

Network Notifications

New Hampshire



Date: September 30, 2022 Number: 75

To: All WellSense Providers

From: WellSense Health Plan

Subject: **September Medical Policy Network Notifications**

Product: NH Medicaid NH Medicare Advantage

September Network Notifications

The following Well Sense Health Plan medical policies will be updated with revisions to clinical review criteria and/or applicable coding included in the medical policies (excluding industry-wide code updates and/or codes that do not require prior authorization). The revised medical policies will be effective on December 1, 2022:

1. **Clinical Review Criteria, OCA 3.201**
2. **Complementary and Alternative Medicine, OCA 3.194**
3. **Gender Affirmation Services, OCA 3.11**
4. **Occupational Therapy in the Outpatient Setting, OCA 3.543**
5. **Pelvic Floor Stimulation for the Treatment of Incontinence and/or Overactive Bladder, OCA 3.561**
6. **Physical Therapy in the Outpatient Setting, OCA 3.544**
7. **Sacral Nerve Stimulation, OCA 3.563**
8. **Speech Therapy, OCA 3.542**
9. **Temporomandibular Joint Disorders, OCA 3.968**

General Information

All Well Sense Health Plan medical policies are located on the Provider's page at <https://www.wellsense.org/providers/nh/policies> under the Policies link. If you do not have Web

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access, you may contact your provider relations representative for a copy of the policies. The updated policies listed above will be posted on the website and available from your provider relations representative on October 1, 2022.

Questions?

If you have any questions about this Network Notification, please contact your dedicated provider relations consultant or call the Provider Line at 877-957-1300, option 3 (for NH Medicaid) or 866-808-3833 (for Medicare Advantage). Well Sense Health Plan [Network Notifications](#) and [Reimbursement Policies](#) are available online at wellsense.org.

Clinical Review Criteria

Policy Number: OCA 3.201

Version Number: 30

Version Effective Date: 11/01/22

Impacted Products

- All Products**
- NH Medicaid
- NH Medicare Advantage
- MA MassHealth ACO
- MA MassHealth MCO
- MA Qualified Health Plans/Employer Choice Direct
- MA Senior Care Options

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

Policy Summary

This policy defines the Plan's process for making utilization review decisions using written clinical review criteria based on sound and current clinical evidence. The Plan 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 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 and pharmacy policies, InterQual[®] criteria, and clinical guidelines established by delegated management partners (for related services provided to Plan members for applicable Plan products). All Plan-adopted written clinical review criteria are reviewed at least annually and are developed in accordance with contractual requirements, state and federal regulations, and guidelines from accrediting organizations, including National Committee for Quality Assurance (NCQA). Review the Plan's *Prior Authorization/Notification Requirements Matrix*, *Code Look-up Tools*, medical and pharmacy policies, and the Plan's pharmacy formulary (available via the drug search tool or the formulary guidebook) to determine if prior authorization is required.

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. 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 Plan complies with coverage guidelines for all applicable state and federally-mandated benefits. 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 discriminate, arbitrarily deny, or impose stricter requirements by reducing the amount, duration, or scope of required and medically necessary services for ANY Plan member based on the member's diagnosis, type of illness, health status or condition, sex, gender identity or dysphoria, or sexual orientation.

See the member's product-specific handbook on the Plan's website for benefit coverage guidelines and a summary of member rights and responsibilities, as well as the Plan's process for receiving and promptly resolving inquires, grievances, 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 *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.

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 internal medical policies and Plan pharmacy policies, InterQual® criteria, and clinical guidelines established by delegated management partners (for related services provided Plan members for applicable Plan products). 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 and documented in internally developed medical and pharmacy policies.

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, medical/pediatric/surgical subspecialties, and geriatrics. 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, 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, 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, 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 and pharmacy policies, InterQual® criteria, 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 and/or licensed Plan pharmacists consider member-specific factors 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 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. 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 reliability 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).

Delegated Management

The Plan's delegated clinical vendors conduct utilization management for behavioral health services, radiology services, pharmacy services, 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 developed 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 Plan's 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 and clinical policy criteria, unless specifically delegated such as the Plan's Medicare product lines. 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 of the Plan's Massachusetts and New Hampshire products is Cornerstone Health Solutions.

- f. Radiology Services, Musculoskeletal Services, Genetic Testing, and Outpatient Rehabilitation Services (AIM Specialty Health):

For dates of service on or after November 1, 2022, the Plan has delegated the management of radiology services, musculoskeletal services (i.e., spine surgeries, joint surgeries, and interventional pain management treatments), and genetic testing to an NCQA-accredited managed care clinical vendor, AIM Specialty Health. AIM manages outpatient rehabilitation services (i.e., physical therapy, occupational therapy, and speech therapy after the initial evaluation) provided to Plan members for dates of services on or after December 1, 2022. AIM develops and utilizes criteria to make utilization management decisions for requested 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 these delegated 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, biologic, or drug that will be used to prevent, diagnose, stabilize, or treat a disease, condition, or disorder that results in health impairment or disability, 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 any member-specific factor impacting care, including one or more of the following:

