BOSTON MEDICAL CENTER HEALTHNet PLAN

bmchp.org | 888-566-0008

WELL SENSE HEALTH PLAN

wellsense.org | 877-957-1300

Administrative Policy

Clinical Technology Evaluation

Policy Number: OCA 3.13
Version Number: 27
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 purpose of this policy is to define the process for evaluating new technology and the new application of existing technology (herein these technologies are referred to as "clinical technology") and the subsequent development of medical criteria to ensure that members have equitable access to safe and effective care. All Plan policies are developed in accordance with state, federal and accrediting organization guidelines and requirements, including the National Committee for Quality Assurance (NCQA). The Plan and the Plan's delegated clinical vendors conducting utilization management do NOT discriminate, arbitrarily deny, and/or impose stricter requirements by reducing the amount, duration, and/or scope of required and medically necessary services based on the member's diagnosis, type of illness, health status or condition, sex, gender identity/gender dysphoria, and/or sexual orientation. 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.

+ *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 WellSense Health Plan.

See the member's product-specific handbook for a summary of member rights and responsibilities, as well as the Plan's process for receiving and promptly resolving inquires, grievances, and/or appeals from a member (or an authorized representative acting on behalf of the member). Member appeals may be related to issues that include but are not limited to benefit coverage, the evaluation of clinical technology (including new technology and a new indication for an established technology), and/or the application of the Plan's clinical review criteria for the member's requested indication for treatment. The Plan's clinical review criteria include the Plan's internally developed criteria specified in medical policies and pharmacy policies, InterQual® criteria utilized by the Plan, and clinical guidelines established by delegated management partners (for related services provided Plan members for applicable Plan products), as specified in the Plan's *Clinical Review Criteria* administrative policy, policy number OCA 3.201.

Plan guidelines (including but not limited to appeals and/or clinical reconsiderations) comply with all applicable Plan contract terms with providers, employers, governmental agencies, and other contracting entities. Review the Plan's *Prior Authorization/Notification Requirements Matrix* for a list of services that require prior authorization or Plan notification and 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 look-up tools, medical policies, reimbursement policies, provider manual, member benefit documents, and member handbooks are available at www.bmchp.org for BMC HealthNet Plan members (with Senior Care Options/SCO benefit documents and SCO Appeals and Grievances page available at www.SeniorsGetMore.org) and posted at www.wellsense.org for WellSense Health Plan members (with benefit documents for WellSense Medicare Advantage HMO members available at www.WellSense.org/Medicare).

The Plan's *Cosmetic, Reconstructive, and Restorative Services* medical policy, policy number OCA 3.69, includes the product-specific definitions of cosmetic services and reconstructive surgery and procedures. 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. Product-specific definitions for "medically necessary" services (i.e., medical necessity) are listed in the Plan's *Medically Necessary* medical policy, policy number OCA 3.14. 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. Review the Plan's applicable reimbursement policy for payment guidelines related to clinical trials.

Policy Statement

The Plan evaluates the utilization of new technology and new indications for established technologies (i.e., clinical technology). Clinical technology includes new medical or behavioral health technology; new technology related to pharmacotherapy, medical device, and/or biological product; and/or the application of an established technology for a new treatment indication. The assessment of clinical

technology is conducted to determine if the technology improves the quality of life and health outcomes. Clinical technology is evaluated in a manner that also considers the individual health care needs of the member. Each of the Plan's partner clinical vendors evaluates new technology and new application(s) of an established technology for delegated utilization management services on behalf of Plan members, developing and implementing clinical review criteria when appropriate, as specified in this policy and included in the Delegated Management section of the Plan's *Clinical Review Criteria* policy, policy number OCA 3.201.

Procedure

A. **Overview**:

The Plan evaluates new technology and the new application of existing technology (i.e., clinical technology) through the Medical Policy, Criteria, and Technology Assessment Committee (MPCTAC) and/or the Pharmacy & Therapeutics (P&T) Committee. When a new technology or a new application of an existing technology does not have established clinical review criteria for the requested indication, the medical necessity of the service is determined on a case-by-case basis by a Plan Medical Director during the Plan prior authorization process. The Plan Medical Director will evaluate valid scientific evidence to determine the clinical validity and clinical utility of the service for the requested indication and compare the findings with the established standard of care. The service may include a treatment, procedure, supply, device, biological product, or drug and will be used to prevent, diagnose, stabilize, and/or treat a disease, condition, and/or disorder that results in health impairment and/or disability, and/or the service allows the member to attain, maintain, or regain functional capacity. In addition, individual consideration conducted by the Plan Medical Director includes an assessment of ALL of the following member-specific factors that may impact care, as specified below in items 1 through 16:

1. Member's condition; AND
2. Member's comorbidities (including the assessment of ongoing and/or chronic conditions with services authorized in a manner that reflects the member's continuing need for such services and supports for stabilization of one or more ongoing and/or chronic conditions); AND
3. Member's age (i.e., neonates, infants, children, adolescents, adults, or older adults), including the assessment of the member's age-appropriate growth, development, and competencies related to treatment, as well as evaluation of age-related and condition-specific healthcare needs and associated issues; AND
4. Relevant past medical/surgical/behavioral health/dental/pharmacotherapy history; AND
5. Complications experienced by the member; AND
6. Progression of the member's condition, illness, or injury; AND
7. Diagnostic test results, when applicable; AND

