Evolent Clinical Guideline 3206 for Nexavar™ (sorafenib)

Guideline Number:	Applicable Codes	
Evolent_CG_3206		
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Original Date:	**Last Revised Date:**	**Implementation Date:**
January 2012	November 2025	November 2025

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STATEMENT

Purpose

To define and describe the accepted indications for Nexavar (sorafenib) usage in the treatment of cancer, including FDA approved indications, and off-label indications.

Evolent is responsible for processing all medication requests from network ordering providers. Medications not authorized by Evolent may be deemed as not approvable and therefore not reimbursable.

The use of this drug must be supported by one of the following: FDA approved product labeling, CMS-approved compendia, National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO) clinical guidelines, or peer-reviewed literature that meets the requirements of the CMS Medicare Benefit Policy Manual Chapter 15.

INDICATIONS

Continuation requests for a not-approvable medication shall be exempt from this Evolent policy provided

- The member has not experienced disease progression on the requested medication AND
- The requested medication was used within the last year without a lapse of more than 30 days of having an active authorization AND
- Additional medication(s) are not being added to the continuation request.

Hepatocellular Carcinoma (HCC)

- Nexavar (sorafenib) use is supported as a single agent in members with Child-Pugh Class A or B unresectable HCC, in the subsequent line setting

CHILD-PUGH SCORE

Chemical and Biochemical Parameters	Scores (Points) for Increasing Abnormality		
	1	2	3
Encephalopathy (grade)[1]	None	1–2	3–4
Ascites	Absent	Slight	Moderate
Albumin (g/dL)	>3.5	2.8–3.5	<2.8
Prothrombin time[2] Seconds over control INR	 <4 <1.7	 4–6 1.7–2.3	 >6 >2.3
Bilirubin (mg/dL) • For primary biliary cirrhosis	<2 <4	2–3 4–10	>3 >10

Class A = 5–6 points; Class B = 7–9 points; Class C = 10–15 points.

Renal Cell Carcinoma (RCC)

- NOTE: Nexavar (sorafenib) is not supported by Evolent Policy as initial or subsequent treatment for recurrent/metastatic RCC. This policy position is based on the lack of Level 1 Evidence (randomized clinical trials and/or meta-analyses) to show superior outcomes with Nexavar (sorafenib) compared to Evolent

recommended alternatives agents/regimens, including but not limited to regimens at **Evolent Pathways**.

Thyroid Carcinoma

- Nexavar (sorafenib) may be used as a single agent in members with locally recurrent or metastatic, progressive, differentiated thyroid carcinoma that is refractory to radioactive iodine treatment

CONTRAINDICATIONS/WARNINGS

- Contraindications
  - Known severe hypersensitivity to sorafenib or any component of the formulation
  - Use in combination with carboplatin and paclitaxel in patients with squamous cell lung cancer

EXCLUSION CRITERIA

- Concurrent use with other tyrosine kinase inhibitors or chemotherapy.
- Disease progression while receiving Nexavar (sorafenib).
- Dosing exceeds single dose limit of Nexavar (sorafenib) 400 mg.
- Treatment with Nexavar (sorafenib) exceeds the maximum limit of Nexavar (sorafenib) 120 (200 mg) tablets a month.
- Investigational use of Nexavar (sorafenib) with an off-label indication that is not sufficient in evidence or is not generally accepted by the medical community. Sufficient evidence that is not supported by CMS recognized compendia or acceptable peer reviewed literature is defined as any of the following:
  - Whether the clinical characteristics of the patient and the cancer are adequately represented in the published evidence.
  - Whether the administered chemotherapy/biologic therapy/immune therapy/targeted therapy/other oncologic therapy regimen is adequately represented in the published evidence.
  - Whether the reported study outcomes represent clinically meaningful outcomes experienced by patients. Generally, the definitions of Clinically Meaningful outcomes are those recommended by ASCO, e.g., Hazard Ratio of less than 0.80 and the recommended survival benefit for OS and PFS should be at least 3 months.
  - Whether the experimental design, considering the drugs and conditions under investigation, is appropriate to address the investigative question. (For example, in some clinical studies, it may be unnecessary or not feasible to use randomization, double blind trials, placebos, or crossover).
  - That non-randomized clinical trials with a significant number of subjects may be a basis for supportive clinical evidence for determining accepted uses of drugs.
  - That case reports are generally considered uncontrolled and anecdotal

information and do not provide adequate supportive clinical evidence for determining accepted uses of drugs.

- That abstracts (including meeting abstracts) without the full article from the approved peer-reviewed journals lack supporting clinical evidence for determining accepted uses of drugs.

CODING AND STANDARDS

Codes

- J8999 - sorafenib

Applicable Lines of Business

☐	CHIP (Children's Health Insurance Program)
☒	Commercial
☒	Exchange/Marketplace
☒	Medicaid
☐	Medicare Advantage

POLICY HISTORY

Date	Summary
November 2025	• Converted to new Evolent guideline template • This guideline replaces UM ONC_1194 Nexavar (sorafenib) • Updated indication section • Added Child-Pugh Score table under HCC indication • Updated references
November 2024	• Updated NCH verbiage to Evolent

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Services Clinical Guideline Review Committee

Disclaimer

Evolent Clinical Guidelines do not constitute medical advice. Treating health care professionals are solely responsible for diagnosis, treatment, and medical advice. Evolent uses Clinical Guidelines in accordance with its contractual obligations to provide utilization management. Coverage for services varies for individual members according to the terms of their health care coverage or government program. Individual members' health care coverage may not utilize some Evolent Clinical Guidelines. Evolent clinical guidelines contain guidance that requires prior authorization and service limitations. A list of procedure codes, services or drugs may not be all inclusive and does not imply that a service or drug is a covered or non-covered service or drug. Evolent reserves the right to review and update this Clinical Guideline in its sole discretion. Notice of any changes shall be provided as required by applicable provider agreements and laws or regulations. Members should contact their Plan customer service representative for specific coverage information.

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