Nexavar® (sorafenib)
(Oral)

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I. Length of Authorization [6,22,28]

- Coverage will be provided for six months and may be renewed (unless otherwise specified).
  - For Ovarian Cancer, coverage will be provided for a total of six 21-day cycles and may not be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

- Nexavar 200 mg tablets: 4 tablets per day

B. Max Units (per dose and over time) [HCPCS Unit]:

- Desmoid tumors: 400 mg daily
- All other indications: 800 mg daily

III. Initial Approval Criteria [1]

Coverage is provided in the following conditions:

- Patient is at least 18 years of age, unless otherwise specified; **AND**

Universal Criteria [1]

- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications; **AND**
  - Coadministration with neomycin; **AND**
  - Coadministration with drugs that prolong QT/QTc interval (e.g., amiodarone, sotalol, levofloxacin, venlafaxine, quetiapine, sumatriptan, etc.), or if therapy is unavoidable,

the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**

Renal Cell Cancer † Φ [1,10,11]

- Used as a single agent; **AND**
- Patient has advanced disease

Hepatocellular Carcinoma (HCC) † Φ [1,2,5,9]

- Used as a single agent; **AND**
  - Patient has unresectable disease; **OR**
  - Patient has Child-Pugh Class A or B7 disease only; **AND**
    - Patient has metastatic disease or extensive liver tumor burden; **OR**
    - Patient has liver-confined disease that is inoperable by performance status, comorbidity, or with minimal or uncertain extrahepatic disease

Angiosarcoma ‡ [2,7,17]

- Used as a single agent

Desmoid Tumors (Aggressive Fibromatosis) ‡ [2,7,16,29]

- Used as a single agent; **AND**
- Timeframe for a treatment response is more critical; **AND**
- Used as primary treatment or for treatment of gross residual disease (R2 resection) in abdominal wall tumors; **AND**
  - Patient has ongoing progression with potential morbidity or significant symptoms in anatomic location where progression would not be morbid; **OR**
  - Patient has documented progression in anatomic location where progression would be morbid; **OR**
  - Patient has no documented progression in anatomic location where progression would be morbid but there are concerns for morbidity or significant symptoms

Gastrointestinal Stromal Tumors (GIST) ‡ [2,13-15,25]

- Patient has unresectable, recurrent, or metastatic disease; **AND**
- Used as a single agent; **AND**
- Used after failure on approved therapies including each of the following: imatinib, sunitinib, regorafenib, and ripretinib

Solitary Fibrous Tumor ‡ [2,7,18]

- Used as a single agent

Thyroid Carcinoma – Medullary ‡ Φ [2,8]

- Used as a single agent; **AND**
- Patient has recurrent or persistent metastatic disease; **AND**
- Patient has progressive or symptomatic disease; **AND**
  - Treatment with clinical trials, vandetanib, or cabozantinib are not available or appropriate; **OR**
  - Disease has progressed on vandetanib or cabozantinib

Thyroid Carcinoma – Differentiated (Follicular Carcinoma/Hürthle Cell Carcinoma/Papillary Carcinoma) † Φ [1,2,8,12]

- Used as a single agent; **AND**
- Patient has recurrent, persistent, or metastatic disease; **AND**
  - Patient is refractory to radioactive iodine; **OR**
  - Patient has progressive and/or symptomatic disease that is not susceptible to radioactive iodine (RAI) therapy **‡**

Chordoma ‡ [2,4,19,20]

- Used as a single agent for recurrent disease with conventional or chondroid histology

Osteosarcoma ‡ [2,4,21]

- Patient has relapsed, refractory, or metastatic disease; **AND**
- Used as a single agent; **AND**
- Used as second line therapy

Ovarian Cancer (Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer) ‡ [2,6,22,28]

- Patient has recurrent or persistent disease; **AND**
- Used in combination with topotecan; **AND**
- Patient has platinum-resistant disease; **AND**
- Patient is not experiencing an immediate biochemical relapse (i.e., rising CA-125 without radiographic evidence of disease)

