BlueCross BlueShield of Arizona
An Independent Licensee of the Blue Cross and Blue Shield Association

PHARMACY COVERAGE GUIDELINES	**ORIGINAL EFFECTIVE DATE: 3/17/16**
SECTION: DRUGS	**LAST REVIEW DATE: 3/15/18**
	LAST CRITERIA REVISION DATE: 3/15/18
	ARCHIVE DATE:

NEXAVAR® (sorafenib tosylate) oral tablet

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Pharmacy Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Pharmacy Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Pharmacy Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Pharmacy Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

This Pharmacy Coverage Guideline does not apply to FEP or other states' Blues Plans.

Information about medications that require precertification is available at www.azblue.com/pharmacy.

Some large (100+) benefit plan groups may customize certain benefits, including adding or deleting precertification requirements.

All applicable benefit plan provisions apply, e.g., waiting periods, limitations, exclusions, waivers and benefit maximums.

Precertification for medication(s) or product(s) indicated in this guideline requires completion of the request form in its entirety with the chart notes as documentation. All requested data must be provided. Once completed the form must be signed by the prescribing provider and faxed back to BCBSAZ Pharmacy Management at (602) 864-3126 or emailed to Pharmacyprecert@azblue.com. **Incomplete forms or forms without the chart notes will be returned.**

NEXAVAR® (sorafenib tosylate) oral tablet (cont.)

Description:

Nexavar (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.

Nexavar (sorafenib)

Medication class:
Antineoplastic - Kinase Inhibitors

FDA-approved indication(s):
- Unresectable hepatocellular carcinoma
- Advanced renal cell carcinoma
- Locally recurrent or metastatic, progressive, differentiated thyroid carcinoma refractory to radioactive iodine treatment

Recommended Dose:
- 400 mg (2 tablets) twice daily

Maximum dosage
- Not stated

Available Dosage Forms:
- Tablet: 200 mg

Warnings, Precautions, and other Clinical Information:
- Temporary or permanent discontinuation of Nexavar should be considered in patients who develop cardiac ischemia and/or infarction
- If any bleeding requires medical intervention, permanent discontinuation of Nexavar should be considered
- Severe or persistent hypertension despite use of anti-hypertensive therapy, consider temporary or permanent discontinuation of Nexavar
- Dermatologic toxicities may require interruption and/or decrease dose; permanently discontinue for severe or persistent reactions, or if Stevens-Johnson syndrome and toxic epidermal necrolysis is suspected
- Discontinue Nexavar for gastrointestinal perforation
- Avoid use in patients with congenital long QT syndrome
- Discontinue for unexplained transaminase elevations
- The pharmacokinetics of Nexavar have not been studied in patients with severe hepatic impairment (Child-Pugh Class C)
- The pharmacokinetics of Nexavar have not been studied in patients who are on dialysis
- Woman patient of child bearing potential should be warned against becoming pregnant
- Woman patient of child bearing potential should use effective contraception
- Woman patient who is breast feeding an infant or child should stop breast feeding
- Males patient with female partner of reproductive potential should use effective contraception
- Avoid use with strong CYP3A4 inducers
- The mean relative bioavailability of tablets of Nexavar is 38-49% compared to an oral solution

NEXAVAR® (sorafenib tosylate) oral tablet (cont.)

- The safety and effectiveness of Nexavar has not been established in patients with non-small cell lung cancer
- Use in combination with gemcitabine/cisplatin is not recommended in patients with squamous cell lung cancer

Criteria:

- **Criteria for initial therapy**: Nexavar (sorafenib) is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

  1. Prescriber is an Oncologist

  2. Individual is 18 years of age or older

  3. A confirmed diagnosis of **ONE** of the following:
     - Unresectable hepatocellular carcinoma (HCC)
     - Advanced renal cell carcinoma (RCC)
     - Locally recurrent or metastatic, progressive, differentiated thyroid carcinoma (DTC) refractory to radioactive iodine treatment

  4. **ALL** of the following baseline tests have been completed before initiation of treatment:
     - Pregnancy test in a woman of child bearing potential, unless is using effective contraception

  5. There are **NO** contraindications.
     - Contraindications include:
       - Individual with severe hypersensitivity to sorafenib or any other component of Nexavar
       - Nexavar in combination with carboplatin and paclitaxel in patients with squamous cell lung cancer