- (1) Member's condition;
- (2) Member's comorbidities;
- (3) Member's age, including the assessment of the member's age-appropriate growth, development, and competencies, as well as evaluation of age-related and condition-specific healthcare needs and associated issues;
- (4) Relevant past medical/surgical/behavioral health/dental/pharmacotherapy history;
- (5) Complications;
- (6) Progression of the member's condition, illness, or injury;
- (7) Diagnostic test results;
- (8) Treatment outcomes;
- (9) Treatment options;
- (10) Psychosocial circumstances;
- (11) Home and environmental factors impacting member's clinical condition (e.g., homelessness, employment status, poverty, neighborhood);
- (12) Other healthcare services requested and/or provided to the member to integrate healthcare for continuity, coordination, and collaboration of services;

- (13) Local healthcare delivery system's ability to meet the healthcare needs of the member's specific condition;
- (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);
- (15) Other factors related to the member's plan of care or health outcomes; AND/OR
- (16) If applicable, verification that the requested device, therapeutic, biologic, or drug is being prescribed/requested and will be utilized according to its FDA-approved or compendia indication 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 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, biologic, 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 any member-specific factors impacting care, including one or more of the following:

- (1) Member's condition;
- (2) Member's comorbidities;

- (3) Member's age, including the assessment of the member's age-appropriate growth, development, and competencies, as well as evaluation of age-related and condition-specific healthcare needs and associated issues;
- (4) Relevant past medical/surgical/behavioral health/dental/pharmacotherapy history;
- (5) Complications;
- (6) Progression of the member's condition, illness, or injury;
- (7) Diagnostic test results;
- (8) Treatment outcomes;
- (9) Treatment options;
- (10) Psychosocial circumstances;
- (11) Home and environmental factors impacting member's clinical condition (e.g., homelessness, employment status, poverty, neighborhood);
- (12) Other healthcare services requested and/or provided to the member to integrate healthcare for continuity, coordination, and collaboration of services;
- (13) Local healthcare delivery system's ability to meet the healthcare needs of the member's specific condition;
- (14) Member's reasonable accessibility to a qualified provider with appropriate credentials, licensure, clinical expertise 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, or durable medical equipment (prosthetics, orthotics and supplies);
- (15) Other factors related to the member's plan of care or health outcomes; AND/OR
- (16) If applicable, verification that the requested device, system, biologic, or drug is being prescribed/requested and will be utilized according to its FDA-approved or compendia indication and guideline information, including intended use for the member's age and medical condition.

c. Clinical Vendor Evaluation of New Technology:

The Plan's partner clinical vendors evaluate 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, 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 oral or written 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 provider manual on the Plan's website. 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. The current version of clinical review criteria is available to all providers, members, and the general public on the Plan's 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, 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 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; AND

- e. Review of position papers and guidelines established or endorsed by nationally recognized medical associations, specialty societies, dental organizations, or governmental agencies, including but not limited to practice guidelines adopted by the Plan; AND
- f. Clinical studies 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) 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, biologics, 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), U.S. Center for Disease Control and Prevention (CDC), Center for Medicare & Medicaid Services (CMS), Massachusetts Executive Office of Health and Human Services, 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 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 at any time through the Plan's Provider Information Mailbox available at Provider.Info@BMCHP-wellsense.org. The Plan will thoroughly research recommendations and comments submitted from providers.

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; the Plan will evaluate provider feedback submitted by practicing practitioners when evaluating applicable 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, 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, 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 (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.

Providers may email feedback on the Plan's internal medical policies to the Medical Policy Mailbox at medical.policy@bmchp-wellsense.org. It is important to include the medical policy title and policy number with the comments so Plan staff can thoroughly research the issue. An integral component of the Plan's annual medical policy review process is to evaluate provider comments and recommendations.

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) 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 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 guidelines in both item (1) and item (2):

- (1) The Plan's OCA UM staff applies clinical review criteria consistently for all Plan members according to the standards specified in this policy (e.g., requests for transplant services), as well as complying with the Plan's out-of-network guidelines and product-specific requirements outlined in the *Out-of-Network Services* medical policy, policy number OCA 3.18. When standard clinical criteria are not met, 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, biologic, 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 any member-specific factors impacting care, including one or more of the following:
 - (a) Member's condition;
 - (b) Member's comorbidities;
 - (c) Member's age, including the assessment of the member's age-appropriate growth, development, and competencies, as well as evaluation of age-related and condition-specific healthcare needs and associated issues;
 - (d) Relevant past medical/surgical/behavioral health/dental/pharmacotherapy history;
 - (e) Complications;
 - (f) Progression of the member's condition, illness, or injury;
 - (g) Diagnostic test results;
 - (h) Treatment outcomes;
 - (i) Treatment options;
 - (j) Psychosocial circumstances;
 - (k) Home and environmental factors impacting member's clinical condition (e.g., homelessness, employment status, poverty, neighborhood);

