Reference number(s)
2027-A

Specialty Guideline Management sorafenib-Nexavar

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Nexavar	sorafenib

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indications[1,2]

Hepatocellular Carcinoma

Nexavar is indicated for the treatment of patients with unresectable hepatocellular carcinoma (HCC).

Renal Cell Carcinoma

Nexavar is indicated for the treatment of patients with advanced renal cell carcinoma (RCC).

Differentiated Thyroid Carcinoma

Nexavar is indicated for the treatment of patients with locally recurrent or metastatic, progressive, differentiated thyroid carcinoma (DTC) that is refractory to radioactive iodine treatment.

Compendial Uses[3-5]

- Hepatocellular carcinoma

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- Acute myeloid leukemia with FLT3-ITD mutation
- Bone cancer
    - Osteosarcoma
    - Chordoma
- Epithelial ovarian cancer, fallopian tube cancer, and primary peritoneal cancer
- Gastrointestinal stromal tumors (GIST)
- Medullary, papillary, oncocytic/Hürthle cell, or follicular thyroid carcinoma
- Myeloid/lymphoid or mixed lineage neoplasms with eosinophilia and FLT3 rearrangement in chronic phase or blast phase
- Soft tissue sarcoma subtypes
    - Angiosarcoma
    - Desmoid tumors (aggressive fibromatosis)
    - Solitary fibrous tumor
    - Leiomyosarcoma

All other indications are considered experimental/investigational and not medically necessary.

Documentation

Submission of the following information is necessary to initiate the prior authorization review:

- Documentation of laboratory report confirming FLT3-ITD mutation, where applicable.
- Documentation of laboratory report confirming KIT and PDGFRA mutation, where applicable.
- Documentation of laboratory report confirming FLT3 rearrangement, where applicable.

Coverage Criteria

Hepatocellular Carcinoma (HCC)[1-3]

Authorization of 12 months may be granted for treatment of HCC as a single agent.

Renal Cell Carcinoma (RCC)[1,2]

Authorization of 12 months may be granted for treatment of advanced RCC.

Acute Myeloid Leukemia (AML)[3,5]

Authorization of 12 months may be granted for treatment of AML with FLT3-ITD mutation when either of the following criteria are met:

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- The disease is relapsed/refractory and the requested medication will be used in combination with azacitidine or decitabine.
- The requested medication will be used for maintenance therapy after hematopoietic stem cell transplant (HSCT) as a single agent.

Bone Cancer[3]

Authorization of 12 months may be granted for treatment of bone cancer as a single agent for the following subtypes:

- Relapsed/refractory or metastatic osteosarcoma as second line therapy.
- Recurrent conventional chordoma (including chondroid).

Epithelial Ovarian Cancer/Fallopian Tube Cancer/Primary Peritoneal Cancer[3]

Authorization of 12 months may be granted for treatment of persistent or recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer if the disease is platinum-resistant and the requested medication will be used in combination with topotecan.

Gastrointestinal Stromal Tumor (GIST)[3]

Authorization of 12 months may be granted for treatment of residual, unresectable, tumor rupture, or recurrent/metastatic imatinib-sensitive KIT and PDGFRA mutant-positive (except PDGFRA exon 18 mutation positive) GIST as a single agent when the member has failed at least four FDA-approved therapies (e.g., imatinib, sunitinib, regorafenib, ripretinib).

Medullary Thyroid Carcinoma[3]

Authorization of 12 months may be granted for treatment of recurrent or metastatic medullary thyroid carcinoma as a single agent and either of the following criteria is met:

- Member has disease progression while on FDA approved systemic therapy options (e.g., vandetanib [Caprelsa], cabozantinib [Cometriq]).
- Member has an intolerance or contraindication to FDA approved systemic therapy options (e.g., vandetanib [Caprelsa], cabozantinib [Cometriq]).

Myeloid/Lymphoid Neoplasms with Eosinophilia[3]

Authorization of 12 months may be granted for treatment of myeloid and/or lymphoid neoplasms with eosinophilia and FLT3 rearrangement in the chronic phase or blast phase.

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Papillary, Oncocytic/Hürthle Cell, or Follicular Thyroid Carcinoma[1-3]

Authorization of 12 months may be granted for treatment of papillary, oncocytic/Hürthle cell, or follicular thyroid carcinoma as a single agent when both of the following criteria are met:

- The disease is locoregional, unresectable, progressive and/or symptomatic, or metastatic.
- Radioactive iodine (RAI) therapy is not indicated, is contraindicated, or has been unsuccessful.

Soft Tissue Sarcoma[3-5]

Authorization of 12 months may be granted for treatment for the following types of soft tissue sarcoma:

- Leiomyosarcoma
- Angiosarcoma, solitary fibrous tumor, or desmoid tumor/aggressive fibromatosis, as single agent therapy.

Continuation of Therapy

GIST[3]

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for treatment of GIST when there is no evidence of unacceptable toxicity while on the current regimen.

All Other Indications

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for all other indications in the coverage criteria section when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

References

1. Nexavar [package insert]. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc.; August 2023.
2. Sorafenib [package insert]. Morgantown, WV: Mylan Pharmaceuticals Inc.; March 2026.
3. The NCCN Drugs & Biologics Compendium® © 2026 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed May 11, 2026.
4. Santoro A, Comandone A, et al. Phase II prospective study with sorafenib in advanced soft tissue sarcomas after anthracycline-based therapy. Ann Oncol. 2013. 24 (4): 1093-8.
5. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com. Accessed May 11, 2026.

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