VENTURA COUNTY
HEALTH CARE PLAN

PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Cometriq Prior Authorization Policy
- Cometriq™ (cabozantinib capsules – Exelixis)

REVIEW DATE: 06/02/2021

OVERVIEW

Cometriq is a kinase inhibitor 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**: The NCCN guidelines (version 4.2021 – March 3, 2021) recommends the use of single agent Cometriq (cabozantinib) for RET gene rearrangements (category 2A).[2]
- **Thyroid carcinoma**: NCCN guidelines (version 1.2021 – April 9, 2021) lists surgery as the main treatment option for medullary thyroid cancer.[2] Cometriq (cabozantinib capsules) or Caprelsa (category 1) are the preferred treatment for unresectable locoregional disease and distant metastatic disease or progressive distant metastatic disease. The guidelines recommend that Cometriq can be considered if clinical trials or other systemic therapies are not available or appropriate for the treatment of progressive and/or symptomatic unresectable locoregional recurrent or persistent disease or distant metastatic disease that is not amendable to radioactive iodine (RAI) therapy. This recommendation is for follicular, Hürthle cell, and papillary cancer subtypes (all category 2A).[4]

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 the following criteria:

FDA-Approved Indication

1. **Thyroid Carcinoma, Medullary.** Approve for 3 years if the patient is ≥ 18 years of age.

Other Uses with Supportive Evidence

2. **Non-Small Cell Lung Cancer.** Approve for 3 years if the patient meets the following criteria (A and B):
   A) Patient is ≥ 18 years of age; AND
   B) Patient has *RET* gene rearrangements.

3. **Thyroid Carcinoma, Differentiated.** Approve for 3 years if the patient meets the following criteria (A, B, and C):

A) Patient is ≥ 18 years of age; AND
B) Patient has differentiated thyroid carcinoma; AND
Note: Examples of differentiated thyroid carcinoma include papillary, follicular, and Hürthle cell thyroid carcinoma.
C) The disease is refractory to radioactive iodine therapy.

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 Zytiga® (abiraterone acetate tablets) 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 (hazard ratio [HR] 0.90; 95% CI: 0.76, 1.06; P = 0.213). 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™ [prescribing information]. San Francisco, CA: Exelixis Inc; January 2020.
2. The NCCN Non-Small Cell Lung Cancer Clinical Practice Guidelines in Oncology (version 4.2021 – March 3, 2021). © 2021 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed May 5, 2021.
3. The NCCN Thyroid Carcinoma Clinical Practice Guidelines in Oncology (version 1.2021 – April 9, 2021). © 2021 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed May 5, 2021.
4. The NCCN Drugs and Biologics Compendium. © 2021 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed May 5, 2021. 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 2017 March 13]. Available from: http://www.clinicaltrials.gov/ct2/show/NCT01522443?term=NCT01522443&rank=1. NLM identifier: NCT01522443.
7. Cabanillas ME, de Souza JA, Geyer S, et al. Cabozantinib as salvage therapy for patients with tyrosine kinase inhibitor-refractory differentiated thyroid cancer: results of a multicenter Phase II International Thyroid Oncology Group Trial. *J Clin Oncol.* 2017;35:3315-3321.