8. Progress with treatment; AND

9. Available treatment options for the member's condition; AND

10. Psychosocial circumstances; AND

11. Home and environmental factors impacting the member's clinical condition (e.g., homelessness, employment status, poverty, neighborhood); AND

12. Other healthcare services requested and/or currently provided to the member to integrate healthcare for continuity, coordination, and collaboration of services; AND

13. Local healthcare delivery system's ability to meet the healthcare needs of the member's specific condition; AND

14. Member's reasonable accessibility to a qualified provider with appropriate credentials, licensure, clinical expertise and/or resources in the applicable clinical area necessary to adequately manage the member's condition (including but not limited to pharmacotherapy, behavioral health services, dental services, radiology services, and/or durable medical equipment, prosthetics, orthotics and supplies); AND

15. Other factors related to the member's plan of care and/or health outcomes; AND

16. 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.

B. **Evaluation Process**:

Clinical technology includes new medical or behavioral health technology; new technology related to pharmacotherapy, medical device, and/or biological product; and/or the application of a new indication for an established technology. The Plan's evaluation process includes the following procedure, as specified below in items 1 through 4:

1. **Identification of Clinical Technology**:

The Plan's process to identify clinical technology includes BOTH of the following action steps, as specified below in items a and b:

a. The Medical Policy, Criteria and Technology Assessment Committee (MPCTAC) and/or the Pharmacy & Therapeutics (P&T) Committee identify clinical technology from ONE (1) or MORE of the following sources, as specified below in items (1) through (10):

(1) Inquiries and/or recommendations from the Plan's pharmacy benefits manager (i.e., Express Scripts for the BMC HealthNet Plan and WellSense Health Plan products)

and/or other of external Plan clinical vendors regarding coverage of clinical technology and associated clinical review criteria;

(2) Recommendations from staff in internal Plan departments, workgroups, and/or committees, including the Utilization Management Committee (UMC);

(3) Recent United States Food and Drug Administration (FDA) approvals for drugs and devices (including new technology and a new application of an established technology);

(4) Recommendations from the Plan's clinical staff, including Medical Directors, Physician Reviewers, licensed pharmacists, registered nurses, and/or other clinicians;

(5) Clinical study results published in peer-reviewed scientific literature;

(6) Internal reports generated by claims data;

(7) Inquiries from providers, members, and/or other Plan partners regarding coverage of clinical technology;

(8) Professional society and/or government agency position papers, practice guidelines, and consensus reports;

(9) New procedure codes for devices, drugs, and/or healthcare services (including medical, surgical, and behavioral health treatments); AND/OR

(10) Review of unbiased, evidence-based assessments of health technologies, clinical programs, and/or healthcare services to determine the impact of intervention(s) on patient safety and clinical outcomes; this includes but is not limited to the evaluation of reports developed by Hayes, a symplr Company; AND

b. Once the clinical technology is identified by the MPCTAC and/or P&T Committee, the applicable committee determines if further evaluation is appropriate utilizing the initial review process outlined below.

2. **Initial Review of Clinical Technology**:

The Plan's initial review process of clinical technology includes BOTH of the following action steps, as specified below in items a and b:

a. MPCTAC or P&T Committee, including a behavioral health clinician when appropriate, conducts an initial review of a clinical technology (i.e., new medical or behavioral health technology; new technology in pharmacotherapy, medical device, and/or biological

product; and/or the application of a new indication for an established technology) when considered appropriate for further evaluation. The initial review of clinical technology includes an assessment and verification of the following evidence, as specified below in items (1) through (5):

(1) The clinical technology, including drugs, biologicals, devices, or other products requiring final approval to market, has final approval for the specified indication from the appropriate governmental body(ies) with the authority to regulate the clinical technology (e.g., the FDA); AND

(2) Scientific evidence from reputable sources is evaluated to permit conclusions concerning the safety and effectiveness of the clinical technology (and associated services) on health outcomes (i.e., proven benefit, unproven benefit, insufficient evidence to determine effect, or documented harm). Sources utilized to conduct the initial evaluation and determine the efficacy and safety of the clinical technology may include: peer-reviewed literature documenting the clinical utility and clinical validity of the intervention(s) based on well-designed and well-conducted investigations; objective scientific reports published by national medical associations; clinical guidance statements from applicable professional associations; industry-standard, evidence-based guidelines and recommendations such as those established by InterQual®, National Institute for Health and Care Excellences, Hayes (a symplr Company), and National Comprehensive Cancer Network; published, clinically validated studies evaluating the use of the clinical technology as an alternative treatment strategy to established interventions considered the standard of care for the specified indication (including the patient's medical condition, age, comorbidities, and other factors applicable to the health outcomes of the clinical technology and associated services); AND

(3) The clinical technology improves the net health outcome and outweighs any harmful effect; AND

(4) The clinical technology is as beneficial and cost-effective as any established alternate treatment for the specified indication, including interventions considered the standard of care; AND

(5) The documented, favorable health outcomes are reasonably expected to be attainable outside of the investigational settings (i.e., in a standard clinical setting) to a degree comparable in the published, scientifically derived and evidence-based investigations; AND

b. Once the initial review of the clinical technology is completed by the MPCTAC or P&T Committee, the committee determines if the clinical technology requires the development

of clinical review criteria (utilizing the process outlined below when clinical review criteria will be established).

3. **Development of Clinical Review Criteria for Clinical Technology**:

If, after the initial review, the MPCTAC or P&T Committee determines that a clinical technology requires the development of clinical review criteria, ALL of the steps listed below in items a through c are followed:

a. Plan clinical staff from the MPCTAC or P&T Committee conducts in-depth research of the clinical technology (beyond the initial evaluation outlined above) that includes a review of BOTH types of information listed in items (1) and (2):

(1) Review of current and objective clinical information related to the clinical technology (and associated services) for the specified clinical indication utilizing ALL sources applicable for the clinical technology listed in items (a) through (f):

(a) Peer reviewed medical literature and journals; AND

(b) Policies, position statements, consensus reports, and standards adopted by governmental agencies which may include but are not limited to the National Institutes of Health (NIH), Agency for HealthCare Research and Quality (AHRQ), Center for Medicare & Medicaid Services (CMS), Massachusetts Executive Office of Health and Human Services, and/or New Hampshire Department of Health and Human Services; AND

(c) Position papers and guidelines established or endorsed by nationally recognized medical associations and specialty societies; AND

(d) U. S. Food and Drug Administration (FDA) current written assessments related to the safety, effectiveness, and approval status of the clinical technology for the intended clinical indication; AND

(e) Review of unbiased, evidence-based assessments of health technologies, clinical programs, and/or healthcare services to determine the impact of intervention(s) on patient safety and clinical outcomes; this include but is not limited to the evaluation of reports developed by Hayes, a symplr Company; AND

(f) Other sources deemed necessary to evaluate the clinical technology (and associated services) for the specified clinical indication and to develop the Plan's clinical review criteria; AND

(2) Evaluation of business impact; AND

b. A draft policy is developed by the clinical pharmacy staff and presented to the P&T Committee for review and approval for pharmacy policies or developed by the Medical Policy staff and presented to the MPCTAC for policy review and approval for other clinical technologies. The draft policy includes evidence-based and scientifically-derived, clinical review criteria that include the following factors when clinically appropriate: comorbidities and relevant past medical/surgical history that are likely to impact clinical outcomes (specified as medical necessity criteria, absolute contraindications, relative contraindications, or limitations); documentation of failed first-line, alternative, or conservative treatment before the requested intervention; values for laboratory tests and/or diagnostic tests as clinical review criteria; and/or age-specific physiological, psychosocial, and/or functional considerations for neonates, infants, children, adolescents, adults, and/or older adults when age-related factors may have an impact on the safe utilization of the clinical technology and/or alter the effectiveness of the intervention and desired clinical outcomes; AND

c. The draft policy is reviewed and revised, as specified below in items (1) through (5):

(1) In consultation with the Plan's Medical Director(s) and other Plan staff, as appropriate; AND

(2) With input from actively practicing specialists and/or professionals or serving as consultants who have expertise and appropriate credentials in the clinical technology and associated services under consideration, as appropriate (e.g., criteria review by board-certified physician experts in the Plan's service area, feedback from participants of the local network-based Provider Advisory Committee, and/or independent medical criteria review from board-certified physician consultants from Advanced Medical Reviews (AMR). Consultants may include but are not limited to pharmacists, community-based providers, behavioral health clinicians, and board-certified physicians actively practicing in specialties that include neonatology, pediatrics, family medicine, internal medicine, medical/surgical subspecialties, and/or geriatrics; AND

(3) In accordance with the Plan's definition of medical necessity, as specified in the Plan's *Medically Necessary* medical policy, policy number OCA 3.14; AND

(4) In accordance with the Plan's procedure for the utilization of clinical review criteria, as specified in the Plan's *Clinical Review Criteria* administrative policy, policy number OCA 3.201; AND

(5) The draft policy will follow the applicable approval process by policy type, as specified below in EITHER item (a) or item (b):

(a) Each medical policy is developed for MPCTAC review, and final approval is required by MPCTAC; OR

(b) Each pharmacy policy is developed for review and final approval by the P&T Committee, and approved pharmacy policies are shared with the Quality Improvement Committee (QIC).

4. **Implementation of Clinical Review Criteria for the Clinical Technology**:

The approved, final version of the internally developed policy (with clinical review criteria for the clinical technology) is implemented, as specified below in BOTH item a and item b:

a. The Plan policy with clinical review criteria for the clinical technology is filed electronically on internal drives and in document libraries, replacing existing policies, as needed (with outdated policies archived); AND

b. The Plan policy with clinical review criteria for the clinical technology is communicated via ALL of methods listed in items (1) through (7):

(1) Inclusion of key staff in the policy development process; AND

(2) Distribution to the Office of Clinical Affairs (OCA), Claims, Finance, and other internal staff, as appropriate; AND

(3) Implementation meetings with clinical operations staff and other internal staff; AND

(4) Written notification to providers via Network Notification at least **60 calendar days** before the implementation date of the Plan policy with clinical review criteria; AND

(5) Posting on the Plan's applicable external website(s), www.bmchp.org and/or www.wellsense.org, and accessible to all providers, members, and the general public for at least **60 calendar days** before the implementation date and while the medical necessity criteria are in effect. Providers may email feedback on the Plan's medical policies and clinical technologies to the Medical Policy Mailbox at medical.policy@bmchp-wellsense.org; AND

(6) Distributed by hard copy, upon written or oral request, to participating providers and/or members whose health benefit plan is subject to the Plan's clinical policy; AND

(7) The Plan will notify the Massachusetts Office of Patient Protection, Massachusetts Executive Office of Health and Human Services (EOHHS), New Hampshire Department of Health and Human Services (DHHS), and the Centers for Medicare & Medicaid Services at least **60 calendar days** before the effective date of the Plan policy with

clinical review criteria (or another timeframe specified by the organization) when clinical criteria are applicable for services that may be provided to the organization's enrollees; a designated contact person must be provided in writing to MPCTAC by the organization or its designee.

Responsibility and Accountability

Responsibility and Accountability for BMC HealthNet Plan Products: The Chief Clinical Officer within the Office of Clinical Affairs is responsible for monitoring and reviewing this policy and procedure on an annual basis.

Responsibility and Accountability for WellSense Health Plan Products: Under the direction of the Chief Clinical Officer, the New Hampshire Medical Director is responsible for monitoring and reviewing this policy annually.

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. 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.

Definitions

Clinical Review Criteria for Utilization Review: When the Plan conducts utilization review (UR), appropriate professional utilization management (UM) Plan staff consistently apply Plan-adopted written clinical review criteria that include the Plan's internally developed criteria specified in medical policies and pharmacy policies, InterQual® criteria utilized by the Plan, and clinical guidelines established by delegated management partners (for related services provided to Plan members for applicable Plan products), as stated in the Delegated Management section of the *Clinical Review Criteria* administrative policy, policy number OCA 3.201. When national clinical guidelines (e.g., InterQual® criteria) are not available or not adopted by the Plan, Plan-specific criteria may be established in internally developed medical policies or pharmacy policies. The development and review of internal clinical review criteria include input from participating practitioners and consultant specialists in the related specialties that may include but are not limited to pharmacists, community-based providers, behavioral health clinicians, and physician specialists in neonatology, pediatrics, family medicine, internal medicine, medical/surgical subspecialties, and geriatrics. The Plan-adopted written clinical review criteria (i.e., the Plan's internal medical policies and pharmacy policies, InterQual® criteria utilized by the Plan, and clinical guidelines utilized by delegated management partners for related services provided to Plan members for applicable Plan products) are objective,

scientifically derived, and evidence-based for the requested service(s) and indication(s) for treatment and are compliant with applicable legal obligations (including all Plan contracts), regulatory requirements, and national accreditation organization standards.

The Plan's clinical review criteria and UM decision tools are applied equitably across the Plan's membership. On at least an annual basis, Plan staff review all clinical review criteria utilized by the Plan and the procedures for applying those clinical review criteria. Updates to clinical review criteria are implemented as new treatments, applications, and technologies are adopted and become components of generally accepted professional practice for behavioral health, medical/surgical services, and/or pharmacotherapy.

The Plan's Office of Clinical Affairs (OCA) UM staff applies the clinical review criteria consistently; however, qualified OCA UM staff also considers member-specific factors impacting the member's individual healthcare needs to determine if the service is medically necessary for the requested indication. The service may include a treatment, procedure, supply, device, biological product, or drug and will be used to prevent, diagnose, stabilize, and/or treat a disease, condition, and/or disorder that results in health impairment and/or disability, and/or the service allows the member to attain, maintain, or regain functional capacity. Individual consideration includes an assessment of ALL of the following member-specific factors that may impact care, as specified below in items 1 through 16:

1. Member's condition; AND
2. Member's comorbidities (including the assessment of ongoing and/or chronic conditions with services authorized in a manner that reflects the member's continuing need for such services and supports for stabilization of one or more ongoing and/or chronic conditions); AND
3. Member's age (i.e., neonates, infants, children, adolescents, adults, or older adults), including the assessment of the member's age-appropriate growth, development, and competencies related to treatment, as well as evaluation of age-related and condition-specific healthcare needs and associated issues; AND
4. Relevant past medical/surgical/behavioral health/dental/pharmacotherapy history; AND
5. Complications experienced by the member; AND
6. Progression of the member's condition, illness, or injury; AND
7. Diagnostic test results, when applicable; AND
8. Progress with treatment; AND
9. Available treatment options for the member's condition; AND
10. Psychosocial circumstances; AND

11. Home and environmental factors impacting the member's clinical condition (e.g., homelessness, employment status, poverty, neighborhood); AND

12. Other healthcare services requested and/or currently provided to the member to integrate healthcare for continuity, coordination, and collaboration of services; AND

13. Local healthcare delivery system's ability to meet the healthcare needs of the member's specific condition; AND

14. Member's reasonable accessibility to a qualified provider with appropriate credentials, licensure, clinical expertise and/or resources in the applicable clinical area necessary to adequately manage the member's condition (including but not limited to pharmacotherapy, behavioral health services, dental services, radiology services, and/or durable medical equipment, prosthetics, orthotics and supplies); AND

15. Other factors related to the member's plan of care and/or health outcomes; AND

16. 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.

When clinical review criteria are not met for a requested treatment such that medical necessity cannot be established for the member's condition or indication for treatment, OCA UM staff engages in discussions with licensed Plan pharmacists, OCA UM clinicians, and/or Plan Medical Directors/Physician Reviewers to determine if the clinical review criteria are appropriate for the member's circumstances or local delivery system (utilizing qualified Plan clinicians applicable for the member's condition and requested treatment). If the clinical review criteria are not appropriate, OCA UM staff may make the utilization determination based on the member's condition and other unique circumstances.

Plan staff (including but not limited to representatives from the Plan's Accreditation, Utilization Management, Pharmacy, and Vendor Management Departments) routinely collects and reviews documentation to verify that quality standards are met by clinical vendors who are delegated to conduct utilization management on behalf of Plan members. In addition, an annual review of each clinical vendor is completed by the Plan's Clinical Vendor Oversight Committee to ensure that each clinical vendor complies with delegated utilization management requirements and that all of the following guidelines are met: each clinical vendor conducts an annual review of its clinical review criteria, approving and implementing criteria that are objective, scientifically derived, and evidence-based for the requested service(s) and indication(s) for treatment and compliant with applicable legal obligations; each clinical vendor completes an annual review and approval of policies and procedures developed to ensure that the clinical vendor's clinical review criteria are consistently applied to Plan members, with individual consideration of the member's condition, comorbidities, age, and other factors related to the member's plan of care and/or health outcomes; and the clinical vendor evaluates new technology and new application(s) of an established technology, developing criteria when clinically appropriate. If established quality standards are not met, the delegated utilization management clinical vendor develops and implements a targeted and measurable corrective action

plan that is monitored by the Plan. Review the Plan's *Clinical Review Criteria* administrative policy, policy number OCA 3.201, for product-specific definitions of clinical review criteria.

Early and Periodic Screening, Diagnostic and Treatment (EPSDT): EPSDT benefits provide comprehensive and preventive health care services for children under age 21 who are enrolled in Medicaid. EPSDT is key to ensuring that children and adolescents receive appropriate preventive, dental, mental health, developmental, and specialty services.

States are required to provide comprehensive services and furnish all Medicaid coverable, appropriate, and medically necessary services needed to correct and ameliorate health conditions, based on certain federal guidelines. EPSDT services include screening, diagnostic, and/or treatment services. Screening services include comprehensive health and developmental history, comprehensive unclothed physical exam, appropriate immunizations (according to the Advisory Committee on Immunization Practices), laboratory tests (including lead toxicity screening), and health education (including but not limited to child development, healthy lifestyles, accident prevention, and disease prevention). Additional EPSDT services include vision services (including but not limited to the diagnosis and treatment for defects in vision such as eyeglasses), dental services (including relief of infections and pain, restoration, maintenance, and emergency services), hearing services (including the diagnosis and treatment for defects in hearing, including hearing aids), and other medically necessary health care services required to treat, correct, and/or reduce illnesses and health conditions. Diagnostic EPSDT services are utilized to conduct a complete evaluation of the member's health condition and assure that comprehensive care is provided. Medically necessary health care services must be provided to treat physical and mental health illnesses or conditions identified by screening or diagnostic procedures. (Source: Medicaid.gov)

Evidence-Based Medicine: The conscientious, explicit, and judicious use of current evidence in making decisions about the care of individual patients. The practice of evidence-based medicine means integrating individual clinical expertise with the best available external clinical evidence from systematic research.

Medical Technology Assessment: The mechanism to evaluate the utilization of new technologies and new applications for existing technologies, including medical and behavioral health procedures, pharmaceuticals, biological products, and devices, to determine whether they may be considered medically necessary. Assessment of a new technology is done to determine if the technology improves the quality of life and health outcomes when compared to treatment considered the standard of care for the specified indication.

Office of Clinical Affairs Staff: Plan staff members within the Office of Clinical Affairs (OCA) that include but are not limited to OCA Utilization Management (UM) staff, Plan licensed pharmacists, Plan Medical Directors, Physician Reviewers, and the Chief Clinical Officer. The Directors of OCA, including the Directors of Utilization Management and the Director of Pharmacy, or their designees are responsible for ensuring OCA UM staff training, evaluating, and monitoring. The Plan's OCA UM staff, Plan licensed pharmacists, and Plan Medical Directors/Physician Reviewers consistently use applicable

Plan clinical review criteria when determining the medical necessity of health care services. The Chief Clinical Officer or designee is responsible for ensuring Medical Director/Physician Reviewer training, evaluation, and monitoring to ensure consistent application of clinical review criteria and medical necessity determinations.

Office of Clinical Affairs Utilization Management Staff: The Plan's Office of Clinical Affairs (OCA) Utilization Management (UM) staff includes both the Pharmacy UM staff and UM staff. Reporting to the Director of Pharmacy, the Pharmacy UM staff reviews requests for pharmacotherapy or directs requests to a partner clinical vendor for delegated utilization management. Reporting to the Directors of Utilization Management, UM staff reviews medical/ surgical/ behavioral health requests for service or directs requests to a partner clinical vendor for delegated utilization management.

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 & Medicaid Services (CMS). Medicare Managed Care Manual. Chapter 4 - Benefits and Beneficiary Protections. 90.5 – Creating New Guidance. Rev 120. Issued 01-16-15, Effective 01-01-15, Implementation 01-01-15.

Centers for Medicare and Medicaid Services (CMS). Transmittals.
Change Healthcare. InterQual® Overview

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

Commonwealth of Massachusetts. Mandatory Benefits Guide. Consumer Affairs and Business Regulation.
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 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 Massachusetts Executive Office of Health and Human Services (EOHHS) and Plan.