Acute Myeloid Leukemia (AML) ‡ [2,3,23,24]

- Patient has FLT3-ITD mutation-positive disease; **AND**
  - Used in combination with azacitidine or decitabine; **AND**
    - Patient has relapsed or refractory disease; **OR**
    - Used as induction therapy in patients ≥ 60 years of age who are not candidates for or decline intensive therapy; **OR**
    - Used as post-induction therapy following response to previous lower intensity therapy with the same regimen in patients ≥ 60 years of age; **OR**

- Used as a component of repeating the initial successful induction regimen for relapsed or refractory disease in patients experiencing a late relapse (≥ 12 months after induction regimen); **AND**
  - Treatment has not been administered continuously; **AND**
  - Treatment was not previously stopped due to development of clinical resistance

Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Fusion Genes ‡ [2,31]

- Patient has eosinophilia and FLT3 rearrangement; **AND**
  - Patient has chronic phase myeloid or lymphoid neoplasms; **AND**
    - Used as a single agent; **OR**
  - Patient has blast phase lymphoid, myeloid, or mixed lineage neoplasms; **AND**
    - Used in combination with ALL- or AML-type induction chemotherapy followed by allogeneic HCT (if eligible)

† FDA Approved Indication(s); ‡ Compendia Approved Indication(s); Φ Orphan Drug

IV. Renewal Criteria [1,2-8]

Coverage can be renewed based upon the following criteria:

- Patient continues to meet universal and other indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in Section III; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: cardiac ischemia and/or infarction, hemorrhage, severe hypertension, transaminase elevations leading to hepatitis, severe dermatologic toxicity (Stevens-Johnson syndrome (SJS), toxic epidermal necrosis (TEN)], gastrointestinal perforation, QT interval prolongation, risk of impaired wound healing, impairment of thyroid stimulating hormone suppression in differentiated thyroid carcinoma, etc.; **AND**

Acute Myeloid Leukemia (AML) [2]

- Disease stabilization or improvement as evidenced by a complete response [CR] (i.e., morphologic, cytogenetic or molecular complete response CR), complete hematologic response or a partial response by CBC, bone marrow cytogenic analysis, QPCR, or FISH

Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Fusion Genes [2]

- Disease response as evidenced by at least one of the following:
  - Decrease in spleen size or improvements in other myelofibrosis symptoms (such as fatigue, bone pain, frequent infections, fever, night sweats, easy bruising/bleeding, etc.)
  - Stabilization or improvement as evidenced by a complete response [CR] (i.e. morphologic, cytogenetic or molecular complete response CR), complete hematologic response or a partial response by CBC, bone marrow cytogenic analysis, QPCR, or FISH

Ovarian Cancer

- May NOT be renewed

All Other Indications

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread

V. Dosage/Administration [1,13-24,26-30]

Indication	Dose
Desmoid Tumors	400 mg taken orally once daily without food (at least 1 hour before or 2 hours after a meal) until disease progression or unacceptable toxicity
Ovarian Cancer	400 mg taken orally twice daily without food (at least 1 hour before or 2 hours after a meal) on days 6 – 15 in combination with topotecan on days 1 – 5 of every 21 day cycle for 6 cycles
All other indications	400 mg (2 x 200 mg) taken orally twice daily without food (at least 1 hour before or 2 hours after a meal) until disease progression or unacceptable toxicity

VI. Billing Code/Availability Information

HCPCS Code:

- J8999 – Prescription drug, oral, chemotherapeutic, not otherwise specified

NDC:

- Nexavar 200 mg tablet: 50419-0488-xx

VII. References

1. Nexavar [package insert]. Wayne, NJ; Bayer Healthcare Pharmaceuticals, Inc; July 2020. Accessed June 2021.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for sorafenib. National Comprehensive Cancer Network, 2021. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed June 2021.
3. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Acute Myeloid Leukemia Version 3.2021. National Comprehensive Cancer Network, 2021. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer

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31. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Fusion Genes Version 3.2021. National Comprehensive Cancer Network, 2021. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Guidelines, go online to NCCN.org. Accessed June 2021.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C22.0	Liver cell carcinoma
C22.3	Angiosarcoma of liver
C22.8	Malignant neoplasm of liver, primary, unspecified as to type
C22.9	Malignant neoplasm of liver, not specified as primary or secondary

ICD-10	ICD-10 Description
C40.00	Malignant neoplasm of scapula and long bones of unspecified upper limb
C40.01	Malignant neoplasm of scapula and long bones of right upper limb
C40.02	Malignant neoplasm of scapula and long bones of left upper limb
C40.10	Malignant neoplasm of short bones of unspecified upper limb
C40.11	Malignant neoplasm of short bones of right upper limb
C40.12	Malignant neoplasm of short bones of left upper limb
C40.20	Malignant neoplasm of long bones of unspecified lower limb
C40.21	Malignant neoplasm of long bones of right lower limb
C40.22	Malignant neoplasm of long bones of left lower limb
C40.30	Malignant neoplasm of short bones of unspecified lower limb
C40.31	Malignant neoplasm of short bones of right lower limb
C40.32	Malignant neoplasm of short bones of left lower limb
C40.80	Malignant neoplasm of overlapping sites of bone and articular cartilage of unspecified limb
C40.81	Malignant neoplasm of overlapping sites of bone and articular cartilage of right limb
C40.82	Malignant neoplasm of overlapping sites of bone and articular cartilage of left limb
C40.90	Malignant neoplasm of unspecified bones and articular cartilage of unspecified limb
C40.91	Malignant neoplasm of unspecified bones and articular cartilage of right limb
C40.92	Malignant neoplasm of unspecified bones and articular cartilage of left limb
C41.0	Malignant neoplasm of bones of skull and face
C41.1	Malignant neoplasm of mandible
C41.2	Malignant neoplasm of vertebral column
C41.3	Malignant neoplasm of ribs, sternum and clavicle
C41.4	Malignant neoplasm of pelvic bones, sacrum and coccyx
C41.9	Malignant neoplasm of bone and articular cartilage, unspecified
C48.0	Malignant neoplasm of retroperitoneum
C48.1	Malignant neoplasm of specified parts of peritoneum
C48.2	Malignant neoplasm of peritoneum, unspecified
C48.8	Malignant neoplasm of overlapping sites of retroperitoneum and peritoneum
C49.A0	Gastrointestinal stromal tumor, unspecified site
C49.A1	Gastrointestinal stromal tumor of esophagus
C49.A2	Gastrointestinal stromal tumor of stomach
C49.A3	Gastrointestinal stromal tumor of small intestine
C49.A4	Gastrointestinal stromal tumor of large intestine
C49.A5	Gastrointestinal stromal tumor of rectum
C49.A9	Gastrointestinal stromal tumor of other sites
C49.0	Malignant neoplasm of connective and soft tissue of head, face and neck
C49.10	Malignant neoplasm of connective and soft tissue of unspecified upper limb, including shoulder
C49.11	Malignant neoplasm of connective and soft tissue of right upper limb including shoulder
C49.12	Malignant neoplasm of connective and soft tissue of left upper limb, including shoulder

