BOSTON MEDICAL CENTER HEALTHNet PLAN

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Pharmacy Policy

Medullary Thyroid Cancer Agents – Unified Formulary

Policy Number: 9.715
Version Number: 2
Version Effective Date: 9/1/2021

Product Applicability ☐ **All Plan+ Products**

Well Sense Health Plan
☐ New Hampshire Medicaid

Boston Medical Center HealthNet Plan
☒ MassHealth- MCO
☒ MassHealth- ACO
☐ Qualified Health Plans/ConnectorCare/Employer Choice Direct
☐ Senior Care Options

Note: Disclaimer and audit information is located at the end of this document.

Prior Authorization Policy

Reference Table:

Drugs that require PA	No PA
Caprelsa® (vandetanib)	
Cometriq® (cabozantinib capsule)	

Procedure:

Approval Diagnosis:	Symptomatic or progressive medullary thyroid cancer
Approval Criteria: **Caprelsa®** (vandetanib)	Prescriber provides documentation of **ALL** of the following: 1. Appropriate diagnosis 2. **ONE** of the following: a. Request is within quantity limit of 30 units/30 days for 300 mg tablets or 60 units/30 days for 100 mg tablets b. Medical necessity for exceeding quantity limit of 30 units/30 days for 300 mg tablets or 60 units/30 days for 100 mg tablets

+ *Plan* refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name Well Sense Health Plan.

	Notes: • *Please see appendix for other oncology indications.*
Approval Criteria: **Cometriq®** (cabozantinib capsule)	Prescriber provides documentation of **ALL** of the following: 1. Appropriate diagnosis 2. **ONE** of the following: a. Requested dose does not exceed 140 mg/day b. Medical necessity for exceeding the 140 mg/day dose
Denial Criteria:	Cases that do not meet the approval criteria will be denied.
	If a request is denied and the prescriber has additional clinical documentation, a **new** prior authorization request must be submitted.
Duration/Quantity of Authorization:	Prior authorization may be issued for up to **3 months**.
Recertification Criteria:	Resubmission by prescriber will infer a positive response to therapy (if the prescriber documents response to therapy, please note in your internal comment) and request can be recertified for **6 months**.

Appendix:

Stability

Stability alone on Caprelsa® (vandetanib) or Cometriq® (cabozantinib capsule) is not a reason to bypass approval criteria. However, requests for members who have already started treatment on these agents should be reviewed with clinical review and approval is strongly considered for any member with any FDA-approved indication.

Grandfathering

Information is not applicable.

Additional Information

Requests for other oncology indications

Caprelsa® (vandetanib) and Cometriq® (cabozantinib) are being studied in a variety of cancer indications. Caprelsa® (vandetanib) is currently being investigated in other thyroid cancers including follicular thyroid cancer, papillary thyroid cancer and anaplastic thyroid cancer. It is also being investigated in other cancers including, but not limited to, breast cancer, colorectal cancer, gliomas, hormone-refractory prostate cancer, non-small cell lung cancer, small cell lung cancer, other neuroendocrine cancers, ovarian cancer and multiple myeloma. Cometriq® (cabozantinib) is currently being investigated for treatment of prostate cancer, pancreatic cancer, glioblastomas, non-small cell lung cancer, multiple myeloma, as well as others. The Version 1.2018 Thyroid Carcinoma NCCN guideline also includes a footnote under the treatment of locally recurrent, advanced, and/or metastatic disease for papillary carcinoma, follicular carcinoma and Hurtle cell carcinoma stating although not FDA approved for treatment of differentiated thyroid cancer, commercially available small-molecule kinase inhibitors, including Caprelsa® (vandetanib) or Cometriq® (cabozantinib), can be considered if clinical trials are not available or appropriate.

Therefore, if a request is received for use in another cancer, it should be forwarded to clinical review. The clinical reviewer should evaluate the request using current NCCN recommendations for the treatment of the cancer and any literature supporting the use of the agent in the requested indication. Due to the seriousness of the disease that is

treated with these agents, if a request is denied, the prescriber should be contacted and informed of the additional clinical documentation that is required on the resubmission.

Additional Drug Information

Caprelsa® (vandetanib) for members with difficulty swallowing solids

- Caprelsa® (vandetanib) tablets should not be crushed
- Tablets may be dispersed in 2 ounces of non-carbonated water (no other liquids should be used) and stirred for ~10 minutes until the tablet is dispersed (it will not dissolve completely)
- The dispersion should be swallowed immediately; this dispersion can also be administered through nasogastric or gastrostomy tubes

Caprelsa® (vandetanib) Dosage Adjustment

- Renal dysfunction
  - Moderate to severe renal impairment: a dose of 200 mg once daily is recommended
- Hepatic dysfunction
  - Not recommended for use in patients with moderate and severe hepatic impairment as safety and efficacy have not been established. There is limited data in patients with liver impairment (serum bilirubin >1.5 times the upper limit of normal)
- Elderly
  - No evidence of overall differences in safety or efficacy observed between elderly and younger adult patients. There is limited data for patients over the age of 75 years and no adjustment is required for patients over the age of 65 years for starting dose
- Toxicity
  - Therapy should be discontinued for the National Cancer Institute Common Terminology Criteria for Adverse Events (CTCAE) grade 3 or greater toxicity until toxicity resolves or improves to CTCAE grade 1 and then therapy should be resumed at a reduced dose
  - The 300 mg daily dose can be reduced to 200 mg (two 100 mg tablets) and then to 100 mg for CTCAE grade 3 or greater toxicities

Cometriq® (cabozantinib) Dosage Adjustment

- Hepatic Impairment
  - In patients with mild to moderate hepatic impairment, the recommended starting dose is 80 mg once daily
  - Not recommended for use in patients with severe hepatic impairment.
- Toxicity
  - Withhold Cometriq® (cabozantinib) for Grade 4 hematologic adverse reactions, Grade 3 or greater non-hematologic adverse reactions or intolerable Grade 2 adverse reactions. Upon resolution/improvement of the adverse reaction reduce the dose as follows:
    - If previously receiving 140 mg daily dose, resume treatment at 100 mg daily
    - If previously receiving 100 mg daily dose, resume treatment at 60 mg daily
    - If previously receiving 60 mg daily dose, resume at 60 mg if tolerated, otherwise, discontinue Cometriq® (cabozantinib)

Historical Timeline

Version	Date	Comments
6.0	7/13/20	Forwarded to MCOs on 08/19/20.

Clinical Background Information and References

Original Approval Date	Original Effective Date	Policy Owner	Approved by
12/1/2020	1/1/2021	Pharmacy Services	Pharmacy & Therapeutics (P&T) Committee

Policy Revisions History			
Review Date	**Summary of Revisions**	**Revision Effective Date**	**Approved by**
12/1/2020	New policy created to align with MH Unified Formulary Policy	1/1/2021	P&T Committee
5/13/2021	No recommended changes or updates.	9/1/2021	P&T Committee

Next Review Date

5/2022

Reference to Applicable Laws and Regulations, If Any

Disclaimer Information

Medical Policies are the Plan's guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member's benefit document, and when appropriate, coordinates with the Member's health care Providers to consider the individual Member's health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan's service area who are medical experts in the particular field,

and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member's benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.