- (l) Other healthcare services requested and/or provided to the member to integrate healthcare for continuity, coordination, and collaboration of services;
 - (m) Local healthcare delivery system's ability to meet the healthcare needs of the member's specific condition;
 - (n) Member's reasonable accessibility to a qualified provider with appropriate credentials, licensure, clinical expertise 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, or durable medical equipment (prosthetics, orthotics and supplies);
 - (o) Other factors related to the member's plan of care or health outcomes; AND/OR
 - (p) If applicable, verification that the requested device, system, biologic, or drug is being prescribed/requested and will be utilized according to its FDA-approved or compendia indication 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 (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
- b. OCA UM staff considers the following characteristics of the healthcare delivery system listed in items (1) through (4) to assess the local healthcare delivery system's ability to meet the member's healthcare needs when applying clinical review criteria to each request:
- (1) Availability and member access to acute and subacute care facilities, including but not limited to acute care inpatient hospitals (with access to inpatient and outpatient specialty hospital services such as major burn care, transplantation, specialty pediatric care, specialty outpatient centers for HIV/AIDS, sickle cell disease, hemophilia, craniofacial and congenital anomalies), surgi-centers, rehabilitation facilities, transitional care facilities, skilled nursing facilities (SNF), home health agencies, and hospice programs, 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, 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, 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 or licensed Plan pharmacist for a determination (utilizing qualified Plan clinicians applicable for the member's condition and requested treatment); AND
- d. When medical necessity cannot be established through existing clinical review criteria, the Plan's Medical Directors 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 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 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 and/or licensed Plan pharmacists also consider member-specific factors 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 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 (according to the definitions of inter-rater reliability, 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, members, regulatory agencies, and accreditation organizations, upon oral or written 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 and Plan's website. 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 current version of clinical review criteria included in the Plan's internal medical policies and internal pharmacy policies are available to all providers, members, and the general public on the Plan's extranet site. Participating providers receive network notifications via email at least 60 calendar days before the effective date of material changes to internal clinical review criteria and/or coding (excluding industry-wide code updates and administrative changes) or when new versions of InterQual® criteria are adopted by the Plan. Copies of internal medical policies with material changes to clinical review criteria and/or coding are included these provider network notifications (sent at least 60 calendar days before the effective date); updated internal medical policies will be available at the Plan's website on the effective date of the revisions. Providers may email feedback on the Plan's medical policies to the Medical Policy Mailbox at medical.policy@bmchp-wellsense.org. It is important to include the medical policy title and policy number with the comments so Plan staff can thoroughly research the issue. An integral component of the Plan's annual medical policy review process is to evaluate provider comments and recommendations.

The Plan will submit material revisions to its medical necessity guidelines, including clinical review criteria and related utilization management protocols, to 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 (CMS) at least 60 calendar days before the effective date of these material revisions (or another timeframe specified by the organization) when these

changes may impact services provided to the organization's enrollees; a designated contact person must be provided in writing to the Medical Policy, Criteria, and Technology Assessment Committee (MPCTAC) by the organization or its designee.

Internal pharmacy policy revisions are communicated to providers 60 calendar days before the effective date of the revisions. Pharmacy policies for the Plan's NH Medicaid product are submitted to DHHS for review and approval prior to implementation. Once approved, pharmacy policies are available on the Plan's website 30 calendar days before the effective date. For Medicaid and commercial lines of business, providers may email feedback on the Plan's pharmacy policies at pharmacym@bmchp-wellsense.org, or provide feedback as part of the UM process during Peer to Peer discussions with the Plan's clinical staff. During the annual pharmacy policy review process, the Plan evaluates provider feedback and recommendations. Pharmacy policies for Medicaid and commercial products are approved by the Plan's Pharmacy & Therapeutics (P&T) Committee. For MA Senior Care Options (SCO) and NH Medicare Advantage products, the pharmacy policies are approved by the Centers for Medicare & Medicaid Services. Pharmacy utilization management functions and the P&T Committee responsibilities are delegated to the Pharmacy Benefit Manager for MA SCO and NH Medicare Advantage products.

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 Medical Officer, Plan Medical Directors, 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 Medical Officer or designee is responsible for ensuring Medical Director training, evaluation, and monitoring to ensure consistent application of clinical review criteria and medical necessity determinations.

Variations

The Plan uses guidance from the Centers for Medicare & Medicaid Services (CMS) for medical necessity and coverage determinations for the Plan's Senior Care Options (SCO) members and New Hampshire 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 (Definition for MassHealth and Senior Care Options 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. 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 and the same services furnished to members under MassHealth fee-for-service, as specified in the Plan's *Medically Necessary* medical policy, policy number OCA 3.14. Any new or amended pre-authorization requirement or restriction shall NOT be implemented unless the Plan's and/or partner clinical vendor's respective website has been updated to clearly reflect the new or amended requirement or restriction.

Clinical Review Criteria (Definition for Qualified Health Plans/ConnectorCare/Employer Choice Direct Definition Products):

In accordance with 958 CMR 3.020, clinical review criteria are the written screening procedures, decisions, abstracts, clinical protocols and/or practice guidelines used by the Plan to determine the medical necessity and appropriateness of health care services. Utilization review criteria shall be up to date and applied consistently by the Plan or the Plan's partner clinical vendor and made easily accessible to members, providers, and the general public on the Plan's website; or, in the alternative, on the Plan's partner clinical vendor's website so long as the Plan provides a link on its website to the vendor's website; provided, however, that the Plan shall not be required to disclose licensed, proprietary criteria purchased by the Plan or partner clinical vendor on its website, but must disclose such criteria to a provider or subscriber upon request. Review the Plan's *Medically Necessary* medical policy, policy number OCA 3.14, for the product-specific definition of medically necessary treatment. Any new or amended pre-authorization requirement or restriction shall NOT be implemented unless the Plan's and/or partner clinical vendor's respective website has been updated to clearly reflect the new or amended requirement or restriction.

Clinical Review Criteria (Definition for New Hampshire Medicaid Product): 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. Medical necessity guidelines established by the Plan will be no more restrictive than the contractual definition of Medically Necessary for the New Hampshire Department of Health and Human Services (DHHS) and the same services furnished in the New Hampshire DHHS fee-for-service Medicaid program, as specified in the Plan's *Medically Necessary* medical policy, policy number OCA 3.14. Any new or amended pre-authorization requirement or restriction shall NOT be implemented unless the Plan's and/or partner clinical vendor's respective website has been updated to clearly reflect the new or amended requirement or restriction.

