

Cabometyx (cabozantinib)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Cabometyx (cabozantinib) Tablets	May be subject to quantity limit

APPROVAL CRITERIA

Requests for Cabometyx (cabozantinib) may be approved if the following criteria are met:

I. Individual has a diagnosis of advanced renal cell carcinoma;

OR

II. Individual has a diagnosis of locally advanced, metastatic, or unresectable hepatocellular carcinoma (Label, NCCN 1); **AND**
Individual has disease progression on or after sorafenib;

OR

III. Individual has a diagnosis of Non-Small Cell Lung Cancer with RET gene rearrangements (NCCN 2A); **AND**
IV. Individual has not received treatment with another RET-targeted agent (for example, selpercatinib);

OR

V. Individual has a diagnosis of Gastrointestinal Stromal Tumors (GIST) (NCCN 2A); **AND**
VI. Individual has unresectable, recurrent, gross residual disease, tumor rupture, or metastatic disease after failure on approved therapies (such as imatinib, sunitinib, and regorafenib, and ripretinib);

OR

VII. Individual has a diagnosis of Bone Cancer- Osteosarcoma or Ewing Sarcoma (NCCN 2A); **AND**
VIII. Individual is using as second-line therapy for relapsed or refractory or metastatic disease;

OR

IX. Individual has a diagnosis of locally advanced or metastatic differentiated thyroid cancer (DTC) (Label); **AND**
X. Individual has disease progression following prior VEGFR-target therapy; **AND**
XI. Individual has disease that is radioactive iodine-refractory or ineligible;

OR

XII. Individual has a diagnosis of endometrial cancer (NCCN 2A); **AND**

- XIII. Individual is using Cabometyx as a single agent; **AND**
XIV. Individual is using as second-line or subsequent therapy for recurrent or metastatic disease.

Note: Do not substitute Cabometyx tablets with cabozantinib capsules.

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2023. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: June 21, 2023.
3. Dhani NC, Hirte HW, Wang L, et al. Phase II Trial of Cabozantinib in Recurrent/Metastatic Endometrial Cancer: A Study of the Princess Margaret, Chicago, and California Consortia (NCI9322/PHL86). Clin Cancer Res. 2020;26(11):2477-2486. doi:10.1158/1078-0432.CCR-19-2576. Available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7269808/>. Accessed July 10, 2023
4. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
5. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2023; Updated periodically.
6. NCCN Clinical Practice Guidelines in Oncology™. © 2023 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on June 21, 2023.
 - a. Bone Cancer. V3.2023. Revised April 4, 2023.
 - b. Non-small cell lung cancer. V3.2023. Revised April 13, 2023.
 - c. Hepatocellular Carcinoma. V1.2023. Revised March 10, 2023.
 - d. Central Nervous System Cancers. V1.2023. Revised March 24, 2023.
 - e. Kidney Cancer. V4.2023. Revised January 18, 2023.
 - f. Uterine Neoplasms. V2.2023. Revised April 28, 2023.
 - g. Thyroid Carcinoma. V2.2023. Revised May 18, 2023.
 - h. Gastrointestinal Stromal Tumors. V1.2023. Revised March 13, 2023.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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