I. Medication Description

Nexavar (sorafenib) is an oral chemotherapy agent that targets both the intracellular RAF/MEK/ERK signaling pathway and the cell surface VEGF (vascular endothelial growth factor)-2/PDGFR (platelet-derived growth factor)-beta signaling cascade. It functions as a multi-kinase inhibitor targeting serine/threonine and receptor tyrosine kinases in both the tumor cells and vasculature. Nexavar works by inhibiting cancer cell proliferation by blocking angiogenesis (the formation of new blood vessels) in tumors and causing cell death.

II. Position Statement

Coverage is determined through a prior authorization process with supporting clinical documentation for every request.

III. Policy

Coverage for Nexavar® is provided for the following indications:

- Advanced Renal Cell Carcinoma (RCC)
  - Clear cell: as first line or subsequent therapy as a single agent for relapse or surgically unresectable stage IV disease
  - Non-clear cell: as first line therapy as a single agent for relapse or surgically unresectable stage IV disease
- Hepatocellular Cancer as a single agent AND
  - Patient is not a candidate for transplant with unresectable disease OR
  - Patient has extensive liver tumor burden or metastatic disease OR
  - Patient has local disease only, but is inoperable/unresectable given the patient’s performance status or comorbidities
- Angiosarcoma: When used as a single agent
- Desmoid Tumors for primary, recurrent, or progressive disease AND
  - As initial treatment for resectable disease OR
  - As adjuvant treatment for gross residual disease OR
  - As initial treatment for unresectable disease or where surgery is contraindicated
- Gastrointestinal Stromal Tumors (GIST) for progressive disease when the patient is no longer receiving benefit from imatinib, sunitinib, or regorafenib
- Thyroid Cancer for symptomatic radioiodine refractory disease AND
  - Distant metastatic disease OR
  - Unresectable recurrent or persistent locoregional disease OR
IV. Quantity Limitations

120 x 200 mg tablets per month (30 days) (all indications) unless titration has occurred due to CYP3A4 induction from concomitant drug therapy.

V. Coverage Duration

Coverage will be provided for 6 months and may be renewed.

VI. Coverage Renewal Criteria

Coverage can be renewed based upon the following criteria:

- Tumor response with stabilization of disease or decrease in size of tumor or tumor spread AND
- Absence of unacceptable toxicity from the drug

VII. Billing/Coding Information

Available as 200mg oral tablets.

VIII. Summary of Policy Changes

- 6/1/11: diagnoses of Angiosarcoma, GIST and Thyroid Cancer added; disease parameters for Renal Cell and Hepatocellular Cancer expanded.
- 6/15/12: no policy changes
- 6/15/13: addition of osteosarcoma as covered indication
- 6/15/14: disease parameters for thyroid cancer and desmoid tumors expanded
- 12/16/14: addition of regorafenib to GIST prior therapy list; addition of AML diagnosis for coverage
- 7/1/15: formulary distinctions made
- 12/15/15: no policy changes
- 9/15/16: policy updated to correspond with current NCCN treatment guidelines

IX. References

1. UpToDate Online, retrieved February 2011
3. Facts and Comparisons Online, retrieved February 2011

The Plan fully expects that only appropriate and medically necessary services will be rendered. The Plan reserves the right to conduct pre-payment and post-payment reviews to assess the medical appropriateness of the above-referenced therapies.

Drug therapy initiated with samples will not be considered as meeting medical necessity for coverage for non-preferred or prior authorized medications.

The preceding policy applies only to members for whom the above named pharmacy benefit medications are included on their covered formulary. Members with closed formulary benefits are subject to trying all appropriate formulary alternatives before a coverage exception for a non-formulary agent will be considered.

The preceding policy is a guideline to allow for coverage of the pertinent medication/product, and is not meant to serve as a clinical practice guideline.