

Clinical Pharmacy Program Guidelines for Nexavar

Program	Prior Authorization
Medication	Nexavar [®] (sorafenib tosylate)
Issue Date	9/2013
Pharmacy and Therapeutics Approval Date	7/2017
Effective Date	9/2017

1. Background:

Nexavar[®] (sorafenib tosylate) is a kinase inhibitor indicated for the treatment of advanced renal cell carcinoma; unresectable hepatocellular carcinoma; and locally recurrent or metastatic, progressive, differentiated thyroid carcinoma refractory to radioactive iodine treatment.¹ The NCCN (National Comprehensive Cancer Network) also recommends use of Nexavar for the treatment of medullary, follicular, Hürthle cell and papillary thyroid carcinomas, gastrointestinal stromal tumors (GIST) in patients no longer receiving benefit from Gleevec[®] (imatinib), Sutent[®] (sunitinib), or Stivarga[®] (regorafenib), soft tissue angiosarcoma, desmoid tumors (aggressive fibromatosis), acute myeloid leukemia, osteosarcoma, chordoma, dedifferentiated chondrosarcoma, high-grade undifferentiated pleomorphic sarcoma (UPS), renal cell carcinoma, and hepatocellular carcinoma.²

2. Coverage Criteria:

<p>A. <u>Renal Cell Carcinoma (RCC)</u></p> <p>1. <u>Initial Authorization</u></p> <p>a. Nexavar will be approved based on <u>both</u> of the following criteria:</p> <p style="padding-left: 40px;">(1) Diagnosis of renal cell carcinoma (RCC)</p> <p style="text-align: center;">-AND-</p> <p style="padding-left: 40px;">(2) <u>One</u> of the following:</p> <p style="padding-left: 80px;">(a) Disease has relapsed</p> <p style="text-align: center;">-OR-</p> <p style="padding-left: 40px;">(b) <u>Both</u> of the following:</p>

- i. Medically or surgically unresectable tumor
- ii. Diagnosis of Stage IV disease

Authorization will be issued for 12 months.

2. Reauthorization

- a. **Nexavar** will be approved based on the following criterion:

- (1) Patient does not show evidence of progressive disease while on Nexavar therapy

Authorization will be issued for 12 months.

B. Hepatocellular Carcinoma

1. Initial Authorization

- a. **Nexavar** will be approved based on **both** of the following criteria:

- (1) Diagnosis of hepatocellular carcinoma

-AND-

- (2) **One** of the following:

- (a) Patient has metastatic disease

-OR-

- (b) Patient has extensive liver tumor burden

-OR-

- (c) Patient is inoperable by performance status or comorbidity (local disease or local disease with minimal extrahepatic disease only)

-OR-

- (d) **Both** of the following:

- i. Patient is not a transplant candidate
- ii. Disease is unresectable

Authorization will be issued for 12 months.

2. Reauthorization

a. **Nexavar** will be approved based on the following criterion:

- (1) Patient does not show evidence of progressive disease while on Nexavar therapy

Authorization will be issued for 12 months.

C. Thyroid Cancer

1. Initial Authorization

a. **Nexavar** will be approved based on **one** of the following criteria:

(1) **All** of the following:

(a) Diagnosis of **one** of the following:

- i. Follicular carcinoma
- ii. Hürthle cell carcinoma
- iii. Papillary carcinoma

-AND-

(b) **One** of the following:

- i. Unresectable recurrent disease
- ii. Persistent locoregional disease
- iii. Metastatic disease

-AND-

(c) **One** of the following:

- i. Patient has symptomatic disease
- ii. Patient has progressive disease

-AND-

(d) Disease is refractory to radioactive iodine treatment

-OR-

(2) **All** of the following:

(a) Diagnosis of medullary thyroid carcinoma

-AND-

(b) **One** of the following:

- i. Disease is progressive
- ii. Disease is symptomatic with distant metastases

-AND-

(c) History of failure, contraindication, or intolerance to **one** of the following:

- i. Caprelsa (vandetanib)
- ii. Cometriq (cabozantinib)

Authorization will be issued for 12 months.

2. Reauthorization

a. **Nexavar** will be approved based on the following criterion:

- (1) Patient does not show evidence of progressive disease while on Nexavar therapy

Authorization will be issued for 12 months.

