BOSTON MEDICAL CENTER HEALTHNet PLAN

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WELL SENSE HEALTH PLAN

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Administrative Policy

Clinical Review Criteria

Policy Number: OCA 3.201
Version Number: 25
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Product Applicability	☒ **All Plan+ Products**
Well Sense Health Plan ☒ Well Sense Health Plan	**Boston Medical Center HealthNet Plan** ☒ MassHealth ACO ☒ MassHealth MCO ☒ Qualified Health Plans/ConnectorCare/Employer Choice Direct ☒ Senior Care Options ◊

Notes:
+ Disclaimer and audit information is located at the end of this document.
◊ The guidelines included in this Plan policy are applicable to members enrolled in Senior Care Options only if there are no criteria established for the specified service in a Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) on the date of the prior authorization request. Review the member's product-specific benefit documents at www.SeniorsGetMore.org to determine coverage guidelines for Senior Care Options.

Policy Summary

The purpose of this policy is to ensure that when making utilization review decisions the Plan uses written clinical review criteria which are based on sound and current clinical evidence, and conducts all utilization review activities in accordance with applicable policies and procedures and the Plan's Utilization Management (UM) Program. Plan-adopted written clinical review criteria are used to determine the medical necessity of services that require utilization review, including medical services, surgical treatment, pharmacotherapy and pharmacy services, behavioral health services, radiological services, dental services, and durable medical equipment, prosthetics, orthotics and supplies (DMEPOS). In addition, clinical review criteria are used to determine the most clinically appropriate

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level of care and intensity of services to ensure the provision of medically necessary services. Plan-adopted written clinical review criteria include the Plan's internally developed medical necessity 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 this policy. All Plan-adopted written clinical review criteria are reviewed at least annually and are developed in accordance with applicable state and federal requirements and guidelines from accrediting organization, including National Committee for Quality Assurance (NCQA). The Plan's clinical coverage criteria and UM decision tools are applied equitably across the Plan's membership. However, the Plan's Office of Clinical Affairs (OCA) UM staff (or the delegated clinical vendor's professional staff when the management of services is delegated to the vendor) will take into account the member's individual needs, circumstances, and healthcare services requested and/or currently provided to the member to integrate healthcare for continuity, coordination, and collaboration of services, as well as assessing the local healthcare delivery system's ability to meet the member's healthcare needs, when determining the medical necessity of services (as specified in the Policy Summary section of this policy). 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 authorizations, as well as authorizations by each of the Plan's delegated clinical vendors conducting utilization management, are based on a comprehensive and individualized needs assessment that addresses all member needs, including but not limited to social determinants of health and a subsequent person-centered planning process. Plan prior authorization requirements (and those of each of the Plan's delegated clinical vendors) comply with parity in mental health and substance use disorders. The Plan and the Plan's delegated clinical vendors conducting utilization management do NOT arbitrarily deny or reduce the amount, duration, and/or scope of required services solely because of the member's diagnosis, type of illness, and/or condition.

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/or clinical guidelines established by delegated management partners (for related services provided Plan members for applicable Plan products).

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. The Boston Medical Center HealthNet Plan Provider Manual (including MassHealth, Qualified Health Plan, and Senior Care Options products) and the product-specific Member Handbooks are available at www.bmchp.org. The Senior Care Options Appeals and Grievances page is maintained at www.SeniorsGetMore.org. The Well Sense Health Plan Provider

Manual and product-specific Well Sense Health Plan Member Handbooks are posted at www.wellsense.org.

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 look-up tools, medical policies, reimbursement policies, and the member's applicable benefit documents are available at www.bmchp.org for BMC HealthNet Plan members (with benefit documents for Senior Care Options members available at www.SeniorsGetMore.org) and posted at www.wellsense.org for Well Sense Health Plan members.

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 *Clinical Technology Evaluation* administrative policy, policy number OCA 3.13, outlines the Plan's process for evaluating new technology and new clinical application(s) of existing technology. Review the Plan's applicable reimbursement policy for payment guidelines related to clinical trials: *Clinical Trials* reimbursement policy, policy number 4.134, for services provided to BMC HealthNet Plan members; *Clinical Trials* reimbursement policy, policy number SCO 4.134, for services provided to Senior Care Options members; and *Clinical Trials* reimbursement policy, policy number WS 4.12, for services rendered to Well Sense Health Plan members.

Policy Statement

When the Plan conducts utilization review (UR), appropriate professional utilization management (UM) Plan staff consistently apply current, Plan-adopted written clinical review criteria, including the Plan's internally developed criteria specified in Plan medical policies and Plan 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 stated in the Delegated Management section of this policy. 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, including but not limited to contractual obligations and the guidelines specified in the Delegated Management section of this policy. 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 and pharmacy policies.

