UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Cabometyx

Program	Prior Authorization
Medication	Cabometyx™ (cabozantinib)
Markets in Scope	Arizona, California, Florida-CHIP, Hawaii, Maryland, Nevada, New Mexico, New York, New York EPP, Ohio, Rhode Island
Issue Date	6/2016
Pharmacy and Therapeutics Approval Date	2/2018
Effective Date	4/2018

1. Background:

Cabometyx™ (cabozantinib) is a kinase inhibitor indicated for the treatment of patients with advanced renal cell carcinoma (RCC).[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.[2]

2. Coverage Criteria:

A. Renal Cell Carcinoma (RCC)

1. Initial Authorization

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

(1) Diagnosis of renal cell carcinoma

-AND-

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

(a) Disease has relapsed

-OR-

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

i. Medically or surgically unresectable tumor
ii. Diagnosis of Stage IV disease

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) (off-label)

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. 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

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Authorization will be issued for 12 months.

3. References:

1. Cabometyx [prescribing information]. South San Francisco, CA: Exelixis, Inc.; December 2017.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed December 28, 2017.

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.