BOSTON MEDICAL CENTER HEALTHNet PLAN

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Pharmacy Policy

Gavreto™

Policy Number: 9.719
Version Number: 1.0
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.

Products Affected:

- Gavreto™ (pralsetinib) 100 mg

The Plan may authorize coverage of the above products for members meeting the following criteria:

Covered Use	All FDA approved indications not otherwise excluded
Exclusion Criteria	None
Required Medical Information	1. Diagnosis of metastatic non-small cell lung cancer; **AND** 2. Member is 18 years of age or older; **AND** 3. Presence of RET gene fusion-positive tumor(s). **OR**

[+] *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.

	1. Diagnosis of advanced or metastatic mutant medullary thyroid cancer; **AND** 2. Member is 12 years of age and older; **AND** 3. Presence of RET gene fusion-positive tumor(s). **OR** 1. Diagnosis of advanced or metastatic thyroid cancer; **AND** 2. Member is 12 years of age and older; **AND** 3. Presence of RET gene fusion-positive tumor(s) **AND** 4. Disease is not manageable using radioactive iodine (RAI) therapy.
Age Restriction	Refer to required medical information
Prescriber Restriction	Prescribed by or in collaboration with an oncologist.
Coverage Duration	6 months
Quantity Limit	120 per 30 days
Other criteria	Reauthorization Criteria: 1. Member has met initial criteria. **AND** 2. Member does not show evidence of progressive disease while on therapy.

Applicable coding:

Clinical Background Information and References

1. Gavreto (pralsetinib) [prescribing information]. South San Francisco, CA: Genentech, Inc; April 2021.
2. National Comprehensive Cancer Network. Non-Small Cell Lung Cancer Version 4.2020. https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf. Accessed April 2021.
3. National Comprehensive Cancer Network. Thyroid Carcinoma Version 2.2019. https://www.nccn.org/professionals/physician_gls/pdf/thyroid.pdf. Accessed April 2021.
4. UpToDate. Gavreto [pralsetinib drug information.] Topic 129470 Version 34.0. Accessed April 2021.

Original Approval Date	Original Effective Date	Policy Owner	Approved by

5/13/2021	9/1/2021	Pharmacy Department	P&T Committee

Policy Revisions History			
Review Date	**Summary of Revisions**	**Revision Effective Date**	**Approved by**
5/13/2021	Policy created	9/1/2021	P&T Committee

Next Review Date

5/2022

Other Applicable Policies

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.