Clinical Policy: Sorafenib (Nexavar)
Reference Number: ERX.SPMN.37
Effective Date: 07/16
Last Review Date: 06/16

See Important Reminder at the end of this policy for important regulatory and legal information.

Policy/Criteria
It is the policy of health plans affiliated with Envolve Pharmacy Solutions® that sorafenib (Nexavar®) is medically necessary when one of the following criteria is met:

I. Initial Approval Criteria
   A. Hepatocellular Carcinoma (must meet all):
      1. Diagnosis hepatocellular carcinoma;
      2. Disease is unresectable;
      3. Prescribed dose of Nexavar does not exceed 800mg/day.

   Approval duration: 6 months

   B. Advanced Renal Cell Carcinoma (RCC) (must meet all):
      1. Diagnosis of renal cell carcinoma;
      2. Disease is advanced (relapse or for surgically unresectable stage IV disease);
      3. Prescribed dose of Nexavar does not exceed 800mg/day.

   Approval duration: 6 months

   C. Differentiated Thyroid Carcinoma (must meet all):
      1. Diagnosis of differentiated thyroid carcinoma;
      2. Disease is refractory to radioactive iodine treatment;
      3. Disease locally recurrent or metastatic, and progressive;
      4. Prescribed dose of Nexavar does not exceed 800mg/day.

   Approval duration: 6 months

D. Other diagnoses/indications: Refer to USS.SPMN.16 - Global Biopharm Policy.
   1. Additional Nexavar uses outlined in the NCCN compendium and which meet NCCN category 1, 2a, or 2b, are covered for the following indications per the ERX.SPMN.16 Global Biopharm Policy:
      a. Acute myeloid leukemia (AML);
      b. Bone cancer – osteosarcoma;
      c. Soft tissue sarcomas:
         i. Angiosarcoma;
         ii. Desmoid tumors (aggressive fibromatosis);
         iii. Gastrointestinal stromal tumors (GIST).
II. Continued Approval
   A. All Indications (must meet all):
      1. Currently receiving medication via health plan benefit or member has previously met all initial approval criteria.

      Approval duration: 6 months

   B. Other diagnoses/indications (must meet 1 or 2):
      1. Currently receiving medication via health plan benefit and documentation supports positive response to therapy; or
      2. Refer to ERX.SPMN.16 - Global Biopharm Policy.

Background
Description/Mechanism of Action:
Sorafenib is a kinase inhibitor that decreases tumor cell proliferation in vitro. Sorafenib was shown to inhibit multiple intracellular (c-CRAF, BRAF and mutant BRAF) and cell surface kinases (KIT, FLT- 3, RET, RET/PTC, VEGFR-1, VEGFR- 2, VEGFR- 3, and PDGFR-ß). Several of these kinases are thought to be involved in tumor cell signaling, angiogenesis and apoptosis.

Formulations:
Nexavar is available in 200 mg tablets for oral administration.

FDA Approved Indication(s):
Nexavar (sorafenib) is a kinase inhibitor/oral tablet indicated for the treatment of:
   • Unresectable hepatocellular carcinoma
   • Advanced renal cell carcinoma
   • Locally recurrent or metastatic, progressive, differentiated thyroid carcinoma refractory to radioactive iodine treatment

Appendices
Appendix A: Abbreviation Key
AML: acute myeloid leukemia
DTC: differentiated thyroid carcinoma
FDA: Food and Drug Administration
GIST: gastrointestinal stromal tumors
NCCN: National Comprehensive Cancer Network
RCC: renal cell carcinoma

Coding Implications
Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.
**HCPCS Codes**

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**Reviews, Revisions, and Approvals**

| Policy created. | 06/16 | 06/16 |

**References**


**Important Reminder**

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.

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