Stivarga (regorafenib)
Effective 01/01/2021

<table>
<thead>
<tr>
<th>Plan</th>
<th>Program Type</th>
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<tbody>
<tr>
<td>□ MassHealth</td>
<td>☑ Prior Authorization</td>
</tr>
<tr>
<td>☑ MassHealth (PUF)</td>
<td>☑ Quantity Limit</td>
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<tr>
<td>□ Commercial/Exchange</td>
<td>□ Step Therapy</td>
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<thead>
<tr>
<th>Benefit</th>
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<tr>
<td>☑ Pharmacy Benefit</td>
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<tr>
<td>□ Medical Benefit (NLX)</td>
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**Specialty Limitations**
This medication has been designated specialty and must be filled at a contracted specialty pharmacy.

**Specialty Medications**
All Plans | Phone: 866-814-5506 | Fax: 866-249-6155

**Non-Specialty Medications**

| 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 |

**Medical Specialty Medications (NLX)**
All Plans | Phone: 844-345-2803 | Fax: 844-851-0882

**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

**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® (cetuximab)
   b. Vectibix® (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® (imatinib)
   b. Sutent® (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® (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:
<table>
<thead>
<tr>
<th>Regimen Abbreviation</th>
<th>Drug Components</th>
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</thead>
<tbody>
<tr>
<td>Stivarga (regorafenib)</td>
<td>40mg tablets</td>
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<td>84 tablets per 28 days</td>
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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**

<table>
<thead>
<tr>
<th>Regimen Abbreviation</th>
<th>Drug Components</th>
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<tbody>
<tr>
<td>5-FU</td>
<td>fluorouracil</td>
</tr>
<tr>
<td>CAPEOX</td>
<td>capecitabine/oxaliplatin</td>
</tr>
<tr>
<td>------------</td>
<td>-------------------------------</td>
</tr>
<tr>
<td>FOLFIRI</td>
<td>leucovorin calcium (folinic acid)/fluorouracil/irinotecan</td>
</tr>
<tr>
<td>FOLFOX</td>
<td>leucovorin calcium (folinic acid)/fluorouracil/oxaliplatin</td>
</tr>
<tr>
<td>FOLFOXIRI</td>
<td>leucovorin calcium (folinic acid)/5-fluorouracil/oxaliplatin/irinotecan</td>
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</table>

References

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.