

Clinical Pharmacy Program Guideline for Cometriq

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| Program | Prior Authorization/Notification |
| Medication | Cometriq® (cabozantinib) |
| Pharmacy & Therapeutics Approval Date | 6/2016 |
| Effective Date | 8/1/2016 |

1. Background:

Cometriq® (cabozantinib) is a kinase inhibitor indicated for the treatment of patients with progressive, metastatic medullary thyroid cancer (MTC).¹

In addition, the National Cancer Comprehensive Network (NCCN) also recommends Cometriq for the treatment of non-small cell lung cancer (NSCLC) with RET gene rearrangement.²

2. Coverage Criteria:

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| <p>A. <u>Medullary Thyroid Cancer (MTC)</u></p> <p>1. <u>Initial Authorization</u></p> <p style="margin-left: 20px;">a. Cometriq will be approved based on the following criterion:</p> <p style="margin-left: 40px;">(1) Diagnosis of medullary thyroid cancer (MTC)</p> <p style="margin-left: 20px;">Authorization will be issued for 12 months.</p> <p>2. <u>Reauthorization</u></p> <p style="margin-left: 20px;">a. Cometriq will be approved based on the following criterion:</p> <p style="margin-left: 40px;">(1) Patient does not show evidence of progressive disease while on Cometriq therapy</p> <p style="margin-left: 20px;">Authorization will be issued for 12 months.</p> <p>B. <u>Non-Small Cell Lung Cancer (NSCLC) (off-label)</u></p> <p>1. <u>Initial Authorization</u></p> <p style="margin-left: 20px;">a. Cometriq will be approved based on both of the following criteria:</p> <p style="margin-left: 40px;">(1) Diagnosis of non-small cell lung cancer (NSCLC)</p> <p style="text-align: center;">-AND-</p> |
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(2) Positive for RET gene rearrangements

Authorization will be issued for 12 months.

2. Reauthorization

a. **Cometriq** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Cometriq therapy

Authorization will be issued for 12 months.

3. References:

1. Cometriq [prescribing information]. South San Francisco, CA: Exelixis, Inc.; November 2012.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed May 11, 2016.

| Program | Prior Authorization - Cometriq (cabozantinib) |
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| Change Control | |
| 7/2013 | Review of clinical criteria. No change to coverage. Updated formatting. |
| 8/2014 | Annual review. Added coverage for NSCLC, clarified thyroid cancer, updated formatting, Background and References. |
| 8/2015 | Annual review with no change to clinical criteria. Increased authorization and reauthorization from 11 months to 12 months for all indications. Updated references. |
| 6/2016 | Updated policy template. Updated clinical criteria to align with E&I except for the <19 criteria. |