

## DRUG QUANTITY MANAGEMENT POLICY – PER RX

**POLICY:** Oncology – Cabometyx Drug Quantity Management Policy – Per Rx

- Cabometyx<sup>®</sup> (cabozantinib tablets – Exelixis)

**REVIEW DATE:** 10/19/2022

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### OVERVIEW

Cabometyx, a kinase inhibitor, is indicated for the following uses:<sup>1</sup>

- **Differentiated thyroid cancer (DTC)**, for the treatment of patients  $\geq 12$  years of age with locally advanced or metastatic disease that has progressed following prior VEGFR-targeted therapy and who are radioactive iodine-refractory or ineligible.
- **Renal cell carcinoma (RCC)**, as monotherapy or in combination with Opdivo<sup>®</sup> (nivolumab for injection) for the first-line treatment of patients with advanced disease.
- **Hepatocellular carcinoma (HCC)**, for the treatment of patients who have been previously treated with Nexavar<sup>®</sup> (sorafenib tablets).

### Dosing

The recommended dose of Cabometyx for HCC or as a single agent for RCC is 60 mg once daily (QD).<sup>1</sup> When used in combination with Opdivo, the dose of Cabometyx is 40 mg QD.

The recommended dose of Cabometyx as a single agent for DTC in patients with a body surface area (BSA)  $\geq 1.2$  m<sup>2</sup> is 60 mg QD.<sup>1</sup> In patients with a BSA  $< 1.2$  m<sup>2</sup> it is 40 mg QD.

The dose and/or frequency of administration may need to be changed due to adverse events, hematological toxicities, drug interactions or hepatic impairment.<sup>1</sup> If Cabometyx will be administered with strong cytochrome P450 (CYP)3A4 inducers, the daily dose will need to be increased by 20 mg (for example, from 60 mg QD to 80 mg QD or from 40 mg QD to 60 mg QD) as tolerated. The maximum daily dose is 80 mg.

### Availability

Cabometyx is available as 20 mg, 40 mg, and 60 mg tablets supplied in bottles of 30 tablets.<sup>1</sup>

### POLICY STATEMENT

This Drug Quantity Management program has been developed to promote the safe, effective, and economic use of Cabometyx. If the Drug Quantity Management rule is not met for the requested at the point of service, coverage will be determined by the Criteria below. All approvals are provided for 1 year in duration.

**Automation:** None.

**Drug Quantity Limits**

<b>Product</b>	<b>Strength/Form</b>	<b>Retail Maximum Quantity per Rx</b>	<b>Home Delivery Maximum Quantity per Rx</b>
Cabometyx® (cabozantinib tablets)	20 mg tablets	30 tablets	90 tablets
	40 mg tablets	30 tablets	90 tablets
	60 mg tablets	30 tablets	90 tablets

**CRITERIA**

Cabometyx 40 mg tablets

1. If the patient is taking a strong cytochrome P450 (CYP)3A4 inducer, approve 60 tablets per dispensing at retail and 180 tablets per dispensing at home delivery.

Note: Strong CYP3A4 inducers include, but are not limited to, rifampicin, carbamazepine, phenobarbital, phenytoin, rifabutin, rifapentine, and St. John's Wort.

Cabometyx 20 mg, 60 mg tablets

No overrides recommended.

**REFERENCES**

1. Cabometyx® tablets [prescribing information]. Alameda, CA: Exelixis; July 2022.