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Section:	Prescription Drugs	**Effective Date:**	April 1, 2025
Subsection:	Antineoplastic Agents	**Original Policy Date:**	October 25, 2015
Subject:	Nexavar	**Page:**	1 of 5

Last Review Date: March 7, 2025

Nexavar

Description

Nexavar (sorafenib)

Background

Nexavar (sorafenib) is an anticancer medicine used to treat certain types of cancer including hepatocellular carcinoma (a type of liver cancer) when it cannot be treated with surgery; renal cell carcinoma (a type of kidney cancer); and differentiated thyroid carcinoma (a type of thyroid cancer) that can no longer be treated with radioactive iodine and is progressing. Nexavar is a kinase inhibitor that decreases tumor cell growth. Nexavar works by inhibiting multiple proteins in cancer cells, limiting cancer cell growth and division (1).

Regulatory Status

FDA-approved indications: Nexavar is a kinase inhibitor indicated for the treatment of (1):

1. Unresectable hepatocellular carcinoma
2. Advanced renal cell carcinoma
3. Locally recurrent or metastatic, progressive, differentiated thyroid carcinoma refractory to radioactive iodine treatment

Off-Label Uses:
Nexavar can be used to treat osteosarcoma, angiosarcoma, desmoid tumors / aggressive fibromatosis, gastrointestinal stromal tumor (GIST) in patients who have been prior therapy with imatinib, sunitinib or regorafenib. Nexavar can also be used to treat thyroid carcinoma in patients who are metastatic or not a candidate for surgery, and cancer can no longer be treated with radioactive iodine (2).

Nexavar is contraindicated in combination with carboplatin and paclitaxel is contraindicated in patients with squamous cell lung cancer (1).

Temporary or permanent discontinuation of Nexavar should be considered in patients who develop cardiac ischemia and/or infarction. Nexavar can also prolong the QT/QTc interval. QT/QTc interval prolongation increases the risk for ventricular arrhythmias. Avoid Nexavar in patients with congenital long QT syndrome. Monitor electrolytes and electrocardiograms in patients with congestive heart failure, bradyarrhythmias, drugs known to prolong the QT interval, including Class Ia and III antiarrhythmics (1).

Nexavar can induce hepatitis which is characterized by a hepatocellular pattern of liver damage with significant increases of transaminases which may result in hepatic failure. Increases in bilirubin and INR may also occur. Monitor liver function tests regularly (1).

The safety and effectiveness of Nexavar in pediatric patients 18 years of age or less have not been studied (1).

Related policies
Ayvakit, Cabometyx, Fotivda, Inlyta, Lenvima, Qinlock, Stivarga, Sutent, Votrient

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Nexavar may be considered **medically necessary** if the conditions indicated below are met.

Nexavar may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnoses

Patients must have **ONE** of the following:

1. Advanced renal cell carcinoma (RCC)

2. Unresectable hepatocellular carcinoma (HCC)

3. Differentiated thyroid carcinoma (DTC)
    a. Locally recurrent or metastatic
    b. Refractory to radioactive iodine treatment

4. Osteosarcoma

5. Angiosarcoma

6. Desmoid Tumors / Aggressive Fibromatosis

7. Gastrointestinal Stromal Tumor (GIST)
    a. Prior therapy with imatinib, sunitinib or regorafenib

AND ALL of the following:

1. Absence of significant or unstable cardiac disease
2. Monitor electrolytes and electrocardiograms on regular basis

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnoses

Patients must have **ONE** of the following:

1. Advanced renal cell carcinoma (RCC)
2. Unresectable hepatocellular carcinoma (HCC)
3. Differentiated Thyroid carcinoma (DTC)
4. Osteosarcoma
5. Angiosarcoma
6. Desmoid Tumors / Aggressive Fibromatosis
7. Gastrointestinal Stromal Tumor (GIST)

AND ALL of the following:

1. Absence of significant or unstable cardiac disease

2. Monitor electrolytes and electrocardiograms on regular basis
3. **NO** disease progression or unacceptable toxicity

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity	200 mg tablets	360 tablets per 90 days
Duration	12 months	

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Nexavar (sorafenib) is a kinase inhibitor indicated for patients with hepatocellular carcinoma in patients who are not a candidates for surgery and no severe hepatic impairment (Child Pugh Class C); thyroid carcinoma in patients who are metastatic or not a candidate for surgery and cancer can no longer be treated with radioactive iodine they express one of the following histologies: papillary, Hurthle cell, follicular or medullary; osteosarcoma; angiosarcoma; desmoid tumors / aggressive fibromatosis; gastrointestinal stromal tumor (GIST) in patients who have been prior therapy with Gleevec, Sutent or Stivarga; and in patients without significant or unstable cardiac disease who are 18 years of age or older (1-2).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Nexavar while maintaining optimal therapeutic outcomes.

References

1. Nexavar [package insert]. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc; August 2023.
2. NCCN Drugs & Biologics Compendium® Sorafenib 2025. National Comprehensive Cancer Network, Inc. Accessed on January 9, 2025.

Policy History

Date	Action
October 2015	Addition to PA
December 2015	Annual review
June 2016	Annual editorial review and reference update Policy code changed from 5.04.60 to 5.21.60
June 2017	Annual editorial review and reference update Addition of age requirement under Renewal section
July 2018	Annual editorial review and reference update Update to diagnoses in initiation and renewal. Must have “advanced” renal cell carcinoma (RCC), “unresectable” hepatocellular carcinoma (HCC) or “differentiated” thyroid carcinoma (DTC) per package insert. Removal of requirements under renal cell carcinoma for relapsed or not a candidate for surgery. Removal of requirements under hepatocellular carcinoma for not a surgical candidate and No Child Pugh Class C hepatic impairment. Addition of quantity limits
March 2019	Annual review and reference update
June 2020	Annual review and reference update
September 2020	Annual review and reference update
June 2021	Annual review and reference update
September 2022	Annual review and reference update
March 2023	Annual review and reference update
March 2024	Annual review and reference update
March 2025	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 7, 2025 and is effective on April 1, 2025.