Inc. Available at: NCCN.org. Updated periodically.

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