UnitedHealthcare

UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2018 P 1196-4
Program	Prior Authorization/Notification
Medication	Cabometyx™ (cabozantinib)
P&T Approval Date	6/2016, 6/2017, 2/2018, 6/2018
Effective Date	9/1/2018: Oxford only: 9/1/2018

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]

Coverage Information:
Members will be required to meet the criteria below for coverage. For members under the age of 19 years, the prescription will automatically process without a coverage review.

Some states mandate benefit coverage for off-label use of medications for some diagnoses or under some circumstances. Some states also mandate usage of other Compendium references. Where such mandates apply, they supersede language in the benefit document or in the notification criteria.

2. Coverage Criteria:

A. Patients less than 19 years of age

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

    a. Patient is less than 19 years of age

Authorization will be issued for 12 months.

B. 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-

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(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.

C. 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

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.

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3. Additional Clinical Rules:

- Supply limits may be in place.

4. 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 April 19, 2018.

Program	Prior Authorization/Notification - 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.
6/2018	Annual review with no changes to clinical criteria.

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