Market Applicability						
Market	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X

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) - relapsed/refractory disease with FMS-like tyrosine kinase-3/internal tandem duplication (FLT3/ITD) mutation and test result confirmed (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); **OR**
V. Advanced or unresectable Hepatocellular Carcinoma (HCC); **OR**
VI. Thyroid Carcinoma, for the following:
    A. Locally recurrent of metastatic, progressive, differentiated thyroid carcinoma (DTC) disease that is refractory to radioactive iodine treatments; **OR**
    B. Papillary, follicular, or Hürthle cell carcinomas where other systemic therapies or clinical trials are unavailable 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, cabozantinib, or vandetanib are not available or appropriate, OR if there is progression on vandetanib or cabozantinib (NCCN 2A);

OR

VII. Soft Tissue Sarcoma, for the following: (NCCN 2A)
    A. Solitary Fibrous tumor; **OR**
    B. Desmoid tumors for primary, recurrent, or progressive disease; **OR**
    C. Angiosarcoma; **OR**
    D. Gastrointestinal stromal tumors with progression after imatinib, sunitinib, and regorafenib

OR

VIII. Ovarian Cancer, for the following (NCCN 2A):

Market Applicability						
Market	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X

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.: 2020. 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: June 15, 2020.
4. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
5. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2020; Updated periodically.
6. NCCN Clinical Practice Guidelines in Oncology™. © 2019 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Accessed on June 15, 2020.
    a. Thyroid Carcinoma. V1.2020. Revised June 12, 2020.
    b. Kidney Cancer. V2.2020. Revised August 5, 2019.
    c. Hepatobiliary Cancers. V3.2020. Revised June 1, 2020.
    d. Bone Cancer. V1.2020. Revised August 12, 2019.
    e. Acute Myeloid Leukemia. V3.2020. Revised December 23, 2019.
    f. Ovarian Cancer. V1.2020. Revised March 11, 2020.