ICD-10	ICD-10 Description
C49.20	Malignant neoplasm of connective and soft tissue of unspecified lower limb, including hip
C49.21	Malignant neoplasm of connective and soft tissue of right lower limb, including hip
C49.22	Malignant neoplasm of connective and soft tissue of left lower limb, including hip
C49.3	Malignant neoplasm of connective and soft tissue of thorax
C49.4	Malignant neoplasm of connective and soft tissue of abdomen
C49.5	Malignant neoplasm of connective and soft tissue of pelvis
C49.6	Malignant neoplasm of connective and soft tissue of trunk, unspecified
C49.8	Malignant neoplasm of overlapping sites of connective and soft tissue
C49.9	Malignant neoplasm of connective and soft tissue, unspecified
C56.1	Malignant neoplasm of right ovary
C56.2	Malignant neoplasm of left ovary
C56.9	Malignant neoplasm of unspecified ovary
C57.00	Malignant neoplasm of unspecified fallopian tube
C57.01	Malignant neoplasm of right fallopian tube
C57.02	Malignant neoplasm of left fallopian tube
C57.10	Malignant neoplasm of unspecified broad ligament
C57.11	Malignant neoplasm of right broad ligament
C57.12	Malignant neoplasm of left broad ligament
C57.20	Malignant neoplasm of unspecified round ligament
C57.21	Malignant neoplasm of right round ligament
C57.22	Malignant neoplasm of left round ligament
C57.3	Malignant neoplasm of parametrium
C57.4	Malignant neoplasm of uterine adnexa, unspecified
C57.7	Malignant neoplasm of other specified female genital organs
C57.8	Malignant neoplasm of overlapping sites of female genital organs
C57.9	Malignant neoplasm of female genital organ, unspecified
C64.1	Malignant neoplasm of right kidney, except renal pelvis
C64.2	Malignant neoplasm of left kidney, except renal pelvis
C64.9	Malignant neoplasm of unspecified kidney, except renal pelvis
C65.1	Malignant neoplasm of right renal pelvis
C65.2	Malignant neoplasm of left renal pelvis
C65.9	Malignant neoplasm of unspecified renal pelvis
C72.0	Malignant neoplasm of spinal cord
C72.1	Malignant neoplasm of cauda equina
C73	Malignant neoplasm of thyroid gland
C92.00	Acute myeloblastic leukemia not having achieved remission
C92.01	Acute myeloblastic leukemia in remission
C92.02	Acute myeloblastic leukemia, in relapse
C92.50	Acute myelomonocytic leukemia not having achieved remission

ICD-10	ICD-10 Description
C92.51	Acute myelomonocytic leukemia in remission
C92.52	Acute myelomonocytic leukemia, in relapse
C92.60	Acute myeloid leukemia with 11q23-abnormality not having achieved remission
C92.61	Acute myeloid leukemia with 11q23-abnormality in remission
C92.62	Acute myeloid leukemia with 11q23-abnormality in relapse
C92.A0	Acute myeloid leukemia with multilineage dysplasia not having achieved remission
C92.A1	Acute myeloid leukemia with multilineage dysplasia in remission
C92.A2	Acute myeloid leukemia with multilineage dysplasia, in relapse
C93.00	Acute monoblastic/monocytic leukemia not having achieved remission
C93.01	Acute monoblastic/monocytic leukemia in remission
C93.02	Acute monoblastic/monocytic leukemia, in relapse
C94.00	Acute erythroid leukemia not having achieved remission
C94.01	Acute erythroid leukemia in remission
C94.02	Acute erythroid leukemia, in relapse
C94.20	Acute megakaryoblastic leukemia not having achieved remission
C94.21	Acute megakaryoblastic leukemia in remission
C94.22	Acute megakaryoblastic leukemia, in relapse
C94.8	Other specified leukemias
C94.80	Other specified leukemias not having achieved remission
C94.81	Other specified leukemias, in remission
C94.82	Other specified leukemias, in relapse
C95.1	Chronic leukemia of unspecified cell type
C95.10	Chronic leukemia of unspecified cell type not having achieved remission
C95.11	Chronic leukemia of unspecified cell type, in remission
C95.12	Chronic leukemia of unspecified cell type, in relapse
C96.Z	Other specified malignant neoplasms of lymphoid, hematopoietic and related tissue
C96.9	Malignant neoplasm of lymphoid, hematopoietic and related tissue, unspecified
D48.1	Neoplasm of uncertain behavior of connective and other soft tissue
Z85.528	Personal history of other malignant neoplasm of kidney
Z85.830	Personal history of malignant neoplasm of bone
Z85.831	Personal history of malignant neoplasm of soft tissue

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD), Local Coverage Determinations (LCDs), and Local Coverage Articles (LCAs) may exist and compliance with these policies is required where applicable. They can be found at: http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC