VENTURA COUNTY
HEALTH CARE PLAN

PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Stivarga Prior Authorization Policy
- Stivarga® (regorafenib tablets – Bayer)

REVIEW DATE: 02/09/2022

OVERVIEW

Stivarga, a kinase inhibitor, is indicated for the following uses:[1]

- **Colorectal cancer**, metastatic, in patients who have been previously treated with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy, an anti-vascular endothelial growth factor (VEGF) therapy, and, if *RAS* wild-type, an anti-epidermal growth factor receptor (EGFR) therapy.
- **Gastrointestinal stromal tumor**, locally advanced, unresectable, or metastatic in patients who have been previously treated with imatinib mesylate and Sutent® (sunitinib capsules).
- **Hepatocellular carcinoma**, in patients who have been previously treated with Nexavar® (sorafenib tablets).

Guidelines

Stivarga is discussed in National Comprehensive Cancer Network (NCCN) guidelines:[2]

- **Bone Cancer**: NCCN guidelines (version 2.2022 – October 8, 2021) recommend Stivarga as a single agent for second-line therapy for relapsed/refractory or metastatic disease for patients with osteosarcoma (category 1), dedifferentiated chondrosarcoma, and high-grade undifferentiated pleomorphic sarcoma (category 2B).[3]
- **Central Nervous System Cancers**: NCCN guidelines (version 2.2021 – September 8, 2021) recommend Stivarga as a single agent for the treatment of recurrent glioblastoma.[4]
- **Colon Cancer and Rectal Cancer**: NCCN guidelines (colon cancer [version 3.2021 –September 10, 2021] and rectal cancer [version 2.2021 – September 10, 2021]) recommend Stivarga as subsequent therapy as a single agent for advanced or metastatic disease not previously treated with Stivarga in patients who have progressed through all available regimens except Stivarga or Lonsurf® (trifluridine and tipiracil tablets) with or without bevacizumab. Stivarga may be given before or after Lonsurf.[5,6]
- **Gastrointestinal Stromal Tumors**: NCCN guidelines (version 1.2022 – January 21, 2022) recommend Stivarga (category 1) as a single agent for treatment of unresectable, recurrent, or metastatic disease with widespread, systemic progression after single-agent therapy with imatinib and Sutent.[7] Stivarga in combination with everolimus tablets is recommended for unresectable, recurrent, or metastatic disease after failure on approved therapies. Stivarga is also recommended as a special consideration for unresectable, succinate dehydrogenase-deficient disease.[7]
- **Hepatobiliary Cancers**: NCCN clinical practice guidelines (version 5.2021 – September 21, 2021) recommend Stivarga for subsequent treatment as a single agent for patients with hepatocellular carcinoma (adenocarcinoma) [Child-Pugh Class A only] and disease progression for the following uses (all are category 1): in patients who are not transplant candidates with unresectable disease; in patients who have liver-confined disease, inoperable by performance status or comorbidity or with minimal or uncertain extrahepatic disease; or in patients who have extensive liver tumor burden or metastatic disease.[8] Stivarga is also recommended as subsequent treatment as a single agent for progression on or after systemic treatment for unresectable or metastatic disease (category 2B).[8]

- **Soft Tissue Sarcoma**: NCCN guidelines (version 3.2021 – January 26, 2022) recommend Stivarga (all category 2A) as a single-agent subsequent therapy for patients with non-adipocytic sarcoma with advanced/metastatic disease, advanced/metastatic pleomorphic rhabdomyosarcoma, angiosarcoma, or solitary fibrous tumor.[9]

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Stivarga. All approvals are provided for the duration noted below.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Stivarga is recommended in those who meet one of the following criteria:

FDA-Approved Indications

1. **Colon and Rectal Cancer.** Approve for 3 years if the patient meets all of the following criteria (A, B, C, D, E, and F):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has advanced or metastatic disease; AND
   - **C)** Patient has been previously treated with a fluoropyrimidine (e.g., capecitabine, 5-fluorouracil [5-FU]); AND
   - **D)** Patient has been previously treated with oxaliplatin; AND
   - **E)** Patient has been previously treated with irinotecan; AND
   - **F)** If the patient's tumor or metastases are wild-type *RAS* (*KRAS* wild-type and/or *NRAS* wild-type) [that is, the tumors or metastases are *KRAS* and/or *NRAS* mutation negative], the patient has tried Erbitux (cetuximab intravenous infusion) or Vectibix (panitumumab intravenous infusion).

2. **Gastrointestinal Stromal Tumor.** Approve for 3 years if the patient meets the following criteria (A and B):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has tried each of the following (i and ii):
     - **i.** Imatinib or Ayvakit (avapritinib tablets); AND
     - **ii.** Sutent (sunitinib malate capsules) or Sprycel (dasatinib tablets).

3. **Hepatocellular Carcinoma.** Approve for 3 years if the patient meets the following criteria (A and B):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has been previously treated with one systemic regimen.
     Note: Examples of a systemic regimen include: Tecentriq (atezolizumab intravenous infusion), bevacizumab intravenous infusion, Nexavar (sorafenib tablets), Lenvima (lenvatinib capsules), Opdivo (nivolumab intravenous infusion), oxaliplatin, fluorouracil.

Other Uses with Supportive Evidence

4. **Glioblastoma.** Approve for 3 years if the patient meets the following criteria (A and B):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has recurrent disease.

5. **Osteosarcoma.** Approve for 3 years if the patient meets both of the following criteria (A, B, and C):
   A) Patient is ≥ 18 years of age; AND
   B) Patient has relapsed/refractory or metastatic disease; AND
   C) Patient has tried one systemic chemotherapy regimen.
   Note: Examples of a systemic chemotherapy regimen contain one of more of the following products: cisplastin, doxorubicin, methotrexate, or ifosfamide.

6. **Soft Tissue Sarcoma.** Approve for 3 years if the patient meets the following criteria (A, B, and C):
   A) Patient is ≥ 18 years of age; AND
   B) Patient has advanced or metastatic disease; AND
   C) Patient has one of the following (i, ii, iii, or iv):
      i. Non-adipocytic sarcoma; OR
      ii. Pleomorphic rhabdomyosarcoma; OR
      iii. Angiosarcoma; OR
      iv. Solitary fibrous tumor.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Stivarga is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Stivarga® tablets [prescribing information]. Whippany, NJ: Bayer; December 2020.
2. The NCCN Drugs and Biologics Compendium. © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on February 4, 2022. Search term: regorafenib.
3. The NCCN Bone Cancer Clinical Practice Guidelines in Oncology (version 2.2022 – October 8, 2021). © 2021 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on February 4, 2022.
4. The NCCN Central Nervous System Cancers Clinical Practice Guidelines in Oncology (version 2.2021 – September 8, 2021). © 2021 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on February 4, 2022.
5. The NCCN Colon Cancer Clinical Practice Guidelines in Oncology (version 3.2021 – September 10, 2021). © 2021 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on February 4, 2022
6. The NCCN Rectal Cancer Clinical Practice Guidelines in Oncology (version 2.2021 – September 10, 2021). © 2021 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on February 4, 2022.
7. The NCCN Gastrointestinal Stromal Tumors Clinical Practice Guidelines in Oncology (version 1.2022 – January 21, 2022). © 2021 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on: February 7, 2021.
8. The NCCN Hepatobiliary Cancers Clinical Practice Guidelines in Oncology (version 5.2021 – September 21, 2021). © 2021 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on February 7, 2022.
9. The NCCN Soft Tissue Sarcoma Clinical Practice Guidelines in Oncology (version 3.2021 – January 26, 2022). © 2021 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on February 7, 2021.