BOSTON MEDICAL CENTER HEALTHNet PLAN

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WELL SENSE HEALTH PLAN

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Medical Policy

Clinical Trials

Policy Number: OCA 3.192
Version Number: 17
Version Effective Date: 12/01/21

Product Applicability	☐ **All Plan+ Products**
WellSense Health Plan	**Boston Medical Center HealthNet Plan**
☒ NH Medicaid	☒ MassHealth ACO
☐ NH Medicare Advantage	☒ MassHealth MCO
	☒ Qualified Health Plans/ConnectorCare/Employer Choice Direct
	☐ Senior Care Options

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

Policy Summary

The Plan considers the costs of patient care services associated with a clinical trial to be **medically necessary** when Plan criteria are met, as specified in the product-specific guidelines included in this policy. All Plan policies are developed in accordance with state, federal and accrediting organization guidelines and requirements, including National Committee for Quality Assurance (NCQA). The Plan complies with coverage guidelines for all applicable state-mandated benefits and federally-mandated benefits that are medically necessary for the member's condition.

Prior authorization is required for participation in a clinical trial when services are covered by the Plan; in addition, any covered service associated with the clinical trial that routinely requires prior authorization will need to follow the standard Plan prior authorization process for that specific service. See the Plan's *Prior Authorization/Notification Requirements Matrix* for a list of services that require prior authorization or Plan notification. Review the Plan's *Prior Authorization CPT Code Look-up Tool* and *HCPCS Code Look-up Tool* for the prior authorization requirement for each of the service's applicable, industry-standard billing code(s). The Plan's prior authorization matrix, CPT/HCPCS code

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look-up tools, medical policies, and reimbursement policies are available at www.bmchp.org for BMC HealthNet Plan products and posted at www.wellsense.org for the WellSense Health Plan products.

It will be determined during the Plan's prior authorization process if the service is considered medically necessary. Product-specific definitions for "medical necessary" services (i.e., medical necessity) are listed in the Plan's *Medically Necessary* medical policy, policy number OCA 3.14. The product-specific definitions of experimental or investigational treatment are listed in the Plan's *Experimental and Investigational Treatment* medical policy, policy number OCA 3.12.

According to the National Institutes of Health (NIH), a clinical trial is a prospective biomedical or behavioral research study of human subjects that is designed to answer specific questions about biomedical or behavioral interventions (drugs, treatments, devices, or new ways of using known drugs, treatments, or devices). Clinical trials are used to determine whether a new experimental drug, treatment, device, or behavioral intervention is safe, efficacious, and effective and may proceed through four (4) phases: Phase I, Phase II, Phase III, or Phase IV. The clinical trial must meet all applicable Plan criteria specified in this policy for the Plan member.

Clinical Criteria for QHP and MassHealth Products

A. Clinical Criteria for Qualified Health Plans/ConnectorCare/Employer Choice Direct (QHP):

The Plan considers the cost of patient care services to be medically necessary for members who are enrolled in a qualified clinical trial when Plan criteria are met in items 1 and 2:

1. Qualified Clinical Trial:

A qualified clinical trial meets ALL of the criteria in items a through i:

a. A Phase I, II, III or IV clinical trial is intended to treat ANY of the conditions in item (1) or item (2):

(1) **Treat cancer** in a member who has been diagnosed with cancer; OR

(2) **Treat a life-threatening disease or condition** in a member who has been diagnosed with a life-threatening disease or condition; AND

Note: A life-threatening disease of condition is defined as any disease or condition from which the likelihood of death is probable unless the course of the disease or condition is interrupted; death need not be imminent for a disease or condition to be life-threatening. (Source: Section 2709 of the Patient Protection and Affordable Care Act codified at 42 U.S.C. § 300gg-8.)

b. The clinical trial has been peer reviewed and is approved by ANY of the entities specified below in items (1) through (6):

   (1) One (1) of the United States National Institutes of Health (NIH); OR

   (2) A cooperative group or center of the NIH; OR

   (3) A qualified nongovernmental research entity identified in guidelines issued by the NIH for center support grants; OR

   (4) The United States Food and Drug Administration (FDA) pursuant to an investigational new drug exemption; OR

