



Prior Authorization Approval Criteria
Department of Pharmacy Services

Generic Name: sorafenib

Brand Name: Nexavar

Medication Class: Multikinase inhibitor; oncology drug

FDA Approved Uses: Advanced renal cell carcinoma (RCC)
Unresectable Hepatocellular Carcinoma (HCC)

Available Dosage Forms: tablets; 200 mg

Usual Dose: 400mg twice a day without food.

Duration of Therapy: Until patient is no longer clinically benefiting from therapy or until unacceptable toxicity occurs.

Approximate monthly cost (based on AWP 2007): \$5,912.40/month

Criteria for Use: *(bullet points below are all inclusive unless otherwise noted)*

- Clinically diagnosed advanced RCC.
- Clinically diagnosed unresectable(HCC)

Criteria for Continuation of Therapy:

- Disease must not have progressed.
- Patient must have <25% increase in bi dimensional tumor measurements from baseline.

Cautions:

- Adverse reactions were diarrhea (43%), rash, hand-foot skin reaction (30%), and fatigue (37%), and hypertension (17%).

Contraindications:

- Known hypersensitivity to sorafenib or any other component of Nexavar.

Not Approved if:

- The above criteria are not met
- Patient has any contraindications to the use of Nexavar



Special Considerations:

- Effect on survival is still unclear.
- Indicated as monotherapy only.
- Management of suspected adverse drug reactions may require temporary interruption and/or dose reduction of Nexavar therapy. When dose reduction is necessary, the dose may be reduced to 400mg once daily. If additional dose reduction is required, Nexavar may be reduced to a single 400mg dose every other day.
- Nexavar will not be filled through retail pharmacies. It will be filled through a network of specialty pharmacy providers including Pharmacare.

P&T Approval: _____ Date: _____