Nexavar (sorafenib)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Nexavar (sorafenib)	May be subject to quantity limit

APPROVAL CRITERIA

Requests for Nexavar (sorafenib) may be approved if the following criteria are met:

Individual has a diagnosis of one of the following:

I. Acute Myeloid Leukemia (AML) with FMS-like tyrosine kinase-3/internal tandem duplication (FLT3/ITD) mutation and one of the following:
   A. Induction of consolidation therapy (NCCN 2A); **OR**
   B. Relapsed or refractory disease (NCCN 2A); **OR**
   C. As maintenance therapy after achieving remission following hematopoietic stem cell transplant (DP B IIa, NCCN 2A); **OR**

II. Bone Cancer – relapsed/refractory or metastatic Osteosarcoma (NCCN 2A); **OR**

III. Bone Cancer – recurrent Chordoma (NCCN 2A); **OR**

IV. Advanced Renal Cell Carcinoma (RCC) (Label); **OR**

V. Advanced, metastatic, or unresectable Hepatocellular Carcinoma (HCC) (Label, NCCN 1, 2A); **OR**

VI. Myeloid/Lymphoid Neoplasms with eosinophilia and FLT3 rearrangement in chronic or blast phase (NCCN 2A); **OR**

VII. Thyroid Carcinoma, for the following:
   A. Locally recurrent of metastatic, progressive, differentiated thyroid carcinoma (DTC) disease that is refractory to radioactive iodine treatments (Label, NCCN 1); **OR**
   B. Papillary, follicular, or Oncocytic cell carcinomas where other systemic therapies or clinical trials are not available or appropriate for treatment of progressive and/or symptomatic iodine-refractory disease (NCCN 2A); **OR**
   C. Medullary carcinomas in treatment of progressive disease or symptomatic distant metastases if clinical trials or systemic therapy options are not available or appropriate, OR if there is progression on systemic therapy options (NCCN 2A);

OR

VIII. Soft Tissue Sarcoma, for the following: (NCCN 1, 2A)
   A. Solitary Fibrous tumor; **OR**
   B. Desmoid tumors (aggressive fibromatoses) (NCCN 1); **OR**
   C. Angiosarcoma; **OR**
   D. Gastrointestinal stromal tumors for unresectable, recurrent, or metastatic disease after failure on approved therapies (imatinib, sunitinib, regorafenib, and standard dose ripretinib);

OR

IX. Ovarian Cancer, Fallopian Tube Cancer, or Primary Peritoneal Cancer, for the following (NCCN 2A):
    A. Individual is using in combination with topotecan for platinum-resistant persistent disease or recurrence.

Requests for Nexavar (sorafenib) may not be approved for the following:

I. In combination with carboplatin and paclitaxel in patients with squamous cell lung cancer.

Key References:

1. Chekerov R, Hilpert F, Mahner S, et al. Sorafenib plus topotecan versus placebo plus topotecan for platinum-resistant ovarian cancer (TRIAS): a multicenter, randomized, double-blind, placebo-controlled, phase 2 trial. Lancet Oncol 2018;19:1247-1258.
2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2023. URL: http://www.clinicalpharmacology.com. Updated periodically.
3. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: July 8, 2023.
4. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
5. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2023; Updated periodically.
6. Burchert A, Bug G, Fritz LV, et al: Sorafenib maintenance after allogeneic hematopoietic stem cell transplantation for acute myeloid leukemia with FLT3-internal tandem duplication mutation (SORMAIN). J Clin Oncol 2020; 38(26):2993-3002.
7. Xuan LI, Wang Y, Huang F, et al: Sorafenib maintenance in patients with FLT3-ITD acute myeloid leukaemia undergoing allogeneic haematopoietic stem-cell transplantation: an open-label, multicentre, randomised phase 3 trial. Lancet Oncol 2020; 21(9):1201-1212.
8. Ohanian M, Garcia-Manero G, Levis M, et al. Sorafenib Combined with 5-azacytidine in Older Patients with Untreated FLT3-ITD mutated Acute Myeloid Leukemia. Am J Hematol 2018; 93:1136-1141.
9. Walz C, Erben P, Ritter M, et al. Response of ETV6-FLT3-positive myeloid/lymphoid neoplasm with eosinophilia to inhibitors of FMS-like tyrosine kinase 3. Blood. 2011;118(8):2239-2242.
10. Falchi L, Mehrotra M, Newberry KJ, et al. ETV6-FLT3 fusion gene-positive, eosinophilia-associated myeloproliferative neoplasm successfully treated with sorafenib and allogeneic stem cell transplant. *Leukemia*. 2014;28(10):2090-2092. doi:10.1038/leu.2014.168.
11. NCCN Clinical Practice Guidelines in Oncology™. © 2023 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Accessed on July 8, 2023.
    a. Thyroid Carcinoma. V2.2023. Revised May 18, 2023.
    b. Hepatocellular Carcinoma. V1.2023. Revised June 17, 2022.
    c. Bone Cancer. V3.2023. Revised April 4, 2023.
    d. Head and Neck Cancers. V2.2023. Revised May 15, 2023.
    e. Acute Myeloid Leukemia. V3.2023. Revised April 5, 2023.
    f. Ovarian Cancer. V2.2023. Revised June 2, 2023.
    g. Soft Tissue Sarcoma. V2.2023. Revised April 25, 2023.
    h. Gastrointestinal Stromal Tumors (GISTs). V1.2023. Revised March 13, 2023.
    i. Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Fusion Genes. V1.2023. Revised May 19. 2023.

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.