POLICY NUMBER UM ONC_1194	**SUBJECT** Nexavar™ (sorafenib)		**DEPT/PROGRAM** UM Dept	**Page 1 of 2**
DATES COMMITTEE REVIEWED 01/04/12, 04/11/12, 11/13/13, 03/06/15, 03/27/15, 07/25/16, 06/09/17, 06/08/18, 05/08/19, 12/11/19, 05/13/20	**APPROVAL DATE** May 13, 2020	**EFFECTIVE DATE** May 29, 2020	**COMMITTEE APPROVAL DATES** (latest version listed last) 01/04/12, 04/11/12, 11/13/13, 03/06/15, 03/27/15, 07/25/16, 06/09/17, 06/08/18, 05/08/19, 12/11/19, 05/13/20	
PRIMARY BUSINESS OWNER: UM **APPROVED BY:** Dr. Andrew Hertler		**COMMITTEE/BOARD APPROVAL** Utilization Management Committee		
URAC STANDARDS HUM 1	**NCQA STANDARDS** UM 2		**ADDITIONAL AREAS OF IMPACT**	
CMS REQUIREMENTS	**STATE/FEDERAL REQUIREMENTS**		**APPLICABLE LINES OF BUSINESS** All	

I. PURPOSE

To define and describe the accepted indications for Nexavar (sorafenib) usage in the treatment of cancer, including FDA approved indications, and off-label indications.

New Century is responsible for processing all medication requests from network ordering providers. Medications not authorized by New Century may be deemed as not approvable and therefore not reimbursable.

The use of this drug must be supported by one of the following: FDA approved product labeling, CMS-approved compendia, National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO) clinical guidelines, or peer-reviewed literature that meets the requirements of the CMS Medicare Benefit Policy Manual Chapter 15.

II. INDICATIONS FOR USE/INCLUSION CRITERIA

1. **PREFERRED MEDICATION GUIDANCE FOR INITIAL REQUEST:**
    a. When health plan Medicaid coverage provisions- including any applicable PDLs (Preferred Drug Lists)- conflict with the coverage provisions in this drug policy, health plan Medicaid coverage provisions take precedence per the **Preferred Drug Guidelines OR**
    b. When health plan Exchange coverage provisions- including any applicable PDLs (Preferred Drug Lists)- conflict with the coverage provisions in this drug policy, health plan Exchange coverage provisions take precedence per the **Preferred Drug Guidelines OR**
    c. For Health Plans that utilize NCH UM Oncology Clinical Policies as the initial clinical criteria, the **Preferred Drug Guidelines shall follow NCH L1 Pathways** when applicable, otherwise shall follow NCH drug policies **AND**
    d. Continuation requests of previously approved non-preferred medication are not subject to this provision **AND**
    e. When available, generic alternatives are preferred over brand-name drugs.
2. **Renal Cell Carcinoma (RCC)**
    a. The preferred tyrosine kinase inhibitor, per NCH Policy & NCH Pathway for advanced or metastatic RCC, is Cabometyx (cabozantinib) or Votrient (pazopanib).
    b. Nexavar (sorafenib) will be used as a single agent for recurrent or metastatic RCC in members who have disease progression, contraindications, or intolerance to prior Pazopanib **AND** Cabozantinib.
3. **Hepatocellular Carcinoma (HCC)**

a. **The preferred agent, per NCH Policy & NCH Pathway, for unresectable or metastatic HCC are as follows:**

i. For first line treatment: Lenvima (Lenvatinib)

ii. For subsequent treatment: Stivarga (regorafenib)

b. Nexavar (sorafenib) use is supported as a single agent in members with Child-Pugh Class A or B7 unresectable HCC, for patients who are intolerant to/have contraindications to Lenvatinib for first line therapy, and who are intolerant to/have contraindications to Stivarga for subsequent line therapy.

4. **Thyroid Carcinoma**

a. The member has locally recurrent or metastatic, progressive, differentiated thyroid carcinoma that is refractory to radioactive iodine treatment **AND**

b. Nexavar (sorafenib) will be used as a single agent.

III. EXCLUSION CRITERIA

1. Off-label indications for Nexavar (sorafenib) in soft tissue sarcoma.
2. Concurrent use with other tyrosine kinase inhibitors or chemotherapy.
3. Disease progression while receiving Nexavar (sorafenib).
4. Dosing exceeds single dose limit of Nexavar (sorafenib) 400 mg.
5. Treatment with Nexavar (sorafenib) exceeds the maximum duration limit of 120 (200 mg) capsules a month.
6. Indications not supported by CMS recognized compendia or acceptable peer reviewed literature.

IV. MEDICATION MANAGEMENT

Please refer to the FDA label/package insert for details regarding these topics**.**

V. APPROVAL AUTHORITY

1. Review – Utilization Management Department
2. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

None

VII. REFERENCES

1. Nexavar prescribing information. Bayer Health Care Pharmaceuticals Inc. Wayne, NJ. 2020.
2. Clinical Pharmacology Elsevier Gold Standard. 2020.
3. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, Co. 2020.
4. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium. 2020.
5. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs . Bethesda, MD. 2020.