   (5) The United States Departments of Defense (DoD) or Veterans Affairs (VA); OR

   (6) With respect to Phase II, III, and IV clinical trials only, a qualified institutional review board; AND

c. The facility and personnel conducting the clinical trial are capable of doing so by virtue of their experience and training and treat a sufficient volume of patients to maintain that expertise; AND

d. With respect to a Phase I clinical trial, the facility is an academic medical center or an affiliated facility, and the clinicians conducting the trial have staff privileges at said academic medical center; AND

e. The Plan member meets the patient selection criteria enunciated in the study protocol for participation in the clinical trial; AND

f. The Plan member has provided informed consent for participation in the clinical trial in a manner that is consistent with current legal and ethical standards; AND

g. The available clinical or pre-clinical data provide a reasonable expectation that the member's participation in the clinical trial will provide a medical benefit that is commensurate with the risks of participation in the clinical trial; AND

h. The clinical trial does not unjustifiably duplicate existing studies; AND

i. The clinical trial has a therapeutic intent and must, to some extent, assess the effect of the intervention on the member; AND

2. Patient Care Service:

   For the Plan to consider the cost of a patient care service to be medically necessary, the health care item or service must meet ALL of the criteria in items a through c:

   a. Health care item or service is consistent with the usual and customary standard of care for someone with the member's diagnosis; AND

   b. Health care item or service is consistent with the study protocol for the clinical trial; AND

   c. Health care item or service would be covered if the member did not participate in the clinical trial.

B. Clinical Criteria for MassHealth Product:

   The Plan considers the cost of patient care services to be medically necessary for members who are enrolled in a qualified clinical trial when Plan BOTH criteria are met in item 1 and item 2:

   1. Qualified Clinical Trial:

      A qualified clinical trial meets ALL of the conditions in items a through i:

      a. A Phase I, II, III or IV clinical trial intended to **treat cancer** in a member who has been diagnosed with cancer; AND

      b. The clinical trial has been peer reviewed and is approved by ANY of the following entities listed in items (1) through (6):

         (1) One of the United States National Institutes of Health (NIH); OR

         (2) A cooperative group or center of the NIH; OR

         (3) A qualified nongovernmental research entity identified in guidelines issued by the NIH for center support grants; OR

         (4) The United States Food and Drug Administration (FDA) pursuant to an investigational new drug exemption; OR

         (5) The United States Departments of Defense (DoD) or Veterans Affairs (VA); OR

         (6) With respect to Phase II, III, and IV clinical trials only, a qualified institutional review board; AND

c. The facility and personnel conducting the clinical trial are capable of doing so by virtue of their experience and training and treat a sufficient volume of patients to maintain that expertise; AND

d. With respect to a Phase I clinical trial, the facility is an academic medical center or an affiliated facility, and the clinicians conducting the trial have staff privileges at said academic medical center; AND

e. The Plan member meets the patient selection criteria enunciated in the study protocol for participation in the clinical trial; AND

f. The Plan member has provided informed consent for participation in the clinical trial in a manner that is consistent with current legal and ethical standards; AND

g. The available clinical or pre-clinical data provide a reasonable expectation that the member's participation in the clinical trial will provide a medical benefit that is commensurate with the risks of participation in the clinical trial; AND

h. The clinical trial does not unjustifiably duplicate existing studies; AND

i. The clinical trial has a therapeutic intent and must, to some extent, assess the effect of the intervention on the member; AND

2. Patient Care Service:

   For the Plan to consider the cost of a patient care service to be medically necessary, the health care item or service must meet ALL criteria in items a through c:

   a. Health care item or service is consistent with the usual and customary standard of care for someone with the member's diagnosis; AND

   b. Health care item or service is consistent with the study protocol for the clinical trial; AND

   c. Health care item or service would be covered if the member did not participate in the clinical trial.

Clinical Criteria for WellSense New Hampshire Medicaid Product

The Plan considers the routine patient care cost of services to be medically necessary for WellSense New Hampshire members who are enrolled in a clinical trial when BOTH criteria are met in item 1 and item 2:

1. Clinical Trial:

   ALL of the following criteria are met in items a through f:

   a. The clinical trial is intended to **treat cancer** in a member who has been diagnosed with cancer; AND

   b. The clinical trial has been peer reviewed and is approved by ANY of the entities listed in items (1) through (5):

      (1) One of the United States National Institutes of Health (NIH); OR

      (2) A cooperative group or center of the NIH; OR

      (3) The United States Food and Drug Administration (FDA) pursuant to an investigational new drug exemption; OR