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, and the Chief Medical 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 consistently use applicable Plan clinical review criteria when determining the medical necessity of healthcare services. The Chief Medical Officer or designee is responsible for ensuring Medical Director 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.

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 (Definition 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.

References

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

Centers for Medicare & Medicaid Services (CMS). EPSDT - A Guide for States: Coverage in the Medicaid Benefit for Children and Adolescents. 2014 Jun.

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

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

Centers for Medicare & Medicaid Services (CMS). Medicaid. Early and Periodic Screening, Diagnosis, and Treatment. Medicaid.gov.

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

Centers for Medicare & 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 the New Hampshire Department of Health and Human Services (DHHS) and Plan. Hayes, a symplr Company.

Levenson JL. Psychological factors affecting other medical conditions: Clinical features, assessment, and diagnosis. UpToDate. 2020 Nov 2.

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). Device Labeling.

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

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

Next Review Date

06/01/23

Authorizing Entity

MPCTAC

Appendix

Appendix: Policy History

Other Applicable Policies

Administrative Policy - *Clinical Technology Evaluation*, policy number OCA 3.13
Administrative Policy - *Inter Rater Reliability*, policy number OCA 3.216
Administrative Policy - *Mental Health Parity Administrative Policy - Assurance of Parity between Medical and Behavioral Health Benefits*, policy number BH1
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
Medical Policy - *Out-of-Network Services*, policy number OCA 3.18
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 - *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 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 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 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 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 52.02. Code of Massachusetts Regulations. Division of Insurance. Managed Care Consumer Protections and Accreditation of Carriers. Definitions. Clinical Review Criteria.

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.

211 CMR 52.02. Code of Massachusetts Regulations. Division of Insurance. Managed Care Consumer Protections and Accreditation of Carriers. Definitions. Utilization Review.

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. 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.

Commonwealth of Massachusetts. 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. RSA 417-D:2-b. New Hampshire Revised Statutes Annotated. Women's Health Care. Reconstructive Surgery.

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

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:

Plan refers to Boston Medical Center Health Plan, Inc. which operates under the trade name WellSense Health Plan. 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.

Appendix: Policy History

Original Approval Date	Original Effective Date* and Version	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	Director of Medical Policy as Chair of Medical Policy, Criteria, and Technology Assessment Committee (MPCTAC)	Utilization Management Committee (UMC)

*Effective date for MA QHP commercial product: 01/01/12.

*Effective date for New Hampshire Medicaid product: 01/01/13.

*Effective date for MA Senior Care Options product: 01/01/16.

*Effective date for New Hampshire Medicare Advantage HMO product: 01/01/22.

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

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	Version 7	07/18/12: MPCTAC 08/15/12: MPCTAC

	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."		
08/15/12	Off cycle review for New Hampshire Medicaid product. Revised the 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 delivery system, when clinically appropriate.	Version 9	09/19/12: MPCTAC 09/26/12: QIC
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	06/01/17 Version 15	05/17/17: MPCTAC

	use of these clinical criteria in utilization review activities.		
08/31/17	Updated the definition of Clinical Review Criteria (for Massachusetts 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.	08/31/17 Version 16	08/31/17: MPCTAC (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 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 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
08/01/21	Review for effective date 09/01/21. Administrative changes made to the Policy Summary, Policy Statement, Definitions, References, Other Applicable Policies, and Reference to Applicable Laws and Regulations sections to clarify current guidelines.	09/01/21 Version 26	08/13/21: MPCTAC (electronic vote)
11/01/21	Review for effective date 12/01/21. Added NH Medicare Advantage HMO as an applicable product effective 01/01/22. Administrative changes made to the Policy Summary and Policy Statement sections. Added the Variations section.	12/01/21 Version 27	11/17/21: MPCTAC
07/01/22	Review for effective date 08/01/22. Administrative changes made to the Policy Summary, Policy Statement, Delegated Management, Procedure, Responsibility and Accountability, Definitions, and Other Applicable Policies sections.	08/0/22 Version 28	07/25/22: MPCTAC (electronic vote)
08/01/22	Review for effective date 11/01/22. Revised the list of the Plan's delegated services and partner clinical vendors in the Delegated Management section. eviCore healthcare served as the Plan's delegated vendor for radiology services from 03/15/20 to 10/31/22. Effective 11/01/22, the Plan will delegate the management of radiology services, musculoskeletal services (i.e., spine surgeries, joint surgeries, and interventional pain management treatments), genetic testing, and outpatient rehabilitation services (i.e., physical therapy, occupational therapy, and speech therapy after the initial evaluation) to AIM Specialty Health.	11/01/22 Version 29 Version 29 NOT implemented and replaced with Version 30 as of 11/01/22	08/26/22: MPCTAC (electronic vote)
09/01/22	Review for effective date 11/01/22. Revised the effective date of AIM's management of outpatient rehabilitation services from	11/01/22 Version 30	09/23/22: MPCTAC (electronic vote)

	11/01/22 to 12/01/22 in the Delegated Management section. All other policy revisions approved for Version 29 are implemented in Version 30 as of 11/01/22. Policy added to the Other Applicable Policies section.		
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Medical Policy

Complementary and Alternative Medicine

Policy Number: OCA 3.194

Version Number: 22

Version Effective Date: 12/01/22

Impacted Products

- All Products**
- NH Medicaid
- NH Medicare Advantage
- MA MassHealth ACO
- MA MassHealth MCO
- MA Qualified Health Plans/Employer Choice Direct
- MA Senior Care Options

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

Policy Summary

The Plan considers complementary and alternative medicine (CAM) NOT medically necessary unless the service (including indication for treatment) is covered for the member. Prior authorization from AIM Specialty Health is required for outpatient rehabilitation services.

