UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Nexavar

Program	Prior Authorization
Medication	Nexavar® (sorafenib tosylate)
Markets in Scope	Arizona, Colorado, Hawaii, Maryland, New Jersey, New York, New York EPP, , Pennsylvania- CHIP, Rhode Island, California, Nevada, South Carolina
Issue Date	9/2013
Pharmacy and Therapeutics Approval Date	9/2020
Effective Date	11/2020

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), solitary fibrous tumor/hemangioperyctoma acute myeloid leukemia, osteosarcoma, chordoma, dedifferentiated chondrosarcoma, high-grade undifferentiated pleomorphic sarcoma (UPS), renal cell carcinoma, hepatocellular carcinoma, and for platinum-resistant ovarian cancer.[2]

2. Coverage Criteria:

A. <u>Renal Cell Carcinoma (RCC)</u>

1. <u>Initial Authorization</u>

a. **Nexavar** will be approved based on **<u>both</u>** of the following criteria:

(1) Diagnosis of renal cell carcinoma (RCC)

-AND-

(2) **<u>One</u>** of the following:

(a) Disease has relapsed

-OR-

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

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

1. Initial Authorization

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

(1) Diagnosis of angiosarcoma

-OR-

(2) Diagnosis of 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)

-OR-

(4) Diagnosis of solitary fibrous tumor/hemangiopericytoma

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

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

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.

G. Ovarian Cancer

1. Initial Authorization

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

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

(a) Ovarian cancer
(b) Fallopian tube cancer
(c) Primary peritoneal cancer

-AND-

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

(a) Patient has persistent disease
(b) Patient has recurrent disease

-AND-

(3) Disease is platinum-resistant

-AND-

(4) Used in combination with topotecan

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.

H. NCCN Recommended Regimens

1. Initial Authorization

a. **Nexavar** will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium.

Authorization will be issued for 12 months.

2. Reauthorization

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

(1) Documentation of positive clinical response to Nexavar therapy

Authorization will be issued for 12 months.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place**.**

4. References:

1. Nexavar [package insert]. Wayne, NJ: Bayer HealthCare Pharmaceuticals Inc.;July 2020.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at www.nccn.org . Accessed August 6,2020.

Program	Prior Authorization –Nexavar (sorafenib tosylate)
Change Control	
Date	Change
9/19/2013	New guideline.
3/20/2014	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. 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. References updated to reflect new prescribing information, updated NCCN guidelines. Reference for a clinical study for Nexavar for thyroid carcinoma also added.
12/2015	For hepatocellular carcinoma (HCC), updated criteria to mirror the covered uses listed in the NCCN compendium: • 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 who are inoperable by performance status or comorbidity (local disease or local disease with minimal extrahepatic disease only). • In addition, criteria will now require that patients with unresectable disease are also non-transplant candidates For thyroid carcinoma: • 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 chondorosarcoma, and high-grade undifferentiated pleomorphic sarcoma (UPS) per NCCN guidelines. Updated references.
7/2018	Updated background and added criteria for solitary fibrous tumor/hemangiopericytoma. Added NCCN recommended regimen criteria. Updated references.
9/2019	Updated background and added criteria for platinum-resistant ovarian cancer. Updated references.
9/2020	Annual review with no changes to clinical coverage criteria. Updated references. Added Additional Clinical Rules section.