      (4) The United States Departments of Defense (DoD) or Veterans Affairs (VA); OR

      (5) An Institutional Review Board of an institution in the State of New Hampshire that has a multiple assurance contract approved by the Office of Protection from Research Risks of the NIH; AND

   c. Standard treatment has been or would be ineffective, does not exist, or there is no superior non-investigational treatment alternative; AND

   d. The available clinical or preclinical data provide a reasonable expectation that the treatment will be at least as effective as the non-investigational alternative, if applicable; AND

   e. The facility and personnel providing the treatment are capable of doing so by virtue of their experience, training, and volume of patients treated to maintain expertise; AND

   f. Participating providers obtain the member's informed consent for participation in the clinical trial in a manner that is consistent with current legal and ethical standards and make the consent available to the Plan upon request; AND

2. Routine Patient Care Cost:

   Patient care services do not, under any circumstances, include the costs of the experimental or investigational treatment (such as a drug or device) being tested in the clinical trial, as specified in the Definitions for WellSense New Hampshire Products section of the Plan's *Experimental and*

Investigational medical policy, policy number OCA 3.12. For the Plan to consider the cost of a patient care service to be medically necessary, criteria in BOTH item a and item b must be met:

a. The service is one that the Plan regularly reimburses for its members, health care providers, or health care institutions subject to the terms and conditions of the member's policy and the provider's service agreement with the insurer; AND

b. For the purpose of this policy, it is a reasonable and medically necessary service if it is necessary to administer the drug or use the device under evaluation in the clinical trial.

Limitations and Exclusions for QHP and MassHealth Products

1. Plan Medical Director review is required when a member is concurrently enrolled in MORE than one (1) clinical trial for the same medical condition (even when applicable criteria are met in the Clinical Criteria section).

2. The Plan does NOT cover experimental or investigational treatments, drugs, or procedures, including those used in clinical trials that do NOT meet Plan criteria specified in this policy.

3. The Plan does NOT cover the cost of a consultation solely for the purpose of evaluating a member's eligibility for participation in a clinical trial.

4. The Plan considers ANY of the following costs associated with patient care services for a Phase I through Phase IV clinical trial to NOT be medically necessary (designated by Plan product type), as specified below in EITHER item a or item b:

   a. **Applicable Only to a Plan Member Enrolled in a Qualified Health Plans, ConnectorCare, or Employer Choice Direct Product**:

      ANY of the costs in items (1) through (8) is NOT considered medically necessary:

      (1) An investigational drug or device that has been approved for use in the qualified clinical trial (whether or not the U. S. Food and Drug Administration has approved the drug or device for use in treating the member's particular condition), and the drug or device is paid for by the manufacturer, distributor, or provider of the drug or device; OR

      (2) Non-health care services that a member may be required to receive as a result of being enrolled in the qualified clinical trial; OR

      (3) Costs related to managing the research associated with the qualified clinical trial; OR

      (4) Costs that would not be covered for non-investigational treatments; OR

(5) Any item, service, or cost that is reimbursed or otherwise furnished by the sponsor of the clinical trial; OR

(6) The costs of services which are inconsistent with widely accepted and established national or regional standards of care; OR

(7) The costs of services which are provided primarily to meet the needs of the trial including but not limited to the following: laboratory and imaging tests, measurements, and/or other services which are typically covered but which are being provided at a greater frequency, intensity, and/or duration according to the trial protocol; OR

(8) Services or costs that are NOT covered (as stated in the member's applicable benefit document in effect at the time of review of the prior authorization request and the date of service); OR

b. **Applicable Only to a Plan Member Enrolled in a MassHealth Product**:

ANY of the costs in items (1) through (8) is NOT considered medically necessary:

(1) An investigational drug or device that has been approved for use in the qualified clinical trial (whether or not the United States Food and Drug Administration has approved the drug or device for use in treating the member's particular condition), and the drug or device is paid for by the manufacturer, distributor, or provider of the drug or device; OR

(2) Non-health care services that a member may be required to receive as a result of being enrolled in the qualified clinical trial; OR

(3) Costs related to managing the research associated with the qualified clinical trial; OR

(4) Costs that would not be covered for non-investigational treatments; OR

(5) Any item, service, or cost that is reimbursed or otherwise furnished by the sponsor of the clinical trial; OR

(6) The costs of services which are inconsistent with widely accepted and established national or regional standards of care; OR

(7) The costs of services which are provided primarily to meet the needs of the trial including but not limited to the following: laboratory and imaging tests, measurements, and/or other services which are typically covered but which are being

provided at a greater frequency, intensity, and/or duration according to the trial protocol; OR

(8) Services or costs that are NOT covered (as stated in the member's applicable benefit document in effect at the time of review of the prior authorization request and the date of service).

Limitations and Exclusions for WellSense New Hampshire Medicaid Product

1. Plan Medical Director review is required when a member is concurrently enrolled in MORE than one (1) clinical trial for the same medical condition (even when applicable criteria are met in the Clinical Criteria section).

