Reference number
2027-A

SPECIALTY GUIDELINE MANAGEMENT

NEXAVAR (sorafenib)
sorafenib (generic)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indications
1. Hepatocellular carcinoma
   Nexavar is indicated for the treatment of patients with unresectable hepatocellular carcinoma (HCC).
2. Renal cell carcinoma
   Nexavar is indicated for the treatment of patients with advanced renal cell carcinoma (RCC).
3. Differentiated thyroid carcinoma
   Nexavar is indicated for the treatment of patients with locally recurrent or metastatic, progressive, differentiated thyroid carcinoma (DTC) that is refractory to radioactive iodine treatment.

B. Compendial Uses
1. Hepatocellular carcinoma (Child-Pugh Class A or B7)
   a. Inoperable by performance status, comorbidity or with minimal or uncertain extrahepatic disease
   b. Metastatic disease or extensive liver tumor burden
2. Acute myeloid leukemia with FLT3-ITD mutation
   a. In combination with azacitidine or decitabine in patients age ≥ 60 years as low-intensity treatment induction or post-induction therapy
   b. In combination with azacitidine or decitabine for relapsed or refractory disease
   c. As maintenance therapy after hematopoietic stem cell transplant (HSCT)
3. Soft tissue sarcoma subtypes
   a. Angiosarcoma
   b. Desmoid tumors (aggressive fibromatosis)
   c. Solitary fibrous tumor
   d. Leiomyosarcoma
4. Gastrointestinal stromal tumors (GIST)
5. Thyroid carcinoma (medullary carcinoma, papillary carcinoma, Hürthle cell carcinoma, or follicular carcinoma)
6. Relapsed/refractory or metastatic bone cancer, as second-line therapy as a single agent for the following subtypes:
   a. Osteosarcoma
   b. Dedifferentiated chondrosarcoma
   c. High-grade undifferentiated pleomorphic sarcoma (UPS)
7. Recurrent chordoma
8. Epithelial ovarian cancer, fallopian tube cancer, and primary peritoneal cancer
9. Lymphoid, myeloid or mixed lineage neoplasms with eosinophilia and FLT3 rearrangement in chronic phase or blast phase

All other indications are considered experimental/investigational and not medically necessary.

II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review: FLT3-ITD mutation or FLT3 rearrangement testing results (where applicable)

III. CRITERIA FOR INITIAL APPROVAL

A. Hepatocellular Carcinoma

Authorization of 12 months may be granted for treatment of hepatocellular carcinoma as a single agent.

B. Acute Myeloid Leukemia (AML)

Authorization of 12 months may be granted for treatment of acute myeloid leukemia with FLT3-ITD mutation when either of the following criteria are met:

1. The requested drug will be used in combination with azacitidine or decitabine for either:
   i. Low-intensity treatment induction or post-induction therapy for members 60 years or older
   ii. Relapsed/refractory disease
2. The requested drug will be used as maintenance therapy after HSCT

C. Soft Tissue Sarcoma

Authorization of 12 months may be granted for treatment for the following types of soft tissue sarcoma:

1. Leiomyosarcoma
2. Angiosarcoma, solitary fibrous tumor, or desmoid tumor/aggressive fibromatosis, as single agent therapy.

D. Gastrointestinal Stromal Tumor (GIST)

Authorization of 12 months may be granted for treatment of GIST when either of the following criteria are met:

1. The requested medication will be used as a single agent for unresectable, recurrent/progressive, or metastatic disease and the member has failed at least four FDA-approved therapies (e.g., imatinib, sunitinib, regorafenib, ripretinib)
2. The requested medication will be used for palliation of symptoms if previously tolerated and effective

E. Renal Cell Carcinoma

Authorization of 12 months may be granted for treatment of advanced renal cell carcinoma.

F. Papillary, Hürthle cell, or Follicular Thyroid Carcinoma

Authorization of 12 months may be granted for treatment of progressive and/or symptomatic papillary, Hürthle cell, or follicular thyroid carcinoma not amenable to radioactive iodine (RAI) therapy.

G. Medullary Thyroid Carcinoma

Authorization of 12 months may be granted for treatment of recurrent or metastatic medullary thyroid carcinoma when either of the following criteria are met:

1. Member has an intolerance or contraindication to FDA approved systemic therapy options (e.g., vandetanib [Caprelsa], cabozantinib [Cometriq]); OR
2. Member has disease progression while on FDA approved systemic therapy options (e.g., vandetanib [Caprelsa], cabozantinib [Cometriq]).

H. Bone Cancer

Authorization of 12 months may be granted for treatment as second-line therapy for relapsed/refractory or metastatic disease as a single agent for the following types of bone cancer:

1. Osteosarcoma
2. Dedifferentiated chondrosarcoma
3. High-grade undifferentiated pleomorphic sarcoma (UPS)

I. Chordoma

Authorization of 12 months may be granted for treatment of recurrent chordoma as a single agent.

J. Epithelial Ovarian Cancer/Fallopian Tube Cancer/Primary Peritoneal Cancer

Authorization of 12 months may be granted for treatment of epithelial ovarian, fallopian tube, or primary peritoneal cancer if the disease is platinum-resistant and the requested drug is given in combination with topotecan for persistent disease or recurrence.

K. Myeloid/Lymphoid Neoplasms with Eosinophilia

Authorization of 12 months may be granted for treatment of myeloid and/or lymphoid neoplasms with eosinophilia and FLT3 rearrangement in the chronic phase or blast phase.

IV. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication in Section III when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

V. REFERENCES

1. Nexavar [package insert]. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc.; July 2020.
2. Sorafenib [package insert]. Morgantown, WV: Mylan Pharmaceuticals Inc.; November 2021.
3. The NCCN Drugs & Biologic Compendium 2022 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed May 3, 2022.
4. Santoro A, Comandone A, et al. Phase II prospective study with sorafenib in advanced soft tissue sarcomas after anthracycline-based therapy. Ann Oncol. 2013. 24 (4): 1093-8.
5. Bramwell, VH, Steward WP, et al. Neoadjuvant chemotherapy with doxorubicin and cisplatin in malignant fibrous histiocytoma of bone: A European Osteosarcoma Intergroup study. J Clin Oncol. 1999. 17 (10): 3260-9.
6. IBM Micromedex® DRUGDEX® (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. Available at: https://www.micromedexsolutions.com [available with subscription]. Accessed May 3, 2022.