

PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Sorafenib Prior Authorization Policy

- Nexavar[®] (sorafenib tablets – Bayer/Onyx, generic)

REVIEW DATE: 06/19/2024

OVERVIEW

Sorafenib, a kinase inhibitor, is indicated for the treatment of the following uses:¹

- **Differentiated thyroid carcinoma**, locally recurrent or metastatic, progressive disease that is refractory to radioactive iodine treatment.
- **Hepatocellular carcinoma** that is unresectable.
- **Renal cell carcinoma** that is advanced.

Guidelines

Sorafenib is discussed in the guidelines from the National Comprehensive Cancer Network (NCCN):²

- **Acute Myeloid Leukemia:** NCCN guidelines (version 3.2024 – May 17, 2024) recommend sorafenib + hypomethylating agents (azacitidine or decitabine) for *FLT3*-ITD positive disease for treatment induction or post-induction therapy for patients ≥ 60 years of age and for relapsed/refractory disease (category 2A).³ Single-agent sorafenib is recommended as maintenance therapy for patients who are post-allogeneic stem cell transplantation, in remission, and have a *FLT3*-ITD mutation (category 2A).
- **Bone Cancer:** NCCN guidelines (version 2.2024 – March 12, 2024) recommend sorafenib as a systemic therapy agent, “useful in certain circumstances”, for recurrent chordoma (category 2A).⁴ It also recommends sorafenib for osteosarcoma as a second-line therapy for relapsed/refractory or metastatic disease as a “preferred regimen” (category 2A) and as “other recommended regimens” in combination with everolimus (category 2B).
- **Gastrointestinal Stromal Tumor:** NCCN guidelines (version 1.2024 – March 8, 2024) recommend sorafenib (category 2A) as an additional option, “useful in certain circumstances”, after failure on approved therapies.⁵ The first-line preferred therapies are imatinib or Ayvakit[™] (avapritinib tablets; for patients with *PDGFRA* exon 18 mutation, including the *PDGFRA* D842V mutation); second-line therapy is sunitinib or Sprycel[®] (dasatinib tablets) [for patients with *PDGFRA* exon 18 mutation that are insensitive to imatinib (including the *PDGFRA* D842V mutation)]; third-line therapy is Stivarga[®] (regorafenib tablets); fourth-line therapy is Qinlock[®] (ripretinib tablets).
- **Hepatocellular Carcinoma:** NCCN guidelines (version 1.2024 – April 9, 2024) recommend sorafenib as a first-line systemic therapy option as “other recommended regimens” for Child-Pugh Class A (category 1) or Child Pugh Class B7 (category 2A) and as a subsequent-line therapy if disease progression for Child Pugh Class A or B7 (category 2A) for unresectable, inoperable, or metastatic hepatocellular carcinoma.⁶ The guidelines note that there is limited safety data available for Child-Pugh Class B or C patients, and the dosing is uncertain; this drug should be used with extreme caution in patients with elevated bilirubin levels. The impact of sorafenib on patients potentially eligible for transplant is unknown.
- **Kidney Cancer:** NCCN guidelines (version 4.2024 – May 30, 2024) no longer recommend sorafenib as a treatment option for kidney cancer.⁷ Approval condition left in policy due to FDA approved indication.

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- **Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Gene Fusions:** NCCN guidelines (version 1.2024 – December 21, 2023) recommend sorafenib for myeloid/lymphoid neoplasms with *FLT3* rearrangements (category 2A).⁸
- **Ovarian Cancer Including Fallopian Tube Cancer and Primary Peritoneal Cancer:** NCCN guidelines (version 2.2024 – May 13, 2024) recommend sorafenib + topotecan (category 2A) as “Other Recommended Regimen” option as recurrence therapy for platinum-resistant disease.⁹
- **Soft Tissue Sarcoma:** NCCN guidelines (version 1.2024 – April 26, 2024) recommend sorafenib as single-agent therapy under “useful in certain circumstances” for angiosarcoma (category 2A); sorafenib as a “preferred” single-agent regimen for desmoid tumors (aggressive fibromatosis) (category 1) and for solitary fibrous tumor (category 2A).¹⁰
- **Thyroid Carcinoma:** NCCN guidelines (version 2.2024 – March 12, 2024) for differentiated thyroid carcinoma recommend sorafenib as “other recommended regimens” for progressive and/or symptomatic disease for locally recurrent, advanced, and/or metastatic disease not amenable to radioactive iodine therapy (category 1).¹¹ Sorafenib can be considered for treatment of progressive or symptomatic medullary thyroid disease if clinical trials or preferred systemic therapy options are not available or appropriate, or if there is progression on preferred systemic therapy options.

POLICY STATEMENT

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

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

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

FDA-Approved Indications

1. **Hepatocellular Cancer.** Approve for 1 year if the patient meets BOTH of the following (A and B):
 - A) Patient is ≥ 18 years of age; AND
 - B) Patient has unresectable or metastatic disease.
2. **Renal Cell Cancer.** Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):
 - A) Patient is ≥ 18 years of age; AND
 - B) Patient has relapsed or advanced disease; AND
 - C) Patient has clear cell histology AND
 - D) Patient has tried at least one systemic therapy.
Note: Examples of systemic therapy include Inlyta (axitinib tablets), pazopanib, sunitinib, Cabometyx (cabozantinib tablets).
3. **Thyroid Carcinoma, Differentiated.** Approve for 1 year if the patient meets ALL of the following (A, B, and C):
 - A) Patient is ≥ 18 years of age; AND
 - B) Patient has differentiated thyroid carcinoma; AND
Note: Examples of differentiated thyroid carcinoma include papillary, follicular, and oncocytic carcinoma (formerly Hürthle cell carcinoma).
 - C) The disease is refractory to radioactive iodine therapy.

