BOSTON MEDICAL CENTER HEALTHNet PLAN

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Pharmacy Policy

Non-Formulary Exceptions

Policy Number: 9.051
Version Number: 2.0
Version Effective Date: 1/1/2022

Product Applicability	☐ **All Plan[+] Products**
Well Sense Health Plan ☐ New Hampshire Medicaid	**Boston Medical Center HealthNet Plan** ☐ MassHealth ☒ Qualified Health Plans/ConnectorCare/Employer Choice Direct ☐ Senior Care Options

Policy Summary

The Plan will authorize coverage of drugs not on the formulary when appropriate criteria are met.

Description of Item or Service

The drug formulary was developed as a means to assure quality clinical care concurrent with pharmacy management. All non-formulary drugs are not on the formulary and require prior authorization. This may include brand name products with generic equivalents, new to market medications, "convenience packaged" medications, branded combinations of two or more medications combined in one dosage form (polypills) and other non-preferred agents.

Policy

The Plan may authorize coverage of non-formulary medications for members meeting the following criteria:

Initial Criteria	Documentation of the following:

[+] *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. The requested medication does not fall within a class of medications under the Plan's Drug Benefit Exclusion; ***AND*** 2. An appropriate diagnosis that is a FDA approved indication for the requested medication or is supported by one or more citations included or approved for inclusion in the following compendia: American Hospital Formulary Service Drug Information, DRUGDEX Information System, United States Pharmacopeia-Drug Information (or its successor publications) or National Comprehensive Cancer Network (categories 1, 2a, 2b only); ***AND*** 3. The dosage and quantity of medication prescribed is consistent with dosing listed in manufacturer package labeling for the prescribed indication; ***AND*** 4. One of the following: a. An allergy, contraindication, adverse event, or inadequate response to a trial of at least **4** preferred medications in the same therapeutic category that are FDA approved for the same indication or are considered the standard of care for the indication (if available); ***OR*** b. An indication that is unique to the non-formulary agent (including age-specific indications); ***AND*** 5. **If requesting "convenience packing" or "polypill" only**: a. A treatment failure due to poor compliance with individually prescribed covered medications belonging to the same therapeutic class as those contained in the "convenience packaging" or "polypill" to treat the particular medical condition (within the last 120 days); ***AND*** b. For combination products or long-acting formulations: Combination products- clinical justification is provided as to why the member cannot take the preferred medications separately; Long-acting formulations- clinical justification is provided as to why the member cannot take the immediate release formulation of the preferred medication; ***AND*** 6. If the request is for a multi-source brand medication, **OR** a branded medication with an authorized generic **<u>one</u>** of the following: a. Adverse reaction, allergy or sensitivity to a generic/authorized generic equivalent; ***OR*** b. Therapeutic failure with a generic/authorized generic equivalent; ***OR*** Special circumstances exist that preclude the use of a generic/authorized generic equivalent of the brand medication for the member
Continuation of Therapy	Documentation of the following:

	1. Initial criteria is met; ***AND*** 2. The clinical condition has improved or stabilized without treatment-related adverse events
Duration of Approval	1 year

For Qualified Health Plan (QHP) members, non-formulary medications meeting the above criteria will be covered in formulary Tier 3

Limitations

A request for coverage will only be considered for approval when the indication and dosage meets FDA-approved labeling OR the indication is unique to a non-formulary drug and is supported by the compendia of current literature^

The Plan will ***not*** approve coverage of non-formulary medications in the following instances:

- When the criteria above has not been met
- When branded "convenience packaged" medications contain topical medications and/or medical supplies (e.g. topical rinses, alcohol pads, combs, etc).
- *Continuation of medications that a member has been receiving may not be considered medically necessary for the following
    - Patient has received manufacturer supplied samples from the prescriber; OR
    - Patient has utilized a manufacturer's free coverage assistance programs or copay assistance programs to establish therapy
- The drug is being prescribed for a medically accepted indication that is **not** a covered benefit as defined in the Plan's Member Handbook https://www.bmchp.org/I-Am-A/Member/Get-Care/Your-Benefits

During instances of when a brand-name product is preferred over the generic/authorized generic equivalent, requests for the generic/authorized generic equivalent will be reviewed using the non-formulary policy

Coverage of over the counter (OTC) items will be limited to only those listed on the formulary. The plan will cover OTC products listed on the PDL if the member has a prescription from a licensed provider that meet all legal requirements for a prescription

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	Policy 9.080 Discontinued. Created new policy.	1/1/2021	P&T Committee
8/12/2021	P&T Annual Review: added language that previous trial and failure be with drugs within the same therapeutic category that are FDA approved for the same indication or are considered the standard of care for the indication; Verbiage change made to replace 'Non Preferred' with 'Non Formulary'	1/1/2022	P&T Committee

Next Review Date

8/2022

Other Applicable Policies

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.