

5.21.033

---

<b>Section:</b>	Prescription Drugs	<b>Effective Date:</b>	April 1, 2024
<b>Subsection:</b>	Antineoplastic Agents	<b>Original Policy Date:</b>	April 26, 2013
<b>Subject:</b>	Cometriq	<b>Page:</b>	1 of 5

---

**Last Review Date:** March 8, 2024

---

## 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 Uses: (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).

<b>Section:</b>	Prescription Drugs	<b>Effective Date:</b>	April 1, 2024
<b>Subsection:</b>	Antineoplastic Agents	<b>Original Policy Date:</b>	April 26, 2013
<b>Subject:</b>	Cometriq	<b>Page:</b>	2 of 5

---

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** if the conditions indicated below are met.

Cometriq may be considered **investigational** 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

---

<b>Section:</b>	Prescription Drugs	<b>Effective Date:</b>	April 1, 2024
<b>Subsection:</b>	Antineoplastic Agents	<b>Original Policy Date:</b>	April 26, 2013
<b>Subject:</b>	Cometriq	<b>Page:</b>	3 of 5

---

2. Non-small cell lung cancer (NSCLC)

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

1. **NO** recent history of hemorrhage or hemoptysis
2. Prescriber agrees to discontinue therapy if gastrointestinal (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 **ALL** 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

<b>Section:</b>	Prescription Drugs	<b>Effective Date:</b>	April 1, 2024
<b>Subsection:</b>	Antineoplastic Agents	<b>Original Policy Date:</b>	April 26, 2013
<b>Subject:</b>	Cometriq	<b>Page:</b>	4 of 5

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.; August 2023.
2. NCCN Drugs & Biologics Compendium<sup>®</sup> Cabozantinib 2024. National Comprehensive Cancer Network, Inc. Accessed on January 24, 2024.
3. NCCN Clinical Practice Guidelines in Oncology<sup>®</sup> Non-Small Cell Lung Cancer (Version 1.2024). National Comprehensive Cancer Network, Inc. December 2023. Accessed on January 24, 2024.

## 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
March 2022	Annual review and reference update

# 5.21.033

---

<b>Section:</b>	Prescription Drugs	<b>Effective Date:</b>	April 1, 2024
<b>Subsection:</b>	Antineoplastic Agents	<b>Original Policy Date:</b>	April 26, 2013
<b>Subject:</b>	Cometriq	<b>Page:</b>	5 of 5

---

March 2023	Annual review and reference update. Changed policy number to 5.21.033
March 2024	Annual editorial review and reference update. Changed word “physician” to “prescriber” for requirement to discontinue therapy for GI perforation or fistula formation

## Keywords

---

**This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 8, 2024 and is effective on April 1, 2024.**