MEDICAL MUTUAL®

Drug Policy

Policy:	Cometriq (cabozantinib capsules)	Annual Review Date: 02/18/2021 Last Revised Date: 02/18/2021

OVERVIEW

Cometriq is a kinase inhibitor FDA approved for the treatment of patients with progressive, metastatic medullary thyroid cancer (MTC) and non-small cell lung cancer. In vitro biochemical and cellular assays have shown Cometriq to inhibit the tyrosine kinase activity of rearranged during transfection (RET) proto-oncogene, MET, vascular endothelial cell growth factor receptor (VEGFR)-1, -2, and -3, KIT, tyrosine-related kinase B (TrkB), Fms-like tyrosine kinase 3 (FLT-3), AXL, and TIE-2. The role of these receptor tyrosine kinases are in both normal cellular function and pathologic processes such as oncogenesis, metastasis, tumor angiogenesis, and maintenance of the tumor microenvironment.

POLICY STATEMENT

This policy involves the use of Cometriq. Prior authorization is recommended for pharmacy benefit coverage of Cometriq. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Cometriq as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Cometriq be prescribed by or in consultation with a physician who specializes in the condition being treated. In order to be considered for coverage, Cometriq must be prescribed by or in consultation with a hematologist or oncologist. All approvals for initial therapy are provided for the initial approval duration noted below.

RECOMMENDED AUTHORIZATION CRITERIA

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

1. <u>Medullary Thyroid Cancer (MTC)</u>

Criteria. *Patient must meet the following criteria*

A. Patient has unresectable locoregional disease that is symptomatic or progressive by RECIST criteria; OR
B. Patient has asymptomatic distant metastatic disease that is unresectable and progressive by RESICT criteria; OR
C. Patient has recurrent, progressive disease or symptomatic distant metastatic disease

OTHER USES WITH SUPPORTIVE EVIDENCE

2. **Hürthle Cell, Papillary, Follicular Thyroid Carcinoma**
   Criteria. *Patient must meet the following criteria*
   - **A.** Clinical trials and/or other systemic therapies are not available or appropriate for treatment of progressive or symptomatic iodine-refractory thyroid carcinoma; AND
   - **B.** Carcinoma is unresectable, recurrent, or persistent locoregional disease OR distant metastatic disease

3. **Non-Small Cell Lung Cancer (NSCLC) with RET Gene Rearrangements**
   Criteria. *Approve.*

4. **Patients with another indication that is not listed but is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation**
   Criteria. *Prescriber will provide specific diagnosis for documentation.*

5. **Patient has been started on Cometriq**
   Criteria. *Approve for an indication or condition addressed as an approval in this document.*

Initial Approval/ Extended Approval.
A) *Initial Approval:* 1 year
B) *Extended Approval:* 1 year

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Cometriq has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or

performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Cometriq™ [prescribing information]. San Francisco, CA: Exelixis Inc; October 2020.
2. The NCCN Thyroid Carcinoma Clinical Practice Guidelines in Oncology (Version 2.2017). © 2018 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed March 9, 2018.
3. The NCCN Non-Small Cell Lung Cancer Clinical Practice Guidelines in Oncology (Version 3.2018). © 2018 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed March 9, 2018.
4. Cabozantinib. In: DRUGDEX [online database]. Truven Health Analytics. Greenwood Village, CO. Last updated 6 February 2019. Accessed on 20 February 2019.