BlueCross BlueShield Federal Employee Program

NEXAVAR
(sorafenib)

RATIONALE FOR INCLUSION IN PA PROGRAM

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 age or less have not been studied (1).

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.