PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Sorafenib Prior Authorization Policy
- Nexavar® (sorafenib tablets – Bayer/Onyx, generic)

REVIEW DATE: 06/22/2022

OVERVIEW

Nexavar, a kinase inhibitor, is indicated for the treatment of the following uses:[1]

- **Differentiated thyroid carcinoma**, locally recurrent or metastatic, progressive disease that is refractory to radioactive iodine treatment.
- **Hepatocellular carcinoma** that is unresectable.
- **Renal cell carcinoma** that is advanced.

Guidelines

Nexavar is discussed in the guidelines from the National Comprehensive Cancer Network (NCCN):[2]

- **Acute Myeloid Leukemia**: NCCN guidelines (version 2.2022 – June 14, 2022) recommend Nexavar + hypomethylating agents (azacitidine or decitabine) for *FLT3*-ITD positive disease for treatment induction or post-induction therapy for patients ≥ 60 years of age and for relapsed/refractory disease (category 2A).[3] Single-agent Nexavar is recommended as maintenance therapy for patients who are post-allogeneic stem cell transplantation, in remission, and have a *FLT3*-ITD mutation (category 2A).
- **Bone Cancer**: NCCN guidelines (version 2.2022 – October 8, 2021) recommend Nexavar as a systemic therapy agent, useful in certain circumstances, for recurrent chordoma (category 2A).[4] It also recommends Nexavar for osteosarcoma as a second-line therapy for relapsed/refractory or metastatic disease as a preferred regimen (category 2A) and as other recommended regimens in combination with everolimus [category 2B].
- **Gastrointestinal Stromal Tumor**: NCCN guidelines (version 1.2022 – January 21, 2022) recommend Nexavar (category 2A) as an additional option, useful in certain circumstances, after failure on approved therapies.[5] The first-line preferred therapies are imatinib or Ayvakit™ (avapritinib tablets; for patients with *PDGFRA* exon 18 mutation, including the *PDGFRA* D842V mutation); second-line therapy is Sutent® (sunitinib) or Sprycel® (dasatinib tablets) [for patients with *PDGFRA* exon 18 mutation that are insensitive to imatinib (including the *PDGFRA* D842V mutation); third-line therapy is Stivarga® (regorafenib tablets); fourth-line therapy is Qinlock® (ripretinib tablets).
- **Hepatobiliary Cancers**: NCCN guidelines (version 1.2022 – March 29, 2022) recommend Nexavar as a first-line systemic therapy option as other recommended regimens for Child-Pugh Class A (category 1) or Child Pugh Class B7 (category 2A) and as a subsequent-line therapy if disease progression for Child Pugh Class A or B7 (category 2A) for unresectable, inoperable, or metastatic hepatocellular carcinoma.[6] The guidelines note that there is limited safety data available for Child-Pugh Class B or C patients, and the dosing is uncertain; this drug should be used with extreme caution in patients with elevated bilirubin levels. The impact of Nexavar on patients potentially eligible for transplant is unknown.
- **Kidney Cancer**: NCCN guidelines (version 4.2022 – December 21, 2021) recommend single-agent Nexavar for subsequent therapy, useful in certain circumstances, for clear cell histology for relapse or stage IV disease (category 3).[7]

- **Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Fusion Genes**: NCCN guidelines (version 1.2022 – April 14, 2022) recommend Nexavar for myeloid/lymphoid neoplasms with *FLT3* rearrangements (category 2A).[8]
- **Ovarian Cancer Including Fallopian Tube Cancer and Primary Peritoneal Cancer**: NCCN guidelines (version 1.2022 – January 18, 2022) recommend Nexavar + topotecan (category 2A) as other recommended regimen option as recurrence therapy for platinum-resistant disease.[9]
- **Soft Tissue Sarcoma**: NCCN guidelines (version 2.2022 – May 17, 2022) recommend Nexavar as single-agent therapy as other recommended regimen option for angiosarcoma (category 2A); Nexavar as a preferred single-agent regimen for desmoid tumors (aggressive fibromatosis) (category 1) and for solitary fibrous tumor (category 2A).[10]
- **Thyroid Carcinoma**: NCCN guidelines (version 2.2022 – May 5, 2022) for differentiated thyroid carcinoma recommend Nexavar as other recommended regimens for progressive and/or symptomatic disease for locally recurrent, advanced, and/or metastatic disease not amenable to radioactive iodine therapy (category 1).[11] Nexavar can be considered for treatment of progressive or symptomatic medullary thyroid disease if clinical trials or preferred systemic therapy options are not available or appropriate, or if there is progression on preferred systemic therapy options.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Nexavar. All approvals are provided for the duration noted below.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Nexavar is recommended in those who meet one of the following criteria:

FDA-Approved Indications

1. **Hepatocellular Cancer.** Approve for 1 year if the patient meets the following criteria (A and B):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has unresectable or metastatic disease.

2. **Renal Cell Cancer.** Approve for 1 year if the patient meets the following criteria (A, B, C, and D):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has relapsed or advanced disease; AND
   - **C)** Patient has clear cell histology AND
   - **D)** Patient has tried at least one systemic therapy.
     Note: Examples of systemic therapy include Inlyta (axitinib tablets), Votrient (pazopanib tablets), Sutent (sunitinib capsules), Cabometyx (cabozantinib tablets).

