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. Advanced renal cell carcinoma (RCC)
   2. Unresectable hepatocellular carcinoma (HCC)
   3. Locally recurrent or metastatic, progressive, differentiated thyroid carcinoma (DTC) that is refractory to radioactive iodine treatment

B. Compendial Uses
   1. HCC
      a. Patients who are nontransplant candidates with unresectable disease
      b. Patients who are inoperable by performance status or comorbidity
      c. Patients who have extensive liver tumor burden or metastatic disease
   2. Acute myeloid leukemia
   3. Thyroid carcinoma (medullary, papillary, Hürthle cell, or follicular)

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

II. CRITERIA FOR INITIAL APPROVAL

A. Hepatocellular Carcinoma
Authorization of 12 months may be granted for treatment of hepatocellular carcinoma.

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

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

D. Thyroid Carcinoma
Authorization of 12 months may be granted for treatment of medullary, papillary, Hürthle cell, or follicular thyroid carcinoma.

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.; December 2017.
2. The NCCN Drugs & Biologic Compendium® © 2018 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed May 18, 2018.
3. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®): Hepatobiliary Cancers. Version 1.2018. Accessed May 18, 2018. https://www.nccn.org/professionals/physician_gls/pdf/hepatobiliary.pdf.
4. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®): Acute Myeloid Leukemia. Version 1.2018. Accessed May 18, 2018. https://www.nccn.org/professionals/physician_gls/pdf/aml.pdf.
5. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®): Kidney Cancer. Version 4.2018. Accessed May 18, 2018. https://www.nccn.org/professionals/physician_gls/pdf/kidney.pdf.
6. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®): Thyroid Carcinoma. Version 2.2017. Accessed May 18, 2018. https://www.nccn.org/professionals/physician_gls/pdf/thyroid.pdf.
7. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®): Soft Tissue Sarcoma. Version 2.2018. Accessed May 18, 2018. https://www.nccn.org/professionals/physician_gls/pdf/sarcoma.pdf.