Contract between New Hampshire Department of Health and Human Services (DHHS) and Plan.

Hayes, a symplr Company.

Medicaid.gov. Early and Periodic Screening, Diagnostic, and Treatment. Centers for Medicare & Medicaid Services.

National Committee for Quality Assurance (NCQA). HEDIS® & Performance Measurement

National Committee for Quality Assurance (NCQA). Utilization Management Accreditation.

National Institute for Health and Care Excellence (NICE). NICE guidance.

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

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). 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

Policy History

Original Approval Date	Original Effective Date* and Version Number	Policy Owner	Original Policy Approved by

Regulatory Approval: 08/01/08 Internal Approval: 06/07/05	06/07/05 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

Note: Policy title was *New Technology* until 05/31/17. Policy title changed to *Clinical Technology Evaluation* as of 06/01/17.

Policy Revisions History

Review Date	Summary of Revisions	Revision Effective Date and Version Number	Approved by
05/09/06	Removed clinical practice guidelines from policy. Added the resources used to evaluate new and existing technology, behavioral health procedures to technology, references and definition of evidence-based medicine.	Version 2	05/09/06: Q&CMC
05/08/07	No changes.	Version 3	05/08/07: MPCTC 05/24/07: Utilization Management Committee (UMC) 06/12/07: Quality Improvement Committee (QIC)
04/22/08	Clarified in the procedure section that the Medical Policy, Criteria and Technology Assessment Committee (MPCTAC) or the Pharmacy & Therapeutics committee (P&T) reviews new medical, behavioral or pharmacy (herein "clinical") technology and devices and new uses of existing technology and devices.	Version 4	04/22/08: UMC 06/19/08: QIC
08/25/09	Updated the purpose section with NCQA information; policy statement with the individual health care needs of the member; procedure section with information about annual updates of all policies and in accordance with the definition of medical necessity; and updated the references.	Version 5	09/22/09: MPCTAC 09/23/09: QIC
07/01/10	Updated committee names, departments and references.	Version 6	07/21/10: MPCTAC 08/25/10: QIC

Policy Revisions History			
07/01/11	Updated references, added commercial language.	Version 7	07/22/11: MPCTAC 08/24/11: QIC
07/01/12	Moved Purpose and Policy Statement sections of policy to the beginning of the document, added reference for the Plan's *Prior Authorization/ Notification Requirements* matrix, and updated reference list.	Version 8	07/18/12: MPCTAC 08/22/12: QIC
08/01/12	Off cycle review for WellSense New Hampshire Medicaid product. Reformatted sequencing, reformatted Procedure, added Responsibility and Accountability section for WellSense New Hampshire Medicaid product and all Plan products.	Version 9	08/22/12: MPCTAC 09/06/12: QIC
06/01/13	Review for effective date 07/18/13. Updated Procedure section, item 3c(2)(g) to include references to DHHS (which requires notification of administrative change to the clinical policy under section 5.1 of the contract).	07/18/13 Version 10	06/19/13: MPCTAC 07/18/13: QIC
12/01/13	Review for effective date 04/01/14. Revised Procedure section to reference Plan external partners.	04/01/14 Version 11	12/18/13: MPCTAC 01/21/14: QIC
06/01/14	Review for effective date 10/01/14. Revised Purpose section. Revised Procedure Section to clarify that pharmacy policies are approved by the P&T Committee (rather than by QIC). Added reference to EnvisionRx Options in the Procedure section. Updated references.	10/01/14 Version 12	06/18/14: MPCTAC 07/09/14: QIC
06/01/15	Review for effective date 07/08/15. Updated references. 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 Procedure section.	07/08/15 Version 13	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.	01/01/16 Version 14	11/18/15: MPCTAC 12/09/15: QIC
06/01/16	Review for effective date 07/13/16. Updated References and References to Applicable Laws and Regulations sections. Administrative change made to the Procedure section.	07/13/16 Version 15	06/15/16: MPCTAC 07/13/16: QIC
05/01/17	Review for effective date 06/01/17. Administrative changes made to Procedure section to clarify the process (but no change to the procedure for reviewing technology).	06/01/17 Version 16	05/17/17: MPCTAC