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The development and review of the Plan's internal clinical criteria include input from participating practitioners and consultant specialists in the related specialties that may include but are not limited to licensed pharmacists, community-based providers, behavioral health clinicians, and physician specialists in neonatology, pediatrics, family medicine, internal medicine, geriatrics, medical subspecialties, and/or surgical subspecialties. Practitioners with professional expertise and relevant credentials in the clinical area being reviewed have the opportunity to advise or comment on the development, adoption, and implementation of all UM criteria utilized by the Plan; this includes feedback from qualified practitioners on staff at the Plan or delegated clinical vendors, outside physician consultants, provider reviewers, participating providers in the Plan's network, and practitioners treating Plan members. 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 implemented by the Plan's delegated management partners for related services provided Plan members by Plan product type) 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 coverage criteria and UM decision tools are applied equitably across the Plan's membership. All Plan-adopted written clinical review criteria (including criteria specified in the Plan's internal medical policies and pharmacy policies, InterQual® criteria utilized by the Plan, and clinical guidelines developed and implemented by the Plan's delegated management partners for related services provided Plan members by Plan product type) are **clinically reviewed at least annually** to verify that these clinical guidelines are developed and implemented in accordance with generally accepted standards of medical/clinical practice which are based on objective and credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, relying on controlled clinical trials. On at least an annual basis, Plan staff confirm that all clinical review criteria utilized by the Plan (including all of the Plan's internal medical policies and pharmacy policies, InterQual® criteria utilized by the Plan, and clinical guidelines implemented by the Plan's delegated management partners for related services provided Plan members by Plan product type) have had an annual clinical review and the procedures for applying those clinical review criteria are documented.

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, dental services, and/or pharmacotherapy. The Plan's Office of Clinical Affairs (OCA) UM staff applies the clinical review criteria consistently. However, OCA UM staff also takes into account the member's individual needs and circumstances; the Plan's Medical Directors/Physician Reviewers and/or licensed Plan pharmacists consider member-specific factors (as specified in item 2a (1) of the Procedure section) when applying clinical criteria to a request for services. 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

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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. The Delegated Management section of this policy includes delegated management guidelines applicable for the Plan's partner clinical vendors, including Plan oversight and the development, review, and application of the clinical vendors' clinical review criteria.

Change Health staff analyze over 3,000 medical literature sources daily to review and update current InterQual® clinical review criteria and to develop criteria for new technologies and new application(s) of existing technologies. InterQual® criteria are developed and implemented in accordance with generally accepted standards of medical/clinical practice which are based on objective and credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, relying on controlled clinical trials. In addition, InterQual® criteria are evaluated by an independent clinical review panel drawn from more than 900 experts for authoritative peer review, utilizing providers with expertise and appropriate credentials in the applicable clinical area under consideration. Inter rater testing is conducted annually by the Plan using the Plan-adopted InterQual® criteria sets. InterQual® criteria are revised, as necessary, throughout the year (at least annually but may occur quarterly).

The Plan makes all of its clinical review criteria available to practitioners and members upon request. Providers and member may call or fax the Plan with a request for a copy of the specific criteria, as stated in writing in the Plan's provider manual(s) and Plan's website(s) at www.bmchp.org and/or www.wellsense.org. This access to clinical review criteria includes applicable copyrighted commercial criteria such as those used by the Plan's partner delegated clinical vendors and Plan-adopted InterQual® criteria. The Plan's internal clinical review criteria (included in the Plan's medical policies and internal pharmacy policies) are posted on the Plan's applicable website(s), www.bmchp.org and/or www.wellsense.org. New and amended internal clinical review criteria included in the Plan's medical policies and internal pharmacy policies are updated and available to providers, members, and the general public on the Plan's applicable website(s) before the implementation of internal policy revisions. Internal medical policies with substantive revisions to clinical review criteria and/or applicable coding (excluding industry-wide code updates and administrative changes) are posted on the appropriate website(s) at least 60 calendar days before the effective date of the substantive policy revisions and are accessible to all providers, members, and the general public for 60 calendar days before the implementation date and while the medical necessity criteria are in effect. In addition, participating providers receive network notifications (via postcard, letter, email, and/or provider newsletter) at least 60 calendar days before the effective date of substantive revisions to clinical review criteria and/or applicable coding included in internal policies and/or when new versions of InterQual® criteria are adopted by the Plan.

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Delegated Management

The Plan's delegated clinical vendors conduct utilization management for behavioral health services, radiology services, pharmacy benefits administration, dental services, and durable medical equipment, prosthetics, orthotics and supplies on behalf of Plan members (when applicable for the Plan product). Practitioners with clinical expertise in the area being reviewed have the opportunity to advise or comment on the development, adoption, and implementation of utilization management criteria established by the Plan's delegated management partners; this includes feedback from qualified practitioners on staff at the Plan or delegated clinical vendors, outside physician consultants, provider reviewers, participating providers in the Plan's network, and practitioners treating Plan members.

All Plan-adopted written clinical review criteria, including clinical guidelines established by delegated management partners, are reviewed at least annually (or more frequently when policy revisions require more immediate implementation). Clinical review criteria utilized by the Plan's delegated clinical vendors are develop with oversight by the clinical vendor's Medical Director who is an actively practicing physician and who is responsible for the oversight of the clinical vendor's utilization management program. Proposed new and revised clinical guidelines are evaluated by the clinical vendor's expert panel, all of whom are practicing clinicians and acknowledged experts in the relevant fields and pertinent specialties. All clinical review criteria are developed in accordance with applicable state and federal requirements and guidelines from applicable national accreditation organizations.

The clinical review criteria and UM decision tools from each of the Plan's delegated clinical vendors are applied equitably across the Plan's membership. However, the delegated clinical vendor's professional staff (when the management of services is delegated to the clinical vendor) will take into account the member's individual needs, circumstances, and healthcare services requested and/or currently provided to the member to integrate healthcare for continuity, coordination, and collaboration of services, as well as assessing the local healthcare delivery system's ability to meet the member's healthcare needs, when determining the medical necessity of services. Inter rater reliability testing is utilized by the Plan's delegated clinical vendors to assess the consistency and adherence to clinical review criteria. At least quarterly, the consistency with which the healthcare professionals involved in prior authorization apply criteria in decision making is evaluated by the delegated clinical vendors using a variety of mechanisms. The application of medical necessity criteria by Medical Directors and non-physician reviewers are assessed to ensure consistency and accuracy in the application of the clinical review criteria. Results are reported to the Plan.

