

## Pharmacy Policy

---

# Prescription Compounds

**Policy Number:** 9.054

**Version Number:** 1.0

**Version Effective Date:** 1/1/2022

### Product Applicability All Plan<sup>+</sup> 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.

## Summary

---

The Plan provides coverage of certain prescription compounds when prescribed for Medically Necessary indications. The Plan may authorize coverage of other prescription compounds when appropriate criteria are met.

## Description of Item or Service

---

Prescription compounds are drugs prepared using a combination of active and non-active ingredients, to create formulations that provide unique routes of delivery for certain patient-specific conditions and administration requirements. Compounds are necessary when commercially available formulations are not available and do not meet the needs of individual patients. Compounds should not be manufactured in large scale, but should be made specifically for each patient. All ingredients used for each compound should be

<sup>+</sup> 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.

medically necessary to fulfill the needs of the prescription. Ingredients used to enhance the compound, such as flavoring, but are not clinically essential to the compound will not be covered by the Plan.

## Policy

---

The Plan may provide coverage for prescription compounds for members meeting the following criteria.

### For members in Special Kids Special Care Program:

1. Request is for a compound; **AND**
2. There is a rejected point of service claim for the specific compounded medication; **AND**
3. The primary ingredient within the compound is covered by the plan; **OR**
4. All of the following criteria must be met:
  - a. Request includes name of service, treatment procedure, supply, device, biological product or drug; **AND**
  - b. Requested treatment has final approval from the appropriate governmental regulatory body(ies) to market the technology (for example, the U.S. Food and Drug Administration or other federal governmental body with authority to regulate the technology); **AND**
  - c. Authoritative evidence support the conclusions concerning the effect of the requested treatment on health outcomes; **AND**
  - d. Requested treatment improves the net health outcome of the member and outweigh any harmful effect; **AND**
  - e. Requested treatment is as beneficial as any established alternative; **AND**
  - f. Outcomes with the requested treatment are attainable outside the investigational or experimental settings; **AND**
  - g. In determining medical necessity, have ALL of the following member-specific factors been considered/applied: (a) the member's age; (b) the member's comorbidities (including ongoing and/or chronic conditions), and relevant past medical/surgical/behavioral health/dental/ pharmacotherapy history; (c) diagnostic test results, when applicable; (d) complications experienced by the member; (e) progression of the member's condition, illness, or injury; (f) the member's progress of treatment; **AND**
  - h. In determining medical necessity, have ALL of the following member-specific factors been considered/applied: (a) the member's psychosocial circumstances; (b) the member's home and environmental factors impacting the member's clinical condition (for example, homelessness, employment status, poverty, neighborhood); (c) other factors related to the member's plan of care and/or health outcomes; (d) other healthcare services requested and/or currently provided to the member to integrate healthcare for continuity, coordination, and collaboration of services; (e) available treatment options for the member's condition; (f) if applicable, verification that the requested device, system, biological product, or drug is being prescribed/requested and will be utilized according to its FDA-approved clearance and guideline information, including intended use for the member's age and medical condition; **AND**
  - i. Requested treatment is reasonably calculated to prevent, diagnose, prevent the worsening of, alleviate, correct, or cure conditions in the member 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**
  - j. Prescriber attests that there is no other medical service or site of service, comparable in effect, available, and suitable for the member requesting the service, that is more conservative or less costly; **AND**

<sup>\*</sup> 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.

- k. Prescriber attests that the quality of the requested service meets professionally-recognized standards of health care, and is substantiated by records, including evidence of such medical necessity and quality

**Members in MassHealth ACO and MCO:**

1. Request is for a compound; **AND**
2. There is a rejected point of service claim for the specific compounded medication; **AND**
3. One of the following:
  - A. All ingredients within the compound are covered by the plan and are not excluded ; **OR**
  - B. All ingredients are not covered by the plan but the pharmacy is willing to process the claim with Submission Clarification Code -8; **OR**
4. If member is under age 21, all of the following criteria must be met
  - a) Request includes name of service, treatment procedure, supply, device, biological product or drug; **AND**
  - b) Requested treatment has final approval from the appropriate governmental regulatory body(ies) to market the technology (for example, the U.S. Food and Drug Administration or other federal governmental body with authority to regulate the technology); **AND**
  - c) Authoritative evidence support the conclusions concerning the effect of the requested treatment on health outcomes; **AND**
  - d) Requested treatment improves the net health outcome of the member and outweigh any harmful effect; **AND**
  - e) Requested treatment is as beneficial as any established alternative; **AND**
  - f) Outcomes with the requested treatment are attainable outside the investigational or experimental settings; **AND**
  - g) In determining medical necessity, have ALL of the following member-specific factors been considered/applied: (a) the member's age; (b) the member's comorbidities (including ongoing and/or chronic conditions), and relevant past medical/surgical/behavioral health/dental/ pharmacotherapy history; (c) diagnostic test results, when applicable; (d) complications experienced by the member; (e) progression of the member's condition, illness, or injury; (f) the member's progress of treatment; **AND**
  - h) In determining medical necessity, have ALL of the following member-specific factors been considered/applied: (a) the member's psychosocial circumstances; (b) the member's home and environmental factors impacting the member's clinical condition (for example, homelessness, employment status, poverty, neighborhood); (c) other factors related to the member's plan of care and/or health outcomes; (d) other healthcare services requested and/or currently provided to the member to integrate healthcare for continuity, coordination, and collaboration of services; (e) available treatment options for the member's condition; (f) if applicable, verification that the requested device, system, biological product, or drug is being prescribed/requested and will be utilized according to its FDA-approved clearance and guideline information, including intended use for the member's age and medical condition; Requested treatment is reasonably calculated to prevent, diagnose, prevent the worsening of, alleviate, correct, or cure conditions in the member 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**

<sup>\*</sup> 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.

- i) Requested treatment is reasonably calculated to prevent, diagnose, prevent the worsening of, alleviate, correct, or cure conditions in the member 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**
- j) Prescriber attests that there is no other medical service or site of service, comparable in effect, available, and suitable for the member requesting the service, that is more conservative or less costly; **AND**
- k) Prescriber attests that the quality of the requested service meets professionally-recognized standards of health care, and is substantiated by records, including evidence of such medical necessity and quality

### **Prior Authorization – (Duration of Approval: six months)**

A prior authorization request will be required for all prescription compounds that do not meet the criteria above. These requests will be approved when the following criteria are met.

### **Limitations**

---

The Plan will *not* approve coverage of prescription compounds in the following instances:

- Compound contains only over-the-counter ingredients
- Compound contains only non-active ingredients
- Compounds containing non-covered bulk chemical products
- Compounds containing Plan excluded products
- For the treatment of plan excluded indications
- When the above criteria are not met

Other Applicable Policies:

OCA 3.14 Medical Necessity Policy

### **Clinical Background Information and References**

---

N/A

---

<sup>\*</sup> 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.

Original Approval Date	Original Effective Date	Policy Owner	Approved by
8/12/2021	1/1/2022	Pharmacy Services	Pharmacy & Therapeutics (P&T) Committee

Policy Revisions History			
Review Date	Summary of Revisions	Revision Effective Date	Approved by
8/12/2021	P&T Review: New policy created	1/1/2022	P&T Committee

### Next Review Date

8/2022

### 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.

<sup>\*</sup> 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.