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), inoperable or metastatic disease
2. Acute myeloid leukemia with FLT3-ITD mutation
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, oncocytic/Hürthle cell carcinoma, or follicular carcinoma)
6. Osteosarcoma
7. 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 any of the following criteria are met:
1. For use in low-intensity treatment induction, post-induction therapy, or consolidation therapy as a single agent or in combination with azacitidine or decitabine
2. For use in relapsed/refractory disease in combination with azacitidine or decitabine
3. For use in maintenance therapy after HSCT as a single agent

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 as a single agent for residual, unresectable, recurrent, or metastatic/tumor rupture disease and the member has failed at least four FDA-approved therapies (e.g., imatinib, sunitinib, regorafenib, ripretinib)

E. Renal Cell Carcinoma
Authorization of 12 months may be granted for treatment of advanced renal cell carcinoma.

F. Papillary, Oncocytic, or Follicular Thyroid Carcinoma
Authorization of 12 months may be granted for treatment of progressive and/or symptomatic papillary, oncocytic/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 of bone cancer as a single agent for the following subtypes:
1. Relapsed/refractory or metastatic osteosarcoma, as second line therapy
2. Recurrent chordoma

I. 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.

J. 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 2023 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed May 4, 2023.
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. IBM Micromedex® DRUGDEX® (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. Available at: https://www.micromedexsolutions.com [available with subscription]. Accessed May 4, 2023.