BOSTON MEDICAL CENTER HEALTHNet PLAN

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WELL SENSE HEALTH PLAN

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Pharmacy Policy

Non-Preferred Drugs

Policy Number: 9.080
Version Number: 3.0
Version Effective Date: 05/08/2020

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

Policy Summary

The Plan will authorize coverage of non-preferred medications 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-preferred drugs require prior authorization and are subject to quantity limitations. 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-preferred medications for members meeting the following criteria:

+ *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

Prior Authorization – (Duration of Approval: Non-maintenance drugs – up to 1 year, Maintenance drugs – up to 2 years)

A prior authorization request is required for all non-preferred medications (which can include prescriptions for New-To-Market medications or new indication(s) for currently available medications awaiting review by the Plan's P&T committee. This also includes most prescriptions where the prescriber has indicated that he or she would like the brand name version of a generically available medication dispensed by writing, "No substitution" on the prescription and includes other non-preferred agents. These requests will be approved when the following criteria are met:

Initial Criteria **See below for criteria for branded products with generics available**	Documentation of the following: 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 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 (if available); ***OR*** b. An indication that is unique to the non-preferred agent (including age-specific indications); ***OR*** c. Covered alternatives are not suitable and put member at clinically unacceptable risk; ***OR*** d. **If requesting "convenience packing" or "polypill" only**: 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)

Initial Requests for Brand-name medications with AB-rated generic equivalents	Documentation of the following: 1. An allergy to one of the inactive ingredient(s) found in the generic version(s) of the medication that is not found in the brand name medication; ***AND*** 2. An inadequate response or intolerance to a trial of at least two other covered alternatives (one if less than two available) within the same therapeutic class as the requested medication.
Continuation of Therapy	Documentation of the following: 1. Initial criteria is met; ***AND*** 2. Clinically unacceptable risk with a change in therapy to a covered agent; ***AND*** 3. Compliance with the requested therapy and the clinical condition has improved or stabilized without treatment-related adverse events

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

Limitations

The Plan will ***not*** approve coverage of non-preferred 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

Clinical Background Information and References

Original Approval Date	Original Effective Date	Policy Owner	Approved by
3/08/2018	07/24/2018	Pharmacy Services	Pharmacy & Therapeutics (P&T) Committee

Policy Revisions History			
Review Date	**Summary of Revisions**	**Revision Effective Date**	**Approved by**
03/14/2019	P&T Annual Review: No changes recommended	07/01/2019	P&T Committee
02/13/2020	P&T Annual Review: No changes recommended	05/08/2020	P&T Committee

Next Review Date

02/11/2021

Other Applicable Policies

Definitions

MassHealth Contract Definition of Medically Necessary or Medical Necessity: In accordance with 130 CMR 450.204, medically necessary services are those services that include:

1. Which are reasonably calculated to prevent, diagnose, prevent the worsening of, alleviate, correct, or cure conditions in the Enrollee that endanger life, cause suffering or pain, cause physical deformity or malfunction, threaten to cause or to aggravate a disability, or result in illness or infirmity; AND

2. For which there is no other medical service or site of service, comparable in effect, available, and suitable for the Enrollee requesting the service, that is more conservative or less costly. Medically necessary services must be of a quality that meets professionally recognized standards of health care, and must be substantiated by records including evidence of such medical necessity and quality.

Qualified Health Plans/ConnectorCare/Employer Choice Direct Definition of Medically Necessary (or Medical Necessity): Health care services that are consistent with generally accepted principles of professional medical practice as determined by whether: (a) the service is the most appropriate available supply or level of service for the member in question considering the potential benefits and harms to the member; (b) the service is known to be effective, based on scientific evidence, professional standards and expert opinion, in improving health outcomes; or (c) for services and interventions not in widespread use, the service is based on scientific evidence.

Reference to Applicable Laws and Regulations, If Any

1. Contract between the Commonwealth Health Insurance Connector Authority and Plan.
2. Contract between the Massachusetts Executive Office of Health and Human Services (EOHHS) and Plan.
3. Contract between the New Hampshire Department of Health and Human Services and Plan.

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.