2. The Plan does NOT cover experimental or investigational treatments, drugs, or procedures, including those used in clinical trials that do NOT meet Plan criteria specified in this policy.

3. The Plan considers ANY the following costs associated with a Phase I through Phase IV clinical trial in items a through e to NOT be medically necessary**:**

   a. Non-routine patient care costs including ANY listed in items (1) through (5):

      (1) The cost of an investigational new drug or device that is not approved for market for any indication by the United States Food and Drug Administration (FDA); OR

      (2) The cost of a non-health care service that a member may be required to receive as a result of the treatment being provided for the purposes of the clinical trial; OR

      (3) The costs of services that are clearly inconsistent with widely accepted and established regional or national standards of care for a particular diagnosis; OR

      (4) Costs associated with managing the research associated with the clinical trial; OR

      (5) Non-covered costs under the member's policy, plan, or contract, as stated in the member's applicable benefit document in effect at the time of review of the prior authorization request and the date of service; OR

   b. The investigational item or service itself; OR

   c. Items and/or services customarily provided by the research sponsors free of charge for any enrollee in the trial; OR

   d. Items and/or services provided solely to satisfy data collection and analysis needs and are not used in the direct clinical management of the member; OR

e. The cost of a consultation solely for the purpose of evaluating a member's eligibility for participation in a clinical trial.

Applicable Coding

Providers are responsible for obtaining prior authorization for the services specified in the Clinical Criteria section and Limitations and Exclusions section, even if an applicable code appropriately describing the service that is the subject of this Plan policy is not included in the Applicable Coding section of this Plan policy. Review the Plan's reimbursement policies for Plan billing guidelines, including the Plan's *Clinical Trials* reimbursement policy applicable for the member's product. Coverage for services is subject to benefit eligibility under the member's benefit plan in effect at the time of the service. Member benefit documents are available at www.bmchp.org for BMC HealthNet Plan members and posted at www.wellsense.org for WellSense New Hampshire Medicaid members.

References

Commonwealth of Massachusetts. Division of Insurance (DOI) Bulletins.

Commonwealth of Massachusetts. MassHealth Provider Bulletins.

Commonwealth of Massachusetts. MassHealth Provider Manuals

Commonwealth of Massachusetts. MassHealth Transmittal Letters

National Comprehensive Cancer Network (NCCN). NCCN Oncology Research Program (ORP).

New Hampshire Department of Health and Human Services. Billing Manuals

New Hampshire Department of Health and Human Services. Provider Notices.

U. S. Food and Drug Administration (FDA). 510(k) Premarket Notification.

U.S. Food and Drug Administration (FDA). Clinical Trials and Human Subject Protection

U. S. Food and Drug Administration (FDA). Device Labeling.

U. S. Food and Drug Administration (FDA). Drug Approvals and Databases.

U. S. Food and Drug Administration (FDA). Medical Device Databases.

U.S. National Institutes of Health. ClinicalTrials.gov. Find a Study.

World Health Organization. International Clinical Trials Registry Platform (ICTRP).

Policy History

Original Approval Date	Original Effective Date* and Version Number	Policy Owner	Original Policy Approved by
Regulatory Approval: N/A Internal Approval: 07/28/09: Medical Policy, Criteria, and Technology Assessment Committee (MPCTAC) 08/26/09: Quality Improvement Committee (QIC)	01/01/10 Version 1	Medical Policy Manager as Chair of MPCTAC	MPCTAC and QIC

*Effective Date for the BMC HealthNet Plan Commercial Product: 01/01/12
*Effective Date for the WellSense New Hampshire Medicaid Product: 01/01/13

Policy Revisions History			
Review Date	**Summary of Revisions**	**Revision Effective Date and Version Number**	**Approved by**
07/01/10	References were updated and the policy was formatted into criteria template.	Version 2	07/21/10: MPCTAC 08/25/10: QIC
07/01/11	Added definition for Commercial product: An investigational drug or device but a drug or device that has been approved for use in the qualified clinical trial, whether or not the Food and Drug Administration has approved the drug or device for use in treating the patient's particular condition, shall be a patient care service to the extent that the drug or device is not paid for by the manufacturer, distributor or provider of the drug or device.	Version 3	07/22/11: MPCTAC 08/24/11: QIC
07/01/12	Updated references, and added statement in Summary section that all Patient Care Services require prior authorization.	Version 4	07/18/12: MPCTAC 08/22/12: QIC
08/15/12	Off-cycle review for WellSense New Hampshire Health Plan, revised Summary section, reformatted as policy statement, revised definitions for consistency with NH law, updated references.	Version 5	08/30/12: MPCTAC 09/06/12: QIC
04/01/13	Review for effective date 08/01/13. Referenced the following documents: *Experimental and Investigational Treatment* and *Medically Necessary*	08/01/13 Version 6	04/17/13: MPCTAC 05/16/13: QIC

