

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, metastatic, or relapsed renal cell carcinoma (Label, NCCN 2A);

OR

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

OR

- IV. Individual has a diagnosis of recurrent, advanced, or metastatic Non-Small Cell Lung Cancer with RET gene rearrangements (NCCN 2A); **AND**
- V. Individual has disease progression following first-line pralsetinib or selpercatinib;

OR

- VI. Individual has a diagnosis of Gastrointestinal Stromal Tumors (GIST) (NCCN 2A); **AND**
- VII. 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

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

OR

- X. Individual has a diagnosis of locally advanced, progressive, symptomatic, or metastatic differentiated thyroid cancer (DTC) (Label, NCCN 2A)); **AND**
- XI. Individual has disease progression following prior VEGFR-target therapy; **AND**
- XII.

OR

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

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

OR

- XIII. Individual has a diagnosis of alveolar soft part sarcoma or extraskeletal myxoid chondrosarcoma (NCCN 2A); **AND**
- XIV. Individual is using as a single-agent therapy;

OR

- XV. Individual has a diagnosis of neuroendocrine tumors (including lung, thymus, gastrointestinal tract, pancreas, or well-differentiated grade 3 neuroendocrine tumors) (Label, NCCN 1, 2A).

Note: Do not substitute Cabometyx tablets with cabozantinib capsules.

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2025. 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>. Updated periodically.
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.; 2025; Updated periodically.
6. NCCN Clinical Practice Guidelines in Oncology™. © 2025 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on June 17, 2024.
 - a. Bone Cancer. V2.2024. Revised March 12, 2024.
 - b. Non-small cell lung cancer. V6.2024. Revised June 14, 2024.
 - c. Hepatocellular Carcinoma. V1.2024. Revised April 9, 2024.
 - d. Central Nervous System Cancers. V1.2024. Revised May 31, 2024.
 - e. Kidney Cancer. V4.2024. Revised May 30, 2024.
 - f. Uterine Neoplasms. V2.2024. Revised March 6, 2024.
 - g. Thyroid Carcinoma. V2.2024. Revised March 12, 2024.
 - h. Gastrointestinal Stromal Tumors. V1.2024. Revised March 8, 2024.

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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