Drugs Therapy Guidelines

**Nexavar® (sorafenib)**

<table>
<thead>
<tr>
<th>Medical Benefit</th>
<th>Applicable</th>
<th>Effective: 10/11/17</th>
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<tbody>
<tr>
<td>Pharmacy- Formulary 1</td>
<td>x</td>
<td>Next Review: 9/18</td>
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<tr>
<td>Pharmacy- Formulary 2</td>
<td>x</td>
<td>Date of Origin: 3/25/08</td>
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<td>Pharmacy- Formulary 4/AON</td>
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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 of Nexavar is available when the following criteria have been met:

- Member is at least 18 years of age **AND**
- The medication is prescribed by a hematologist/oncologist **AND**
- The requested use is supported by the National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines (NCCN Guidelines®) and/or NCCN Drugs & Biologics Compendium (NCCN Compendium®) with a recommendation of category level 1 or 2A.

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
- 10/11/17: coverage criteria updated to allow use as supported by current NCCN 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.

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 medication 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.