Custom Criteria for
BlueCross Blue Shield of Rhode Island Commercial

NEXAVAR® (sorafenib)

GPI CODING:

215330604003**

DESCRIPTION:

Sorafenib is a multi-target kinase inhibitor that targets serine/threonine and receptor tyrosine kinases in both the tumor cell and tumor vasculature. Targeted kinases include intracellular kinases (CRAF, BRAF, and mutant BRAF) and cell surface kinases (KIT, FLT-3, RET, VEGFR-1, 2, and 3, and PDGFR-β). RAF kinase is an enzyme in the RAS pathway. Sorafenib inhibits the RAF kinase constituent of the mitogen-activated protein kinase (MAPK) signaling cascade. Inhibition of the MAPK signaling cascade results in reversal of aberrant cellular growth activity and decreased cellular proliferation. In addition, sorafenib specifically inhibits two VEGF receptors (VEGFR-2 and -3) which are key receptor kinases involved in angiogenesis. The anti-cancer activity of sorafenib appears to be cytostatic, requiring continued drug exposure for tumor growth inhibition.

APPROVAL DURATION:

Quantity limit: 4 tablets/day
Initial approvals and renewals: 12 months.

CRITERIA FOR NEXAVAR

I. Patient is ≥18 years of age **AND**
II. Patient should not have squamous cell lung cancer being treated with carboplatin and paclitaxel **AND**
III. Patient has one of the following diagnoses:
   A. Advanced renal cell carcinoma **OR**
   B. Unresectable hepatocellular carcinoma **OR**
   C. Off label uses for oncology drugs if considered medically acceptable in one or more of the following compendia (i.e., Micromedex DrugDex, AHFS, Clinical Pharmacology, and NCCN.) *A use is identified by a compendium as medically accepted if the:*
      i. Indication is a Category 1 or 2A in NCCN,
      ii. Indication is a Class I, Class IIa or Class IIb in DrugDex,
      iii. Narrative text in AHFS or Clinical Pharmacology is supportive; or
      iv. *The use is supported by clinical research in 2 or more peer-reviewed medical journals*

Authorization for continued use shall be reviewed at least every 12 months to confirm the following: patient has had a measurable response to therapy.