Below are delegated management guidelines applicable for the Plan's partner clinical vendors, including Plan oversight and the development, review, and application of the clinical vendors' clinical review criteria, as specified below in items 1 through 3:

1. **Plan's Delegated Services and Partner Clinical Vendors**:

   When applicable for the Plan product, the following services are managed by a delegated clinical vendor for a Plan member, as stated in items a through f:

a. Behavioral Health Services (Beacon Health Strategies, LLC):

   Effective March 1, 2010, the Plan delegated management of behavioral health services to an NCQA-accredited managed behavioral health organization (MBHO), Beacon Health Strategies, LLC. The MBHO has its own clinical criteria policy which has been approved as part of delegation oversight.

b. Dental Services (DentaQuest for Senior Care Options Members):

   Effective June 18, 2015, the Plan delegated dental services to Dental Service of Massachusetts, Inc. (DSM) for DentaQuest to administer the Senior Care Options (SCO) dental benefit. This clinical vendor establishes policies for communicating criteria to providers and the vendor has its own clinical criteria policy and procedure which has been approved as part of delegation oversight.

c. Dental Services (Delta Dental for Qualified Health Plan Pediatric Members):

   Effective November 23, 2016, the Plan delegated dental services to Dental Service of Massachusetts, Inc. (DSM) for Delta Dental to administer the Qualified Health Plans (QHP) pediatric dental benefit. This clinical vendor establishes policies for communicating criteria to providers and DSM has its own clinical criteria policy and procedures which have been approved as part of delegation oversight.

d. Durable Medical Equipment, Prosthetics, Orthotics and Supplies (Northwood, Inc.):

   Effective April 1, 2011, the Plan delegated management of durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) to a URAC-accredited DMEPOS clinical vendor, Northwood, Inc. The Plan has retained the management of medical necessity denial decisions and notifications. This clinical vendor has its own clinical criteria policy and procedure which has been approved as part of delegation oversight.

e. Pharmacy Benefits Manager (Express Scripts):

   Effective January 1, 2021, Express Scripts is the Plan's pharmacy benefits manager for the BMC HealthNet Plan and Well Sense Health Plan products. Express Scripts adopts the guidelines included in this Plan's *Clinical Review Criteria* administrative policy and adheres to the Plan's administrative UM policies. Policies delegated to Express Scripts have been approved as part of delegation oversight. Effective December 1, 2019, the Plan's pharmacy mail order company for all BMC HealthNet Plan products and Well Sense Health Plan products is Cornerstone Health Solutions.

f. Radiology Services (eviCore healthcare):

Effective March 15, 2010, the Plan delegated the management of radiology services to an NCQA-accredited managed care clinical vendor, eviCore healthcare (formerly known as MedSolutions, Inc.). eviCore develops and utilizes criteria to make utilization management decisions for requested radiology services, establishes policies for communicating those criteria to providers and members, and evaluates consistency in the application of those criteria through inter rater reliability testing when determining medical necessity for radiology services.

2. **Clinical Vendor Clinical Review:**

a. Review and Application of Clinical Vendor's Established Clinical Review Criteria:

The Plan's Clinical Vendor Oversight Committee conducts an annual review of each clinical vendor that conducts delegated management for Plan members to ensure that all of the following guidelines are met: each clinical vendor conducts an annual review of its clinical 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 criteria are consistently applied to Plan members for a requested service. 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. The clinical vendor will also consider member-specific factors impacting the member's individual healthcare needs when applying clinical review criteria to determine if the service is medically necessary for the requested indication. 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

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(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. Clinical Vendor Review of Requested Service Without Written Clinical Review Criteria:

If written clinical review criteria have not been established for the requested service (for the specified indication) by the Plan's delegated management clinical vendors, these clinical vendors will use published and applicable generally accepted, scientifically-based standards of care and objective and credible scientific evidence published in peer-reviewed medical/clinical literature, and/or reviewing observational studies for a request for services for a Plan member to make medical necessity determination. If scientifically-based standards of care are not available, observational studies from more than one (1) institution

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that suggest a causal relationship between the service or treatment and health outcomes may be used by the delegated utilization management clinical vendor to make medical necessity determinations if these observational studies are clinically appropriate with respect to the member's clinical presentation. The Plan's delegated management clinical vendors will also consider 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

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(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.

c. Clinical Vendor Evaluation of New Technology:

The clinical vendor evaluates new technology and new application(s) of an established technology to develop new clinical review criteria (or revise established clinical review criteria) when clinically appropriate. The Plan's partner clinical vendor will use published and applicable generally accepted, scientifically-based standards of care and objective and credible scientific evidence published in peer-reviewed medical/clinical literature, and/or reviewing observational studies for the new technology or new application(s) of an existing technology to establish written clinical review criteria that will be used to make medical necessity determinations (in addition to individual consideration of the member's status and healthcare needs). When a requested service that does not have established, applicable clinical review criteria, the medical necessity of the service is determined on a case-by-case basis for individual consideration, as specified above in the Clinical Vendor Review of Requested Service Without Written Clinical Review Criteria section.

d. Out-of-Network Providers:

The clinical vendor will authorize a member's care from an out-of-network provider when, as determined by the clinical vendor, the care and necessary resources are needed by the member are not available or are not reasonably accessible to the member.

e. Input from Practicing Practitioners:

Actively practicing practitioners with appropriate credentials and clinical expertise in the applicable clinical area have the opportunity to submit comments on clinical review criteria utilized by clinical vendors who are delegated to conduct utilization management on behalf of Plan members (with feedback related to the development, ongoing management, and/or application of those criteria). Practitioners may submit feedback through the Plan's Provider Information Mailbox available at Provider.Info@BMCHP-wellsense.org.

