CareFirst Family of health care plans

CVS caremark™

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. Soft tissue sarcoma subtypes:
   - Angiosarcoma
   - Desmoid tumors (aggressive fibromatosis)
   - Gastrointestinal stromal tumors (GIST)
4. Relapsed or stage IV RCC
5. Medullary thyroid carcinoma
6. Osteosarcoma
7. Chordoma

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. Soft Tissue Sarcoma (STS)
Authorization of 12 months may be granted for treatment of soft tissue sarcoma when the STS subtype is: gastrointestinal stromal tumor (GIST), angiosarcoma, or desmoid tumor/aggressive fibromatosis

D. Renal Cell Carcinoma

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

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

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

G. Chordoma
Authorization of 12 months may be granted for treatment of chordoma.

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® © 2017 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed July 24, 2017.
3. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®): Hepatobiliary Cancers. Version 2.2017. Accessed July 25, 2017. https://www.nccn.org/professionals/physician_gls/pdf/hepatobiliary.pdf.
4. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®): Acute Myeloid Leukemia. Version 3.2017. Accessed July 25, 2017. https://www.nccn.org/professionals/physician_gls/pdf/aml.pdf.
5. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®): Kidney Cancer. Version 2.2017. Accessed July 24, 2017. 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 July 24, 2017. https://www.nccn.org/professionals/physician_gls/pdf/thyroid.pdf.