



## **RATIONALE FOR INCLUSION IN PA PROGRAM**

### **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).

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).

### **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.; August 2023.
2. NCCN Drugs & Biologics Compendium® Cabozantinib 2025. National Comprehensive Cancer Network, Inc. Accessed on January 14, 2025.
3. NCCN Clinical Practice Guidelines in Oncology® Non-Small Cell Lung Cancer (Version 3.2025). National Comprehensive Cancer Network, Inc. January 2025. Accessed on January 14, 2025.