Clinical Policy: Sorafenib (Nexavar)

Reference Number: CP.PHAR.69
Effective Date: 07.01.11
Last Review Date: 05.26
Line of Business: Commercial, HIM/ICHRA, Medicaid Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Sorafenib (Nexavar®) is a kinase inhibitor.

FDA Approved Indication(s)

Nexavar (sorafenib) is indicated for the treatment of:

- Unresectable hepatocellular carcinoma (HCC);
- Advanced renal cell carcinoma (RCC);
- Locally recurrent or metastatic, progressive, differentiated thyroid carcinoma (DTC) that is refractory to radioactive iodine treatment.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that sorafenib and Nexavar are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Hepatocellular Carcinoma (must meet all)**:**

1. Diagnosis of HCC;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Prescribed as a single agent;
5. For Nexavar requests, member must use sorafenib, unless contraindicated or clinically significant adverse effects are experienced;
6. Request meets one of the following (a or b):*
   a. Dose does not exceed 800 mg per day;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration:
Medicaid/HIM/ICHRA – 12 months
Commercial – 12 months or duration of request, whichever is less

B. Renal Cell Carcinoma (must meet all)**:**

1. Diagnosis of advanced RCC;
2. Prescribed by or in consultation with an oncologist;

3. Age ≥ 18 years;
4. For Nexavar requests, member must use sorafenib, unless contraindicated or clinically significant adverse effects are experienced;
5. Request meets one of the following (a or b):*
   a. Dose does not exceed 800 mg per day;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

   **Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration:
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C. Differentiated Thyroid Carcinoma (must meet all)**:**

1. Diagnosis of DTC (includes papillary, follicular, oncocytic [formerly known as Hürthle cell] carcinoma);
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. For papillary or follicular carcinoma, disease is refractory to radioactive iodine treatment;
5. Disease has both of the following characteristics (a and b):
   a. Progressive or symptomatic;
   b. Unresectable, locally recurrent, persistent, or metastatic;
6. For Nexavar requests, member must use sorafenib, unless contraindicated or clinically significant adverse effects are experienced;
7. Request meets one of the following (a or b):*
   a. Dose does not exceed 800 mg per day;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

   **Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration:
Medicaid/HIM/ICHRA – 12 months
Commercial – 12 months or duration of request, whichever is less

D. Medullary Thyroid Carcinoma (off-label) (must meet all)**:**

1. Diagnosis of metastatic medullary thyroid carcinoma (MTC);
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Member meets one of the following (a or b):
   a. Disease progression on preferred systemic therapy (e.g., Caprelsa®, Cometriq®, Gavreto®, or Retevmo®), unless clinically significant adverse effects are experienced or contraindicated;
   b. Clinical trials are not available or appropriate;

   **Prior authorization may be required for Caprelsa and Cometriq*
5. For Nexavar requests, member must use sorafenib, unless contraindicated or clinically significant adverse effects are experienced;
6. Request meets one of the following (a or b):*
   a. Dose does not exceed 800 mg per day;

b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration:
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Commercial – 12 months or duration of request, whichever is less

E. Acute Myeloid Leukemia (off-label) (must meet all)**:**

1. Diagnosis of acute myeloid leukemia;
2. Prescribed by or in consultation with an oncologist or hematologist;
3. Age ≥ 18 years;
4. Disease is FLT3-ITD mutation-positive;
5. Prescribed in one of the following ways (a or b):
   a. In combination with azacitidine or decitabine for relapsed/refractory disease;
   b. As a single agent for maintenance therapy for member in remission post-allogeneic stem cell transplantation;
6. For Nexavar requests, member must use sorafenib, unless contraindicated or clinically significant adverse effects are experienced;
7. Request meets one of the following (a or b):*
   a. Dose does not exceed 800 mg per day;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration:
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Commercial – 12 months or duration of request, whichever is less

F. Bone Cancer (off-label) (must meet all)**:**

1. Diagnosis of one of the following bone cancers (a or b):
   a. Osteosarcoma, and sorafenib will be used for second-line therapy as a single agent or in combination with everolimus;*
      **Prior authorization may be required for everolimus*
   b. Chordoma, and sorafenib will be used as single agent therapy for treatment of recurrent disease;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. For Nexavar requests, member must use sorafenib, unless contraindicated or clinically significant adverse effects are experienced;
5. Request meets one of the following (a or b):*
   a. Dose does not exceed 800 mg per day;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration:
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G. Soft Tissue Sarcoma (off-label) (must meet all)**:**
1. Diagnosis of one of the following soft tissue sarcomas (a, b, c, or d):
   a. Angiosarcoma;
   b. Desmoid tumors (aggressive fibromatosis);
   c. Solitary fibrous tumor;
   d. Gastrointestinal stromal tumors (GIST);
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Prescribed as a single agent;
5. For GIST, all of the following (a, b, and c):
   a. Disease is gross residual (R2 resection), unresectable, tumor rupture, recurrent/progressive, or metastatic;
   b. Disease is imatinib-sensitive, and one of the following (i or ii):
      i. KIT mutant;
      ii. PDGFRA mutant (except PDGFRA exon 18 mutant GIST that is insensitive to imatinib);
   c. Member experienced disease progression on imatinib, sunitinib, Stivarga®, and Qinlock™;*

