Clinical Policy: Cabozantinib (Cometriq, Cabometyx)

Reference Number: PA.CP.PHAR.111
Effective Date: 06/13
Last Review Date: 04/17

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™).

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. Medullary Thyroid Cancer (must meet all):

1. Diagnosis of progressive, metastatic medullary thyroid cancer;
2. Request is for Cometriq;
3. Member does not have a recent history of hemorrhage or hemoptysis;
4. Prescribed dose of Cometriq does not exceed the following (a or b):
   a. 140 mg per day;
   b. If taking a strong CYP3A4 inducer (e.g., phenytoin, carbamazepine, rifampin, rifabutin, rifapentine, phenobarbital): 180 mg per day.

Approval Duration: 6 months

B. Renal Cell Carcinoma (must meet all):

1. Diagnosis of advanced renal cell carcinoma;
2. Request is for Cabometyx;
3. Member has received prior anti-angiogenic therapy (e.g., Votrient; Sutent; Inlyta; Nexavar; Avastin in combination with interferon alfa);
4. Prescribed dose of Cabometyx does not exceed the following (a or b):
   a. 60 mg per day;
   b. If taking a strong CYP3A4 inducer (e.g., phenytoin, carbamazepine, rifampin, rifabutin, rifapentine, phenobarbital): 80 mg per day.

Approval Duration: 6 months

C. Other diagnoses/indications: Refer to PA.CP.PHAR.57 - Global Biopharm Policy.

1. Additional Cometriq uses, as outlined in the NCCN compendium and meeting NCCN category 1, 2a, or 2b, are covered for the following indications per the PA.CP.PHAR.57 Global Biopharm Policy:
   a. Non-small cell lung cancer.

II. Continued Approval

A. Medullary Thyroid Cancer (must meet all)**:**

1. 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. Prescribed dose of Cometriq does not exceed the following (a or b):
   a. 140 mg per day;
   b. If taking a strong CYP3A4 inducer (e.g., phenytoin, carbamazepine, rifampin, rifabutin, rifapentine, phenobarbital): 180 mg per day.

Approval Duration: 12 months

B. Renal Cell Carcinoma

1. 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 unacceptable toxicity; attestation that member continues to experience clinical benefit from therapy);
3. Prescribed dose of Cabometyx does not exceed the following (a or b):
   a. 60 mg per day;
   b. If taking a strong CYP3A4 inducer (e.g., phenytoin, carbamazepine, rifampin, rifabutin, rifapentine, phenobarbital): 80 mg per day.

Approval Duration: 12 months

C. 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; or
2. Refer to PA.CP.PHAR.57 - Global Biopharm Policy**.**

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

References

1. Cometriq Prescribing Information. South San Francisco, CA: Exelixis, Inc.; May 2016. Available at http://www.cometriq.com/. Accessed March 22, 2017.
2. Cabometyx Prescribing Information. South San Francisco, CA: Exelixis, Inc.; April 2016. Available at: https://www.cabometyx.com/. Accessed March 28, 2017.
3. Cabozantinib. In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at www.NCCN.org. Accessed March 22, 2017.