

**Stivarga (regorafenib)  
Effective 01/01/2021**

<b>Plan</b>	<input type="checkbox"/> MassHealth <input checked="" type="checkbox"/> MassHealth (PUF) <input type="checkbox"/> Commercial/Exchange	<b>Program Type</b>	<input checked="" type="checkbox"/> Prior Authorization <input checked="" type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
<b>Benefit</b>	<input checked="" type="checkbox"/> Pharmacy Benefit <input type="checkbox"/> Medical Benefit (NLX)		
<b>Specialty Limitations</b>	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
<b>Contact Information</b>	<b>Specialty Medications</b>		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	<b>Non-Specialty Medications</b>		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	<b>Medical Specialty Medications (NLX)</b>		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
<b>Exceptions</b>	N/A		

### Overview

Stivarga is a kinase inhibitor indicated for the treatment of patients with:

- Metastatic colorectal cancer (CRC) who have been previously treated with fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy, an antiVEGF therapy, and, if RAS wild-type, an anti-EGFR therapy.
- Locally advanced, unresectable or metastatic gastrointestinal stromal tumor (GIST) who have been previously treated with imatinib mesylate and sunitinib malate.
- Hepatocellular carcinoma (HCC) who have been previously treated with sorafenib

### Coverage Guidelines

Authorization may be reviewed on a case by case basis for members new to AllWays Health Partners who are currently receiving treatment with Stivarga, excluding when the product is obtained as samples or via manufacturer's patient assistance programs

**OR**

Authorization may be granted if the member meets **ALL** following criteria and documentation has been submitted:

#### For Metastatic Colorectal Cancer

Prescriber provides documentation of **ALL** of the following:

1. Diagnosis of metastatic colorectal cancer
2. Prescriber is an oncologist
3. Appropriate dose



4. Physician documented inadequate response or adverse reaction to **ONE** of the following regimens or a contraindication to **ALL** of the following regimens (*see appendix for components of commonly used regimens for Colorectal cancer*):
  - a. CAPEOX
  - b. FOLFIRI
  - c. FOLFOX
  - d. FOLFOXIRI
  - e. irinotecan-based therapy
  - f. oxaliplatin-based therapy
5. If KRAS/NRAS/BRAF wild-type cancer is present, physician documented inadequate response or adverse reaction to **ONE** or a contraindication to **BOTH** of the following:
  - a. Erbitux<sup>®</sup> (cetuximab)
  - b. Vectibix<sup>®</sup> (panitumumab)

**For Gastrointestinal Stromal Tumor**

Prescriber provides documentation of **ALL** of the following:

1. Diagnosis of gastrointestinal stromal tumor
2. Prescriber is an oncologist
3. Appropriate dose
4. Physician documented inadequate response, adverse reaction, or a contraindication to **BOTH** of the following:
  - a. Gleevec<sup>®</sup> (imatinib)
  - b. Sutent<sup>®</sup> (sunitinib)

**For Hepatocellular Carcinoma**

Prescriber provides documentation of **ALL** of the following:

1. Diagnosis of hepatocellular carcinoma
2. Prescriber is an oncologist
3. Appropriate dose
4. Member has Child-Pugh Class A
5. Physician documented inadequate response, adverse reaction or a contraindication to Nexavar<sup>®</sup> (sorafenib)

**Continuation of Therapy**

Reauthorization requires physician attestation of continuation of therapy and positive response to therapy.

**Limitations**

1. Initial approvals and reauthorizations will be granted for 6 months
2. The following quantity limits apply:

Stivarga (regorafenib) 40mg tablets	84 tablets per 28 days
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\*Any requests for over the quantity limit must be reviewed against the Global Quantity Limit criteria.

**Appendix**

**Components of Commonly Used Regimens for Treatment of Colorectal Cancer**

Regimen Abbreviation	Drug Components
5-FU	fluorouracil



CAPEOX	capecitabine/oxaliplatin
FOLFIRI	leucovorin calcium (folinic acid)/fluorouracil/irinotecan
FOLFOX	leucovorin calcium (folinic acid)/fluorouracil/oxaliplatin
FOLFOXIRI	leucovorin calcium (folinic acid)/5-fluorouracil/oxaliplatin/irinotecan

**References**

1. Stivarga [package insert]. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc.; June 2020.

**Review History**

10/9/2020: Created criteria to be in compliance with the Masshealth partial unified formulary requirements effective 1/1/21.

**Disclaimer**

AllWays Health Partners complies with applicable federal civil rights laws and does not discriminate or exclude people on the basis of race, color, national origin, age, disability, or sex.