DRUG QUANTITY MANAGEMENT POLICY – PER RX

POLICY: Oncology – Cabometyx Drug Quantity Management Policy – Per Rx
- Cabometyx® (cabozantinib tablets – Exelixis)

REVIEW DATE: 11/18/2024

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

Cabometyx, a kinase inhibitor, is indicated for the following uses:[1]

- **Differentiated thyroid cancer (DTC)**, for the treatment of patients ≥ 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® (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® (sorafenib tablets).

Dosing

The recommended dose of Cabometyx for HCC or as a single agent for RCC is 60 mg once daily (QD).[1] 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) ≥ 1.2 m^2 is 60 mg QD.[1] In patients with a BSA < 1.2 m^2 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.[1] 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.

Cabometyx is also used off-label for several indications. Dosing is similar to that of the FDA-approved indications.

Availability

Cabometyx is available as 20 mg, 40 mg, and 60 mg tablets supplied in bottles of 30 tablets.[1]

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.

Drug Quantity Limits

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

Oncology - Cabometyx Drug Quantity Management Policy - Per Rx product(s) is(are) covered as medically necessary when the following criteria is(are) met. Any other exception is considered not medically necessary.

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; September 2023.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	11/01/2023
Annual Revision	No criteria changes.	11/18/2024