3. **Thyroid Carcinoma, Differentiated.** Approve for 1 year if the patient meets the following criteria (A, B, and C):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has differentiated thyroid carcinoma; AND
     Note: Examples of differentiated thyroid carcinoma include papillary, follicular, and Hürthle cell thyroid carcinoma.
   - **C)** The disease is refractory to radioactive iodine therapy.

Other Uses with Supportive Evidence

4. **Acute Myeloid Leukemia.** Approve for 1 year if the patient meets the following criteria (A, B, and C):
   A) Patient-is ≥ 18 years of age; AND
   B) Patient has *FLT3*-ITD mutation-positive disease as detected by an approved test; AND
   C) Patient meets one of the following criteria (i or ii):
      i. This medication is used in combination with azacitidine or decitabine; OR
      ii. Patient has had an allogeneic stem cell transplant and is in remission.

5. **Bone Cancer.** Approve for 1 year if the patient meets the following criteria (A and B):
   A) Patient is ≥ 18 years of age; AND
   B) Patient meets ONE of the following criteria (i or ii):
      i. Patient has recurrent chordoma; OR
      ii. Patient meets both of the following criteria (a and b):
         a) Patient has osteosarcoma; AND
         b) Patient has tried one systemic chemotherapy regimen.
         Note: Examples of a systemic chemotherapy regimen contain one of more of the following products: cisplastin, doxorubicin, methotrexate, or ifosfamide.

6. **Gastrointestinal Stromal Tumor.** Approve for 1 year if the patient meets the following criteria (A and B):
   A) Patient is ≥ 18 years of age; AND
   B) Patient has previously tried each of the following (i, ii, iii, and iv):
      i. One of imatinib or Ayvakit (avapritinib tablets); AND
      ii. One of Sutent (sunitinib capsules) or Sprycel (dasatinib tablets); AND
      iii. Stivarga (regorafenib tablets); AND
      iv. Qinlock (ripretinib tablets).

7. **Myeloid/Lymphoid Neoplasms with Eosinophilia.** Approve for 1 year if the patient meets the following criteria (A and B):
   A) Patient is ≥ 18 years of age; AND
   B) The tumor has an *FLT3* rearrangement.

8. **Ovarian, Fallopian Tube, Primary Peritoneal Cancer**. Approve for 1 year if the patient meets the following criteria (A, B, and C):
   A) Patient is ≥ 18 years of age; AND
   B) Patient has platinum-resistant disease; AND
   C) Nexavar is used in combination with topotecan.

9. **Soft Tissue Sarcoma:** Approve for 1 year if the patient meets the following criteria (A and B):
   A) Patient is ≥ 18 years of age; AND
   B) Patient has ONE of the following diagnoses (i, ii, or iii):
      i. Angiosarcoma; OR
      ii. Desmoid tumors (aggressive fibromatosis); OR
      iii. Solitary Fibrous Tumor/Hemangiopericytoma.

10. **Thyroid Carcinoma, Medullary.** Approve for 1 year if the patient meets the following criteria (A and B):
    A) Patient is ≥ 18 years of age; AND
    B) Patient has tried at least one systemic therapy.

Note: Examples of systemic therapy include: Caprelsa (vandetanib tablets), Cometriq (cabozantinib capsules), Retevmo (selpercatinib capsules), and Gavreto (pralsetinib capsules).

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Nexavar is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Nexavar® tablets [prescribing information]. Wayne, NJ: Bayer; July 2020.
2. The NCCN Drugs and Biologics Compendium. © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed June 14, 2022. Search term: sorafenib
3. The NCCN Acute Myeloid Leukemia Clinical Practice Guidelines in Oncology (version 1.2022– April 14, 2022). © 2022 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed June 15, 2022.
4. The NCCN Bone Cancer Clinical Practice Guidelines in Oncology (version 2.2022 – October 8, 2021). © 2021 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed June 14, 2022.
5. The NCCN Gastrointestinal Stromal Tumor (GIST) Clinical Practice Guidelines in Oncology (version 1.2022– January 21, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed June 15, 2022.
6. The NCCN Hepatobiliary Cancer Clinical Practice Guidelines in Oncology (version 1.2022– March 29, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed June 16, 2022.
7. The NCCN Kidney Cancer Clinical Practice Guidelines in Oncology (version 4.2022 – December 21, 2021). © 2021 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed June 15, 2022.
8. The NCCN Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Fusion Genes Clinical Practice Guidelines in Oncology (version 1.2022– April 14, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed June 15, 2022.
9. The NCCN Ovarian Cancer Including Fallopian Tube Cancer and Primary Peritoneal Cancer Clinical Practice Guidelines in Oncology (version 1.2022– January 18, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed June 16, 2022.
10. The NCCN Soft Tissue Sarcoma Clinical Practice Guidelines in Oncology (version 2.2022– May 17, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed June 16, 2022.
11. The NCCN Thyroid Carcinoma Clinical Practice Guidelines in Oncology (version 2.2022– May 5, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed June 16, 2022.