If the practitioner would like to provide input on a clinical vendor's clinical review criteria and have those comments considered during the criteria's next annual review, supporting documentation must be provided that includes position statements developed or endorsed by nationally recognized professional associations, consensus reports or guidelines from specialty societies, and/or standards adopted by governmental agencies (e.g., National Institutes of Health, Agency for HealthCare Research and Quality, Center for Medicare & Medicaid Services, Massachusetts Executive Office of Health and Human Services, and/or New Hampshire Department of Health and Human Services). Published scientific evidence from additional reputable sources may also be submitted for consideration.

Issues related to clinical review criteria that must be addressed before each clinical vendor's annual review will be evaluated immediately during a prior authorization request for services; clinical vendors conducting delegated utilization will engage in individual case discussions with qualified clinicians applicable for the member's condition and requested treatment to determine if the clinical review criteria are appropriate for the member's circumstances or care provided by a local delivery system according to the guidelines specified below in the Application of the Plan's Clinical Review Criteria section of this policy.

f. Access to Clinical Review Criteria:

The Plan makes all of its clinical review criteria available to practitioners and members upon request. Providers and member may call or fax the Plan with a request for a copy of the specific criteria, as stated in writing in the Plan's provider manual(s) and Plan's website(s) at www.bmchp.org and/or www.wellsense.org. This access to clinical review criteria includes applicable copyrighted commercial criteria used by the Plan's partner delegated clinical vendors. Participating providers are notified at least 60 calendar days before the implement of substantive revisions to applicable coding (excluding industry-wide code updates) and/or clinical review criteria (i.e., implementation of new medical necessity guidelines and/or revised clinical review criteria) used by the Plan's partner delegated clinical vendors. Clinical review criteria are available to all providers, members, and the general public on the applicable extranet site.

3. **Plan Oversight:**

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, including but not limited to contractual obligations and the guidelines specified in this section of this policy related to the development, review, and application of objective,

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scientifically-derived, and evidence-based clinical review criteria, with individual consideration of the member's status (when 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. For services managed by clinical vendors with whom the Plan has delegated utilization management, the Plan evaluates member access to treating facilities and availability of qualified providers (including care from an out-of-network provider when clinically appropriate), member satisfaction, provider satisfaction, member and provider timely access to applicable clinical review criteria, and the vendor's process for evaluating recommended revisions to clinical review criteria submitted by actively practicing practitioners with appropriate credentials and clinical expertise.

Procedure

The Plan-adopted clinical review criteria are developed and implemented in accordance with generally accepted standards of medical/clinical practice which are based on objective and credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, relying on controlled clinical trials. Practitioners with clinical expertise in the area being reviewed have the opportunity to advise or comment on the development, adoption, and implementation of all UM criteria utilized by the Plan; this includes feedback from qualified practitioners on staff at the Plan or delegated clinical vendors, outside physician consultants, provider reviewers, participating providers in the Plan's network, and practitioners treating Plan members.

See the Policy Summary and the Delegated Management sections of this policy for guidelines related to applicable clinical review criteria and services managed by partner clinical vendors with whom the Plan has delegated utilization management (by Plan product), including behavioral health services, radiology services, pharmacy benefits administration, and durable medical equipment, prosthetics, orthotics and supplies. Review the *Clinical Technology Evaluation* administrative policy, policy number OCA 3.13, for a description of the Plan's process for evaluating new technology and the new application of existing technology.

1. **Development and Review of the Plan's Internal Clinical Review Criteria**:

   The Plan's internal clinical review criteria are specified in the Plan's medical policies or pharmacy policies. Internal clinical review criteria are developed, reviewed **at least annually**, and updated as necessary, utilizing the following resources (as applicable) to evaluate the clinical services, treatments, and technologies for the specified indications and the application of medical necessity criteria, as stated below in items a through l:

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

   b. With input from actively practicing specialists and/or professionals or serving as consultants who have expertise and appropriate credentials in the applicable clinical area under consideration, as appropriate; e.g., criteria review by board-certified physician experts in the

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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, dentists, and/or board-certified physicians actively practicing in specialties that include neonatology, pediatrics, family medicine, internal medicine, medical/surgical subspecialties, and/or geriatrics; AND

c. In accordance with the Plan's definition of medical necessity (as specified in the *Medically Necessary* medical policy, policy number OCA 3.14), the Plan's definition of experimental and investigational services (as stated in the *Experimental and Investigational Treatment* medical policy, policy number OCA 3.12), and the Plan's definition of cosmetic and reconstructive or restorative services (as documented in the *Cosmetic, Reconstructive, and Restorative Services* medical policy, policy number OCA 3.69); AND

d. 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

e. Review of position papers and guidelines established or endorsed by nationally recognized medical associations, specialty societies, dental organizations, and governmental agencies, including but not limited to practice guidelines adopted by the Plan; AND

f. Clinical study results published in peer-reviewed scientific literature evaluating the use of the clinical service as an alternative treatment strategy to established interventions considered the standard of care for the specified indication (considering the patient's medical condition, age, comorbidities, and other factors applicable to the health outcomes of the clinical technology and associated services) to determine if the service improves the net health outcome, is cost-effective compared to the standard of care, and if the clinical outcomes outweigh any harmful effects; AND

g. 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

h. When applicable, 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 U.S. Food and Drug Administration); AND

i. 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 (e.g., U.S. Preventive Services Task Force, AAP Bright Futures); AND

j. Published scientific evidence from additional reputable sources concerning the safety and effectiveness of the clinical treatment on health outcomes (i.e., proven benefit, unproven benefit, insufficient evidence to determine effect, or documented harm) such as industry-standard, evidence-based guidelines and recommendations (such as those established by InterQual®, National Institute for Health and Care Excellences, National Comprehensive Cancer Network); AND

