

SPECIALTY GUIDELINE MANAGEMENT

CABOMETYX (cabozantinib)

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 Indication

Cabometyx is indicated for the treatment of patients with:

1. Advanced renal cell carcinoma (RCC)
2. Hepatocellular carcinoma (HCC) who have been previously treated with sorafenib

B. Compendial Uses

1. Relapsed or surgically unresectable stage IV kidney cancer
2. Non-small cell lung cancer
3. Hepatocellular carcinoma (HCC) who have been previously treated with lenvatinib

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

II. CRITERIA FOR INITIAL APPROVAL

A. **Renal Cell Carcinoma**

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

B. **Hepatocellular carcinoma (HCC)**

Authorization of 12 months may be granted for treatment of hepatocellular carcinoma (HCC) who have been previously treated with sorafenib (Nexavar) or lenvatinib (Lenvima).

C. **Non-small Cell Lung Cancer**

Authorization of 12 months may be granted for treatment of RET (rearranged during transfection) positive non-small cell lung cancer.

III. CONTINUATION OF THERAPY

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

IV. REFERENCES

1. Cabometyx [package insert]. South San Francisco, CA: Exelixis, Inc.; January 2019.

Reference number(s)
2212-A

2. The NCCN Drugs & Biologics Compendium® © 2018 National Comprehensive Cancer Network, Inc. <http://www.nccn.org>. Accessed May 8, 2018.
3. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®): Kidney Cancer. Version 4.2018. Accessed May 3, 2018.
https://www.nccn.org/professionals/physician_gls/pdf/kidney.pdf.
4. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®): Hepatobiliary Cancer. Version 1.2019. Accessed February 22, 2019.