BlueCross BlueShield Arizona

An Independent Licensee of the Blue Cross Blue Shield Association

PHARMACY COVERAGE GUIDELINES
SECTION: DRUGS

ORIGINAL EFFECTIVE DATE: 3/17/2016
LAST REVIEW DATE: 2/18/2021
LAST CRITERIA REVISION DATE: 2/18/2021
ARCHIVE DATE:

NEXAVAR® (sorafenib) 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.**

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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 a physician specializing in the patient's diagnosis or is in consultation with an Oncologist, Gastroenterologist, or Nephrologist depending upon indication or use

  2. Individual is 18 years of age or older

  3. A confirmed diagnosis of **ONE** of the following:
     a. Advanced renal cell carcinoma (RCC)

     b. Unresectable hepatocellular carcinoma (HCC)

     c. Locally recurrent or metastatic, progressive differentiated thyroid carcinoma (DTC) that is refractory to radioactive iodine treatment

     d. Other request for a specific oncologic direct treatment use that is found and listed in the National Comprehensive Cancer Network (NCCN) Guidelines with Categories of Evidence and Consensus of 1 and 2A

  4. **ALL** of the following baseline tests have been completed before initiation of treatment:
     a. Negative pregnancy test in a woman of child bearing potential

  5. There are **NO** contraindications.
     a. 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 seen by a physician specializing in the patient's diagnosis or is in consultation with an Oncologist, Gastroenterologist, or Nephrologist depending upon indication or use

  2. Individual's condition has not worsened while on therapy
     a. Worsening is defined as:
        i. There is evidence of disease progression

  3. Individual has been adherent with the medication

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4. Individual has not developed any contraindications or other significant level 4 adverse drug effects that may exclude continued use
    a. Contraindications as listed in the criteria for initial therapy section
    b. Significant adverse effect such as:
        i. Cardiac ischemia and/or infarction
        ii. Bleeding requires medical intervention
        iii. Severe or persistent hypertension despite use of anti-hypertensive therapy
        iv. Severe or persistent cutaneous reactions, or if Stevens-Johnson syndrome and toxic epidermal necrolysis is suspected
        v. Gastrointestinal perforation
        vi. Hepatotoxicity or unexplained transaminase elevations

5. There are no significant interacting drugs

Renewal duration: 6 months

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.

Resources:

Nexavar (sorafenib) product information, revised by Bayer HealthCare Pharmaceuticals, Inc. 07-2020, at DailyMed http://dailymed.nlm.nih.gov. Accessed January 31, 2021.

Nexavar (sorafenib). National Comprehensive Cancer Network (NCCN). NCCN Drugs & Biologics Compendium. 2021; Available at: http://www.nccn.org. Accessed January 31, 2021.

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.