

## Sorafenib

### DESCRIPTION

Sorafenib is a multi-kinase enzyme inhibitor that decreases tumor cell proliferation in vitro and inhibits tumor angiogenesis. The exact mechanism of the antineoplastic activity of sorafenib has not been fully elucidated. It appears to inhibit signal transduction pathways involving multiple intracellular and cell surface kinases in vitro.

An example of a preparation of sorafenib is Nexavar®.

### REFER TO DECISION SUPPORT TREE

### POLICY

- Sorafenib for the treatment of renal cell carcinoma is considered **medically necessary** if the medical appropriateness criteria are met. **(See Medical Appropriateness below.)**
- Sorafenib for the treatment of hepatocellular carcinoma is considered **medically necessary** if the medical appropriateness criteria are met. **(See Medical Appropriateness below.)**
- Sorafenib for the treatment of other conditions / diseases is considered **investigational**.

### MEDICAL APPROPRIATENESS

- Sorafenib is considered **medically appropriate** for the treatment of **ANY ONE** of the following:
  - Advanced renal cell carcinoma (i.e., unresectable and / or metastatic clear cell renal carcinoma)
  - Unresectable hepatocellular carcinoma

### APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

Tennessee State law requires coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is relative to life-threatening illnesses, such as cancer, AIDS, and coronary heart disease and recognized in one of the standard reference compendia (As defined in the statute: The United States Pharmacopoeia Drug Information, The American Medical Association Drug Evaluations, & The American Hospital Formulary Service Drug Information) or in the medical literature. This law is applicable to all fully insured members. The law is not applicable to self-funded accounts, but coverage for off-label uses may be provided based on the contractual agreement.

- The NCCN Drugs & Biologics Compendium recognizes the use of sorafenib for additional uses beyond the FDA-approved labeling in the treatment of the following conditions (Refer to the NCCN Drugs & Biologics Compendium or NCCN Clinical Practice Guidelines for detailed recommendations):
  - Kidney cancer
  - Soft Tissue Sarcoma of the following:
    - Gastrointestinal stromal tumors (GIST)
    - Soft tissue sarcoma of the extremity
    - Retroperitoneal/ Intra-abdominal
  - Thyroid carcinoma of the following:
    - Follicular carcinoma
    - Hürthle cell carcinoma
    - Medullary carcinoma
    - Papillary carcinoma



## ADDITIONAL INFORMATION

For appropriate dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., The American Hospital Formulary Service Drug Information).

Well-designed, randomized, controlled trials with long-term follow-up are not available to determine the benefits of sorafenib for the treatment of other conditions/diseases.

## SOURCES

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MICROMEDEX Healthcare Series. Drugdex Drug Evaluations. (2009). *Sorafenib*. Retrieved May 25, 2009 from MICROMEDEX Healthcare Series.

National Comprehensive Cancer Network. (2009). NCCN Drugs & Biologics Compendium™. *Sorafenib tosylate*. Retrieved May 25, 2009 from [http://www.nccn.org/professionals/drug\\_compendium/mainpage.aspx](http://www.nccn.org/professionals/drug_compendium/mainpage.aspx).

Two new drugs for renal cell carcinoma. (2007, February). *The Medical Letter on Drug and Therapeutics*, 49 (Issue 1255), 18-20.

U. S. Food and Drug Administration. (2007, November). Center for Drug Evaluation and Research. *Label and Approval History. Nexavar (sorafenib)*. Retrieved May 25, 2009 from [http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.Label\\_ApprovalHistory](http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.Label_ApprovalHistory).

**EFFECTIVE DATE**      12/12/2009

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of Tennessee**

## Pharmaceutical Decision Support Tree

### **Sorafenib (Nexavar®)**

1. Does the individual have a diagnosis of advanced renal cell carcinoma (i.e., unresectable and / or metastatic clear cell renal carcinoma)?

If yes, this satisfies medical necessity and medical appropriateness criteria

If no, go to question #2

2. Does the individual have a diagnosis of hepatocellular carcinoma and is the disease unresectable?

If yes, this satisfies medical necessity and medical appropriateness criteria

If no, this does not meet medical necessity and/or medical appropriateness criteria