MEDICAL MUTUAL®

Drug Policy

Policy:	Cabometyx (cabozantinib tablets)	Annual Review Date: 2/18/2021 Last Revised Date: 3/18/2021

OVERVIEW

Cabometyx is a kinase inhibitor indicated for the treatment of patients with advanced renal cell carcinoma (RCC). It is also indicated for the treatment of patients with hepatocellular carcinoma (HCC) who have been previously treated with Nexavar® (sorafenib tablets). *In vitro* biochemical and cellular assays have shown Cabometyx to inhibit the tyrosine kinase activity of rearranged during transfection (RET), MET, vascular endothelial cell growth factor receptor (VEGFR)-1, -2, and -3, KIT, tyrosine-related kinase B (TrkB), c-ros oncogene 1 (ROS1), TYRO3, MER, Fms-like tyrosine kinase 3 (FLT-3), AXL, and TIE-2. These receptor tyrosine kinases are involved in both normal cellular function and pathologic processes such as oncogenesis, metastasis, tumor angiogenesis, drug resistance, and maintenance of the tumor microenvironment.

POLICY STATEMENT

This policy involves the use of Cabometyx. Prior authorization is recommended for pharmacy benefit coverage of Cabometyx. 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 Cabometyx as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Cabometyx be prescribed by or in consultation with a physician who specializes in the condition being treated. In order to be considered for coverage, Cabometyx 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 Cabometyx is recommended in those who meet the following criteria:

1. **Renal Cell Carcinoma (RCC), Relapsed or Stage IV Disease**
   Criteria. *Approve.*

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

3. **Hepatocellular Carcinoma (HCC)**
   Criteria. *Approve if the patient has previously been treated with sorafenib (Nexavar).*

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 Cabometyx**
   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

Cabometyx 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. Cabometyx™ [prescribing information]. Alameda, CA: Exelixis Inc; January 2021.
2. The NCCN Kidney 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.

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. The NCCN Hepatobiliary Cancers Clinical Practice Guidelines in Oncology (Version 1.2019 – December 17, 2018). © 2018 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed 20 February 2019.
5. Cabozantinib. In: DRUGDEX [online database]. Truven Health Analytics. Greenwood Village, CO. Last updated 6 February 2019. Accessed on 20 February 2019.
6. The NCCN Drugs and Biologics Compendium © 2019 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on 20 February 2019. Search terms: cabozantinib and Cabometyx.