UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 1067-13
Program	Prior Authorization/Notification
Medication	Nexavar® (sorafenib tosylate)
P&T Approval Date	8/2008, 6/2009, 6/2010, 9/2010, 12/2010, 7/2011, 8/2012, 7/2013, 8/2014, 8/2015, 8/2016, 7/2017, 7/2018, 9/2019, 9/2020, 9/2021, 9/2022, 9/2023, 9/2024
Effective Date	12/1/2024

1. Background:

Nexavar® (sorafenib tosylate) is a kinase inhibitor indicated for the treatment of unresectable hepatocellular carcinoma, advanced renal cell carcinoma and locally recurrent or metastatic, progressive, differentiated thyroid carcinoma refractory to radioactive iodine treatment.

The National Comprehensive Cancer Network also recommends the use of Nexavar for the treatment of gastrointestinal stromal tumor (GIST), chordoma, osteosarcoma, acute myeloid leukemia (AML), soft tissue sarcoma, salivary gland tumors, ovarian/fallopian tube cancer/primary peritoneal cancer, and myeloid/lymphoid neoplasms with tyrosine kinase gene fusions.

Coverage Information:
Members will be required to meet the criteria below for coverage. For members under the age of 19 years, the prescription will automatically process without a coverage review.

Some states mandate benefit coverage for off-label use of medications for some diagnoses or under some circumstances. Some states also mandate usage of other Compendium references. Where such mandates apply, they supersede language in the benefit document or in the notification criteria.

2. Coverage Criteria[a]:

A. Patients less than 19 years of age

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

   a. Patient is less than 19 years of age

   Authorization will be issued for 12 months.

B. Renal Cell Carcinoma (RCC)

1. **Initial Authorization**

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

      (1) Diagnosis of renal cell carcinoma (RCC)

-AND-

(2) **One** 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.

C. 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.

D. 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. Oncocytic 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.

E. 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 (regorafenig)
iv. Qinlock (ripretinib)

-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.

F. 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.

G. 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.

H. 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.

I. Salivary Gland Tumor

1. **Initial Authorization**

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

(1) Diagnosis of salivary gland tumor

-AND-

(2) Disease is **one** of the following:

(a) Recurrent and unresectable
(b) Metastatic

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.

J. Myeloid/Lymphoid Neoplasms

1. **Initial Authorization**

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

(1) Diagnosis of myeloid/lymphoid neoplasm with eosinophilia and FLT3 rearrangement

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.

K. NCCN Recommended Regimens

The drug has been recognized for treatment of the cancer indication by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B.

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

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 limit may be in place.

4. References:

1. Nexavar [package insert]. Wayne, NJ: Bayer HealthCare Pharmaceuticals Inc.; August 2023.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at www.nccn.org . Accessed July 28, 2024.

Program	Prior Authorization/Notification - Nexavar (sorafenib tosylate)
Change Control	
8/2014	Annual review with changes to Coverage Criteria for hepatocellular carcinoma, GIST and Thyroid Cancer. Updated formatting, Background and References.
9/2014	Administrative change - Tried/Failed exemption for State of New Jersey removed.
8/2015	Annual review. Updated thyroid cancer and osteosarcoma criteria. Moved GIST criteria under soft tissue sarcoma. Added AML criteria. Increased authorization and reauthorization from 6 months to 12 months for all indications. Updated background and references.
7/2016	Annual review. Revised criteria for renal cell cancer. Updated references.
7/2017	Annual review. 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	Annual review. Updated background and added criteria for solitary fibrous tumor/hemangiopericytoma. Updated references.
9/2019	Annual review. Updated background and added criteria for platinum-resistant ovarian cancer. Updated references. Added general NCCN recommended review criteria.
9/2020	Annual review with no changes to clinical coverage criteria. Updated references.
9/2021	Annual review with no changes to coverage criteria. Updated references.
9/2022	Annual review. Added criteria for salivary gland tumors and myeloid/lymphoid neoplasms. Added state mandate disclaimer and updated references.
9/2023	Replaced Hürthle cell with Oncocytic within Thyroid Cancer coverage criteria. Added Qinlock to NCCN recommended first-line therapies for

	GIST. Updated background and references.
9/2024	Annual review with no changes. Updated references.