Clinical Policy: Sorafenib (Nexavar)

Reference Number: PA.CP.PHAR.69
Effective Date: 01/18
Last Review Date: Revision Log

Description
The intent of the criteria is to ensure that patients follow selection elements established by Pennsylvania Health and Wellness® clinical policy for sorafenib (Nexavar®).

Policy/Criteria
It is the policy of health plans affiliated with Pennsylvania Health and Wellness® that Nexavar is **medically necessary** when one of the following criteria is met:

I. Initial Approval Criteria

A. Hepatocellular Carcinoma (must meet all):
1. Diagnosis of hepatocellular carcinoma;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Prescribed dose of Nexavar does not exceed 800 mg/day.

Approval duration: 6 months

B. Renal Cell Carcinoma (must meet all):
1. Diagnosis of renal cell carcinoma;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Prescribed dose of Nexavar does not exceed 800 mg/day.

Approval duration: 6 months

C. Differentiated Thyroid Carcinoma (must meet all)**:**
1. Diagnosis of DTC (includes papillary, follicular, Hürthle cell carcinoma);
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Disease is refractory to radioactive iodine treatment;
5. Disease is locally recurrent or metastatic, and progressive;
6. Dose does not exceed 800 mg/day.

Approval duration: 6 months

D. Medullary Thyroid Carcinoma (off-label) (must meet all)**:**
1. Diagnosis of medullary thyroid carcinoma (MTC);
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. 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;

**Prior authorization is (or may be) required*

5. Dose is supported by practice guidelines or peer-reviewed literature (*prescriber must submit supporting evidence*).

Approval duration: 6 months

E. Acute Myeloid Leukemia (off-label) (must meet all)**:**

1. Diagnosis of relapsed or refractory acute myeloid leukemia;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Disease is FLT3-ITD mutation-positive;
5. Prescribed in combination with azacitidine or decitabine;
6. Dose is supported by practice guidelines or peer-reviewed literature (*prescriber must submit supporting evidence*).

Approval duration: 6 months

F. 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;

   **Prior authorization is (or may be) required*
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Dose is supported by practice guidelines or peer-reviewed literature (*prescriber must submit supporting evidence*).

Approval duration: 6 months

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

1. Diagnosis of one of the following soft tissue sarcomas (a, b, c, or d):
   a. Angiosarcoma as single-agent therapy;
   b. Desmoid Tumors (aggressive fibromatosis);
   c. Solitary Fibrous Tumor/Hemangiopericytoma as single-agent therapy;
   d. Gastrointestinal stromal tumors (GIST) with disease progression after single-agent therapy with imatinib*, sunitinib*, or regorafenib*;

   **Prior authorization is (or may be) required*
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Dose is supported by practice guidelines or peer-reviewed literature (*prescriber must submit supporting evidence*).

Approval duration: 6 months

Approval duration: 6 months

II. Continued Approval

A. All Indications in Section I (must meet all)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies;
2. No disease progression or unacceptable toxicity.

Approval duration: 12 months

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

1. Currently receiving medication via Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies.

   Approval duration: Duration of request or 6 months (whichever is less); or

2. Refer to PA.CP.PHAR.57 - 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, mutant BRAF) and cell surface kinases (KIT, FLT- 3, RET, RET/PTC, VEGFR-1, VEGFR- 2, VEGFR- 3, PDGFR-ß). Several of these kinases are thought to be involved in tumor cell signaling, angiogenesis and apoptosis.

Formulations:
Nexavar: 200 mg tablets for oral administration.

FDA Approved Indications:
Nexavar (sorafenib) is a kinase inhibitor/oral tablet formulation indicated for the treatment of patients with:

- Unresectable hepatocellular carcinoma;
- Advanced renal cell carcinoma;
- Locally recurrent or metastatic, progressive, differentiated thyroid carcinoma that is refractory to radioactive iodine treatment.

Reviews, Revisions, and Approvals	Date	Approval Date
2Q 2018 annual review: Added age; added NCCN compendium use for solitary fibrous tumor/hemangiopericytoma; summarized NCCN and FDA approved uses for improved clarity; added specialist involvement in care; references reviewed and updated.	01.17.18	04.18

Reviews, Revisions, and Approvals	Date	Approval Date

References

1. Nexavar Prescribing Information. Whippany, NJ: Bayer HealthCare Pharmaceuticals, Inc.; July 2015. Available at http://labeling.bayerhealthcare.com/html/products/pi/Nexavar_PI.pdf. Accessed January 10, 2018.
2. Sorafenib. In: National Comprehensive Cancer network Drug and Biologics Compendium. Available at ncccn.org. Accessed January 10, 2018.Hepatobiliary cancers (Version 1.2017). In: National Comprehensive Cancer Network Guidelines. Available at nccn.org. Accessed January 10, 2018.
3. Kidney cancer (Version 2.2017). In: National Comprehensive Cancer Network Guidelines. Available at nccn.org. Accessed January 10, 2018.
4. Thyroid carcinoma (Version 1.2017). In: National Comprehensive Cancer Network Guidelines. Available at nccn.org. Accessed January 10, 2018.