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

l. With input from actively practicing practitioners with appropriate credentials and clinical expertise in the applicable clinical area who have the opportunity to submit comments on clinical review criteria utilized for Plan members (with feedback related to the development, ongoing management, and/or application of those criteria). Practitioners may submit feedback through the Plan's Provider Information Mailbox available at Provider.Info@BMCHP-wellsense.org. The Plan will accept provider comments at any time and adequately research the feedback submitted by the practicing practitioners. 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.

   If the practitioner would like to provide input on clinical review criteria that will be considered during the internal policy's next annual review, it is recommended that comments and supporting references be submitted to the Plan a few months before the applicable policy's scheduled annual review date (as specified in the Next Review Date section at the end of each internal policy). Supporting documentation must include position statements developed or endorsed by nationally recognized professional associations, consensus reports or guidelines from specialty societies, and/or standards adopted by governmental agencies (e.g., National Institutes of Health, Agency for HealthCare Research and Quality, Center for Medicare & Medicaid Services, Massachusetts Executive Office of Health and Human Services, and/or New Hampshire Department of Health and Human Services). Published scientific evidence from additional reputable sources may also be submitted for consideration.

   Issues related to clinical review criteria that must be addressed before the policy's annual review date will be evaluated immediately during a prior authorization request for services; OCA UM staff will engage in individual case discussions with licensed Plan pharmacists, OCA UM clinicians, and/or Plan Medical Directors/Physician Reviewers (utilizing qualified Plan clinicians applicable for the member's condition and requested treatment) to determine if the clinical review criteria are appropriate for the member's circumstances or care provided by a local

delivery system according to the guidelines specified below in the Application of the Plan's Clinical Review Criteria section of this policy.

2. **Application of Plan's Internal Clinical Review Criteria and Plan-Adopted InterQual® Criteria**:

Review the Policy Summary and the Delegated Management sections (rather than this section of the policy) for guidelines related to clinical review criteria and services managed by partner clinical vendors with whom the Plan has delegated utilization management (by Plan product). Application of the Plan's clinical review criteria (including internal clinical review criteria and InterQual® criteria used by the Plan) follows the procedure specified below in items a through g:

a. The Plan's Office of Clinical Affairs (OCA) includes OCA UM staff, Plan licensed pharmacists, and Plan Medical Directors/Physician Reviewers who apply applicable Plan clinical review criteria consistently when determining the medical necessity of healthcare services. The Plan's OCA 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 according to BOTH of the guidelines specified below in items (1) and (2):

(1) While the Plan's OCA UM staff applies the clinical review criteria consistently, 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 (a) through (p):

(a) Member's condition; AND

(b) 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

(c) 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

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(d) Relevant past medical/surgical/behavioral health/dental/pharmacotherapy history; AND

(e) Complications experienced by the member; AND

(f) Progression of the member's condition, illness, or injury; AND

(g) Diagnostic test results, when applicable; AND

(h) Progress with treatment; AND

(i) Available treatment options for the member's condition; AND

(j) Psychosocial circumstances; AND

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

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

(m) Local healthcare delivery system's ability to meet the healthcare needs of the member's specific condition; AND

(n) 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

(o) Other factors related to the member's plan of care and/or health outcomes; AND

(p) If applicable, verification that the requested device, system, biological product, or drug is being prescribed/requested and will be utilized according to its FDA-approved clearance and guideline information, including intended use for the member's age and medical condition; AND

(2) When clinical review criteria are NOT met for a specified service such that medical necessity cannot be established, OCA UM staff will engage in individual case discussions with licensed Plan pharmacists, OCA UM clinicians, and/or Plan Medical Directors/Physician Reviewers (utilizing qualified Plan clinicians applicable for the member's condition and requested treatment) to determine if the clinical review criteria are appropriate for the member's circumstances or care provided by a local delivery system. 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; AND

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b. OCA UM staff considers the following characteristics of the healthcare delivery system to assess the local healthcare delivery system's ability to meet the member's healthcare needs when applying clinical review criteria to each request, as specified below in items (1) through (4):

(1) Availability and member access to acute and subacute care facilities, including but not limited to acute care inpatient hospitals, surgi-centers, rehabilitation facilities, transitional care facilities, skilled nursing facilities (SNF), and/or home health agencies, as applicable for the member's clinical needs; AND

(2) Member's reasonable accessibility to a qualified provider with appropriate credentials and clinical expertise in the applicable clinical area necessary to adequately treat the member's condition; □ AND

□ Note: The Plan will authorize a member's care from an out-of-network provider when, as determined by the Plan, the care needed by the member is not available or is not reasonably accessible to the member.