Other Uses with Supportive Evidence

4. **Acute Myeloid Leukemia.** Approve for 1 year if the patient meets ALL of the following (A, B, and C):
 - A) Patient is ≥ 18 years of age; AND
 - B) Patient has *FLT3*-ITD mutation-positive disease as detected by an approved test; AND
 - C) Patient meets ONE of the following (i or ii):
 - i. This medication is used in combination with azacitidine or decitabine; OR
 - ii. Patient has had an allogeneic stem cell transplant and is in remission.

5. **Bone Cancer.** Approve for 1 year if the patient meets BOTH of the following (A and B):
 - A) Patient is ≥ 18 years of age; AND
 - B) Patient meets ONE of the following (i or ii):
 - i. Patient has recurrent chordoma; OR
 - ii. Patient meets BOTH of the following (a and b):
 - a) Patient has osteosarcoma; AND
 - b) Patient has tried one systemic chemotherapy regimen.
Note: Examples of a systemic chemotherapy regimen contain one of more of the following products: cisplatin, doxorubicin, methotrexate, or ifosfamide.

6. **Gastrointestinal Stromal Tumor.** Approve for 1 year if the patient meets BOTH of the following (A and B):
 - A) Patient is ≥ 18 years of age; AND
 - B) Patient has previously tried ALL of the following (i, ii, iii, and iv):
 - i. One of imatinib or Ayvakit (avapritinib tablets); AND
 - ii. One of sunitinib or Sprycel (dasatinib tablets); AND
 - iii. Stivarga (regorafenib tablets); AND
 - iv. Qinlock (ripretinib tablets).

7. **Myeloid/Lymphoid Neoplasms with Eosinophilia.** Approve for 1 year if the patient meets BOTH of the following (A and B):
 - A) Patient is ≥ 18 years of age; AND
 - B) The tumor has an *FLT3* rearrangement.

8. **Ovarian, Fallopian Tube, Primary Peritoneal Cancer.** Approve for 1 year if the patient meets ALL of the following (A, B, and C):
 - A) Patient is ≥ 18 years of age; AND
 - B) Patient has platinum-resistant disease; AND
 - C) Sorafenib is used in combination with topotecan.

9. **Soft Tissue Sarcoma.** Approve for 1 year if the patient meets BOTH of the following (A and B):
 - A) Patient is ≥ 18 years of age; AND
 - B) Patient has ONE of the following diagnoses (i, ii, or iii):
 - i. Angiosarcoma; OR
 - ii. Desmoid tumors (aggressive fibromatosis); OR
 - iii. Solitary Fibrous Tumor/Hemangiopericytoma.

Thyroid Carcinoma, Medullary. Approve for 1 year if the patient meets BOTH of the following (A and B):

- A) Patient is ≥ 18 years of age; AND
- B) Patient has tried at least one systemic therapy.

Note: Examples of systemic therapy include: Caprelsa (vandetanib tablets), Cometriq (cabozantinib capsules), Retevmo (selpercatinib capsules), and Gavreto (pralsetinib capsules).

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Nexavar 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

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3. The NCCN Acute Myeloid Leukemia Clinical Practice Guidelines in Oncology (version 3.2024 – May 17, 2024). © 2024 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed June 17, 2024.
4. The NCCN Bone Cancer Clinical Practice Guidelines in Oncology (version 2.2024 – March 12, 2024). © 2024 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed June 17, 2024.
5. The NCCN Gastrointestinal Stromal Tumor (GIST) Clinical Practice Guidelines in Oncology (version 1.2024 – March 8, 2024). © 2024 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed June 17, 2024.
6. The NCCN Hepatocellular Carcinoma Clinical Practice Guidelines in Oncology (version 1.2024 – April 9, 2024). © 2024 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed June 17, 2024.
7. The NCCN Kidney Cancer Clinical Practice Guidelines in Oncology (version 4.2024 – May 30, 2024). © 2024 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed June 17, 2024.
8. The NCCN Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Gene Fusions Clinical Practice Guidelines in Oncology (version 1.2024 – December 21, 2023). © 2023 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed June 17, 2024.
9. The NCCN Ovarian Cancer Including Fallopian Tube Cancer and Primary Peritoneal Cancer Clinical Practice Guidelines in Oncology (version 2.2024 – May 13, 2024). © 2024 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed June 17, 2024.
10. The NCCN Soft Tissue Sarcoma Clinical Practice Guidelines in Oncology (version 1.2024 – April 26, 2024). © 2024 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed June 17, 2024.
11. The NCCN Thyroid Carcinoma Clinical Practice Guidelines in Oncology (version 2.2024 – March 12, 2024). © 2024 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed June 17, 2024.