

Clinical Pharmacy Program Guidelines for Cometriq

Program	Prior Authorization
Medication	Cometriq [®] (cabozantinib)
Markets in Scope	Arizona, California, Hawaii, Maryland, Nevada, New Jersey, New York, New York EPP, Pennsylvania-CHIP, Rhode Island, South Carolina
Issue Date	7/2013
Pharmacy and Therapeutics Approval Date	6/2020
Effective Date	8/2020

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, hürthle, and papillary thyroid carcinomas. NCCN also recommends Cometriq for the treatment of non-small cell lung cancer (NSCLC) with RET gene rearrangement.²

Cometriq has a black box warning for perforations and fistulas, and hemorrhage. Please see full prescribing information for additional details.

2. Coverage Criteria:

A. Thyroid Carcinoma

1. Initial Authorization

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

(1) **One** of the following:

(a) Diagnosis of medullary carcinoma

-OR-

(b) **All** of the following:

i. Diagnosis of **one** of the following:

- Follicular carcinoma

- Hürthle cell carcinoma
- Papillary carcinoma

-AND-

ii. Clinical trials or other systemic therapies are not available or appropriate

-AND-

iii. Disease is at least **one** of the following:

- Progressive
- 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.

B. 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.

C. NCCN Recommended Regimens

1. Initial Authorization

a. **Cometriq** will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium.

Authorization will be issued for 12 months.

2. Reauthorization

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

(1) Documentation of positive clinical response to Cometriq therapy

Authorization will be issued for 12 months.

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]. South San Francisco, CA: Exelixis, Inc.; January 2020.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed April 29, 2020.

Program	Prior Authorization - 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	Updated policy template. Updated clinical criteria to align with Employer and Individual except for the <19 criteria.
6/2017	Changed MTC clinical criteria to Thyroid Cancer to include NCCN expanded thyroid cancer indications. Updated background and references.
6/2018	Added NCCN recommended regimen criteria. Updated references.
6/2019	Annual review. Revised criteria for thyroid carcinoma. Updated references.
6/2020	Annual review. Updated references. Added Additional Clinical Rules section.