Drug Quantity Management – Per Rx
Oncology – Cometriq® (cabozantinib capsules)

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Product Identifier(s)

Effective 1/1/23 to 3/21/23: 109497

Effective 3/22/23: 103246

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. 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.

National Formulary Medical Necessity

This Drug Quantity Management program has been developed to promote the safe, effective, and economic use of Cometriq. If the Drug Quantity Management rule is not met for the requested medication 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	Package Size	Maximum Quantity per Rx
Cometriq® (cabozantinib capsules)	60 mg daily dose carton	1 carton
	100 mg daily dose carton	1 carton
	140 mg daily dose carton	1 carton

Cigna covers quantities as medically necessary when the following criteria are met:

Cometriq 100 mg daily dose carton:

1. If an individual is taking Cometriq concomitantly with a CYP3A4 inducer, approve up to two daily dose cartons per dispensing.

Conditions Not Covered

Any other exception is considered not medically necessary.

Background

Overview
Cometriq, a kinase inhibitor, is indicated for the treatment of patients with progressive, metastatic **medullary thyroid cancer**.[1]

Dosing
The recommended dose for medullary thyroid cancer is Cometriq 140 mg once daily without food until disease progression or unacceptable toxicity.[1]

Off-Label Use
The dosing used in clinical trials for differentiated thyroid cancer was cabozantinib 60 mg daily.[2] The dosing used in clinical trials for non-small cell lung cancer was Cometriq 60 mg to100 mg once daily.[3-4]

Availability
Cometriq is available as a 20 mg and 80 mg capsule, which are supplied in daily dose cartons. Each daily dose carton contains four blister cards and each blister card is a 7-day supply.[1]

Product	Packet Size	Quantity
Cometriq® (cabozantinib capsules)	140 mg daily dose carton	4 x (7 x 80 mg capsules + 21 x 20 mg capsules)
	100 mg daily dose carton	4 x (7 x 80 mg capsules + 7 x 20 mg capsules)
	60 mg daily dose carton	4 x (21 x 20 mg capsules)

Dose Modifications
The daily Cometriq dose should be increased by 40 mg as tolerated if used concomitantly with a strong cytochrome P450 (CYP)3A4 inducers. The daily dose should not exceed 180 mg. Dose may also need to be adjusted to manage adverse events, for hepatic impairment, and for coadmistration with strong CYP3A inhibitors.[1]

References

1. Cometriq® capsules [prescribing information]. San Francisco, CA: Exelixis; October 2020.
2. Brose MS, Robinson B, Sherman S, et al. Cabozantinib for radioactive-refractory differentiated thyroid cancer (COSMIC-311): a randomized, double-blind, placebo-controlled, phase 3 trial. *Lancet Oncol*. 2021; 22(8):1126-1138.
3. Drilon A, Rekhtman N, Arcila M, et al. Cabozantinib in patients with advanced *RET*-rearranged non-small-cell lung cancer: an open-label, single-centre, phase 2, single-arm trial. *Lancet Oncol.* 2016; 17(12):1653-1660.
4. Hellerstedt BA, Vogelzang NJ, Kluger HM. Results of a phase II placebo-controlled randomized discontinued trial of cabozantinib in patients with non-small cell lung cancer. *Clin Lung Cancer*.2019; 20(2):74-81.

Revision History

Type of Revision	Summary of Changes	Approval Date
New Policy	--	03/09/2022