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), as a first-line treatment in combination with nivolumab
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)
7. Endometrial carcinoma

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 GIST when either of the following criteria are met:
1. The member meets all of the following criteria:
   i. Member has unresectable, recurrent/progressive or metastatic disease
   ii. Member has failed at least four FDA-approved therapies (e.g., imatininb, sunitinib, regorafenib, ripretinib)
   iii. The requested medication will be used as a single agent
2. The requested medication will be used for palliation of symptoms if previously tolerated and effective.

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

H. Endometrial Carcinoma
Authorization of 12 months may be granted for treatment of recurrent or metastatic endometrial carcinoma as a single agent for subsequent therapy.

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® © 2022 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed May 3, 2022.