Policy Revisions History			
	Updated the policy title and the Summary, Policy Statement, Definitions, References, and References to Applicable Laws and Regulations sections.		
08/31/17	Updated the Product Applicability and References sections to incorporate the Accountable Care Organization (ACO).	08/31/17 Version 17	08/31/17: MPCTAC (electronic vote)
06/01/18	Review for effective date 07/01/18. Updated the Purpose, References, Other Applicable Policies, and Reference to Applicable Laws and Regulations sections.	07/01/18 Version 18	06/20/18: MPCTAC
09/01/18	Review for effective date 12/01/18. Updated criteria in the Procedure section (clarifying the existing process).	12/01/18 Version 19	09/19/18: MPCTAC
06/01/19	Review for effective date 07/01/19. Administrative changes made to the Policy Summary (formerly Purpose section), Procedure, Definitions, References, and Reference to Applicable Laws and Regulations sections to clarify the existing process.	07/01/19 Version 20	06/19/19: MPCTAC
12/01/19	Review for effective date 01/01/20. Administrative change made to the Procedure section.	01/01/20 Version 21	12/18/19: MPCTAC
06/01/20	Review for effective date 07/01/20. Administrative changes made to the Policy Summary, Procedure, References, and Reference to Applicable Laws and Regulations sections.	07/01/20 Version 22	06/17/20: MPCTAC
12/01/20	Review for effective date 01/01/21. Administrative changes made to the Procedure, Responsibility and Accountability, and Definitions sections.	01/01/21 Version 23	12/16/20: MPCTAC
12/22/20	Review for effective date 01/01/21 (replacing version 23). Updated documentation related to the Plan's Pharmacy Manager, Express Scripts, and the role of the Pharmacy Department staff in the Procedure section.	01/01/21 Version 24	12/23/20: MPCTAC (electronic vote)
06/01/21	Review for effective date 07/01/21. Clarified current guidelines with administrative changes made to the Policy Summary, Procedure, and Definitions sections. Updated References section.	07/01/21 Version 25	06/16/21: MPCTAC
08/01/21	Review for effective date 09/01/21. Administrative changes made to the Policy Summary, Procedure, Definitions, References,	09/01/21 Version 26	08/13/21: MPCTAC (electronic vote)

Policy Revisions History			
	Other Applicable Policies, and Reference to Applicable Laws and Regulations sections to clarify current guidelines.		
11/01/21	Review fore effective date 12/01/21. Added WellSense Medicare Advantage HMO as an applicable product effective 01/01/22. Administrative changes made to the Policy Summary and Procedure section. Added the Variations section.	12/01/21 Version 27	11/17/21: MPCTAC

Next Review Date

06/01/22

Authorizing Entity

MPCTAC

Other Applicable Policies

Administrative Policy - *Clinical Review Criteria*, policy number OCA 3.201
Medical Policy - *Clinical Trials*, policy number OCA 3.192
Medical Policy - *Cosmetic, Reconstructive, and Restorative Services*, policy number OCA 3.69
Medical Policy - *Experimental and Investigational*, policy number OCA 3.12
Medical Policy - *Medically Necessary*, policy number OCA 3.14
Reimbursement Policy - *Clinical Trials*, policy number 4.134
Reimbursement Policy - *Clinical Trials*, policy number SCO 4.134
Reimbursement Policy - *Clinical Trials*, policy number WS 4.12
Reimbursement Policy - *Early Intervention*, policy number 4.3
Reimbursement Policy - *Early and Periodic Screening, Diagnosis and Treatment (EPSDT)*, policy number WS 4.15
Reimbursement Policy - *General Billing and Coding Guidelines*, policy number 4.31
Reimbursement Policy - *General Billing and Coding Guidelines*, policy number SCO 4.31
Reimbursement Policy - *General Billing and Coding Guidelines*, policy number WS 4.17
Reimbursement Policy - *General Clinical Editing and Payment Accuracy Review Guidelines*, policy number 4.108
Reimbursement Policy - *Hospital*, policy number WS 4.21
Reimbursement Policy - *Inpatient Hospital*, policy number 4.110
Reimbursement Policy - *Inpatient Hospital*, policy number SCO 4.110
Reimbursement Policy - *Non-Participating Provider*, policy number WS 4.5
Reimbursement Policy - *Non-Reimbursed Codes*, policy number 4.38
Reimbursement Policy - *Non-Reimbursed Codes*, policy number WS 4.38

Reimbursement Policy - *Outpatient Hospital*, policy number SCO 4.17
Reimbursement Policy - *Physician and Non-Physician Practitioner Services*, policy number 4.608
Reimbursement Policy - *Physician and Non-Physician Practitioner Services*, policy number SCO 4.608
Reimbursement Policy - *Physician and Non-Physician Practitioner Services*, policy number WS 4.28
Reimbursement Policy - *Provider Preventable Conditions and Serious Reportable Events*, policy number 4.610
Reimbursement Policy - *Provider Preventable Conditions and Serious Reportable Events*, policy number SCO 4.610
Reimbursement Policy - *Provider Preventable Conditions and Serious Reportable Events*, policy number WS 4.29

Reference to Applicable Laws and Regulations

42 CFR 405.1060. Code of Federal Regulations. Applicability of National Coverage Determinations.

42 CFR 422.205. Code of Federal Regulations. Public Health. Centers for Medicare & Medicaid Services. Medicare Advantage Program. Provider Antidiscrimination Rules.

42 CFR 438.100. Code of Federal Regulations. Public Health, Centers for Medicare & Medicaid Services. Managed Care. Enrollee Rights and Protections. Enroll Rights.

42 CFR 438.210. Code of Federal Regulations. Public Health. Centers for Medicare & Medicaid Services. Medical Assistance Programs. Managed Care. Coverage and Authorization of Services.

42 CFR 440.210. Code of Federal Regulations. Public Health. Centers for Medicare & Medicaid Services. Medical Assistance Programs. Medical Assistance Programs. Required Services for the Categorically Needy.

42 CFR 441.56. Code of Federal Regulations. Public Health. Centers for Medicare & Medicaid Services. Medical Assistance Programs. Medical Assistance Programs. Requirements and Limits Applicable to Specific Services. Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) of Individuals Under Age 21. Required Activities.

