SPECIALTY GUIDELINE MANAGEMENT

COMETRIQ (cabozantinib)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indication

Treatment of progressive, metastatic medullary thyroid cancer (MTC).

- B. <u>Compendial Uses</u>
 - 1. Follicular, Hürthle cell, and papillary thyroid carcinoma
 - 2. Non-small cell lung cancer with RET gene arrangements

All other indications are considered experimental/investigational and not medically necessary.

II. DOCUMENTATION

Submission of RET gene rearrangement documentation is necessary to initiate the prior authorization review for the indication of non-small cell lung cancer.

III. CRITERIA FOR INITIAL APPROVAL

A. Follicular, Hurthle Cell, and Papillary Thyroid carcinoma

Authorization of 12 months may be granted for treatment of follicular, Hürthle cell, or papillary thyroid carcinoma when all of the following criteria are met:

- 1. The disease is not amenable to radioactive iodine (RAI) therapy.
- 2. The disease has progressed after treatment with lenvatinib or sorafenib.

B. Medullary Thyroid Carcinoma

Authorization of 12 months may be granted for treatment of medullary thyroid carcinoma.

C. Non-small cell lung cancer (NSCLC)

Authorization of 12 months may be granted for treatment of recurrent, advanced, or metastatic NSCLC with RET gene rearrangements when used as a single agent.

IV. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section III when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

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V. REFERENCES

- 1. Cometriq [package insert]. Alameda, CA: Exelixis, Inc.; October 2020.
- 2. The NCCN Drugs & Biologics Compendium[®] © 2022 National Comprehensive Cancer Network, Inc. Available at: https://www.nccn.org. Accessed August 4, 2022.

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