Clinical Policy: Cabozantinib (Cometriq, Cabometyx)

Reference Number: PA.CP.PHAR.111
Effective Date: 06/13
Last Review Date: 07/18

Coding Implications
Revision Log

Description
The intent of the criteria is to ensure that patients follow selection elements established by Pennsylvania Health and Wellness® clinical policy for cabozantinib (Cometriq™, Cabometyx™).

FDA Approved Indication(s)
Cometriq is indicated the treatment of patients with progressive, metastatic medullary thyroid cancer (MTC).

Cabometyx is indicated for the treatment of patients with advanced renal cell carcinoma (RCC).

Policy/Criteria
It is the policy of health plans affiliated with Pennsylvania Health and Wellness that Cometriq and Cabometyx are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Renal Cell Carcinoma (must meet all):
1. Diagnosis of RCC;
2. Prescribed by or in consultation with an oncologist;
3. Request is for Cabometyx;
4. Age ≥ 18 years;
5. Dose does not exceed 80 mg/day.

B. Medullary Thyroid Cancer (must meet all):
1. Diagnosis of progressive, metastatic MTC;
2. Prescribed by or in consultation with an oncologist;
3. Request is for Cometriq;
4. Age ≥ 18 years;
5. Dose does not exceed 180 mg/day.

Approval Duration: 6 months

C. Non-Small Cell Lung Cancer (off-label) (must meet all)**:**
1. Diagnosis of non-small cell lung cancer (NSCLC) with RET gene rearrangements;
2. Prescribed by or in consultation with an oncologist;
3. Request is for Cabometyx;
4. Age ≥ 18 years;
5. Request meets one of the following (a or b):
   a. Dose does not exceed 60 mg/day;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval Duration: 6 months

Other diagnoses/indications: Refer to PA.CP.PMN.53

II. Continued Approval

1. **All Indications in Section I** (must meet all Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria or Continuity of Care Policy (PA.LTSS.PHAR.01) applies;
   2. Documentation of positive response to therapy (e.g.: no disease progression, no unacceptable toxicity);3.If request is for a dose increase, request meets one of the following (a or b):
   a. New dose does not exceed the maximum dosing listed in Section I;
   b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval Duration: 12 months

A. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy or Continuity of Care Policy (PA.LTSS.PHAR.01) applies; **Approval duration: Duration of request or 6 months (whichever is less)**; or

1. Refer to PA.CP.PMN.53

Background

Description/Mechanism of Action:

Cabozantinib is an oral kinase inhibitor. In vitro biochemical and/or cellular assays have shown that cabozantinib inhibits the tyrosine kinase activity of RET, MET, VEGFR-1, -2 and -3, KIT, TRKB, FLT-3, AXL, and TIE-2. These receptor tyrosine kinases are involved in both normal cellular function and pathologic processes such as oncogenesis, metastasis, tumor angiogenesis, and maintenance of the tumor microenvironment.

Formulations:

Cabozantinib (Cometriq) capsules: 20 mg and 80 mg
Cabozantinib (Cabometyx) tablets: 20 mg, 40 mg, and 60 mg

FDA Approved Indication:

Cometriq is a kinase inhibitor/oral capsule indicated for:

- Treatment of patients with progressive, metastatic medullary thyroid cancer.

Cabometyx is a kinase inhibitor/oral tablet indicated for:

- Treatment of patients with advanced renal cell carcinoma who have received prior anti-angiogenic therapy.

Coding Implications
Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J8999	Prescription drug, oral, chemotherapeutic, NOS

Reviews, Revisions, and Approvals	Date	Approval Date
Removed safety requirement for hemorrhage and hemoptysis per CPAC safety guidance endorsed by medical affairs. For RCC, modified redirection to apply only for clear cell histology, requiring NCCN Category 1 recommended alternatives. Added off-label use for RCC with non-clear cell histology and NSCLC. References reviewed and updated.	02/18	

References
1. Cometriq Prescribing Information. South San Francisco, CA: Exelixis, Inc.; October 2017. Available at http://www.cometriq.com/downloads/Cometriq_Full_Prescribing_Information.pdf. Accessed November 8, 2017.
2. Cabometyx Prescribing Information. South San Francisco, CA: Exelixis, Inc.; April 2016. Available at: https://www.cabometyx.com/downloads/CABOMETYXUSPI.pdf. Accessed November 8, 2017.
3. Cabozantinib. In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at www.NCCN.org. Accessed November 8, 2017.
4. Drilon A, Rekhtman N, Arcila M, et al. Cabozantinib in patients with advanced RET-rearranged non-small-cell lung cancer: an open-label, single-centre, phase 2, single-arm trial. Lancet Oncology. 2016 Dec;17(12):1653-1660.
5. National Comprehensive Cancer Network. Kidney Cancer Version 1.2018 – September 7, 2017. Available at: https://www.nccn.org/professionals/physician_gls/pdf/kidney.pdf. Accessed November 8, 2017.
6. National Comprehensive Cancer Network. Non-Small Cell Lung Cancer Version 9.2017 – September 28, 2017. Available at: https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf. Accessed November 8, 2017.
7. National Comprehensive Cancer Network. Thyroid carcinoma Version 2.2017. Available at https://www.nccn.org/professionals/physician_gls/pdf/thyroid.pdf. Accessed November 8, 2017.