DRUG QUANTITY MANAGEMENT POLICY – PER RX

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

REVIEW DATE: 03/03/2025

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 WHERE APPROPRIATE AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. WHERE COVERAGE FOR CARE OR SERVICES DOES NOT DEPEND ON SPECIFIC CIRCUMSTANCES, REIMBURSEMENT WILL ONLY BE PROVIDED IF A REQUESTED SERVICE(S) IS SUBMITTED IN ACCORDANCE WITH THE RELEVANT CRITERIA OUTLINED IN THE APPLICABLE COVERAGE POLICY, INCLUDING COVERED DIAGNOSIS AND/OR PROCEDURE CODE(S). REIMBURSEMENT IS NOT ALLOWED FOR SERVICES WHEN BILLED FOR CONDITIONS OR DIAGNOSES THAT ARE NOT COVERED UNDER THIS COVERAGE POLICY (SEE "CODING INFORMATION" BELOW). WHEN BILLING, PROVIDERS MUST USE THE MOST APPROPRIATE CODES AS OF THE EFFECTIVE DATE OF THE SUBMISSION. CLAIMS SUBMITTED FOR SERVICES THAT ARE NOT ACCOMPANIED BY COVERED CODE(S) UNDER THE APPLICABLE COVERAGE POLICY WILL BE DENIED AS NOT COVERED. 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

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

There are also data to support the off-label use of Cometriq in patients with differentiated thyroid cancer and non-small cell lung cancer.[2-4] The Cometriq dosing used in clinical trials for differentiated thyroid cancer was 60 mg daily.[2] The dosing used in clinical trials for non-small cell lung cancer was 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	Package Size	Quantity
Cometriq® (cabozantinib capsules)	60 mg daily dose carton	4 x (21 x 20 mg capsules)
	100 mg daily dose carton	4 x (7 x 80 mg capsules + 7 x 20 mg capsules)
	140 mg daily dose carton	4 x (7 x 80 mg capsules + 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]

POLICY STATEMENT

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	Retail Maximum Quantity per Rx	Home Delivery Maximum Quantity per Rx
Cometriq® (cabozantinib capsules)	60 mg daily dose carton (84 capsules [20 mg capsules])	84 capsules (1 carton)	252 capsules (3 cartons)
	100 mg daily dose carton (56 capsules [28 x 80 mg capsules + 28 20 mg capsules])	56 capsules (1 carton)	168 capsules (3 cartons)
	140 mg daily dose carton (112 capsules [28 x 80 mg capsules + 84 x 20 mg capsules])	112 capsules (1 carton)	336 capsules (3 cartons)

Oncology – Cometriq 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

Cometriq 60 mg daily dose carton

No overrides recommended.

Cometriq 100 mg daily dose carton

1. If a patient is taking Cometriq concomitantly with a cytochrome P450 (CYP)3A4 inducer, approve 112 capsules (2 cartons) per dispensing at retail or 336 capsules (6 cartons) per dispensing at home delivery.

Cometriq 140 mg daily dose carton

No overrides recommended.

REFERENCES

1. Cometriq® capsules [prescribing information]. San Francisco, CA: Exelixis; August 2023.
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.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	Policy was updated to reflect the existing quantity limits when a product is obtained via home delivery.	03/10/2023
Annual Revision	No criteria changes.	03/27/2024
Annual Revision	No criteria changes.	03/03/2025