UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Cabometyx

Program	Prior Authorization
Medication	Cabometyx® (cabozantinib)
Markets in Scope	Arizona, California, Hawaii, Maryland, Nevada, New Jersey, New York, New York EPP, Pennsylvania- CHIP, Rhode Island, South Carolina
Issue Date	6/2016
Pharmacy and Therapeutics Approval Date	3/2020
Effective Date	5/2020

1. Background:

Cabometyx® (cabozantinib) is a kinase inhibitor indicated for the treatment of patients with advanced renal cell carcinoma (RCC) and patients with hepatocellular carcinoma (HCC) who have been previously treated with Nexavar (sorafenib).[1] In addition, the National Cancer Comprehensive Network (NCCN) recommends Cabometyx for the treatment of non-small cell lung cancer (NSCLC) with RET gene rearrangement and HCC as a single agent for progressive disease in patients who have unresectable disease and are not a transplant candidate, are inoperable by performance status or comorbidity, have local disease, or have metastatic disease or extensive liver tumor burden.[2]

2. Coverage Criteria:

A. Renal Cell Carcinoma (RCC)

1. Initial Authorization

a. **Cabometyx** will be approved based on the following criteria:

(1) Diagnosis of advanced renal cell carcinoma

Authorization will be issued for 12 months.

2. Reauthorization

a. **Cabometyx** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Cabometyx therapy

Authorization will be issued for 12 months.

B. Non-Small Cell Lung Cancer (NSCLC)

1. Initial Authorization

a. **Cabometyx** will be approved based on **both** of the following criteria:

(1) Diagnosis of non-small cell lung cancer (NSCLC)

-AND-

(2) Positive for RET gene rearrangements

Authorization will be issued for 12 months.

2. Reauthorization

b. **Cabometyx** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Cabometyx therapy

Authorization will be issued for 12 months.

C. Hepatocellular Carcinoma

1. Initial Authorization

a. Cabometyx will be approved based on **both** of the following criteria:

(1) Diagnosis of hepatocellular carcinoma

-AND-

(2) **One** of the following:

(a) History of failure or intolerance to Nexavar (sorafenib)

-OR-

(b) Patient has metastatic disease

-OR-

(c) Patient has extensive liver tumor burden

-OR-

(d) Patient is inoperable by performance status or comorbidity, or has local disease or local disease with minimal extrahepatic disease only

-OR-

(e) **Both** of the following:

i. Patient is not a transplant candidate
ii. Disease is unresectable

Authorization will be issued for 12 months.

2. Reauthorization

a. Cabometyx will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Cabometyx therapy

Authorization will be issued for 12 months.

D. NCCN Recommended Regimens

1. Initial Authorization

a. **Cabometyx** will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium.

Authorization will be issued for 12 months.

2. Reauthorization

a. **Cabometyx** will be approved based on the following criterion:

(1) Documentation of positive clinical response to Cabometyx therapy

Authorization will be issued for 12 months.

3. References:

1. Cabometyx [package insert]. South San Francisco, CA: Exelixis, Inc.; January 2020.

2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed February 3, 2020.

Program	Prior Authorization - Cabometyx (cabozantinib)
Change Control	
6/2016	New Program.
6/2017	Annual review with no changes to clinical criteria.
2/2018	Updated background and criteria to include new indication for first line therapy for RCC. Added coverage for NCCN recommended use for NSCLC. Added a section for NCCN recommended regimens to account for NCCN updates that occur outside of scheduled policy reviews.
6/2018	Updated references. No change to clinical criteria.
3/2019	Updated background and criteria to include indication for HCC. Updated references.
3/2020	Annual review. Updated RCC criteria to align with label. Updated references.