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Policy Revisions History			
	medical policies, *Reimbursement Guideline - Clinical Trials* policy, and the Plan's prior authorization matrix. Updated Policy Summary section, revised Applicable Coding section, and added text to Description of Item or Service section. Moved criteria from Definitions section to the Medical Policy Statement section or Limitations section. Added limitations and revised criteria. Added Clinical Background Information, Definitions, and References sections. Revised WellSense New Hampshire criteria so clinical trials applies to the treatment of cancer.		
04/01/14	Review for effective date 08/01/14. Added note to header and revised Summary section. Revised medical criteria in the Medical Policy Statement section to include coverage of clinical trials for life threatening diseases or conditions (as well as cancer diagnoses) for the BMC HealthNet Plan's Commercial, Commonwealth Care, and Qualified Health Plan products. Added Qualified Health Plans as an applicable product for the policy. Revised language in the Applicable Coding section and Clinical Background Information section.	08/01/14 Version 7	04/16/14: MPCTAC 05/14/14: QIC
06/01/15	Review for effective date 10/01/15. Updated references section. Added limitation. Removed Commonwealth Care, Commonwealth Choice, and Employer Choice from the list of applicable products because the products are no longer available.	10/01/15 Version 8	06/17/15: MPCTAC 07/08/15: QIC
11/01/15	Review for effective date 01/01/16. Updated template with list of applicable products and notes. Updated References section. Administrative changes made to the Medical Policy Statement section without changing criteria.	01/01/16 Version 9	11/18/15: MPCTAC 12/09/15: QIC
06/01/16	Review for effective date 08/01/16. Updated with administrative changes to the Definitions, Clinical Background Information, References, and Reference to Applicable Laws and Regulations sections.	08/01/16 Version 10	06/15/16: MPCTAC 07/13/16: QIC
06/01/17	Review for effective date 07/01/17. Administrative changes made to the Policy Summary, Limitations, Applicable Coding, Clinical Background Information, References, Reference to Applicable Laws and	07/01/17 Version 11	06/21/17: MPCTAC

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Policy Revisions History			
	Regulations, and Other Applicable Policies sections.		
02/01/18	Review for effective date 03/01/18. Administrative change made to the Medical Policy Statement for WellSense New Hampshire Products section.	03/01/18 Version 12	02/21/18: MPCTAC
06/01/18	Review for effective date 07/01/18. Administrative changes made to the References, Other Applicable Policies, and Applicable Laws and Regulations sections.	07/01/18 Version 13	06/20/18: MPCTAC
05/01/19	Review for effective date 08/01/19. Administrative changes made to the Medical Policy Statement for BMC HealthNet Plan Products, Limitations for WellSense New Hampshire Products, References, Other Applicable Policies, and Reference to Applicable Laws and Regulations sections. Revised criteria in the Limitations for BMC HealthNet Plan Products section.	08/01/19 Version 14	05/15/19: MPCTAC
06/01/20	Review for effective date 09/01/20. Revised criteria in the Medical Policy Statement for Qualified Health Plans/ConnectorCare/Employer Choice Direct (QHP) section. Administrative changes made to the Applicable Coding, References, and Reference to Applicable Laws and Regulations sections.	09/01/20 Version 15	06/17/20: MPCTAC
06/01/21	Review for effective date 07/01/21. Administrative changes made to the References and Reference to Applicable Laws and Regulations sections.	07/01/21 Version 16	06/16/21: MPCTAC
11/01/21	Review for effective date 12/01/21. Adopted new medical policy template; removed administrative sections, Medical Policy Statement section renamed Clinical Criteria section, and Limitations section renamed Limitation and Exclusions section. Administrative changes made to the Policy Summary, Clinical Criteria for QHP and MassHealth Products, Clinical Criteria for WellSense New Hampshire Medicaid Product, Limitations and Exclusions for QHP and MassHealth Products, Limitations and Exclusions for WellSense New Hampshire Medicaid Product, Applicable Coding, and References sections. Removed Senior Care Options as an applicable product.	12/01/21 Version 17	11/17/21: MPCTAC

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Next Review Date

06/01/22

Authorizing Entity

MPCTAC

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.

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