42 CFR Parts 438, 440, 456, and 457. Code of Federal Register. Vol. 81. No. 61. Medicaid and Children's Health Insurance Programs; Mental Health Parity and Addiction Equity Act of 2008; the Application of Mental Health Parity Requirements to Coverage Offered by Medicaid Managed Care Organizations, the Children's Health Insurance Program (CHIP), and Alternative Benefit Plans. Centers for Medicare & Medicaid Services (CMS). 2016 Mar 30.

42 USC § 18001. United States Code. Patient Protection and Affordable Care Act. 2010.

78 FR 48164-69. Federal Register. Centers for Medicare & Medicaid Services (CMS). Medicare Program. Revised Process for Making National Coverage Determinations. 2013 Aug 7.

130 CMR. Code of Massachusetts Regulations. Division of Medical Assistance.

130 CMR 410.00. Code of Massachusetts Regulations. Division of Medical Assistance. Outpatient Hospital Services.

130 CMR 415.000. Code of Massachusetts Regulations. Division of Medical Assistance. Acute Inpatient Hospital Services.

130 CMR 433.00. Code of Massachusetts Regulations. Division of Medical Assistance. Physician Services.

130 CMR 440.00. Division of Medical Assistance. Code of Massachusetts Regulations. Early Intervention Program Services.

130 CMR 450.000. Code of Massachusetts Regulations. Division of Medical Assistance. Administrative and Billing Regulations.

130 CMR 450.117(J). Code of Massachusetts Regulations. Division of Medical Assistance. Administrative and Billing Regulations. Managed Care Participation. Compliance with Mental Health Parity Law.

211 CMR 52.00. Code of Massachusetts Regulations. Division of Insurance. Managed Care Consumer Protections and Accreditation of Carriers.

211 CMR 52.02. Code of Massachusetts Regulations. Division of Insurance. Managed Care Consumer Protections and Accreditation of Carriers. Definitions. Medical Necessity or Medically Necessary.

958 CMR 3.020. Code of Massachusetts Regulations. Health Insurance Consumer Protection. Definitions. Clinical Review Criteria.

958 CMR 3.020. Code of Massachusetts Regulations. Health Insurance Consumer Protection. Definitions. Utilization Review.

958 CMR 3.020. Code of Massachusetts Regulations. Health Insurance Consumer Protection. Definitions. Medical Necessity or Medically Necessary.

958 CMR 3.020. Code of Massachusetts Regulations. Health Insurance Consumer Protection. Definitions. Utilization Review.

958 CMR 3.101. Code of Massachusetts Regulations. Health Insurance Consumer Protection. Definitions. Carrier's Medical Necessity Guidelines.

958 CMR 3.400. Code of Massachusetts Regulations. Health Insurance Consumer Protection. External Review

Commonwealth of Massachusetts. Chapter 207 of the Acts of 2010 - An Act Relative to Insurance Coverage for Autism.

Commonwealth of Massachusetts. General Laws.

Commonwealth of Massachusetts. Mandatory Benefits Guide. Consumer Affairs and Business Regulation.

Commonwealth of Massachusetts. Massachusetts General Laws Mandating that Certain Health Benefits Be Provided By Commercial Insurers, Blue Cross and Blue Shield and Health Maintenance Organizations. Regulatory Citations. 2017 Oct 24.

He-W 500. New Hampshire Code of Administrative Rules. Medical Assistance.

He-W 530.01(e). New Hampshire Code of Administrative Rules. Medical Assistance. Service Limits, Co-Payments, and Non-Covered Services. Definitions. Medically Necessary.

He-W 530.05(b)(4). New Hampshire Code of Administrative Rules. Medical Assistance. Non-Covered Services. Experimental or Investigational Procedures.

He-W 531. New Hampshire Code of Administrative Rules. Medical Assistance. Physician Services.

He-W 531.01(a). New Hampshire Code of Administrative Rules. Medical Assistance. Physician Services. Cosmetic Purpose.

He-W 543. New Hampshire Code of Administrative Rules. Medical Assistance. Hospital Services.

He-W 546. New Hampshire Code of Administrative Rules. Medical Assistance. Early and Periodic Screening, Diagnosis and Treatment Service.

MGL c 1760. Massachusetts General Laws. Health Insurance Consumer Protections.

The Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA). The Center for Consumer Information & Insurance Oversight. Centers for Medicare and Medicaid Services (CMS).

New Hampshire Department of Health and Human Services (DHHS). Certified Administrative Rules. New Hampshire Title XXXVII Insurance. Chapter 417-D Women's Health Care. Section 417-D:2-b Reconstructive Surgery.

Newborns' and Mothers Health Protection Act of 1996 (NMHPA). The Center for Consumer Information & Insurance Oversight. Centers for Medicare and Medicaid Services (CMS).

RSA Chapter 420-E. New Hampshire Revised Statutes. Insurance. Licensure of Medical Utilization Review Entitles.

Social Security Act. TITLE XXI—State Children's Health Insurance Program.

Social Security Act. Title XIX. 1902(a)(43), 1905(a)(4)(B), 1905(r). Grants to States for Medical Assistance Programs. Early and Periodic Screening, Diagnosis, and Treatment (EPSDT).

Social Security Act. Title XXI. State Children's Health Insurance Program.

U.S. Women's Health and Cancer Right Act of 1998.

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.

[+] *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 WellSense Health Plan.