  Initial approval duration: 6 months

- **Criteria for continuation of coverage (renewal request):** Nexavar (sorafenib) is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

  1. Individual continues to be in consultation with an Oncologist

  2. Individual's condition has not worsened while on therapy
     - Worsening is defined as:

  3. Individual has been adherent with the medication

  4. Individual has not developed any contraindications or other significant level 4 adverse drug effects that may exclude continued use
     - Contraindications as listed in the criteria for initial therapy section

NEXAVAR® (sorafenib tosylate) oral tablet (cont.)

- Significant adverse effect such as:
  - Cardiac ischemia and/or infarction
  - Bleeding requires medical intervention
  - Severe or persistent hypertension despite use of anti-hypertensive therapy
  - Severe or persistent cutaneous reactions, or if Stevens-Johnson syndrome and toxic epidermal necrolysis is suspected
  - Gastrointestinal perforation
  - Hepatotoxicity or unexplained transaminase elevations

5. There are no significant interacting drugs

Renewal duration: 6 months

Resources:

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.

Nexavar. Package Insert. Revised by manufacturer 07-2015. Accessed 02-07-2017, 02-28-2018.

Nexavar. Package Insert. Revised by manufacturer 07-2015. Accessed 02-07-2017.

Nexavar. Package Insert. Revised by manufacturer 11-2013. Accessed 03-03-2016.

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Fax completed prior authorization request form to 602-864-3126 or email to pharmacyprecert@azblue.com.
Call 866-325-1794 to check the status of a request.
All requested data must be provided. **Incomplete forms or forms without the chart notes will be returned.**
Pharmacy Coverage Guidelines are available at www.azblue.com/pharmacy.

Pharmacy Prior Authorization Request Form

Do not copy for future use. Forms are updated frequently.
REQUIRED: Office notes, labs, and medical testing relevant to the request that show medical justification are required.

Member Information

Member Name (first & last):	Date of Birth:	Gender:	BCBSAZ ID#:
Address:	City:	State:	Zip Code:

Prescribing Provider Information

Provider Name (first & last):	Specialty:	NPI#:	DEA#:
Office Address:	City:	State:	Zip Code:
Office Contact:	Office Phone:	Office Fax:	

Dispensing Pharmacy Information

Pharmacy Name:	Pharmacy Phone:	Pharmacy Fax:

Requested Medication Information

Medication Name:	Strength:	Dosage Form:
Directions for Use:	Quantity: / Refills:	Duration of Therapy/Use:

☐ Check if requesting **brand** only ☐ Check if requesting **generic**

☐ Check if requesting continuation of therapy (prior authorization approved by BCBSAZ expired)

Turn-Around Time For Review

☐ Standard ☐ Urgent. Sign here: _____ ☐ Exigent (requires prescriber to include a written statement)

Clinical Information

1. **What is the diagnosis? Please specify below.**

   ICD-10 Code: _____ **Diagnosis Description:** _____

2. ☐ Yes ☐ No **Was this medication started on a recent hospital discharge or emergency room visit?**

3. ☐ Yes ☐ No **There is absence of ALL contraindications.**

4. **What medication(s) has the individual tried and failed for this diagnosis? Please specify below.**
Important note: Samples provided by the provider are not accepted as continuation of therapy or as an adequate trial and failure.

Medication Name, Strength, Frequency	Dates started and stopped or Approximate Duration	Describe response, reason for failure, or allergy

5. **Are there any supporting labs or test results? Please specify below.**

Date	Test	Value

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Pharmacy Prior Authorization Request Form

6. Is there any additional information the prescribing provider feels is important to this review? Please specify below.
For example, explain the negative impact on medical condition, safety issue, reason formulary agent is not suitable to a specific medical condition, expected adverse clinical outcome from use of formulary agent, or reason different dosage form or dose is needed.

Signature affirms that information given on this form is true and accurate and reflects office notes

Prescribing Provider's Signature: Date:

Please note: Some medications may require completion of a drug-specific request form.

Incomplete forms or forms without the chart notes will be returned.

Office notes, labs, and medical testing relevant to the request that show medical justification are required.