BOSTON MEDICAL CENTER HEALTHNet PLAN

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WELL SENSE HEALTH PLAN

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Medical Policy

Experimental and Investigational Treatment

Policy Number: OCA 3.12
Version Number: 20
Version Effective Date: 12/01/21

Product Applicability	☒ **All Plan+ Products**
WellSense Health Plan ☒ NH Medicaid ☒ NH Medicare Advantage	**Boston Medical Center HealthNet Plan** ☒ MassHealth ACO ☒ 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

Experimental and investigational treatment, as described in this policy, is not covered by the Plan. 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. 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's *Prior Authorization/Notification Requirements Matrix* includes a list of services that require prior authorization. Review the Plan's *Prior Authorization CPT Code Look-up Tool* and *Prior Authorization HCPCS Code Look-up Tool* for the prior authorization guidelines for each of the service's applicable, industry-standard billing code(s). The Plan's prior authorization matrix, CPT/HCPCS code look-up tools, medical policies, and reimbursement policies are available at www.bmchp.org for BMC HealthNet Plan members (including Senior Care Options member) and posted at www.wellsense.org for WellSense Health Plan members.

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It will be determined during the Plan's prior authorization process if a service is considered experimental and investigational for the requested indication. The Plan's *Medically Necessary* medical policy, policy number OCA 3.14, specifies the product-specific definitions of medically necessary treatment. See the product-specific definitions of cosmetic services and reconstructive surgery and procedures in the Plan's *Cosmetic, Reconstructive, and Restorative Services* medical policy, policy number OCA 3.69. The Plan's *Clinical Review Criteria* administrative policy, policy number OCA 3.201, includes product-specific definitions of clinical review criteria, a summary of the Plan's procedure for applying clinical review criteria to services that require prior authorization, and specifies which entities are responsible for the development, implementation, and monitoring of the Plan's clinical review criteria. The Plan's *Clinical Technology Evaluation* administrative policy, policy number OCA 3.13, includes definitions for evidence-based medicine and medical technology assessment, and the policy outlines the process for evaluating new technology and the new application of existing technology. Review the Plan's applicable *Clinical Trials* reimbursement policy if the requested service is related to a clinical trial: reimbursement policy number 4.134 for BMC HealthNet Plan members, reimbursement policy number SCO 4.134 for Senior Care Options members, or reimbursement policy number WS 4.12 for WellSense New Hampshire Medicaid members.

Member benefit documents are available at the following websites: www.bmchp.org for BMC HealthNet Plan members, www.SeniorsGetMore.org for Senior Care Options members, www.wellsense.org for WellSense New Hampshire Medicaid members, and www.WellSense.org/Medicare for WellSense Medicare Advantage HMO members.

Clinical Criteria

See Product-Specific Definitions section of this policy for applicable criteria by Plan product**.**

Limitations and Exclusions

Experimental and investigational treatment, as described in this policy, is NOT covered for Plan members due to limited evidence demonstrating the clinical utility and clinical validity of treatment.

Variations

The Plan uses guidance from the Centers for Medicare & Medicaid Services (CMS) for medical necessity and coverage determinations for Senior Care Options (SCO) members and WellSense Medicare Advantage HMO members, including but not limited to national coverage determinations (NCDs), local coverage determinations (LCDs), local coverage articles (LCAs), and documentation included in Medicare manuals. Verify CMS guidelines in effect on the date of the prior authorization request that are appropriate for the service and indication for treatment. When there is no guidance from CMS for the requested service, Plan-adopted clinical review criteria will be used to determine the medical necessity of the service.

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Product-Specific Definitions

1. **Qualified Health Plans, ConnectorCare, and Employer Choice Direct Definitions**:

   The fact that a treatment is offered as a last resort does not mean that it is not an experimental or investigational treatment.

   a. **Experimental or Investigational/Experimental or Investigational Treatment**:

      A treatment, service, procedure, supply, device, biological product, or drug (collectively "treatment") is considered to be experimental or investigational for use in the diagnosis or treatment of a medical condition if ANY of the following is true, as specified below in items (1) through (5):

      (1) In the case of a drug, device, or biological product, it cannot be marketed lawfully without the approval of the U.S. Food and Drug Administration (FDA) and final approval has not been given by the FDA; OR

      (2) The treatment is described as experimental (or investigational, unproven, or under study) in the written informed consent document provided, or to be provided, to the member by the health care professional or facility providing the treatment; OR

      (3) Authoritative evidence (as defined below in this product-specific section) does not permit conclusions concerning the effect of the treatment on health outcomes; OR

      (4) There is insufficient authoritative evidence that the treatment improves the net health outcome. (Net health outcome means that the treatment's beneficial effects on health outcomes outweigh any harmful effects of the treatment on health outcomes. See definition of Authoritative Evidence specified below.) There is insufficient authoritative evidence that the treatment is as beneficial as any established alternative. This means that the treatment does not improve net outcome as much as or more than established alternatives; OR

      (5) There is insufficient authoritative evidence that the treatment's improvement in health outcomes is attainable outside the investigational setting. (See the definition of Authoritative Evidence specified below.)

