Cometriq

Description

Cometriq (cabozantinib)

Background
Cometriq 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 boxed warning regarding the risks of gastrointestinal (GI) perforations, fistula formation and hemorrhage. 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 28 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 moderate or severe hepatic impairment as safety and efficacy have not been established (1).

Safety and effectiveness 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 is 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**

**Duration** 12 months

**Rationale**

**Summary**

Cometriq is a kinase inhibitor indicated for the treatment of patients with progressive, metastatic medullary thyroid cancer (MTC). 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), proteinuria, or reversible posterior leukoencephalopathy syndrome (RPLS). Safety and effectiveness 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

Policy History

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<td>June 2013</td>
<td>Addition to PA</td>
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<tr>
<td>September 2014</td>
<td>Annual editorial review</td>
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<td></td>
<td>Removal of moderate to severe hepatic impairment and (RPLS) from renewal</td>
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<tr>
<td>June 2015</td>
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<td>June 2016</td>
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<td></td>
<td>Policy code changed from 5.04.33 to 5.21.33</td>
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<td>June 2017</td>
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<td>Addition of NSCLC to initiation and renewal criteria</td>
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<td>Annual review and reference update</td>
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Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 20, 2019 and is effective on July 1, 2019.