(3) Covered benefits for acute and subacute care facilities, including but not limited to acute care inpatient hospitals, surgi-centers, rehabilitation facilities, transitional care facilities, SNF, and/or home health agencies, as applicable for the member's clinical needs; AND

(4) The ability of acute and subacute care facilities, including but not limited to acute care inpatient hospitals, surgi-centers, rehabilitation facilities, transitional care facilities, SNF, and/or home health agencies, to provide the following services, as specified below in BOTH items (a) and (b):

(a) Provide the recommended medically necessary services to the member within the estimated amount, frequency, and duration of treatment (including the estimated length of stay, when applicable); medically necessary services required by the member and provided by the facility/treating provider may include routine medical/surgical services, highly specialized healthcare services (such as transplant services or cancer care), rehabilitative care, habilitative services, and/or support services after hospital discharge; AND

(b) Provide the medically necessary clinical support to the Plan member after the member's hospital discharge and/or transition to a less intense clinical setting or to home, as applicable for the member's treatment plan; AND

c. When an OCA UM staff member is unable to authorize care by establishing medical necessity, the OCA UM staff will forward the request and documentation to the appropriate Medical Director/Physician Reviewer or licensed Plan pharmacist for a determination (utilizing qualified Plan clinicians applicable for the member's condition and requested treatment); AND

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d. When medical necessity cannot be established through existing clinical review criteria, the Plan's Medical Directors/Physician Reviewers and/or licensed Plan pharmacists consider alternate methods of determining medical necessity, as defined in the *Medically Necessary* medical policy, policy number OCA 3.14. If Plan-adopted written clinical review criteria have not been established for the requested service for the specified indication, the Plan's Medical Directors/Physician Reviewers and/or licensed Plan pharmacists will use published and applicable generally accepted, scientifically-based standards of care to determine medical necessity. If scientifically-based standards of care are not available, observational studies from more than one (1) institution that suggest a causal relationship between the service or treatment and health outcomes may be used by the Plan's Medical Directors/Physician Reviewers and/or licensed Plan pharmacists to make medical necessity determinations if these observational studies are clinically appropriate with respect to the member's clinical presentation. The Plan's Medical Directors/Physician Reviewers and/or licensed Plan pharmacists also consider member-specific factors (as specified in item 2a (1) of this Procedure section) when applying clinical criteria, evaluating standards of care and credible scientific evidence published in peer-reviewed medical/clinical literature, and/or reviewing observational studies for a request for services for a Plan member to make medical necessity determinations; AND

e. The Medical Policy, Criteria, and Technology Assessment Committee (MPCTAC), Pharmacy and Therapeutics (P&T) Committee, Utilization Management Committee (UMC), and other applicable committees meet annually or more frequently as needed to review and/or and authorize all clinical review criteria used by the Plan along with the policies and procedures for application; AND

f. OCA UM staff training and annual inter rater reliability (IRR) testing are conducted to review the application of internal clinical review criteria (including criteria in the Plan's internal medical policies and internal pharmacy policies) and Plan-adopted InterQual® criteria to ensure the consistency of medical necessity determinations among the OCA UM staff, Plan pharmacists, and Plan Medical Directors/Physician Reviewers (according to the definitions of IRR, OCA Staff, and OCA UM Staff in the Definitions section of this policy); AND

g. The Plan makes all of its clinical review criteria available to practitioners and members upon request. Providers and member may call or fax the Plan with a request for a copy of the specific criteria, as stated in writing in the Plan's provider manual(s) and Plan's website(s) at www.bmchp.org and/or www.wellsense.org. This access to clinical review criteria includes applicable copyrighted commercial criteria such as those used by the Plan's partner delegated clinical vendors and Plan-adopted InterQual® criteria. The Plan's internal clinical review criteria (included in the Plan's medical policies and internal pharmacy policies) are posted on the Plan's applicable website(s), www.bmchp.org and/or www.wellsense.org. New and amended internal clinical review criteria included in the Plan's medical policies and internal pharmacy policies are updated and available to providers, members, and the general public on the Plan's applicable

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website(s) before the implementation of internal policy revisions. In addition, participating providers receive network notifications (via postcard, letter, and/or email) when there are substantive revisions to internal clinical review criteria and/or when new versions of InterQual® criteria are adopted by the Plan.

Responsibility and Accountability

See the Policy Summary and Delegated Management sections of this policy for guidelines related to clinical review criteria and services managed by clinical vendors with whom the Plan has delegated utilization management (by Plan product), including behavioral health services, radiology services, dental services, pharmacy benefits administration, and durable medical equipment, prosthetics, orthotics and supplies. Responsibility and accountability related to the development, implementation, and monitoring of the Plan's internal clinical review criteria (included in the Plan's medical policies and internal pharmacy policies) are specified below in items 1 through 4:

1. The Utilization Management Committee (UMC), chaired by the Director of UM Program Oversight and Member Appeals and Grievances**,** oversees and is accountable for the adoption, development, review, update, and implementation of the Plan's clinical review criteria. Generally, the Plan adopts nationally developed and accepted criteria (e.g., InterQual®). When national criteria are not available or not utilized by the Plan, Plan-specific criteria may be developed that are objective, scientifically derived, and evidence-based, with input from participating practitioners and consistent with applicable legal, regulatory, and national accreditation organization standards.

2. The Medical Policy, Criteria, and Technology Assessment Committee (MPCTAC) is responsible for developing and approving medical policies, and the Pharmacy and Therapeutics (P&T) Committee is responsible for developing and approving pharmaceutical coverage policies.

3. The Directors of OCA (including but not limited to the Directors of Utilization Management and the Director of Pharmacy), Chief Clinical Officer, Plan Medical Directors/Physician Reviewers, Plan pharmacists, and other OCA UM staff use the Plan's clinical review criteria in accordance with applicable Plan policies and procedures.

