UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Stivarga

Program	Prior Authorization
Medication	Stivarga® (regorafenib)
Markets in Scope	Arizona, California, Hawaii, Maryland, Nevada, New Jersey, New York, New York EPP, Pennsylvania-CHIP, Rhode Island, South Carolina
Issue Date	6/2013
Pharmacy and Therapeutics Approval Date	6/2020
Effective Date	8/2020

1. Background:

Stivarga (regorafenib) 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 anti-VEGF 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 (Gleevec) and Sutent (sunitinib malate); hepatocellular carcinoma (HCC) who have been previously treated with Nexavar (sorafenib tosylate).[1] The National Cancer Comprehensive Network (NCCN) also recommends use of Stivarga in colon cancer, rectal cancer, soft tissue sarcomas, hepatobiliary cancers, osteosarcoma, and glioblastoma.[2]

Stivarga contains a black boxed warning for hepatotoxicity. Please see full prescribing information for additional details.

2. Coverage Criteria:

A. <u>Colorectal Cancer (CRC)</u>

1. <u>Initial Authorization</u>

a. **Stivarga** will be approved based on **<u>all</u>** of the following criteria:

(1) Diagnosis of advanced or metastatic colorectal cancer

-AND-

(2) History of failure, contraindication, or intolerance to treatment with **<u>all</u>** of the following:

(a) Oxaliplatin-based chemotherapy
(b) Irinotecan-based chemotherapy
(c) Fluoropyrimidine-based chemotherapy
(d) Anti-VEGF therapy, -based chemotherapy

-AND-

(3) **One** of the following:

(a) Tumor is *RAS* mutant-type

-OR-

(b) **Both** of the following:

1. Tumor is *RAS* wild-type
2. History of failure, contraindication, or intolerance to anti-EGFR therapy

Authorization will be issued for 12 months.

2. Reauthorization

a. **Stivarga** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Stivarga therapy

Authorization will be issued for 12 months.

B. Soft Tissue Sarcoma (STS)

1. Initial Authorization

a. **Stivarga** will be approved based on **one** of the following criteria:

(1) Diagnosis of **one** of the following:

(a) Soft Tissue Sarcoma - extremity/superficial trunk or head/neck that is non-adipocytic with stage IV or recurrent disease with disseminated metastases
(b) Soft Tissue Sarcoma - retroperitoneal/intra-abdominal that is non-adipocytic, unresectable, or progressive disease
(c) Pleomorphic rhabdomyosarcoma

-OR-

(2) **All** of the following:

(a) Diagnosis of gastrointestinal stromal tumor (GIST)

-AND-

(b) Disease is **one** of the following:

- Progressive
- Locally advanced
- Unresectable
- Metastatic

-AND-

(c) History of failure, contraindication, or intolerance to **one** of the following:

- imatinib mesylate (Gleevec)
- Sutent (sunitinib malate)

Authorization will be issued for 12 months.

2. Reauthorization

a. **Stivarga** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Stivarga therapy

Authorization will be issued for 12 months.

C. Hepatobiliary Cancers

1. Initial Therapy

a. **Stivarga** will be approved based on **one** of the following criteria:

(1) **All** of the following:

(a) Diagnosis of **one** of the following:

i. Gallbladder cancer
ii. Extrahepatic cholangiocarcinoma
iii. Intrahepatic cholangiocarcinoma

-AND-

(b) Disease is unresectable or metastatic

-OR-

(2) **All** of the following

(a) Diagnosis of hepatocellular carcinoma

-AND-

(b) History of failure, contraindication or intolerance to Nexavar (sorafenib tosylate)

Authorization will be issued for 12 months.

2. Reauthorization Criteria

a. **Stivarga** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Stivarga therapy

Authorization will be issued for 12 months.

D. Osteosarcoma

1. Initial Therapy

a. Stivarga will be approved based on **all** of the following criteria:

(1) Diagnosis of **one** of the following:
a. Osteosarcoma
b. Dedifferentiated chondrosarcoma
c. High grade undifferentiated pleomorphic sarcoma (UPS)

-AND-

(2) Disease is **one** of the following:

a. Relapsed/refractory

b. Metastatic

-AND-

(3) Used as second-line therapy

Authorization will be issued for 12 months.

2. Reauthorization Criteria

a. Stivarga will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Stivarga therapy

Authorization will be issued for 12 months.

E. Glioblastoma

1. Initial Therapy

a. Stivarga will be approved based on **all** of the following criteria:

(1) Diagnosis of recurrent glioblastoma

Authorization will be issued for 12 months.

2. Reauthorization Criteria

a. Stivarga will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Stivarga therapy

Authorization will be issued for 12 months.

F. NCCN Recommended Regimens

1. Initial Authorization

a. **Stivarga** will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium.

Authorization will be issued for 12 months.

2. Reauthorization

a. **Stivarga** will be approved based on the following criterion:

(1) Documentation of positive clinical response to Stivarga therapy

Authorization will be issued for 12 months.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Stivarga [package insert]. Whippany, NJ: Bayer Healthcare Pharmaceuticals, Inc. February 2020.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed May 8, 2020.

Program	Prior Authorization- Stivarga (regorafenib)
Change Control	
Date	Change
6/2013	New drug policy
6/2016	Updated clinical criteria to align with E&I notification policy and updated policy template
6/2017	Updated coverage criteria to include hepatobiliary cancer to align with updated package insert. Updated background and references.
8/2017	Added contraindication to trial/failure language for Nexavar in the Hepatobiliary Cancer section.
6/2018	Added NCCN recommended regimen criteria. Updated references.
6/2019	Updated criteria for colorectal cancer and soft tissue sarcoma based on NCCN guidelines. Updated background and references.
6/2020	Annual review. Updated criteria for hepatobiliary carcinoma according to NCCN guidelines. Addition of osteosarcoma and glioblastoma according to NCCN. Updated references. Added Additional Clinical Rules Section.