

PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Cometriq Prior Authorization Policy

- Cometriq® (cabozantinib capsules – Exelixis)

REVIEW DATE: 06/12/2024

OVERVIEW

Cometriq, a kinase inhibitor, is indicated for the treatment of patients with progressive, metastatic medullary thyroid cancer.¹

Guidelines

Cometriq is discussed in guidelines from the National Comprehensive Cancer Network (NCCN):

- **Non-Small Cell Lung Cancer:** NCCN guidelines (version 5.2024 – April 23, 2024) recommend the use of Cometriq under “Useful in Certain Circumstances” for *RET* gene rearrangements (category 2A) for first-line and subsequent therapy.²
- **Thyroid Carcinoma:** NCCN guidelines (version 2.2024 – March 12, 2024) list surgery as the main treatment option for medullary thyroid cancer.³ Cometriq or Caprelsa® (vandetanib tablets) (both category 1) are the “preferred” treatments for recurrent or persistent disease that is locoregional or metastatic. The guidelines also state that cabozantinib under “Useful in Certain Circumstances” (category 1 for papillary; category 2A for follicular and oncocytic) can be considered if patient has progression after Lenvima® (lenvatinib capsules) and/or sorafenib for the treatment of locally recurrent, advanced, and/or metastatic disease that is not amendable to radioactive iodine therapy; this recommendation is for follicular, oncocytic, and papillary cancer subtypes.⁴ For differentiated thyroid cancer subtypes, the guidelines have changed the naming of Hürthle cell neoplasm to oncocytic carcinoma.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Cometriq. All approvals are provided for the duration noted below.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Cometriq is recommended in those who meet one of the following criteria:

FDA-Approved Indication

1. **Thyroid Carcinoma, Medullary.** Approve for 1 year if the patient is ≥ 18 years of age.

Other Uses with Supportive Evidence

2. **Non-Small Cell Lung Cancer.** Approve for 1 year if the patient meets BOTH of the following (A and B):
 - A) Patient is ≥ 18 years of age; AND
 - B) Patient has *RET* gene rearrangements.

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3. **Thyroid Carcinoma, Differentiated.** Approve for 1 year if the patient meets ALL of the following (A, B, C and D):

A) Patient is ≥ 12 years of age; AND

B) Patient has differentiated thyroid carcinoma; AND

Note: Examples of differentiated thyroid carcinoma include papillary, follicular, and oncocytic carcinoma (formerly Hürthle cell carcinoma).

C) The disease is refractory to radioactive iodine therapy; AND

D) Patient has tried Lenvima (lenvatinib capsules) or sorafenib tablets.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Cometriq is not recommended in the following situations:

1. **Metastatic Castration-Resistant Prostate Cancer (mCRPC).** Results from the COMET-1 Phase III pivotal study with cabozantinib 60 mg tablets in men with mCRPC are published.⁵ Patients included in the study had disease progression after treatment with docetaxel as well as abiraterone acetate and/or Xtandi® (enzalutamide capsules). The study failed to meet its primary endpoint of demonstrating statistically significant increase in overall survival (OS) compared with prednisone. The median OS with cabozantinib was 11.0 months vs. 9.8 months with prednisone, which was not statistically significant. Based on these results, the second Phase III study, COMET-2 has been discontinued.⁶
2. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Cometriq® capsules [prescribing information]. San Francisco, CA: Exelixis; August 2023.
2. The NCCN Non-Small Cell Lung Cancer Clinical Practice Guidelines in Oncology (version 5.2024 – April 23, 2024). © 2024 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed June 10, 2024.
3. The NCCN Thyroid Carcinoma Clinical Practice Guidelines in Oncology (version 2.2024 – March 12, 2024). © 2024 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed June 10, 2024.
4. The NCCN Drugs and Biologics Compendium. © 2024 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed June 10, 2024. Search term: cabozantinib.
5. Smith M, De Bono J, Sternberg C, et al. Phase III study of cabozantinib in previously treated metastatic castration-resistant prostate cancer: COMET-1. *J Clin Oncol*. 2016;34:3005-3013.
6. Exelixis. Study of cabozantinib (XL184) versus mitoxantrone plus prednisone in men with previously treated symptomatic castration-resistant prostate cancer (COMET-2). In: ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). 2000- [cited 2024 June 10]. Available from: <http://www.clinicaltrials.gov/ct2/show/NCT01522443?term=NCT01522443&rank=1>. NLM identifier: NCT01522443.