4. The Directors of OCA, including but not limited to the Directors of Utilization Management and the Director of Pharmacy, or their designee(s) are responsible for ensuring OCA UM staff training, evaluating, and monitoring. 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.

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Definitions:

Clinical Review Criteria (for BMC HealthNet Plan Products): Criteria used to determine the most clinically appropriate and necessary level of care and intensity of services to ensure the provision of medically necessary services. Review the Plan's *Medically Necessary* medical policy, policy number OCA 3.14, for the product-specific definition of medically necessary treatment. For the MassHealth ACO product, medical necessity guidelines established by the Plan will be no more restrictive than the applicable contractual MassHealth ACO and MCO definition of Medically Necessary or Medical Necessity, as specified in the Plan's *Medically Necessary* medical policy, policy number OCA 3.14. Additionally, if there is a change in the Plan's medical necessity review process, the Plan will notify the Executive Office of Health and Human Services (EOHHS) no less than 60 calendar days prior to any change (or another timeframe as specified by EOHHS).

Clinical Review Criteria (for Well Sense Health Plan Products): A set of medical decision standards employed in the utilization review process in order to ensure members receive appropriate care, at an appropriate time, in an appropriate setting by an appropriate provider and at an appropriate level of care. Criteria are consistent with an efficient and effective utilization of resources available to recipients.

Inter Rater Reliability (IRR): A performance measurement tool used to compare and evaluate the level of consistency in healthcare determinations between two (2) or more medical and behavioral health utilization management (UM) clinicians. The tool is used to minimize variation in the application of clinical review criteria and identify potentially avoidable utilization target areas that need improvement and evaluate the ability to identify quality of care issues.

Office of Clinical Affairs (OCA) Staff: Plan staff members within the 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 healthcare 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 (OCA) Utilization Management (UM) Staff: The Plan's OCA 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, appropriately qualified UM staff reviews medical, surgical, behavioral health, and/or dental requests for service or directs requests to a partner clinical vendor for delegated utilization management.

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Plan-Adopted Clinical Review Criteria: Written clinical review criteria used to determine medical necessity, including internally developed criteria specified in Plan medical policies and Plan 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).

Practitioner (for the Qualified Health Plans, ConnectorCare, and Employer Choice Direct): A professional who provides healthcare services. Practitioners are usually required to be licensed as defined by law.

Utilization Review (UR): A set of formal techniques designed to monitor the use of, or evaluate the clinical necessity, appropriateness, efficacy, or efficiency of, healthcare services, procedures, or settings. Such techniques may include, but are not limited to, ambulatory review, prospective review, second opinion, certification, concurrent review, case management, discharge planning, and/or retrospective review.

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Policy History

Original Approval Date	Original Effective Date* and Version Number	Policy Owner	Original Policy Approved by
Regulatory Approval: 08/01/08 MH Review: 02/19/10 Internal Approval: 07/24/07 and 08/13/07	08/13/07 Version 1	Medical Policy Manager as Chair of Medical Policy, Criteria, and Technology Assessment Committee (MPCTAC)	Utilization Management Committee (UMC)

*Effective Date for the BMC HealthNet Plan Commercial Product(s): 01/01/12
*Effective Date for the Well Sense Health Plan New Hampshire Medicaid Product(s): 01/01/13
*Effective Date for the Senior Care Options Product(s): 01/01/16

Note: Policy title was *Clinical Criteria* until 07/31/17. Policy title changed to *Clinical Review Criteria* as of 08/01/17.

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Policy Revisions History			
Review Date	**Summary of Revisions**	**Revision Effective Date and Version Number**	**Approved by**
04/22/08	Typos and formatting corrected. Removed bullet stating Chief Medical Officer conducts review on all criteria annually.	Version 2	04/22/08: UMC
05/07/08	Added authority for plan pharmacists to render pharmacy denials.	Version 3	05/20/08: UMC 06/19/08: Quality Improvement Committee (QIC)
08/20/09	Changed titles within Health Services, minor typos and formatting, updated references, changed definition for clinical criteria.	Version 4	09/22/09: UMC 09/23/09: QIC
07/21/10	Updated names, departments and references, extra definition for medically necessary was removed.	Version 5	07/21/10: MPCTAC 08/25/10: QIC
07/01/11	Added medically necessary definition and language for Commercial product.	Version 6	07/22/11: MPCTAC 08/24/11: QIC
07/01/12	References updated, moved Purpose section of policy to the beginning of the document and added reference for the Plan's Prior Authorization/ Notification Requirements matrix. Referenced the Plan's Medically Necessary policy for a definition of medically necessary for each member type and deleted medically necessary definitions from this policy. Added language regarding delegated management in Policy Statement section. Added reference to Physician Reviewers in policy. Changed definition title from "Clinical Criteria" to "Clinical Review Criteria."	Version 7	07/18/12: MPCTAC 08/15/12: MPCTAC
08/15/12	Off cycle review for Well Sense Health Plan, revised Purpose, Definitions, Policy Statement, reformatted Procedure, updated references for all Plan products.	Version 8	08/17/12: MPCTAC 09/13/12: QIC
9/01/12	Added language to clarify the Plan's UR process that includes the evaluation of member's circumstances and local	Version 9	09/19/12: MPCTAC 09/26/12: QIC

