Nexavar

Description

Nexavar (sorafenib)

Background

Nexavar 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 indication: 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
Cabometyx, Inlyta, Lenvima,, 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 for patients 18 years of age or older for the treatment of advanced renal cell carcinoma (RCC), unresectable hepatocellular carcinoma (HCC), differentiated thyroid carcinoma (DTC), Osteosarcoma, Angiosarcoma, Desmoid tumors/Aggressive Fibromatosis, and Gastrointestinal Stromal Tumors (GISTs) and when the conditions indicated below are met.

Nexavar is considered investigational in patients less than 18 years of age and 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

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

Rationale

Summary
Nexavar is a kinase inhibitor indicated for patients with hepatocellular carcinoma in patients who are not 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


Policy History

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<tr>
<th>Date</th>
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<tbody>
<tr>
<td>October 2015</td>
<td>Addition to PA</td>
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<tr>
<td>December 2015</td>
<td>Annual review</td>
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<tr>
<td>June 2016</td>
<td>Annual editorial review and reference update</td>
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<tr>
<td>June 2017</td>
<td>Policy code changed from 5.04.60 to 5.21.60</td>
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<tr>
<td>June 2017</td>
<td>Annual editorial review and reference update</td>
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<tr>
<td>July 2018</td>
<td>Addition of age requirement under Renewal section</td>
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<tr>
<td>July 2018</td>
<td>Annual editorial review and reference update</td>
<td></td>
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<tr>
<td>July 2018</td>
<td>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</td>
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<td>March 2019</td>
<td>Annual review and reference update</td>
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Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 15, 2019 and is effective on April 1, 2019.