   **Prior authorization may be required for these agents*
6. For Nexavar requests, member must use sorafenib, unless contraindicated or clinically significant adverse effects are experienced;
7. Request meets one of the following (a or b):*
   a. Dose does not exceed 800 mg per day;
   b. Dose is supported by practice guidelines or peer-reviewed literature (*prescriber must submit supporting evidence*).

   **Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration:
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H. Ovarian Cancers (off-label) (must meet all)**:**
1. Diagnosis of one of the following (a - f):
   a. Epithelial ovarian, fallopian tube, or primary peritoneal cancer;
   b. Clear cell carcinoma of the ovary;
   c. Mucinous carcinoma of the ovary;
   d. Carcinosarcoma (malignant mixed Müllerian tumors);
   e. Low-grade serous carcinoma;
   f. Grade 1 endometrioid carcinoma;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Disease is platinum-resistant (i.e., cancer returns less than 6 months after finishing platinum-based chemotherapy);
5. Disease is persistent or recurrent;
6. Prescribed in combination with topotecan;
7. For Nexavar requests, member must use sorafenib, unless contraindicated or clinically significant adverse effects are experienced;

8. Request meets one of the following (a or b):*
   a. Dose does not exceed 800 mg per day;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

   **Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration:
Medicaid/HIM/ICHRA – 12 months
Commercial – 12 months or duration of request, whichever is less

I. Myeloid/Lymphoid Neoplasms (off-label) (must meet all)**:**

1. Diagnosis of lymphoid, myeloid, or mixed lineage neoplasms with all of the following (a, b, and c):
   a. Eosinophilia;
   b. FLT3 rearrangement;
   c. In blast or chronic phase;
2. Prescribed by or in consultation with an oncologist or hematologist;
3. Age ≥ 18 years;
4. For Nexavar requests, member must use sorafenib, unless contraindicated or clinically significant adverse effects are experienced;
5. Request meets one of the following (a or b):*
   a. Dose does not exceed 800 mg per day;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

   **Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration:
Medicaid/HIM/ICHRA - 12 months
Commercial - 12 months or duration of request, whichever is less

J. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace/ICHRA, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace/ICHRA, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace/ICHRA, and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. All Indications in Section I (must meet all)**:**

1. Currently receiving medication via Centene benefit or documentation supports that member is currently receiving Nexavar for a covered indication and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. For Nexavar requests, member must use sorafenib, unless contraindicated or clinically significant adverse effects are experienced;
4. If request is for a dose increase, request meets one of the following (a or b):*
   a. New dose does not exceed 800 mg per day;
   b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration:
Medicaid/HIM/ICHRA – 12 months
Commercial – 12 months or duration of request, whichever is less

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace/ICHRA, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace/ICHRA, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace/ICHRA, and CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace/ICHRA, and CP.PMN.53 for Medicaid, or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

DTC: differentiated thyroid carcinoma
FDA: Food and Drug Administration
HCC: hepatocellular carcinoma
MTC: medullary thyroid carcinoma
RCC: renal cell carcinoma

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Caprelsa® (vandetanib)	MTC: 300 mg PO QD	300 mg/day
Cometriq® (cabozantinib)	MTC: 140 mg PO QD	180 mg/day
imatinib (Gleevec®)	Soft Tissue Sarcoma, GIST: 400 mg PO QD	800 mg/day
sunitinib (Sutent®)	Soft Tissue Sarcoma, GIST: 37.5 to 50 mg PO QD	50 mg/day
Stivarga® (regorafenib)	Soft Tissue Sarcoma, GIST: 160 mg PO QD	160 mg/day
Qinlock™ (ripretinib)	GIST: 150 mg PO QD	150 mg/day

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s):
  - Known severe hypersensitivity to sorafenib or any other component of Nexavar
  - Nexavar use in combination with carboplatin and paclitaxel in patients with squamous cell lung cancer
- Boxed warning(s): none reported

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
HCC, RCC, DTC	400 mg PO BID	800 mg/day

