SPECIALTY GUIDELINE MANAGEMENT

NEXAVAR (sorafenib)

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

B. Compendial Uses
1. Relapsed or surgically unresectable RCC
2. Osteosarcoma
3. Soft tissue sarcoma subtypes:
   - Angiosarcoma
   - Desmoid tumors (aggressive fibromatosis)
   - Gastrointestinal stromal tumors (GIST)
4. Medullary thyroid carcinoma:
   - Progressive disease
   - Symptomatic distant metastatic disease
5. Acute myeloid leukemia

All other indications are considered experimental/investigational and are not a covered benefit.

II. CRITERIA FOR INITIAL APPROVAL

A. Acute Myeloid Leukemia
Authorization of 12 months may be granted to members for the treatment of relapsed or refractory acute myeloid leukemia when the member has FLT3-ITD mutation-positive disease.

B. Hepatocellular Carcinoma
Authorization of 12 months may be granted to members for the treatment of unresectable hepatocellular carcinoma.

C. Renal Cell Carcinoma
Authorization of 12 months may be granted to members for the treatment of relapsed or unresectable renal cell carcinoma.

D. Soft Tissue Sarcoma (STS)
Authorization of 12 months may be granted to members prescribed Nexavar for the treatment of soft tissue sarcoma when the member meets ANY of the following criteria:

a. The STS subtype is gastrointestinal stromal tumor (GIST).
b. The STS subtype is angiosarcoma
c. The STS subtype is desmoid tumor/aggressive fibromatosis

E. Thyroid Carcinoma

1. Papillary, Hurthle cell, or Follicular Thyroid Carcinoma
Authorization of 12 months may be granted to members prescribed Nexavar for the treatment of unresectable or metastatic papillary, Hurthle cell, or follicular thyroid carcinoma.

2. Medullary Thyroid Carcinoma
Authorization of 12 months may be granted to members prescribed Nexavar for the treatment of progressive or metastatic medullary thyroid carcinoma.

F. Osteosarcoma
Authorization of 12 months may be granted to members for the treatment of osteosarcoma.

III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

IV. REFERENCES

1. Nexavar [package insert]. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc.; November 2013.
2. The NCCN Drugs & Biologic Compendium™ © 2016 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed June 28, 2016. https://www.nccn.org/professionals/drug_compendium/content/contents.asp.
3. The NCCN Clinical Practice Guidelines in Oncology: Hepatobiliary Cancers. Version 2.2016. Accessed August 2, 2016. https://www.nccn.org/professionals/physician_gls/pdf/hepatobiliary.pdf.
4. The NCCN Clinical Practice Guidelines in Oncology: Kidney Cancer. Version 3.2016. Accessed August 2, 2016. https://www.nccn.org/professionals/physician_gls/pdf/kidney.pdf.
5. The NCCN Clinical Practice Guidelines in Oncology: Thyroid Carcinoma. Version 1.2016. Accessed August 2, 2016. https://www.nccn.org/professionals/physician_gls/pdf/thyroid.pdf/.
6. The NCCN Clinical Practice Guidelines in Oncology: Acute Myeloid Leukemia. Version 2.2016. Accessed August 2, 2016. https://www.nccn.org/professionals/physician_gls/pdf/aml.pdf.