BlueCross BlueShield Arizona

An Independent Licensee of the Blue Cross Blue Shield Association

PHARMACY COVERAGE GUIDELINE

NEXAVAR® (sorafenib) oral
Sorafenib oral

This Pharmacy Coverage Guideline (PCG):
- Provides information about the reasons, basis, and information sources we use for coverage decisions
- Is not an opinion that a drug (collectively "Service") is clinically appropriate or inappropriate for a patient
- Is not a substitute for a provider's judgment (Provider and patient are responsible for all decisions about appropriateness of care)
- Is subject to all provisions e.g. (benefit coverage, limits, and exclusions) in the member's benefit plan; and
- Is subject to change as new information becomes available.

Scope
- This PCG applies to Commercial and/or Marketplace plans
- This PCG does not apply to the Federal Employee Program, Medicare Advantage, Medicaid or members of out-of-state Blue Cross and/or Blue Shield Plans

Instructions & Guidance
- To determine whether a member is eligible for the Service, read the entire PCG.
- This PCG is used for FDA approved indications including, but not limited to, a diagnosis and/or treatment with dosing, frequency, and duration.
- Use of a drug outside the FDA approved guidelines, refer to the appropriate Off-Label Use policy.
- The "Criteria" section outlines the factors and information we use to decide if the Service is medically necessary as defined in the Member's benefit plan.
- The "Description" section describes the Service.
- The "Definition" section defines certain words, terms or items within the policy and may include tables and charts.
- The "Resources" section lists the information and materials we considered in developing this PCG
- **We do not accept patient use of samples as evidence of an initial course of treatment, justification for continuation of therapy, or evidence of adequate trial and failure.**
- Information about medications that require prior authorization is available at www.azblue.com/pharmacy. You must fully complete the request form and provide chart notes, lab workup and any other supporting documentation. The prescribing provider must sign the form. Fax the form to BCBSAZ Pharmacy Management at (602) 864-3126 or email it to Pharmacyprecert@azblue.com.

Medical Necessity Requirements for NEXAVAR (sorafenib) and Sorafenib generic

Criteria for Initial Therapy:

Prescriber Qualifications
- Prescribed by an Oncologist, Gastroenterologist, or Nephrologist, or in consultation with one

Indication
- Unresectable hepatocellular carcinoma
- Advanced renal cell carcinoma
- Locally recurrent or metastatic, progressive differentiated thyroid carcinoma that is refractory to radioactive iodine treatment

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- Other oncologic direct treatment uses listed in the National Comprehensive Cancer Network (NCCN) Guidelines with Categories of Evidence and Consensus of 1 and 2A

Age Requirement
- 18 years or older

Baseline Clinical Evaluation
- Negative pregnancy test in a woman of childbearing potential
- Eastern Cooperative Oncology Group (ECOG) Performance Status of 0 to 1

Brand Specific Criteria
- **For brand Nexavar:** Failure (trial for at least three months duration), contraindication per United States Food and Drug Administration (FDA) label, intolerance, or is not a candidate for **generic sorafenib**. **Note**: Any failure, contraindication, or intolerance to the generic drugs should be reported to the FDA (see Definitions section)

Safety
- Not on dialysis
- Does not have severe hepatic impairment (Child Pugh Class C)
- No concomitant use with:
  - Strong CYP3A4 inducers (e.g., rifampin, rifabutin, phenobarbital, carbamazepine)
  - Medicinal products with known potential to prolong QT/QTc interval (e.g., amiodarone, quinidine, moxifloxacin, haloperidol, quetiapine, methadone)
  - Carboplatin and paclitaxel in patients with squamous cell lung cancer

Documentation Requirements
- A completed request form must be submitted including:
  - Chart notes
  - Lab results (pregnancy test, ECOG status)
  - Supporting clinical documentation

Initial Therapy Criteria Approval Duration
- 6 months OR end of plan year

Criteria for Continuation of Therapy (renewal therapy):
Note: Manufacturer assistance (e.g., coupons, samples, etc.) are not considered for continuation of therapy.

Prescriber Qualification
- Continues to be seen by an Oncologist, Gastroenterologist, or Nephrologist or is in consultation with one

Clinical Response
- No evidence of disease progression or unacceptable toxicity

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Adherence

- Adherence to the prescribed therapy regimen has been documented

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  - Carboplatin and paclitaxel in patients with squamous cell lung cancer
- If clinically appropriate, withhold, reduce dose, or permanently discontinue based on severity, recurrence, persistence, or duration of adverse reaction including:
  - Moderate or greater cardiac ischemia and/or infarction
  - Life threatening congestive heart failure
  - Moderate or greater bleeding requiring medical intervention
  - Severe or persistent or life threatening hypertension despite anti hypertensive therapy
  - Gastrointestinal perforation
  - Severe or greater hepatotoxicity or unexplained transaminase elevations
  - Any life threatening non hematologic toxicity
  - Third occurrence of severe moist desquamation, ulceration, blistering, or severe pain of hands or feet resulting in inability to work or perform daily activities
  - Fourth occurrence of moderate painful erythema and swelling of hands or feet and/or discomfort affecting normal activities
  - Severe or persistent cutaneous reactions, or suspected Stevens Johnson syndrome or toxic epidermal necrolysis

Documentation Requirements

- Chart notes
- Supporting clinical documentation with evidence of improvement in given indication
- Lab values that confirm safe use

Continuation Therapy Criteria Approval Duration

- 12 months OR end of plan year

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Criteria for Off-Label Use Requests:

Criteria for a request for non-FDA use or indication, treatment with dosing, frequency, or duration outside the FDA-approved dosing, frequency, and duration, refer to one of the following Pharmacy Coverage Guideline:

1. Off-Label Use of Non-Cancer Medications
2. Off-Label Use of Cancer Medications

Description:

Nexavar (sorafenib) and generic sorafenib are indicated for the treatment of unresectable hepatocellular carcinoma; advanced renal cell carcinoma; and locally recurrent or metastatic, progressive, differentiated thyroid carcinoma (DTC) refractory to radioactive iodine treatment.

Sorafenib is a kinase inhibitor that decreases tumor cell proliferation. It inhibits multiple intracellular and cell surface kinases that are thought to be involved in tumor cell signaling, angiogenesis and apoptosis.

Definitions:

U.S. Food and Drug Administration (FDA) MedWatch Forms for FDA Safety Reporting
MedWatch Forms for FDA Safety Reporting | FDA

Resources:

Nexavar (sorafenib) tab product information, revised by Bayer HealthCare Pharmaceuticals, Inc. 08-2023. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed November 10, 2025.

Sorafenib tab product information, revised by Mylan Pharmaceuticals Inc. 07-2024. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed January 29, 2026.

National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology (NCCN Guidelines®): Hepatocellular Carcinoma Version 2.2025 – Updated October 22, 2025. Available at https://www.nccn.org. Accessed January 29, 2026.

National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology (NCCN Guidelines®): Kidney Cancer Version 1.2026 – Updated July 24, 2025. Available at https://www.nccn.org. Accessed January 29, 2026.

National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology (NCCN Guidelines®): Thyroid Carcinoma Version 1.2025 – Updated March 27, 2025. Available at https://www.nccn.org. Accessed January 29, 2026.

Off Label Use of Cancer Medications: A.R.S. §§ 20-826(R) & (S). Subscription contracts; definitions.

Off Label Use of Cancer Medications: A.R.S. §§ 20-1057(V) & (W). Evidence of coverage by health care service organizations; renewability; definitions.

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