VENTURA COUNTY
HEALTH CARE PLAN

PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 06/16/2021

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.

The safety and efficacy have not been established in pediatric patients.

Guidelines

Nexavar is discussed in the guidelines from the National Comprehensive Cancer Network (NCCN)[2]:
- **Acute Myeloid Leukemia**: NCCN guidelines (version 3.2021 – March 2, 2021) 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. It also recommends Nexavar + hypomethylating agents (azacitidine or decitabine) for *FLT3*-ITD mutation for relapsed/refractory disease.[3]
- **Bone Cancer**: NCCN guidelines (version 1.2021 – November 20, 2020) recommend Nexavar as a systemic therapy agent, useful in certain circumstances, for recurrent chordoma (category 2A). 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 Afinitor (everolimus) [category 2B].[4]
- **Gastrointestinal Stromal Tumor (GIST)**: NCCN guidelines (version 1.2021 – October 30, 2020) recommend Nexavar (category 2A) as an additional option after failure on approved therapies, useful in certain circumstances. The first-line therapies are imatinib or Ayvakit™ (avapritinib tablets; for GIST with *PDGFRA* exon 18 mutation, including the *PDGFRA* D842V mutation); second-line therapy is Sutent® (sunitinib); third-line therapy is Stivarga® (regorafenib); fourth-line therapy is Qinlock® (ripretinib).[5]
- **Hepatobiliary Cancers**: NCCN guidelines (version 2.2021 – April 16, 2021) 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]
- **Kidney Cancer**: NCCN guidelines (version 4.2021 – April 19, 2021) recommend single-agent Nexavar (category 2B) for subsequent therapy, useful in certain circumstances, for clear cell histology for relapse or stage IV disease.[7]
- **Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Fusion Genes**: NCCN guidelines (version 3.2021 – August 21, 2020) recommend Nexavar (category 2A) for myeloid/lymphoid neoplasms with *FLT3* rearrangements.[8]
- **Ovarian Cancer Including Fallopian Tube Cancer and Primary Peritoneal Cancer**: NCCN guidelines (version 1.2021 – February 26, 2021) recommend Nexavar + Hycamtin® (topotecan) (category 2A) as other recommended regimen option for platinum-resistant disease.[9]

- **Soft Tissue Sarcoma**: NCCN guidelines (version 2.2021 – April 28, 2021) 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 1.2021 – April 9, 2021) for differentiated thyroid carcinoma recommend Nexavar (category 2A) for progressive and/or symptomatic disease for unresectable locoregional recurrent or persistent disease not amenable to radioactive iodine therapy or distant metastatic disease not amendable to radioactive iodine therapy. 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.[11]

POLICY STATEMENT

Prior authorization is recommended for prescription benefit coverage of Nexavar. All approvals are provided for 3 years.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

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

FDA-Approved Indications

1. **Hepatocellular Cancer.** Approve for 3 years 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 3 years 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 3 years 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 3 years 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 is using Nexavar in combination with azacitidine or decitabine.

5. **Bone Cancer.** Approve for 3 years 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 (i or ii):
      i. Patient has recurrent chordoma; OR
      ii. Patient meets both of the following (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 3 years 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. Imatinib or Ayvakit (avapritinib tablets); AND
      ii. Sutent (sunitinib capsules); AND
      iii. Stivarga (regorafinib tablets); AND
      iv. Qinlock (ripretinib tablets).

7. **Myeloid/Lymphoid Neoplasms with Eosinophilia.** Approve for 3 years 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 3 years 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 3 years 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 3 years 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 (carbozantinib 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. © 2021 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org/. Accessed May 18, 2021. Search term: sorafenib
3. The NCCN Acute Myeloid Leukemia Clinical Practice Guidelines in Oncology (version 3.2021– March 2, 2021). © 2021 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org/. Accessed May 18, 2021.
4. The NCCN Bone Cancer Clinical Practice Guidelines in Oncology (version 1.2021– November 20, 2020). © 2021 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org/. Accessed May 18, 2021.
5. The NCCN Gastrointestinal Stromal Tumor (GIST) Clinical Practice Guidelines in Oncology (version 1.2021– October 30, 2020). © 2021 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org/. Accessed May 18, 2021.
6. The NCCN Hepatobiliary Cancer Clinical Practice Guidelines in Oncology (version 2.2021– April 16, 2021). © 2021 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org/. Accessed May 18, 2021.
7. The NCCN Kidney Cancer Clinical Practice Guidelines in Oncology (version 4.2021– April 19, 2021). © 2021 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed May 18, 2021.
8. The NCCN Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Fusion Genes Clinical Practice Guidelines in Oncology (version 3.2021– August 21, 2020). © 2021 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org/. Accessed May 18, 2021.
9. The NCCN Ovarian Cancer Including Fallopian Tube Cancer and Primary Peritoneal Cancer Clinical Practice Guidelines in Oncology (version 1.2021– February 26, 2021). © 2021 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org/. Accessed May 18, 2021.
10. The NCCN Soft Tissue Sarcoma Clinical Practice Guidelines in Oncology (version 2.2021– April 28, 2021). © 2021 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org/. Accessed May 18, 2021.
11. The NCCN Thyroid Carcinoma Clinical Practice Guidelines in Oncology (version 1.2021– April 9, 2021). © 2021 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org/. Accessed May 18, 2021.