Applicable Drugs: Nexavar (sorafenib)

Preferred: sorafenib (generic)

Non-preferred: N/A

Date of Origin: 2/1/2013

Date Last Reviewed / Revised: 10/16/2026

PRIOR AUTHORIZATION CRITERIA

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

I. Documentation of one of the following FDA-approved diagnoses A through C 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.
   ii. Sorafenib will be used as a single agent.

B. Renal cell carcinoma (RCC)
   iii. Documentation of relapsed or advanced renal cell carcinoma.
   iv. Documentation of clear cell histology.
   v. 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
   iv. Sorafenib will be used as a single agent.

Other Uses With Supportive Evidence

D. Acute myeloid leukemia (AML)
E. Bone cancer
F. Gastrointestinal stromal tumors (GIST)
G. Medullary thyroid carcinoma (MTC)
H. Myeloid/Lymphoid Neoplasms
I. Ovarian, Fallopian Tube, Primary Peritoneal Cancer
J. Soft tissue sarcoma

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 National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1 or 2A.

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

1. Nexavar. Prescribing information. Bayer Healthcare; 2023. Accessed October 15, 2026. https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/021923Orig1s026lbl.pdf
2. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Hepatocellular Carcinoma. Version 1.2025. Updated March 20, 2025. Accessed October 15, 2026. Available at: https://www.nccn.org/professionals/physician_gls/pdf/hcc.pdf.
3. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Kidney Cancer. Version 2.2027. Updated October 7, 2026. Accessed October 15, 2026. Available at: https://www.nccn.org/professionals/physician_gls/pdf/kidney.pdf.

4. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Thyroid Carcinoma. Version 2.2026. Updated June 2, 2026. Accessed October 15, 2026. Available at: https://www.nccn.org/professionals/physician_gls/pdf/thyroid.pdf.
5. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Soft Tissue Sarcoma. Version 5.2026. Updated July 23, 2026. Accessed October 15, 2026. Available at: www.nccn.org/professionals/physician_gls/pdf/sarcoma.pdf
6. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Acute Myeloid Leukemia. Version 5.2026 Updated July 15, 2026. Accessed October 15, 2026. Available at: www.nccn.org/professionals/physician_gls/pdf/aml/pdf
7. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Bone Cancer. Version 1.2027. Updated July 21, 2026. Accessed October 15, 2026. Available at: www.nccn.org/professionals/physician_gls/pdf/bone.pdf
8. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Gastrointestinal Stromal Tumors. Version 1.2025. Updated January 13, 2026. Accessed October 15, 2026. Available at: www.nccn.org/professionals/physician_gls/pdf/gist.pdf
9. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Gene Fusions. Version 2.2026. Updated August 5, 2026. Accessed October 15, 2026. Available at: www.nccn.org/professionals/physicians_gls/pdf/mlne.pdf
10. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Ovarian Cancer. Version 4.2026. Updated April 10, 2026. Accessed October 15, 2026. 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.