Clinical Criteria

The member's product-specific benefit documents will determine coverage for CAM services, as specified below in items 1 and 2:

1. The Plan considers CAM services NOT medically necessary for Plan members, except as covered in the member's applicable benefit documents.
2. There may be separate medical policies that address the treatment of specific conditions or procedures that supersede this policy. See the Plan's *Prior Authorization/Notification Requirements* matrix available at the Plan's website for prior authorization guidelines by service type.

Limitations and Exclusions

The Plan considers CAM to NOT be medically necessary due to insufficient scientific evidence demonstrating the clinical validity and clinical utility of treatment unless the service (including indication for treatment) is covered for the member. CAM include but are not limited to any of the following services:

1. Whole medicine systems (e.g., homeopathic and naturopathic medicine, traditional Chinese medicine such as Ayurveda).
2. Mind body medicine to improve the mind's ability to affect bodily function and symptoms (e.g., biofeedback except for treatment of urinary incontinence, hypnotherapy/hypnosis, meditation, prayer, mental healing, therapies that use creative outlets such as art, music, or dance).
3. Substances found in nature (e.g., herbal products, vitamins, dietary supplements).
4. Manipulative and body based practices (e.g., massage, myotherapy, craniosacral therapy, osteopathic manipulation, hippotherapy, yoga, reflexology).
5. Energy medicine (e.g., Reiki, therapeutic touch, pulsed fields, magnetic fields, electromagnetic, or alternating-current or direct-current field).

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 NH 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. At the time of the Plan's most recent policy review, there was no applicable clinical policies by CMS. Verify CMS guidelines in effect on the date of the prior authorization request for the service and indication for treatment. When there is no guidance from CMS for the requested service, plan-adopted clinical review criteria will be used to determine the medical necessity of the service.

Applicable Coding

The Plan utilizes up-to-date, industry-standard Current Procedural Terminology (CPT) codes, Health Care Common Procedure Coding System (HCPCS) codes, and International Statistical Classification of Diseases and Related Health Problems, 10th revision (ICD-10) diagnosis codes in the Plan's medical policies. Since these codes may be updated at different intervals than the medical policy review cycle, the list of applicable codes included in a policy is informational only and may not be all inclusive. Applicable codes are subject to change without prior notification and do not guarantee member coverage or provider reimbursement. Review the Plan's reimbursement policies for Plan billing guidelines. Providers are responsible for obtaining prior authorization for the services specified in the Clinical Criteria section and Limitations and Exclusions section of a medical policy, even if an

applicable code appropriately describing the service is not included in the policy's Applicable Coding section. Providers are expected to report all services using the most up-to-date, industry-standard procedures and diagnosis codes at the time of the service.

CPT/HCPCS Codes	Description: Service is considered NOT medically necessary, except as specified in the member's applicable benefit document
90880	Hypnotherapy Plan note: Code is NOT payable for the Senior Care Options product.
M0075	Cellular therapy Plan note: Code is NOT payable for the Senior Care Options and NH Medicare Advantage HMO products.

References

American Chronic Pain Association (ACPA). ACPA Resource Guide to Chronic Pain management, An Integrated Guide to Medical, Interventional, Behavioral Pharmacologic and Rehabilitation Therapies. Feinberg S (ed.) American Chronic Pain Association Inc., Rocklin, California. 2019.

American College of Chest Physicians (ACCP). Deng GE, Rausch SM, Jones LW, Gulati A, Kumar NB, Greenlee H, Pietanza MC, Cassileth BR. Complementary therapies and integrative medicine in lung cancer: diagnosis and management of lung cancer, 3rd ed: ACCP evidence-based clinical practice guidelines. Chest. 2013 May;143(5 Suppl):e420S-36S. doi: 10.1378/chest.12-2364. PMID: 23649450.

American College of Physicians (ACP). Qaseem A, Wilt TJ, McLean RM, Forcica MA; Clinical Guidelines Committee of the American College of Physicians. Noninvasive Treatments for Acute, Subacute and Chronic Low Back Pain: A Clinical Guideline from the ACP. Ann Intern Med. 2017 Apr 4;166(7):514-30. doi: 10.7326/M16-2367. Epub 2017 Feb 14. PMID: 28192789.

American Society of Anesthesiologists (ASA), American Society of Regional Anesthesia and Pain Medicine (ASRA). Rosenquist RW, Benzon HT, Connis RT, De Leon-Casasola OA, Glass D, Korevaar WC, Cynwyd B, Mekhail NA, Merrill DG, Nickinovich DG, Rathnmell JP, Nai-Mei Sang C, Simon DL; ASA Task Force on Chronic Pain Management. Practice guidelines for chronic pain management: an updated report by the ASA Task Force on Chronic Pain Management and the ASRA. Anesthesiology. 2010 Apr;112(4):810-33. doi: 10.1097/ALN.0b013e3181c43103. PMID: 20124882.

