

## PRIOR AUTHORIZATION POLICY

**POLICY:** Oncology - Nexavar® (sorafenib tablets – Bayer/Onyx)

**DATE REVIEWED:** 05/20/2020

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### OVERVIEW

Nexavar, a kinase inhibitor, is indicated for the treatment of patients with unresectable hepatocellular carcinoma (HCC), treatment of patients with advanced renal cell carcinoma (RCC), and for the treatment of patients with locally recurrent or metastatic, progressive, differentiated thyroid carcinoma (DTC) that is refractory to radioactive iodine treatment.<sup>1</sup> Nexavar decreases tumor cell proliferation *in vitro*, and was shown to inhibit multiple intracellular and cell surface kinases, several of which are thought to be involved in tumor cell signaling, angiogenesis, and apoptosis.

### Guidelines

The National Comprehensive Cancer Network (NCCN) Compendium recommends Nexavar use for acute myeloid leukemia, for hepatobiliary cancer, kidney cancer, thyroid cancer, ovarian cancer, bone cancer, and soft tissue sarcoma.<sup>2</sup>

### 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. Renal Cell Carcinoma (RCC).** Approve for 3 years in patients who meet the following criteria (A and B):
    - A) The patient has relapsed or Stage IV clear cell histology RCC; AND
    - B) The patient has tried at least one prior systemic therapy.  
Note: Examples include Inlyta (axitinib tablets), Votrient (pazopanib tablets), Sutent (sunitinib capsules), Cabometyx (cabozantinib tablets).
  - 2. Differentiated (i.e. papillary, follicular, and Hürthle cell) Thyroid Carcinoma.** Approve for 3 years if refractory to radioactive iodine therapy.
  - 3. Hepatocellular Carcinoma (HCC), Unresectable.** Approve for 3 years.
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### Other Uses with Supportive Evidence

4. **Acute Myeloid Leukemia (AML).** Approve for 3 years if disease is *FLT3*-ITD mutation-positive as detected by an approved test.
5. **Angiosarcoma.** Approve for 3 years.
6. **Chordoma.** Approve for 3 years in patients with recurrent disease.
7. **Desmoid Tumors (aggressive fibromatosis).** Approve for 3 years.
8. **Gastrointestinal Stromal Tumor (GIST).** Approve for 3 years if the patient meets the following criteria (A, B, and C):
  - A) Patient has previously tried imatinib (Gleevec® tablets, generics); AND
  - B) Patient has previously tried Sutent (sunitinib capsules); AND
  - C) Patient has previously tried Stivarga® (regorafenib tablets).
9. **Medullary Thyroid Carcinoma.** Approve for 3 years if the patient has tried Caprelsa® (vandetanib tablets) or Cometriq® (cabozantinib capsules).
10. **Ovarian, Fallopian Tube, Primary Peritoneal Cancer.** Approve for 3 years if the patient meets the following criteria (A and B):
  - A) The patient has platinum-resistant disease; AND
  - B) Nexavar is used in combination with topotecan.
11. **Osteosarcoma.** Approve for 3 years if the patient meets the following criteria (A and B):
  - A) Patient has tried chemotherapy; AND
  - B) Patient has relapsed/refractory or metastatic disease.
12. **Solitary Fibrous Tumor and Hemangiopericytoma.** Approve for 3 years.

### CONDITIONS NOT RECOMMENDED FOR APPROVAL

Nexavar has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. Rationale for non-coverage for these specific conditions is provided below. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval.)

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; December 2017.
  2. The NCCN Drugs and Biologics Compendium. © 2020 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed May 18, 2020. Search term: sorafenib.
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