STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

REGORAFENIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
REGORAFENIB	STIVARGA	39665		GPI-10 (2153305000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic colorectal cancer (CRC) and meet **ALL** of the following criteria?
   - The patient has received previous treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy (e.g., FOLFOX, FOLFIRI, FOLFOXIRI, CapeOx, infusional 5-FU/LV, capecitabine)
   - The patient has received previous treatment with an anti-VEGF therapy (e.g., Avastin [bevacizumab], Zaltrap [ziv-aflibercept])

   If yes, continue to #2.
   If no, continue to #4.

2. Is the colorectal cancer RAS wild-type (mutation negative)?

   If yes, continue to #3.
   If no, **approve for 12 months by HICL or GPI-10 with a quantity limit of #84 per 28 days.**

3. Has the patient received previous treatment with an anti-EGFR therapy (e.g., Erbitux [cetuximab], Vectibix [panitumumab])?

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #84 per 28 days.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

4. Does the patient have a diagnosis of locally advanced, unresectable, or metastatic gastrointestinal stromal tumor (GIST) **AND** meet the following criterion?
   - The patient has received previous treatment with Gleevec (imatinib) and Sutent (sunitinib)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #84 per 28 days.**
   If no, continue to #5.

5. Does the patient have a diagnosis of hepatocellular carcinoma (HCC) **AND** meet the following criterion?
   - The patient has received previous treatment with Nexavar (sorafenib)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #84 per 28 days.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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REGORAFENIB

GUIDELINE FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **REGORAFENIB (Stivarga)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Metastatic colorectal cancer (CRC: a type of digestive cancer that has spread to other parts of the body)
   2. Locally advanced, unresectable, or metastatic gastrointestinal stromal tumor (GIST: a type of digestive tumor that has spread from where it started to nearby tissue or lymph nodes, unable to remove by surgery, or has spread to other parts of the body)
   3. Hepatocellular carcinoma (HCC: a type of liver cancer)

B. **If you have metastatic colorectal cancer, approval also requires:**
   1. You had previous treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy such as FOLFOX, FOLFIRI, FOLFOXIRI, CapeOx, infusional 5-FU/LV, capecitabine
   2. You had previous treatment with an anti-VEGF therapy such as Avastin (bevacizumab), Zaltrap (ziv-aflibercept)
   3. If you have RAS wild-type (a type of unmutated gene) metastatic colorectal cancer, approval also requires you had previous treatment with an anti-EGFR therapy such as Erbitux (cetuximab), Vectibix (panitumumab)

C. **If you have locally advanced, unresectable, or metastatic gastrointestinal stromal tumor, approval also requires:**
   1. You had previous treatment with Gleevec (imatinib) and Sutent (sunitinib)

D. **If you have hepatocellular carcinoma, approval also requires:**
   1. You had previous treatment with Nexavar (sorafenib)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Stivarga.

REFERENCES

- Stivarga [Prescribing Information]. Wayne, NJ: Bayer HealthCare Pharmaceuticals Inc, December 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/22
Created: 10/12
Client Approval: 03/22
P&T Approval: 07/17