VI. Product Availability

Tablet: 200 mg

VII. References

1. Nexavar Prescribing Information. Whippany, NJ: Bayer HealthCare Pharmaceuticals, Inc.; August 2023. Available at: https://labeling.bayerhealthcare.com/html/products/pi/Nexavar_PI.pdf. Accessed January 23, 2026.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at https://www.nccn.org/professionals/drug_compendium/content/. Accessed January 27, 2026.
3. National Comprehensive Cancer Network. Gastrointestinal Stromal Tumors Version 1.2026. Available at: https://www.nccn.org/professionals/physician_gls/pdf/gist.pdf. Accessed January 27, 2026.
4. National Comprehensive Cancer Network. Acute Myeloid Leukemia Version 3.2026. Available at: https://www.nccn.org/professionals/physician_gls/pdf/aml.pdf. Accessed January 27, 2026.
5. National Comprehensive Cancer Network. Bone Cancer Version 2.2026. Available at: https://www.nccn.org/professionals/physician_gls/pdf/bone.pdf. Accessed January 27, 2026.

6. National Comprehensive Cancer Network. Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Gene Fusion Version 1.2026. Available at: https://www.nccn.org/professionals/physician_gls/pdf/mlne.pdf. Accessed January 27, 2026.
7. National Comprehensive Cancer Network. Ovarian Cancer/Fallopian Tube Cancer/Primary Peritoneal Cancer Version 3.2025. Available at: https://www.nccn.org/professionals/physician_gls/pdf/ovarian.pdf. Accessed January 27, 2026.
8. National Comprehensive Cancer Network. Soft Tissue Sarcoma Version 1.2026. Available at: https://www.nccn.org/professionals/physician_gls/pdf/sarcoma.pdf. Accessed January 27, 2026.
9. National Comprehensive Cancer Network. Thyroid Carcinoma Version 1.2025. Available at: https://www.nccn.org/professionals/physician_gls/pdf/thyroid.pdf. Accessed January 27, 2026.
10. National Comprehensive Cancer Network. Hepatocellular Carcinoma Version 2.2025. Available at: https://www.nccn.org/professionals/physician_gls/pdf/hcc.pdf. Accessed January 27, 2026.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
2Q 2022 annual review: modified commercial approval duration from length of benefit to "12 months or duration of request, whichever is less"; added oral oncology generic redirection if available language per template; per NCCN for RCC added additional diagnosis options for relapsed or stage IV disease, for DTC added additional diagnosis options for unresectable or persistent disease, for AML removed requirement that disease is relapsed or refractory as Nexavar can be used for induction, for AML added additional option for use as a single agent for maintenance therapy for member in remission post-allogeneic stem cell transplantation, for soft tissue sarcoma clarified desmoid tumors requests should be used as single-agent therapy, for GIST added Sprycel as a possible prior therapy option, added off-label criteria set for lymphoid, myeloid or mixed lineage neoplasms; references reviewed and updated.	02.10.22	05.22
Template changes applied to other diagnoses/indications.	10.12.22	
2Q 2023 annual review: for generic redirection removed "if available" as generic is now available; per NCCN Compendium added additional ovarian cancer subtypes; references reviewed and updated.	01.06.23	05.23
2Q 2024 annual review: for DTC clarified reference to oncocytic (formerly known as Hürthle cell) carcinoma per NCCN; for MTC clarified disease progression on preferred systemic therapy and included Gavreto and Retevmo as additional examples; for acute myeloid leukemia added option for FLT3 mutation-positive disease and use for induction or consolidation per NCCN Compendium; for GIST added requirement for use as single-agent therapy and removed Sprycel	01.10.24	05.24

Reviews, Revisions, and Approvals	Date	P&T Approval Date
from the list of required prior therapies; references reviewed and updated.		
2Q 2025 annual review: revised policy/criteria section to also include generic sorafenib; revised the following per NCCN – for HCC, removed requirement for confirmation of Child-Pugh class A or B7 status and added requirement for use as a single agent; for RCC, removed qualifiers of "relapsed" and "stage IV"; for DTC, added coverage for symptomatic disease; for MTC, specified that disease must be metastatic; for acute myeloid leukemia, restricted combination use to relapsed/refractory disease and removed allowance for single agent use for induction/consolidation therapy; references reviewed and updated.	02.04.25	05.25
2Q 2026 annual review: for DTC, modified requirement for radioactive iodine-refractory disease to apply only to papillary and follicular carcinomas per NCCN; for GIST, added disease qualifiers along with requirement that disease is imatinib-sensitive KIT or PDGFRA mutant per NCCN; for Medicaid and HIM, extended initial approval duration from 6 to 12 months; references reviewed and updated. Added ICHRA line of business.	03.30.26	05.26

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to

applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members, and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.