Clinical Policy: Sorafenib (Nexavar)
Reference Number: ERX.SPA.13
Effective Date: 07.01.16
Last Review Date: 05/17
Line of Business: Commercial [Prescription Drug Plan] Revision Log

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

**Description**
Sorafenib (Nexavar®) is a kinase inhibitor.

**FDA approved indication**
Nexavar is indicated:
- For the treatment of unresectable hepatocellular carcinoma
- For the treatment of advanced renal cell carcinoma
- For the treatment of locally recurrent or metastatic, progressive, differentiated thyroid carcinoma refractory to radioactive iodine treatment

**Policy/Criteria**
*Provider must submit documentation (including office chart notes and lab results) supporting that member has met all approval criteria*

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ that Nexavar is **medically necessary** when the following criteria are met:

**I. Initial Approval Criteria**

**A. Hepatocellular Carcinoma** (must meet all)**:**
1. Diagnosis of hepatocellular carcinoma (HCC);
2. Disease is unresectable;
3. Dose does not exceed 800 mg/day.

**Approval duration: 6 months**

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

**Approval duration: 6 months**

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

**Approval duration: 6 months**

**D. Acute Myeloid Leukemia** (off-label) (must meet all)**:**
1. Diagnosis of relapsed or refractory acute myeloid leukemia;
2. Disease is FLT3-ITD mutation-positive;
3. Nexavar will be used in combination with azacitidine or decitabine;
4. Member is unable to tolerate more aggressive regimens;

5. Documentation supports failure of or presence of clinically significant adverse effects or contraindication to an FDA-approved medication for the relevant diagnosis (provided that such agent is commercially available).

**Approval duration: 6 months**

**E. Bone Cancer** (off-label) (must meet all)**:**

1. Diagnosis of one of the following bone cancers (a or b):
   a. Osteosarcoma, and Nexavar will be used for second-line therapy as a single agent or in combination with everolimus;
   b. Chordoma, and Nexavar will be used as single agent therapy for treatment of recurrent disease;
2. Documentation supports failure of or presence of clinically significant adverse effects or contraindication to an FDA-approved medication for the relevant diagnosis (provided that such agent is commercially available).

**Approval duration: 6 months**

**F. Soft Tissue Sarcoma** (off-label) (must meet all)**:**

1. Diagnosis of one of the following soft tissue sarcomas (a, b, or c):
   a. Angiosarcoma, and Nexavar will be used as single agent therapy;
   b. Primary, recurrent, or progressive desmoid tumors (aggressive fibromatosis), and Nexavar will be used as initial or adjuvant treatment;
   c. Progressive gastrointestinal stromal tumors (GIST), and member is no longer receiving benefit from imatinib, sunitinib, or regorafenib;
2. Documentation supports failure of or presence of clinically significant adverse effects or contraindication to an FDA-approved medication for the relevant diagnosis (provided that such agent is commercially available).

**Approval duration: 6 months**

**G. Medullary Thyroid Carcinoma** (off-label) (must meet all)**:**

1. Diagnosis of medullary thyroid carcinoma;
2. Disease is progressive, or there are symptomatic distant metastases;
3. Member meets one of the following (a or b):
   a. Disease progression on vandetanib or cabozantinib, unless contraindicated or clinically significant adverse effects are experienced;
   b. Clinical trials are not available or appropriate;
4. Documentation supports failure of or presence of clinically significant adverse effects or contraindication to an FDA-approved medication for the relevant diagnosis (provided that such agent is commercially available).

**Approval duration: 6 months**

**H. Other diagnoses/indications**

1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized)

## II. Continued Therapy

**A. All Indications** (must meet all)**:**

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions or member has previously met initial approval criteria;
2. Documentation of positive response to therapy, including no disease progression;
3. For HCC, RCC, and DTC, if request is for a dose increase, new dose does not exceed 800 mg/day.

**Approval duration: 12 months**

**B. Other diagnoses/indications** (must meet 1 or 2)**:**

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.

**Approval duration: Duration of request or 12 months (whichever is less)**; or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized)

**III. Diagnoses/Indications for which coverage is NOT authorized:**

**A.** Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – ERX.PA.01 or evidence of coverage documents

**IV. Appendices/General Information**

*Appendix A: Abbreviation/Acronym Key*
DTC: differentiated thyroid carcinoma
FDA: Food and Drug Administration
HCC: hepatocellular carcinoma
RCC: renal cell carcinoma

**V. Dosage and Administration**

| Indication | Dosing Regimen | Maximum Dose |
|---|---|---|
| Hepatocellular carcinoma | 400 mg orally twice daily | 800 mg/day |
| Renal cell carcinoma | | |
| Thyroid carcinoma | | |

**VI. Product Availability**

Tablet: 200 mg

**VII. References**

1. Nexavar Prescribing Information. Whippany, NJ: Bayer HealthCare Pharmaceutical Inc.; November 2013. Available at http://www.nexavar-us.com. Accessed April 19, 2017.
2. Sorafenib. In: National Comprehensive Cancer Network Drug and Biologics Compendium. Available at www.NCCN.org. Accessed April 19, 2017.
3. Kidney cancer (Version 2.2016). In: National Comprehensive Cancer Network Guidelines. Available at NCCN.org. Accessed April 8, 2016.
4. Thyroid carcinoma (Version 2.2015), In: National Comprehensive Cancer Network Guidelines. Available at NCCN.org. Accessed April 19, 2016.
5. Hepatobiliary cancers (Version 1.2016), In: National Comprehensive Cancer Network Guidelines. Available at NCCN.org. Accessed April 20, 2016.

| Reviews, Revisions, and Approvals | Date | P&T Approval Date |
|---|---|---|
| Policy created | 05/16 | 06/16 |
| Increased continued approval duration from 6 months to 12 months. Split NCCN off-label uses into their own criteria sets per updated template. | 04/17 | 05/17 |
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**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.