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Policy Revisions History			
	delivery system, when clinically appropriate.		
06/01/13	Review for effective date 07/18/13. Revised title of chair for the Utilization Management Committee.	07/18/13 Version 10	06/19/13: MPCTAC 07/18/13: QIC
06/01/14	Review for effective date 10/01/14. Updated Purpose, Policy Statement, Delegated Management, Procedure, Responsibility and Accountability, Definitions, and References sections.	10/01/14 Version 11	06/09/14: MPCTAC 07/09/14: QIC
06/01/15	Review for effective date 07/08/15. 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 Purpose, Policy Statement, Delegated Management, and Procedure sections.	07/08/15 Version 12	06/17/15: MPCTAC 07/08/15: QIC
09/01/15	Review for effective date 10/14/15. Added reference to eviCore healthcare in the Delegated Management section. Updated list of applicable products, including the removal of Common-wealth Care, Commonwealth Choice, and Employer Choice because the products are no longer available.	10/14/15 Version 13	09/16/15: MPCTAC 10/14/15: QIC
06/01/16	Review for effective date 07/13/16. Updated with administrative changes to the Delegated Management, References, and References to Applicable Laws and Regulations sections.	07/13/16 Version 14	06/15/16: MPCTAC 07/13/16: QIC
05/01/17	Review for effective date 06/01/17. Administrative changes made to the policy title and the Purpose, Policy Statement, Responsibility and Accountability, Definitions, References, and Reference to Applicable Laws and Regulations sections to clarify the Plan's clinical criteria review process and the use of these clinical criteria in utilization review activities.	06/01/17 Version 15	05/17/17: MPCTAC
08/31/17	Updated the definition of Clinical	08/31/17	08/31/17: MPCTAC

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Policy Revisions History			
	Review Criteria (for BMC HealthNet Plan Products) to include requirements for the medical necessity guidelines applicable for the Accountable Care Organization (ACO). Updated Product Applicability and Reference sections to incorporate ACO.	Version 16	(electronic vote)
06/01/18	Review for effective date 07/01/18. Administrative changes made to the Policy Statement, Procedure, Responsibility and Accountability, References, Other Applicable Policies, and Reference to Applicable Laws and Regulations sections.	07/01/18 Version 17	06/20/18: MPCTAC
09/01/18	Review for effective date 12/01/18. Administrative changes made to the Purpose and Policy Summary sections. Updated criteria in the Procedure section (clarifying the existing process).	12/01/18 Version 18	09/19/18: MPCTAC
11/01/18	Review for effective date 12/01/18. Administrative changes made to the Policy Statement, Delegated Management, and Procedure sections to clarify the existing process available for practitioners to submit comments related to clinical review criteria.	12/01/18 Version 19	11/21/18: MPCTAC
06/01/19	Review for effective date 07/01/19. Administrative changes made to the Policy Summary (formerly Purpose section), Policy Statement, Delegated Management, Procedure, Definitions, Responsibility and Accountability, 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 changes made to the Delegated Management and Procedure sections.	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	07/01/20 Version 22	06/17/20: MPCTAC

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Policy Revisions History			
	sections.		
12/01/20	Review for effective date 01/01/21. Administrative changes made to the Delegated Management, 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, in the Delegated Management 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, Policy Statement, Delegated Management, and Procedure sections to clarify existing guidelines. Updated References section.	07/01/21 Version 25	06/16/21: MPCTAC

Last Review Date

06/01/21

Next Review Date

06/01/22

Authorizing Entity

MPCTAC

Other Applicable Policies

Administrative Policy - *Clinical Technology Evaluation,* policy number OCA 3.13
Administrative Policy - *Inter Rater Reliability*, policy number OCA 3.216
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 Treatment*, 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

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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 - *General Clinical Editing and Payment Accuracy Review Guidelines*, policy number SCO 4.108
Reimbursement Policy - *General Clinical Editing and Payment Accuracy Review Guidelines*, policy number WS 4.18
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 4.17
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 438.100. Code of Federal Regulations. Public Health, Centers for Medicare & Medicaid Services. Managed Care. Enrollee Rights and Protections. Enroll Rights.

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.

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

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.

114.3 CMR 17.00. Code of Massachusetts Regulations. Division of Health Care Finance and Policy. Medicine.

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.

130 CMR 450.204. Code of Massachusetts Regulations. Division of Medical Assistance. Administrative and Billing Regulations. Medically Necessary.

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

211 CMR 52.03. Code of Massachusetts Regulations. Definitions. Medical Necessity or Medically Necessary.

958 CMR 128.020. Code of Massachusetts Regulations. External Review.

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

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Commonwealth of Massachusetts. General Laws. Accessed at: https://malegislature.gov/Laws/GeneralLaws

Commonwealth of Massachusetts. Mandatory Benefits Guide. Consumer Affairs and Business Regulation. Accessed at: http://www.mass.gov/ocabr/docs/doi/consumer/healthlists/mndatben.pdf

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. Accessed at: https://www.mass.gov/files/documents/2017/10/27/mndatben.pdf

Commonwealth of Massachusetts. MassHealth Provider Regulations. Accessed at: https://www.mass.gov/service-details/masshealth-provider-regulations

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

He-W 530. New Hampshire Code of Administrative Rules. Medical Assistance. Service Limits, Co-Payments, and Non-Covered Services.

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 233. Massachusetts General Laws. An Act Relative to HIV-Associated Lipodystrophy Syndrome Treatment.

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).

Newborns' and Mothers Health Protection Act of 1996 (NMHPA). 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. Accessed at: https://www.dhhs.nh.gov/oos/bhfa/rules.htm

New Hampshire Title XXXVII Insurance. Chapter 417-D Women's Health Care. Section 417-D:2-b Reconstructive Surgery.

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.

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.

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