

Generic Name: Sorafenib

Therapeutic Class or Brand Name: Nexavar

Applicable Drugs (if Therapeutic Class): N/A

Preferred: generic sorafenib

Non-preferred: N/A

Date of Origin: 2/1/2013

Date Last Reviewed / Revised: 11/18/2024

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through V are met)

- I. Documentation of one of the following diagnoses A through J AND must meet all criteria listed under the applicable diagnosis:

FDA-Approved Indication(s)

- A. Hepatocellular carcinoma (HCC).
 - i. Documentation of unresectable or metastatic hepatocellular carcinoma.
- B. Renal cell carcinoma (RCC)
 - i. Documentation of relapsed or advanced renal cell carcinoma.
 - ii. Documentation of clear cell histology.
 - iii. Documentation of trial and failure of at least 1 systemic therapy.
- C. Thyroid carcinoma, differentiated (DTC)
 - i. Documentation of differentiated thyroid carcinoma (examples include: papillary, follicular, and oncocytic.)
 - ii. Documentation of recurrent, unresectable, or metastatic disease.
 - iii. Documentation of disease refractory to radioactive iodine treatment.

Other Uses With Supportive Evidence

- D. Soft tissue sarcoma
 - i. Diagnosis of desmoid tumor (aggressive fibromatosis), angiosarcoma, or solitary fibrous tumor/hemangiopericytoma.
- E. Acute myeloid leukemia (AML)
 - i. Documentation of FLT3-ITD mutation
 - ii. Meets ONE of the following criteria (a or b):
 - a. Used in combination with azacitidine or decitabine
 - b. Post-allogenic stem cell transplant and in remission, with documented history of FLT3-ITD mutation

- F. Bone cancer
 - i. Diagnosis of osteosarcoma or recurrent chordoma
 - a. If osteosarcoma, must be relapsed/refractory or metastatic disease after documented trial of one systemic chemotherapy regimen such as cisplatin, doxorubicin, ifosfamide or methotrexate
- G. Gastrointestinal stromal tumors (GIST)
 - i. Documented trial and failure, intolerance, or contraindication to one of EACH line from a and b:
 - a. imatinib
 - b. sunitinib
- H. Medullary thyroid carcinoma (MTC)
 - i. Recurrent or persistent disease with distant metastases.
 - ii. Documentation of failure, contraindication, or intolerance to at least one prior systemic therapy.
- I. Myeloid/Lymphoid Neoplasms
 - i. Diagnosis of myeloid/lymphoid neoplasm with eosinophilia
 - ii. Documentation of FLT3 rearrangement
- J. Ovarian, Fallopian Tube, Primary Peritoneal Cancer
 - i. Documentation of persistent or recurrent epithelial ovarian cancer, fallopian tube cancer, or primary peritoneal cancer
 - ii. Documentation of platinum-resistant disease (examples: carboplatin or cisplatin)
 - iii. Used in combination with topotecan
- II. Minimum age requirement: 18 years old.
- III. Treatment must be prescribed by or in consultation with an oncologist or hematologist.
- IV. Request is for a medication with the appropriate FDA labeling, or its use is supported by current clinical practice guidelines.
- V. Refer to the plan document for the list of preferred products. If the requested agent is not listed as a preferred product, must have documented treatment failure or contraindication to the preferred product(s).

EXCLUSION CRITERIA

- Nexavar in combination with carboplatin and paclitaxel is contraindicated in patients with squamous cell lung cancer.

OTHER CRITERIA

- N/A

QUANTITY / DAYS SUPPLY RESTRICTIONS

- 120 tablets per 30 days.

APPROVAL LENGTH

- **Authorization:** 1 year.
- **Re-Authorization:** An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and does not show evidence of progressive disease.

APPENDIX

- N/A

REFERENCES

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https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/021923Orig1s026lbl.pdf.
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11. National Comprehensive Cancer Network (NCCN). Ovarian Cancer. Version 3.2024. Updated July 15, 2024. Accessed 10/4/2024. Available at: www.nccn.org/professionals/physician_gls/pdf/ovarian.pdf

DISCLAIMER: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.