Cabozantinib (Cometriq®; Cabometyx™) (Oral)

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I. Length of Authorization

Coverage will be provided for six months and may be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [Pharmacy Benefit]:

Cometriq® capsules:

- 140 mg daily dose carton: 112 capsules per 28 days
  (4 cards each containing: #21 x 20 mg capsules and #7 x 80 mg capsules)
- 100 mg daily dose carton: 56 capsules per 28 days
  (4 cards each containing: #7 x 20 mg capsules and #7 x 80 mg capsules)
- 60 mg daily dose carton: 84 capsules per 28 days
  (4 cards each containing: #21 x 20 mg capsules)

Cabometyx™ tablets:

- Cabometyx 20 mg tablet: 30 tablets per 30 days (1 tablet per day)
- Cabometyx 40 mg tablet: 30 tablets per 30 days (1 tablet per day)
- Cabometyx 60 mg tablet: 30 tablets per 30 days (1 tablet per day)

B. Max Units (per dose and over time) [Medical Benefit]:

- Thyroid Carcinoma
  - 180 mg daily
- All other indications
  - 60 mg daily

III. Initial Approval Criteria

Coverage is provided in the following conditions:

- Patient age is 18 years or older; **AND**
- Patient does not have a recent history of severe hemorrhage; **AND**
- Patient does not have a recent history of gastrointestinal perforations and/or fistula; **AND**

Thyroid Carcinoma (Cometriq®)

- Patient has Medullary disease †; **AND**
  - Patient has progressive, metastatic disease; **OR**
  - Patient has unresectable, symptomatic or structurally progressive locoregional disease; **OR**
- Patient Follicular, Hürthle Cell or Papillary carcinoma ‡; **AND**
  - Patient's has unresectable recurrent, persistent, or metastatic disease; **AND**
  - Patient has progressive and/or symptomatic iodine-refractory disease; **AND**
  - Clinical trials or other therapies are not available or appropriate

Renal Cell Carcinoma (Cabometyx™) †

- Must be used as a single agent; **AND**
  - Patient has advanced, relapsed or unresectable metastatic disease; **AND**
    - Used as primary treatment; OR
    - Used as subsequent therapy for pre-dominantly clear cell histology; **OR**
    - Patient has non-clear cell histology

Non-Small Cell Lung Cancer ‡

- Patient's cancer has confirmed RET gene rearrangements

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s)

IV. Renewal Criteria

Coverage can be renewed based upon the following criteria:

- Patient continues to meet criteria as defined in Section III; **AND**
- Tumor response with stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include:
  - Cometriq®: development of visceral perforation or fistula formation; severe hemorrhage; serious arterial thromboembolic event (e.g., myocardial infarction, cerebral infarction); nephrotic syndrome; malignant hypertension; hypertensive crisis; persistent uncontrolled hypertension despite optimal medical management; osteonecrosis of the jaw; reversible posterior leukoencephalopathy syndrome.
  - Cabometyx™: severe diarrhea, severe hemorrhage, GI perforation and fistula, thromboembolic events, severe hypertension/hypertensive crisis, palmar-plantar erythrodysesthesia syndrome (PPES) and reversible posterior leukoencephalopathy syndrome.

V. Dosage/Administration

Indication	Dose

Thyroid Carcinoma **(Cometriq®)†**	140 mg orally once daily (capsule formulation) • 180mg daily with concomitant strong CYP3A4 inducer • 100mg daily with concomitant strong CYP3A4 inhibitor
Renal Cell Carcinoma (RCC) **(Cabometyx™)†**	60 mg orally once daily (tablet formulation) • Do not eat for at least 2 hours before and at least 1 hour after taking.
Non-Small Cell Lung Cancer (NSCLC)‡	60 mg orally once daily

VI. Billing Code/Availability Information

HCPCS:

J8999 – Prescription drug, oral, chemotherapeutic, not otherwise specified

C9399 – Unclassified drugs or biologicals (*Hospital Outpatient Use ONLY*)

NDC:

- Cometriq 140 mg daily-dose carton: 42388-0011-xx
- Cometriq 100 mg daily-dose carton: 42388-0012-xx
- Cometriq 60 mg daily-dose carton: 42388-0013-xx
- Cabometyx 20 mg tablet: 42388-0024-xx
- Cabometyx 40 mg tablet: 42388-0025-xx
- Cabometyx 60 mg tablet: 42388-0023-xx

VII. References

1. Cometriq® [package insert]. South San Francisco, CA; Exelixis, Inc; October 2017. Accessed December 2017.
2. Cabometyx™ [package insert]. South San Francisco, CA; Exelixis, Inc.; December 2017; Accessed December 2017.
3. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for cabozantinib. National Comprehensive Cancer Network, 2017. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed December 2017.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C33	Malignant neoplasm of trachea
C34.00	Malignant neoplasm of unspecified main bronchus

C34.01	Malignant neoplasm of right main bronchus
C34.02	Malignant neoplasm of left main bronchus
C34.10	Malignant neoplasm of upper lobe, unspecified bronchus or lung
C34.11	Malignant neoplasm of upper lobe, right bronchus or lung
C34.12	Malignant neoplasm of upper lobe, left bronchus or lung
C34.2	Malignant neoplasm of middle lobe, bronchus or lung
C34.30	Malignant neoplasm of lower lobe, unspecified bronchus or lung
C34.31	Malignant neoplasm of lower lobe, right bronchus or lung
C34.32	Malignant neoplasm of lower lobe, left bronchus or lung
C34.80	Malignant neoplasm of overlapping sites of unspecified bronchus or lung
C34.81	Malignant neoplasm of overlapping sites of right bronchus or lung
C34.82	Malignant neoplasm of overlapping sites of left bronchus or lung
C34.90	Malignant neoplasm of unspecified part of unspecified bronchus or lung
C34.91	Malignant neoplasm of unspecified part of right bronchus or lung
C34.92	Malignant neoplasm of unspecified part of left bronchus or lung
C64.1	Malignant neoplasm of right kidney, except renal pelvis
C64.2	Malignant neoplasm of left kidney, except renal pelvis
C64.9	Malignant neoplasm of unspecified kidney, except renal pelvis
C65.1	Malignant neoplasm of right renal pelvis
C65.2	Malignant neoplasm of left renal pelvis
C65.9	Malignant neoplasm of unspecified renal pelvis
C73	Malignant neoplasm of thyroid gland
Z85.118	Personal history of other malignant neoplasm of bronchus and lung
Z85.528	Personal history of other malignant neoplasm of kidney

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD):

N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
E (1)	CA,HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Cahaba Government Benefit Administrators, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC