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Section:	Prescription Drugs	**Effective Date:**	April 1, 2021
Subsection:	Antineoplastic Agents	**Original Policy Date:**	April 26, 2013
Subject:	Cometriq	**Page:**	1 of 5

Last Review Date: March 12, 2021

Cometriq

Description

Cometriq (cabozantinib)

Background
Cometriq (cabozantinib) is a kinase inhibitor that blocks abnormal kinase proteins involved in the development and growth of medullary cancer cells. Cometriq inhibits the tyrosine kinase activity to treat medullary thyroid cancer that has spread to other parts of the body (metastasized). These receptor tyrosine kinases are involved in both normal cellular function and cancer processes such as cancer growth, spreading to other parts of the body, tumor blood vessel formation, and maintenance of the tumor microenvironment (1).

Regulatory Status
FDA-approved indication: Cometriq is a kinase inhibitor indicated for the treatment of progressive, metastatic medullary thyroid cancer (MTC) (1).

Off-Label Use (2-3):
1. Non-small cell lung cancer (NSCLC)

Cometriq carries a warning regarding the risks of gastrointestinal (GI) perforations, fistula formation, hemorrhage, thrombotic events and impaired wound healing. Discontinue Cometriq in patients who experience a perforation or a fistula. Serious and sometimes fatal hemorrhage has occurred with Cometriq. Do not administer Cometriq to patients with a recent history of hemorrhage or hemoptysis (1).

Cometriq therapy should be discontinued in patients who experience hypertensive crisis, myocardial infarction, cerebral infarction, osteonecrosis of the jaw, nephritic syndrome, Palmar-plantar erythrodysesthesia syndrome (PPES) or reversible posterior leukoencephalopathy syndrome (RPLS) (1).

Cometriq therapy should be withheld for dehiscence or wound complications requiring intervention. Stop treatment with Cometriq at least 21 days prior to scheduled surgery and resume after surgery based on clinical judgment of adequate wound healing (1).

Cometriq is not recommended for use in patients with severe hepatic impairment as safety and efficacy have not been established (1).

Cometriq can cause fetal harm. Female patients of reproductive potential should be advised to the potential risk to a fetus and to use effective contraception (1).

Safety and effectiveness of Cometriq in pediatric patients have not been established (1).

Related policies

Caprelsa, Sutent, Votrient

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Cometriq may be considered **medically necessary** in patients 18 years of age and older with the diagnosis of medullary thyroid cancer (MTC) or non-small cell lung cancer (NSCLC); and if the conditions indicated below are met.

Cometriq may be considered **investigational** in patients less than 18 years of age and for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnoses

Patient must have **ONE** of the following:

1. Medullary Thyroid Cancer (MTC)
   a. Progressive and/or metastatic
2. Non-small cell lung cancer (NSCLC)

AND ALL of the following for **BOTH** indications:

1. **NO** recent history of hemorrhage or hemoptysis
2. Physician agrees to discontinue if GI perforation or fistula formation occurs

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnoses

Patient must have **ONE** of the following:

1. Medullary Thyroid Cancer (MTC)
   a. Progressive and/or metastatic

2. Non-small cell lung cancer (NSCLC)

AND NONE of the following for **BOTH** indications:

1. Hemorrhage or hemoptysis
2. Gastrointestinal (GI) perforations or fistula

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary
Cometriq (cabozantinib) is a kinase inhibitor used for the treatment of patients with progressive, metastatic medullary thyroid cancer (MTC) and Non-small cell lung cancer (NSCLC). Discontinue the medication if there are any gastrointestinal perforations, severe hemorrhage, wound complications, thrombotic events, hypertensive crisis, osteonecrosis of the jaw, Palmar-plantar erythrodysesthesia syndrome (PPES), nephrotic syndrome, or reversible posterior leukoencephalopathy syndrome (RPLS). Safety and effectiveness of Cometriq in pediatric patients have not been established (1).

Prior approval is required to ensure the safe, clinically appropriate and cost-effective use of Cometriq while maintaining optimal therapeutic outcomes.

References
1. Cometriq [package insert]. South San Francisco, CA: Exelixis, Inc.; October 2020.
2. NCCN Drugs & Biologics Compendium® 2021. National Comprehensive Cancer Network, Inc.
3. NCCN Clinical Practice Guidelines in Oncology® Non-Small Cell Lung Cancer (Version 2. 2021). National Comprehensive Cancer Network, Inc. December 2020.

Policy History

Date	Action
June 2013	Addition to PA
September 2014	Annual editorial review Removal of moderate to severe hepatic impairment and (RPLS) from renewal
June 2015	Annual editorial review
June 2016	Annual editorial review Policy code changed from 5.04.33 to 5.21.33
June 2017	Annual editorial review and reference update Addition of age limit to renewal requirements
June 2018	Annual editorial review and reference update Addition of NSCLC to initiation and renewal criteria
June 2019	Annual review and reference update
June 2020	Annual review and reference update
March 2021	Annual editorial review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 12, 2021 and is effective on April 1, 2021.