D. Soft Tissue Sarcoma (off-label)

1. Initial Authorization

a. **Nexavar** will be approved based on **one** of the following criteria:

- (1) Diagnosis of angiosarcoma

-OR-

- (2) Diagnosis desmoid tumors / aggressive fibromatosis

-OR-

(3) **Both** of the following:

(a) Diagnosis of progressive gastrointestinal stromal tumors (GIST)

-AND-

(b) History of failure, contraindication, or intolerance to **one** of the following:

- i. Gleevec (imatinib)
- ii. Sutent (sunitinib)
- iii. Stivarga (regorafenib)

Authorization will be issued for 12 months.

2. Reauthorization

a. **Nexavar** will be approved based on the following criterion:

- (1) Patient does not show evidence of progressive disease while on Nexavar therapy

Authorization will be issued for 12 months.

E. Bone Cancer (off-label)

1. Initial Authorization

a. **Nexavar** will be approved based on the following criteria:

(1) **Both** of the following:

(a) Diagnosis of chordoma

-AND-

(b) Disease is recurrent

-OR-

(2) **Both** of the following:

(a) One of the following

- i. Diagnosis of osteosarcoma
- ii. Diagnosis of dedifferentiated chondrosarcoma
- ii. Diagnosis of high-grade undifferentiated pleomorphic sarcoma

(UPS)

-AND-

(b) **Not** used as first-line therapy

Authorization will be issued for 12 months.

2. Reauthorization

a. **Nexavar** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Nexavar therapy

Authorization will be issued for 12 months.

F. Acute Myeloid Leukemia (off-label)

1. Initial Authorization

a. **Nexavar** will be approved based on **all** of the following criteria:

(1) Diagnosis of acute myeloid leukemia (AML)

-AND-

(2) Patient has FLT3-ITD mutation-positive disease

-AND-

(3) **One** of the following:

(a) Patient has relapsed disease

(b) Patient has refractory disease

-AND-

(4) Used in combination with **one** of the following:

(a) Vidaza (azacitidine)

(b) Dacogen (decitabine)

-AND-

(5) Patient is unable to tolerate more aggressive treatment regimens

Authorization will be issued for 12 months.

2. Reauthorization

a. Nexavar will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Nexavar therapy

Authorization will be issued for 12 months.

3. References:

1. Nexavar [package insert]. Wayne, NJ: Bayer HealthCare Pharmaceuticals Inc.; July 2015.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at www.nccn.org. Accessed June 6, 2017.

Program	Prior Authorization –Nexavar (sorafenib tosylate)
Change Control	
Date	Change
9/19/2013	New guideline.
3/20/2014	<p>Updated guideline to reflect new indication for the treatment of patients with locally recurrent or metastatic, progressive, differentiated thyroid carcinoma (DTC) that is refractory to radioactive iodine treatment.</p> <p>Endnote added to further define and clarify “differentiated thyroid carcinoma”. Differentiated thyroid carcinoma includes papillary carcinoma, follicular carcinoma, Hurthle cell carcinoma, and poorly differentiated carcinoma.</p> <p>References updated to reflect new prescribing information, updated NCCN guidelines. Reference for a clinical study for Nexavar for thyroid carcinoma also added.</p>
12/2015	<p>For hepatocellular carcinoma (HCC), updated criteria to mirror the covered uses listed in the NCCN compendium:</p> <ul style="list-style-type: none"> • Patients with the following disease conditions may now be approved for coverage: patients who have metastatic disease, patients who have extensive liver tumor burden, and patients

	<p>who are inoperable by performance status or comorbidity (local disease or local disease with minimal extrahepatic disease only).</p> <ul style="list-style-type: none"> • In addition, criteria will now require that patients with unresectable disease are also non-transplant candidates <p>For thyroid carcinoma:</p> <ul style="list-style-type: none"> • Updated criteria to clarify and specify the diagnoses that fall under differentiated thyroid carcinoma (DTC). Guideline will now require one of the following specific diagnoses: follicular carcinoma, Hurthle cell carcinoma, or papillary carcinoma. In addition, criteria will now allow approval if patient has either a symptomatic or progressive disease, per NCCN guidelines. • Corrected previous typographical error to state radioactive “iodine” treatment, instead of “iodide.” • Added off-label coverage criteria for patients with medullary thyroid carcinoma (MTC), per NCCN compendium. Criteria will require all of the following: diagnosis of disseminated MTC, patient has symptomatic disease, trial/failure of Caprelsa (vandetanib) or Cometriq (cabozantinib), and prescribed by an oncologist. • Changed the length of authorization from 12 months to 6 months
7/2016	Updated clinical criteria to align with Employer Individual notification policy and updated policy to new template
7/2017	Updated background and criteria for the following bone cancers; chordoma, dedifferentiated chondrosarcoma, and high-grade undifferentiated pleomorphic sarcoma (UPS) per NCCN guidelines. Updated references.