

Sorafenib (Nexavar®)

Criteria for Use

March 2020

VA Pharmacy Benefits Management Services, Medical Advisory Panel, and VISN Pharmacist Executives

*The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. **The clinician should utilize this guidance and interpret it in the clinical context of the individual patient. Individual cases that are outside the recommendations should be adjudicated at the local facility according to the policy and procedures of its P&T Committee and Pharmacy Services.***

The Product Information should be consulted for detailed prescribing information.

See the VA National PBM-MAP-VPE Monograph on this drug at www.pbm.va.gov or <http://vaww.pbm.va.gov> for further information.

Exclusion Criteria *If the answer to ANY item below is met, then the patient should NOT receive sorafenib.*

- Care not provided by a VA or VA purchased care (e.g. Community Care Network, Fee Basis) oncology provider
- Liver dysfunction categorized as Child-Pugh class C
- Renal dysfunction requiring hemodialysis
- Pregnancy
- Breastfeeding

Inclusion Criteria *One of the following must be met in order to meet criteria.*

- Other indication(s) – please provide evidence to support use.
- Unresectable or metastatic hepatocellular carcinoma (HCC)

The following criterion pertain to the HCC indication:

- ECOG performance status 0, 1 or 2
- Liver dysfunction categorized as Child-Pugh class A or B
- Adequate hematologic function – defined as hemoglobin \geq 8.5 g/dL, platelet count \geq 60 x 10⁹ /L
- Concomitant use of strong CYP3A4 inducers has been avoided OR if unavoidable, sorafenib dose adjustment considered
- For female patients of child-bearing potential: provided counseling on effective contraception and potential risks vs. benefits of treatment
- For male patients with female partners of child-bearing potential: provided counseling on effective contraception and potential risks vs. benefits of treatment