REGORAFENIB

Generic	Brand	HICL	GCN	Exception/Other
REGORAFENIB	STIVARGA	39665		

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic colorectal cancer (CRC)?

   If yes, continue to #2.
   If no, continue to #5.

2. Is the colorectal cancer KRAS wild type (i.e., not KRAS mutation)?

   If yes, continue to #3.
   If no, continue to #4.

3. Has the patient tried or does the patient have a contraindication to an anti-EGFR therapy (such as Erbitux [cetuximab] or Vectibix [panitumumab])?

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

4. Has the patient tried, or does the patient have a contraindication to **ALL** of the following preferred therapies?
   - An anti-VEGF therapy (such as Avastin [bevacizumab] or Zaltrap [ziv-aflibercept])
   - A fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy (such as FOLFOX, FOLFIRI, FOLFOXIRI, CapeOx, or infusional 5-FU/LV or capecitabine)

   If yes, **approve for 12 months by HICL with a quantity limit of #84 tablets per 28 days.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

5. Does the patient have a diagnosis of locally advanced, unresectable, or metastatic gastrointestinal stromal tumor (GIST)?

   If yes, continue to #6.
   If no, continue to #7.

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REGORAFENIB

GUIDELINE FOR USE (CONTINUED)

6. Has the patient tried or does the patient have a contraindication to Gleevec (imatinib) **AND** Sutent (sunitinib)?

   If yes, **approve for 12 months by HICL with a quantity limit of #84 tablets per 28 days.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

7. Does the patient have a diagnosis of hepatocellular carcinoma (HCC) and has been previously treated with Nexavar (sorafenib)?

   If yes, **approve for 12 months by HICL with a quantity limit of #84 tablets per 28 days.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

DENIAL TEXT: The guideline named **REGORAFENIB (Stivarga)** requires a diagnosis of metastatic colorectal cancer (CRC), hepatocellular carcinoma (HCC), or locally advanced, unresectable, or metastatic gastrointestinal stromal tumor (GIST). In addition, the following criteria must be met:
For the diagnosis of metastatic colorectal cancer (CRC), approval requires a trial with ALL of the following preferred therapies:
- An anti-VEGF therapy (such as Avastin [bevacizumab] or Zaltrap [ziv-aflibercept])
- A fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy (such as FOLFOX, FOLFIRI, FOLFOXIRI, CapeOx, or infusional 5-FU/LV or capecitabine)

For wild type KRAS (no mutation) CRC only, a trial of an anti-EGFR therapy (such as Erbitux [cetuximab] or Vectibix [panitumumab]) is also required.
For the diagnosis of locally advanced, unresectable, or metastatic gastrointestinal stromal tumor (GIST), approval requires a trial with Gleevec (imatinib) and Sutent (sunitinib).
For the diagnosis of hepatocellular carcinoma (HCC), approval requires previous treatment with Nexavar (sorafenib).
These prior therapies may be covered under the medical benefit and/or may require prior authorization.

RATIONALE
To ensure appropriate use of Stivarga consistent with FDA approved indication and dosing.

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REGORAFENIB

FDA APPROVED INDICATIONS

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 anti-VEGF therapy, and, if KRAS 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.

DOSAGE AND ADMINISTRATION

The recommended dose is 160 mg Stivarga (four 40 mg tablets) taken orally once daily for the first 21 days of each 28-day cycle. Continue treatment until disease progression or unacceptable toxicity. Take Stivarga at the same time each day. Swallow tablet whole with water after a low-fat meal that contains less than 600 calories and less than 30% fat. Do not take two doses of Stivarga on the same day to make up for a missed dose from the previous day.

REFERENCES

- Stivarga [Prescribing Information]. Wayne, NJ: Bayer HealthCare Pharmaceuticals Inc, April 2017.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/01/17
Created: 10/12
Client Approval: 08/17
P&T Approval: 07/17