Reference number(s)
2212-A

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 Indications
Cabometyx is indicated for the treatment of patients with:
1. Advanced renal cell carcinoma (RCC)
2. Advanced renal cell carcinoma (RCC) in combination with nivolumab for first-line treatment
3. Hepatocellular carcinoma (HCC) who have been previously treated with sorafenib
4. Locally advanced or metastatic differentiated thyroid cancer (DTC) that has progressed following prior VEGFR-targeted therapy and who are radioactive iodine-refractory or ineligible (adult and pediatric patients 12 years of age and older)

B. Compendial Uses
1. Relapsed or stage IV renal cell carcinoma
2. Non-small cell lung cancer with RET (rearranged during transfection) gene rearrangement
3. Hepatocellular carcinoma as subsequent treatment
4. Ewing Sarcoma
5. Osteosarcoma
6. Gastrointestinal Stromal Tumor (GIST)

All other indications are considered experimental/investigational and not medically necessary.

II. DOCUMENTATION

Submission of RET gene rearrangement documentation is necessary to initiate the prior authorization review for the indication of non-small cell lung cancer.

III. CRITERIA FOR INITIAL APPROVAL

A. Renal Cell Carcinoma
Authorization of 12 months may be granted for treatment of advanced, relapsed, or stage IV renal cell carcinoma when used in either of the following settings:
1. As a single agent.
2. In combination with nivolumab.

B. Hepatocellular Carcinoma
Authorization of 12 months may be granted as a single agent for subsequent treatment of hepatocellular carcinoma.

C. Non-small Cell Lung Cancer
Authorization of 12 months may be granted as a single agent for treatment of recurrent, advanced, or metastatic non-small cell lung cancer with RET gene rearrangement.

D. Ewing Sarcoma
Authorization of 12 months may be granted for treatment of Ewing sarcoma as a single agent for subsequent therapy.

E. Osteosarcoma
Authorization of 12 months may be granted for treatment of osteosarcoma as a single agent for subsequent therapy.

F. Gastrointestinal Stromal Tumor (GIST)
Authorization of 12 months may be granted for treatment of unresectable, recurrent, or metastatic GIST as a single agent when the member has failed at least four FDA-approved therapies (e.g., imatinib, sunitinib, regorafenib, ripretinib).

G. Thyroid Carcinoma
Authorization of 12 months may be granted for treatment of follicular, Hürthle cell, or papillary thyroid carcinoma when all of the following criteria are met:
1. Member has locally advanced or metastatic disease
2. Disease has progressed after VEGFR-targeted therapy (e.g., lenvatinib and sorafenib)
3. Disease is not amenable to radioactive iodine therapy (RAI)
4. Member is at least 12 years old

IV. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section III when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

V. REFERENCES

1. Cabometyx [package insert]. Alameda, CA: Exelixis, Inc.; September 2021.
2. The NCCN Drugs & Biologics Compendium® © 2021 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed May 10, 2021.