UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 1021-12
Program	Prior Authorization/Notification
Medication	Cometriq® (cabozantinib)
P&T Approval Date	02/2013, 07/2013, 8/2014, 8/2015, 6/2016, 6/2017, 6/2018, 6/2019, 6/2020, 6/2021, 6/2022, 6/2023, 6/2024
Effective Date	9/1/2024

1. Background:
Cometriq® (cabozantinib) is a kinase inhibitor indicated for the treatment of patients with progressive, metastatic medullary thyroid cancer (MTC).[1]

In addition, the National Cancer Comprehensive Network (NCCN) recommends Cometriq for the treatment of medullary, follicular, oncocytic and papillary thyroid carcinomas. NCCN also recommends Cometriq for the treatment of non-small cell lung cancer (NSCLC) with RET gene rearrangement.[2]

Coverage Information:
Members will be required to meet the criteria below for coverage. For members under the age of 19 years, the prescription will automatically process without a coverage review.

Some states mandate benefit coverage for off-label use of medications for some diagnoses or under some circumstances. Some states also mandate usage of other Compendium references. Where such mandates apply, they supersede language in the benefit document or in the notification criteria.

2. Coverage Criteria[a]:

A. <u>Patients less than 19 years of age</u>

1. **Cometriq** will be approved based on the following criterion**:**

   a. Patient is less than 19 years of age

Authorization will be issued for 12 months.

B. <u>Thyroid Carcinoma</u>

1. **<u>Initial Authorization</u>**

   a. **Cometriq** will be approved based on the following criterion:

      (1) **<u>One</u>** of the following:

         (a) Diagnosis of medullary carcinoma

         -OR-

         (b) **<u>All</u>** of the following:

i. Diagnosis of **one** of the following:
- Follicular carcinoma
- Oncocytic cell carcinoma
- Papillary carcinoma

-AND-

ii. Disease is progressive after treatment with **one** of the following:
- Lenvima (lenvatinib)
- Nexavar (sorafenib)

-AND-

iii. Disease is at least **one** of the following:
- Symptomatic iodine-refractory
- Unresectable locoregional recurrent or persistent disease
- Distant metastatic disease

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Cometriq** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Cometriq therapy

Authorization will be issued for 12 months.

C. Non-Small Cell Lung Cancer (NSCLC)

1. **Initial Authorization**

a. **Cometriq** will be approved based on **both** of the following criteria:

(1) Diagnosis of non-small cell lung cancer (NSCLC)

-AND-

(2) Positive for RET gene rearrangements

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Cometriq** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Cometriq therapy

Authorization will be issued for 12 months.

D. NCCN Recommended Regimens

The drug has been recognized for treatment of the cancer indication by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Cometriq [prescribing information]. Alameda, CA: Exelixis, Inc.; August 2023.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed May 9, 2024.

Program	Prior Authorization/Notification - Cometriq (cabozantinib)
Change Control	
7/2013	Review of clinical criteria. No change to coverage. Updated formatting.
8/2014	Annual review. Added coverage for NSCLC, clarified thyroid cancer, updated formatting, Background and References.
8/2015	Annual review with no change to clinical criteria. Increased authorization and reauthorization from 11 months to 12 months for all indications. Updated references.
6/2016	Annual review. Updated MTC clinical criteria to include only a diagnosis of MTC. Updated background, formatting and references.
6/2017	Annual review. Changed MTC clinical criteria to Thyroid Cancer to include NCCN expanded thyroid cancer indications. Updated background, formatting and references.
6/2018	Annual review. Updated references.
6/2019	Annual review. Revised criteria for thyroid carcinoma. Updated references.
6/2020	Annual review. Updated references.
6/2021	Annual review. No change to clinical criteria. Updated references.
6/2022	Annual review. Revised clinical criteria for thyroid carcinomas to align

	with NCCN indications. Added NCCN Recommended Regimens to coverage criteria. Updated references.
6/2023	Annual review. Updated Hürthle cell neoplasm to Oncocytic carcinoma in background and criteria per NCCN guidelines. No change in clinical intent of criteria. Updated references and added state mandate footnote.
6/2024	Annual review. Updated references.