   b. **Authoritative Evidence:**

      Authoritative evidence**,** as used in this product-specific definition of experimental or investigational treatment, shall mean only the following:

(1) Reports and articles, of well-designed and well-conducted studies, published in authoritative English-language medical and scientific publications. The publications must be subject to peer review by qualified medical or scientific experts prior to publication. In evaluating this evidence, the Plan takes into consideration both the quality of the published studies and the consistency of results;

(2) Opinions and evaluations by national medical associations, other reputable technology assessment bodies, and health care professionals with recognized clinical expertise in treating the medical condition or providing the treatment. In evaluating this evidence, the Plan takes into consideration the scientific quality of the evidence upon which the opinions and evaluations are based.

c. **Net Health Outcome:**

Net health outcome means that the treatment's beneficial effects on health outcomes outweigh any harmful effects of the treatment on health outcomes.

2. **MassHealth ACO and MassHealth MCO Contract Definition:**

Experimental Treatment: Services for which there is insufficient authoritative evidence that the service is 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 aggravate a disability or result in illness or infirmity.

3. **Definitions for WellSense New Hampshire Medicaid Product:**

The fact that a treatment is offered as a last resort does not mean that it is not an experimental or investigational treatment. If a treatment is experimental or investigational, WellSense New Hampshire Medicaid will not cover (or pay for) that treatment or any related services or drugs that are provided to the member for the purpose of furnishing the experimental or investigational treatment (except as specified in the Plan's *Clinical Trials* medical policy, policy number OCA 3.192).

a. **Experimental or Investigational:**

The Plan considers a procedure, service, test, supply, device, biological product, or drug (collectively "treatment") to be experimental or investigational for use in the diagnosis or treatment of a medical condition if ANY of the following is true, as specified below in items (1) through (7):

(1) The treatment is described as experimental or investigational in the member's benefit documents; OR

(2) The treatment is described as experimental or investigational in any current Centers for Medicare and Medicaid Services National or Local Coverage Determination; OR

(3) In the case of a drug, device, or biological product, it cannot be marketed lawfully without the approval of the U.S. Food and Drug Administration (FDA) and final approval has not been given by the FDA; OR

(4) The treatment is described as experimental (or investigational, unproven, or under study) in the written informed consent document provided, or to be provided, to the member by the health care professional or facility providing the treatment; OR

(5) Authoritative evidence (as defined in this product-specific section) does not permit conclusions concerning the effect of the treatment on health outcomes; OR

(6) There is insufficient authoritative evidence that the treatment improves the net health outcome (as defined in this product-specific section). There is insufficient authoritative evidence that the treatment is as beneficial as any established alternative. This means that the treatment does not improve net outcome as much as or more than established alternatives; OR

(7) There is insufficient authoritative evidence that the treatment's improvement in health outcomes is attainable outside the investigational setting.

b. **Authoritative Evidence:**

Authoritative evidence**,** as used in this product-specific definition of experimental or investigational treatment, shall mean only the following:

(1) Reports and articles, of well-designed and well-conducted studies, published in authoritative English-language medical and scientific publications. The publications must be subject to peer review by qualified medical or scientific experts prior to publication. In evaluating this evidence, the Plan takes into consideration both the quality of the published studies and the consistency of results.

(2) Opinions and evaluations by national medical associations, other reputable technology assessment bodies, and health care professionals with recognized clinical expertise in treating the medical condition or providing the treatment. In evaluating this evidence, the Plan takes into consideration the scientific quality of the evidence upon which the opinions and evaluations are based.

c. **Net Health Outcome:**

Net health outcome means that the treatment's beneficial effects on health outcomes outweigh any harmful effects of the treatment on health outcomes.

References

American Society for Reproductive Medicine (ASRM). Practice Committee of ASRM. Definition of experimental procedures: a committee opinion. Fertil Steril. 2013.

Centers for Medicare and Medicaid Services (CMS). Manuals. Publication # 100-02. Medicare Benefit Policy Manual.

Centers for Medicare and Medicaid Services (CMS). Manuals. Publication # 100-03. Medicare National Coverage Determinations (NCD) Manual.

Centers for Medicare and Medicaid Services (CMS). Medicare Coverage Database (MCD).

Centers for Medicare and Medicaid Services (CMS). Transmittals.

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.

Contract between the Commonwealth Health Insurance Connector Authority and Plan.

Contract between the Massachusetts Executive Office of Health and Human Services (EOHHS) and Plan.

Contract between the Executive Office of Health and Human Services (EOHHS) and the Plan to Serve as an Accountable Care Partnership Plan for the Accountable Care Organization (ACO) Program.

Contract between the New Hampshire Department of Health and Human Services and Plan.

New Hampshire Department of Health and Human Services. Billing Manuals.

New Hampshire Department of Health and Human Services. NH Medicaid Program.

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

Senior Care Options Contract between the Massachusetts Executive Office of Health and Human Services (EOHHS) and Plan and Medicare Advantage Special Needs Plan Contract between the Centers for Medicare & Medicaid Services (CMS) and the Plan.

