

Specialty Pharmacy Program

Nexavar[®] (sorafenib)

DESCRIPTION

Nexavar is an oral antineoplastic agent that inhibits multiple tyrosine kinases that are involved in tumor growth and angiogenesis. Nexavar is indicated for the treatment of hepatocellular carcinoma and renal cell carcinoma.

APPROVAL DURATION

Approval duration: 1 year

APPROVAL CRITERIA

FDA-Approved Indication(s)

1. Treatment of patients with advanced renal cell carcinoma.
2. Treatment of patients with unresectable hepatocellular carcinoma.

Off-Label Indication(s)

Requests for off-label use of Nexavar will be reviewed and approved when sufficiently supported by evidence from major compendia, published peer-reviewed medical literature, nationally accepted practice guidelines, or expert consensus statements. The major compendia that are recognized include AHFS[®] Drug Information, Thomson Micromedex[®], National Comprehensive Cancer Network Drugs and Biologics Compendium[™], and Clinical Pharmacology.