POLICY NUMBER UM ONC_1237	SUBJECT Cometriq/Cabometyx ™ (cabozantinib)		DEPT/PROGRAM UM Dept	PAGE 1 OF 3
DATES COMMITTEE REVIEWED 01/09/13, 01/08/14, 06/10/15, 06/07/16, 05/10/17, 05/07/18, 05/08/19, 12/11/19, 04/08/20	APPROVAL DATE April 8, 2020	EFFECTIVE DATE April 24, 2020	COMMITTEE APPROVAL DATES (latest version listed last) 01/09/13, 01/08/14, 06/10/15, 06/07/16, 05/10/17, 05/07/18, 05/08/19, 12/11/19, 04/08/20	
PRIMARY BUSINESS OWNER: UM APPROVED BY: Dr. Andrew Hertler		COMMITTEE/BOARD APPROVAL Utilization Management Committee		
URAC STANDARDS HUM 1	NCQA STANDARDS UM 2		ADDITIONAL AREAS OF IMPACT	
CMS REQUIREMENTS	STATE/FEDERAL REQUIREMENTS		APPLICABLE LINES OF BUSINESS All	

I. PURPOSE

To define and describe the accepted indications for Cometriq/Cabometyx (cabozantinib) usage in the treatment of cancer, including FDA approved indications, and off-label indications.

New Century is responsible for processing all medication requests from network ordering providers. Medications not authorized by New Century may be deemed as not approvable and therefore not reimbursable.

The use of this drug must be supported by one of the following: FDA approved product labeling, CMS-approved compendia, National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO) clinical guidelines, or peer-reviewed literature that meets the requirements of the CMS Medicare Benefit Policy Manual Chapter 15.

II. INDICATIONS FOR USE/INCLUSION CRITERIA

1. **PREFERRED MEDICATION GUIDANCE FOR INITIAL REQUEST:**
    a. When health plan Medicaid coverage provisions- including any applicable PDLs (Preferred Drug Lists)- conflict with the coverage provisions in this drug policy, health plan Medicaid coverage provisions take precedence per the **Preferred Drug Guidelines OR**
    b. When health plan Exchange coverage provisions- including any applicable PDLs (Preferred Drug Lists)- conflict with the coverage provisions in this drug policy, health plan Exchange coverage provisions take precedence per the **Preferred Drug Guidelines OR**
    c. For Health Plans that utilize NCH UM Oncology Clinical Policies as the initial clinical criteria, the **Preferred Drug Guidelines shall follow NCH L1 Pathways** when applicable, otherwise shall follow NCH drug policies: **Error! Hyperlink reference not valid. AND**
    d. Continuation requests of previously approved non-preferred medication are not subject to this provision **AND**
    e. When available, generic alternatives are preferred over brand-name drugs.
2. **Thyroid Cancer**
    a. COMETRIQ (cabozantinib) is being used for members with any of the following:
        i. Unresectable or metastatic medullary thyroid cancer **OR**
        ii. Unresectable or metastatic papillary, follicular, or Hurthle cell thyroid cancer and the member is refractory to radioactive iodine treatment.

3. **Kidney Cancer**
    a. **NOTE: The preferred tyrosine kinase inhibitor, per NCH Policy & NCH Pathway for advanced/metastatic RCC, is CABOMETYX (cabozantinib) in the first line setting for Intermediate/Poor Risk disease, and for subsequent therapy for any risk disease.**
    b. **IMDC criteria: Please see table below.**

CRITERIA= Assign 1 point for each	**RISK CATEGORIES= RISK SCORE**
Time to systemic treatment less than 1 year from diagnosis	Favorable Risk = 0
Performance Status < 80% Karnofsky Scale	Intermediate Risk = 1-2
Hemoglobin < LLN; <12 g/dL	Poor Risk= 3-6
Calcium > ULN; > 12 mg/dL	
Neutrophils > ULN	
Platelets > ULN	

    c. CABOMETYX (cabozantinib) may be used in metastatic/inoperable renal cell carcinoma in the first line setting for Intermediate/Poor Risk disease (IMDC Criteria) **OR**
    d. Subsequent line therapy regardless of IMDC Risk.
4. **Hepatocellular Carcinoma (HCC)**
    a. **NOTE: The preferred tyrosine kinase inhibitor, per NCH Policy & NCH Pathway, for subsequent line therapy of unresectable or metastatic HCC is REGORAFENIB.**
    b. The member has HCC and CABOMETYX (cabozantinib) is being used as a single agent for unresectable or metastatic disease in members with Child-Pugh Class A only and who have been previously treated with any multi-kinase inhibitor.

III. EXCLUSION CRITERIA

1. Off-label indications for CABOMETYX (cabozantinib) in non-small cell lung cancer.
2. Disease progression while taking Cometriq/Cabometyx (cabozantinib).
3. Dosing exceeds single dose limit of Cometriq 140 mg and Cabometyx 60 mg.
4. Treatment exceeds the maximum limit of Cometriq 90 (20 mg) capsules or 30 (80 mg) capsules per month; Cabometyx 90 (20 mg) or 30 (60 mg) tablets per month.
5. Indications not supported by CMS recognized compendia or acceptable peer reviewed literature.

IV. MEDICATION MANAGEMENT

Please refer to the FDA label/package insert for details regarding these topics.

V. APPROVAL AUTHORITY

1. Review – UM Department
2. Final Approval – UM Committee

VI. ATTACHMENTS

None

VII. REFERENCES

1. Cometriq/Cabometyx prescribing information. Exelixis, Inc. South San Francisco, CA 2020.
2. Clinical Pharmacology Elsevier Gold Standard. 2020.
3. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, Co. 2020.
4. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium. 2020.
5. AHFS Drug Information. American Society of Health-Systems Pharmacists. Bethesda, MD. 2020.