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

Policy History

Original Approval Date	Original Effective Date* and Version Number	Policy Owner	Original Policy Approved by
Regulatory Approval: 08/01/08 Internal Approval: 12/06/05	12/06/05 Version 1	Medical Policy Manager as Chair of Medical Policy, Criteria, and Technology Assessment Committee (MPCTAC)	Quality and Clinical Management Committee (Q&CMC)

*Effective Date for the BMC HealthNet Plan Commercial Product: 01/01/12
*Effective Date for the WellSense New Hampshire Medicaid Product: 01/01/13
*Effective Date for the Senior Care Options Product: 01/01/16
*Effective Date for the WellSense Medicare Advantage HMO Product: 01/01/22

Policy Revisions History			
Review Date	**Summary of Revisions**	**Revision Effective Date and Version Number**	**Approved by**
02/21/07	Updated policy and procedure sections, added Commonwealth Care language and references.	Version 2	02/21/07: Utilization Management Committee (UMC) 03/06/07: Q&CMC
05/20/08	Changed procedure and responsibility section to indicate that the Plan's licensed pharmacists can determine if service requests are considered experimental treatment.	Version 3	05/20/08: UMC
06/19/08	Changed title and all references consistently to "Investigational and Experimental". Changed statement from "For Commonwealth Care Members, the Plan does not cover patient care services provided pursuit	Version 4	06/19/08: Quality Improvement Committee (QIC)

Policy Revisions History			
	to a qualified clinical trial" to "For Commonwealth Care Members, the Plan may cover patient care services provided pursuit to a qualified clinical trial" to allow the Plan to approve member appeals for these services.		
08/25/09	Removed the information about clinical trials in the Policy Statement section and updated references.	Version 5	09/22/09: MPCTAC 09/23/09: QIC
07/01/10	Formatted into criteria template and updated references.	Version 6	07/21/10: MPCTAC 08/25/10: QIC
07/01/11	Added Commercial Plan language and definition for experimental and investigational treatment and updated references.	Version 7	07/22/11: MPCTAC 08/24/11: QIC
08/01/12	Updated references. Revised the following sections: Summary, Description of Item of Service, Medical Policy Statement, and Definitions.	Version 8	07/18/12: MPCTAC 08/22/12: QIC 08/30/12: MPCTAC 09/06/12: QIC
06/01/13	Review for effective date 08/01/13. Revised Summary section.	08/01/13 Version 9	06/19/13: MPCTAC 07/18/13: QIC
06/01/14	Review for effective date 08/01/14. Revised Summary and Definitions section. Replaced reference to Commercial product with Qualified Health Plans, ConnectorCare, Employer Choice Direct, Commonwealth Choice, and Employer Choice. Updated references.	08/01/14 Version 10	06/18/14: MPCTAC 07/09/14: QIC
08/01/15	Review for effective date 08/01/15. Removed Commonwealth Care, Commonwealth Choice, and Employer Choice from the list of applicable products because the products are no longer available. Administrative changes made to the Definitions and References sections.	08/01/15 Version 10	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 Summary and References sections.	01/01/16 Version 11	11/18/15: MPCTAC 12/09/15: QIC
06/01/16	Review for effective date 08/01/16. No revisions.	08/0/16 Version 12	06/15/16: MPCTAC 07/13/16: QIC

Policy Revisions History			
07/01/17	Review for effective date 08/01/17. Administrative changes made to the Policy Summary and Other Applicable Policies sections.	08/01/17 Version 13	07/19/17: MPCTAC
08/31/17	Updated the Product Applicability, Definitions, and References sections to incorporate the Accountable Care Organization (ACO).	08/31/17 Version 14	08/31/17: MPCTAC (electronic vote)
02/01/18	Review for effective date 03/01/18. Administrative change made to the Policy Summary and Definitions sections.	03/01/18 Version 15	02/21/18: MPCTAC
06/01/18	Review for effective date 07/01/18. Administrative changes made to the Policy Summary, References, Other Applicable Policies, and Reference to Applicable Laws and Regulations sections.	07/01/18 Version 16	06/20/18: MPCTAC
06/01/19	Review for effective date 07/01/19. Administrative changes made to the References and Reference to Applicable Laws and Regulations sections.	07/01/19 Version 17	06/19/19: MPCTAC
06/01/20	Review for effective date 07/01/20. Administrative changes made to the References and Reference to Applicable Laws and Regulations sections.	07/01/20 Version 18	06/17/20: MPCTAC
06/01/21	Review for effective date 07/01/21. Updated References section.	07/01/21 Version 19	06/16/21: MPCTAC
11/01/21	Review for effective date 12/01/21. Adopted new medical policy template; removed administrative sections, the Medical Policy Statement section renamed the Clinical Criteria section, the Limitations section renamed the Limitations and Exclusions section, and the Definitions section renamed the Product-Specific Definitions section. Added WellSense Medicare Advantage HMO as an applicable product effective 01/01/22. Administrative changes made to the Policy Summary, Clinical Criteria, Limitations and Exclusions, and References sections.	12/01/21 Version 20	11/17/21: MPCTAC

Next Review Date

06/01/21

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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