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

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

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

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

Chou R, Deyo R, Friedly J, Skelly A, Hashimoto R, Weimer M, Fu R, Dana T, Kraegel P, Griffin J, Grusing S, Brodt E. Noninvasive Treatments for Low Back Pain. Comparative Effectiveness Review No. 169. (Prepared by the Pacific Northwest Evidence-based Practice Center under Contract No. 290-2012-00014-I.) AHRQ Publication No. 16-EHC004-EF. Rockville, MD: Agency for Healthcare Research and Quality. 2016 Feb.

Chou R, Deyo R, Friedly J, Skelly A, Hashimoto R, Weimer M, Fu R, Dana T, Kraegel P, Griffin J, Grusing S, Brodt ED. Nonpharmacologic Therapies for Low Back Pain: A Systematic Review for an American College of Physicians Clinical Practice Guideline. *Ann Intern Med.* 2017 Apr 4;166(7):493-505. doi: 10.7326/M16-2459. Epub 2017 Feb 14. PMID: 28192793.

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

Commonwealth of Massachusetts. MassHealth Provider Bulletins.

Commonwealth of Massachusetts. MassHealth Provider Manuals.

Commonwealth of Massachusetts. MassHealth Transmittal Letters.

Greenlee H, Balneaves LG, Carlson LE, Cohen M, Deng G, Hershman D, Mumber M, Perlmutter J, Seely D, Sen A, Zick SM, Tripathy D; Society for Integrative Oncology. Clinical practice guidelines on the use of integrative therapies as supportive care in patients treated for breast cancer. *J Natl Cancer Inst Monogr.* 2014 Nov;2014(50):346-58. doi: 10.1093/jnci monographs/lgu041. Review. Erratum in: *J Natl Cancer Inst Monogr.* 2015 May;2015(51):98. PMID: 25749602.

Institute for Clinical Systems Improvement (ICSI). Pain: Assessment, Non-Opioid Treatment Approaches and Opioid Management. Eighth Edition. Version 2. 2017 Aug.

Levy SE, Hyman SL. Complementary and alternative medicine treatments for children with autism spectrum disorders. *Child Adolesc Psychiatr Clin N Am.* 2015 Jan;24(1):117-43. doi: 10.1016/j.chc.2014.09.004. Epub 2014 Oct 3. PMID: 25455579.

National Academies of Sciences, Engineering, and Medicine. 2017. Pain management and the opioid epidemic: Balancing societal and individual benefits and risks of prescription opioid use. 2017 Jul 13. Washington, DC: The National Academies Press. doi: <https://doi.org/10.17226/24781>.

National Cancer Institute. National Institutes of Health (NIH). Complementary and Alternative Medicine. 2019 Sep 30.

National Center for Complementary and Integrative Health (NCCIH). National Institutes of Health (NIH). Acupuncture. 2017 Sep 24.

National Center for Complementary and Integrative Health (NCCIH). National Institutes of Health (NIH). Acupuncture: In Depth. 2017 Feb 21.

National Center for Complementary and Integrative Health (NCCIH). National Institutes of Health (NIH). Complementary, Alternative, or Integrative Health: What's In a Name? 2019 Apr 2.

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

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

Office of Patient Centered Care and Cultural Transformation (OPCC&CT). Complementary and Integrative Health (CIH) Resource Guide. Version 2. Last Update: 2017 Oct.

U.S. Department of Veterans Affairs (VA), Department of Defense (DoD). VA/DoD Clinical Practice Guideline for Diagnosis and Treatment of Low Back Pain. Version 2.0 – 2017.

U.S. Department of Veterans Affairs. Department of Defense (DoD). VA/DoD Clinical Practice Guideline for the Management of Chronic Multisymptom Illness CMI 2014.

U.S. National Library of Medicine. National Institutes of Health. Collection Development Manual. Complementary and Alternative Medicine. 2018 Mar 26.

Yuan QL, Guo TM, Liu L, Sun F, Zhang YG. Traditional Chinese medicine for neck pain and low back pain: a systematic review and meta-analysis. PLoS One. 2015 Feb 24;10(2):e0117146. doi: 10.1371/journal.pone.0117146. eCollection 2015. PMID: 25710765.

Next Review Date

02/01/23

Authorizing Entity

MPCTAC

Appendix

Appendix: Policy History

Disclaimer Information:

Plan refers to Boston Medical Center Health Plan, Inc. which operates under the trade name WellSense Health Plan. 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.

Appendix: Policy History

Original Approval Date	Original Effective Date* and Version	Policy Owner	Original Policy Approved by
Regulatory Approval: N/A Internal Approval: 07/28/09: Medical Policy, Criteria, and Technology Assessment Committee (MPCTAC) 08/26/09: Quality Improvement Committee (QIC)	11/01/09 Version 1	Director of Medical Policy as Chair of MPCTAC	MPCTAC and QIC

*Effective Date for QHP Commercial Product: 01/01/12

*Effective Date for Senior Care Options Product: 01/01/16

*Effective Date for NH Medicare Advantage HMO Product: 01/01/22

Policy title was *Complementary and Alternative Medicine, Including Acupuncture Treatment* until 06/30/19. As of 07/01/19, policy title changed to *Complementary and Alternative Medicine, Including Acupuncture*. As of 01/01/22, policy title changed to *Complementary and Alternative Medicine*.

Policy Revisions History			
Review Date	Summary of Revisions	Revision Effective Date and Version Number	Approved by
07/01/10	Removed osteopathic manipulation from the list of CAM services. Changed the "non-covered" language to "not medically necessary," added massage by a massage therapist and updated references.	Version 2	07/21/10: MPCTAC 08/25/10: QIC
07/01/11	Updated references and added commercial language.	Version 3	07/22/11: MPCTAC 08/24/11: QIC
07/01/12	Updated references, added language to Applicable Code section and added applicable code list. Updated Summary section and Applicable Code section to specify that acupuncture is considered a medically necessary service for Commonwealth Care and MassHealth members when used for substance abuse detoxification, as managed and authorized by Beacon Health Strategies. Included statement that acupuncture is not a covered service for Commercial members and	Version 4	07/18/12: MPCTAC 08/22/12: QIC

	added a reference to the Medically Necessary policy in the Summary section.		
05/01/13	Review for effective date 09/01/13. Updated Summary section and applicable code list. Referenced Reimbursement Guidelines: Chiropractic Services (Spinal Manipulation), policy number 4.114. Medical Policy Statement section revised without changing criteria. Hippotherapy added to applicable code list, and the reference to the Hippotherapy policy deleted from Medical Policy Statement section (since Hippotherapy policy will be retired effective 09/01/13). Renumbered policy from OCA: 3.193 to OCA: 3.194.	09/01/13 Version 5	05/15/13: MPCTAC 06/20/13: QIC
05/01/14	Review for effective date 07/01/14. Updated Summary section. Added acupuncture services in the Description of Item or Service and Clinical Background Information sections. Revised language in Medical Policy Statement section and Limitations section without changing criteria. Updated references. Revised policy title.	07/01/14 Version 6	05/21/14: MPCTAC 06/11/14: QIC
01/01/15	Review for effective date 03/01/15. Updated Medical Policy Statement section to clarify guidelines without changing criteria. Updated references.	03/01/15 Version 7	01/21/15: MPCTAC 02/11/15: QIC
04/01/15	Review for effective date 06/01/15. Removed Commonwealth Care, Commonwealth Choice, and Employer Choice from the list of applicable products because the products are no longer available. Administrative changes made to the Applicable Coding section, but no changes made to the code list. Updated Summary and References sections.	06/01/15 Version 8	04/15/15: MPCTAC 05/13/15: QIC
11/25/15	Review for effective date 01/01/16. Updated template with list of applicable products and notes. Administrative changes made to the Summary, Medical Policy Statement, and Limitations section without revising criteria. Revised language in the Applicable Coding section.	01/01/16 Version 9	11/18/15: MPCTAC 11/25/15: MPCTAC (electronic vote) 12/09/15: QIC
04/01/16	Review for effective date 06/01/16. Updated the Clinical Background Information, References, and Reference to Applicable Laws and Regulations sections.	06/01/16 Version 10	04/20/16: MPCTAC 05/23/16: QIC

04/01/17	Review for effective date 05/08/17. Administrative changes made to the Medical Policy Statement and Applicable Coding sections (without changing the code list or criteria). Updated Definitions, Clinical Background Information, References, and Reference to Applicable Laws and Regulations sections.	05/08/17 Version 11	04/19/17: MPCTAC
02/01/18	Review for effective date 03/01/18. Updated Description of Item or Service and Other Applicable Policies sections.	03/01/18 Version 12	02/21/18: MPCTAC
05/01/18	Review for effective date 06/01/18. Administrative changes made to the Limitations sections. Updated Plan notes in the Applicable Coding section without changing the code list. Removed QHP/ConnectorCare/Employer Choice Direct from the list of applicable products for this policy. Updated Policy Summary, Definitions, References, and Other Applicable Policies sections.	06/01/18 Version 13	05/16/18: MPCTAC
03/01/19	Review for effective date 04/01/19. Administrative changes made to the Description of Item or Service, Limitations, Applicable Coding (with Plan notes added), References, and Other Applicable Policies sections.	04/01/19 Version 14	03/20/19: MPCTAC
04/01/19	Review for effective date 05/01/19. Administrative changes made to the Policy Summary, Description of Item or Service, Medical Policy Statement, and Limitations sections. Revised the policy title. Removed non-payable code listed as not medical necessary (administrative change) and updated Plan notes in the Applicable Coding section.	05/01/19 Version 15	04/18/19: MPCTAC (electronic vote)
12/01/19	Review for effective date 01/01/20. Administrative changes made to Plan notes in the Applicable Coding section, References section, and Reference to Applicable Laws and Regulations section.	01/01/20 Version 16	12/18/19: MPCTAC
04/01/20	Review for effective date 07/01/20. Administrative changes made to the Policy Summary, Clinical Background Information, References, and Reference to Applicable Laws and Regulations sections. Revised the Plan notes in the Applicable Coding section. Add a prior authorization requirement for acupuncture	07/01/20 Version 17	04/15/20: MPCTAC

	for Senior Care Options members in the Medical Policy Statement and Limitations sections.		
12/01/20	Review for effective date 01/01/21. Administrative changes made to the Description of Item or Service, Medical Policy Statement, Applicable Coding, and References sections.	01/01/21 Version 18	12/16/20: MPCTAC
11/01/21	Review for effective date 12/01/21. Adopted new medical policy template; removed administrative sections, the Medical Policy Statement section renamed the Clinical Criteria section, and the Limitations section renamed the Limitations and Exclusions section. Added NH Medicare Advantage HMO as an applicable product effective 01/01/22. Administrative changes made to the Policy Summary, Clinical Criteria, Limitations and Exclusions, Applicable Coding, and References sections.	01/01/22 Version 19	11/17/21: MPCTAC
12/01/21	Review for effective date 01/01/22. Removed acupuncture references. Review the Plan's <i>Acupuncture</i> medical policy, policy number OCA 3.17, rather than this policy for acupuncture services as of 01/01/22.	01/01/22 Version 20	12/15/21: MPCTAC
08/01/22	Review for effective date 11/01/22. Administrative changes made to the Policy Summary, Clinical Criteria, and Limitations and Exclusions sections. Revised coding in the Applicable Coding section.	11/01/22 Version 21 Version 21 NOT implemented; Version 20 effective 01/01/22 to 11/30/22	08/26/22: MPCTAC (electronic vote)
09/01/22	Review for effective date 12/01/22. The effective date of AIM Specialty Health's management of outpatient rehabilitation services changed from 11/01/22 to 12/01/22. Administrative changes made to the Policy Summary, Clinical Criteria, and Limitations and Exclusions sections. Revised coding in the Applicable Coding section.	12/01/22 Version 22	09/23/22: MPCTAC (electronic vote)



Medical Policy

Gender Affirmation Services

Policy Number: OCA 3.11

Version Number: 22

Version Effective Date: 12/01/22

Impacted Products

- All Products**
- NH Medicaid
- NH Medicare Advantage
- MA MassHealth ACO
- MA MassHealth MCO
- MA Qualified Health Plans/Employer Choice Direct
- MA Senior Care Options

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

Policy Summary

Gender affirmation surgeries and permanent hair removal require prior authorization and are considered medically necessary for a member seeking treatment for gender dysphoria when Plan medical criteria are met. Gender affirmation surgeries may include one (1) or more surgical procedures and are part of a complex treatment plan involving medical, surgical, and behavioral health interventions to achieve the desired outcomes for the individual.

Voice therapy is considered medically necessary as a treatment option for gender dysphoria when AIM clinical appropriateness guidelines are met; prior authorization from AIM Specialty Health is required. 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 for ANY Plan member based on the member's diagnosis, type of illness, health status or condition, sex, gender identity/gender dysphoria, and/or sexual orientation. The full range of medical and/or surgical treatment options available to individuals diagnosed with gender dysphoria may include, but are not limited to, those listed in professional medical publications such as the current version of WPATH Standards of Care for Health and Transsexual, Transgender and Gender-Nonconforming People.

Breast reconstruction used for the treatment of members with persistent, well-documented gender dysphoria may include the medically necessary surgical removal of breast implants and/or the

replacement of breast implants after implant explantation (including when the implant was initially inserted as a component of a gender affirmation surgery); review the criteria in the *Breast Reconstruction* medical policy, policy number OCA 3.43, rather than the criteria included in this policy. Feminizing/masculinizing hormonal therapy and/or gender affirmation surgeries may limit the member's fertility. Infertility services are covered for some Plan products. Review the Plan's *Infertility Services* medical policy, policy number OCA 3.725.

Clinical Criteria

Applicable criteria must be met for gender affirmation services in item I for gender affirmation surgery and permanent hair removal and/or item II for gender affirmation services that require Plan Medical Director review.

I. The Plan considers gender affirmation services medically necessary for the treatment of gender dysphoria, and Plan prior authorization is required for the services specified in this section. ALL applicable Plan clinical review criteria must be met in items A through C:

A. Referral/Initial Assessment by Qualified Licensed Mental Health Professional:

There is a referral/initial assessment from a licensed qualified mental health professional that contains ALL of the following documentation listed in items 1 through 8:

1. Gender identity resulting in a definitive diagnosis of persistent, well-documented gender dysphoria (meeting DSM-5 criteria) for at least 6 months, history and development of gender dysphoric feelings, and impact of stigma attached to gender nonconformity; AND
2. If living in an identity-congruent gender role, documentation of member's experience, start date, and if living full-time in identity-congruent gender role; AND
3. The member's general identifying characteristics; AND
4. Results of psychosocial assessment, including any diagnoses and confirmation that other behavioral health conditions are appropriately managed, reasonably controlled, and not contributing to gender dysphoria); AND
5. Duration of mental health professional's relationship with member, including type of evaluation and therapy/counseling to date; AND
6. Written clinical rationale supporting member's request for specific treatment(s); AND
7. Statement that mental health professional is available for coordination of care and plan of care is in place; AND
8. Member's psychological readiness for the requested treatment(s) with no contraindications to treatment documented, including member's capacity to make a fully informed decision

and has the capacity to consent for treatment(s), and includes parental or guardian consent (as applicable) if the member is younger than age 18 on the date of service unless the adolescent member is emancipated at the time the service is rendered; AND

B. Member age 18 or older on the date of service; AND

C. Service-Specific Criteria:

Criteria must be met in item 1 for all gender affirmation surgical procedures and procedure specific criteria must be met in item 2:

1. Gender Affirmation Surgical Procedures:

All criteria must be met in items a through e for any gender affirmation surgery:

- a. Requests for prior authorization for each gender affirmation surgery must be submitted by the surgeon (or the surgeon's designee) performing the procedure and accompanied by written clinical documentation; AND
- b. Surgeon has reviewed the documentation by the qualified licensed mental health professional (referenced above in item A), including the DSM-5 diagnosis of gender dysphoria, and documentation from the member's health care provider; AND
- c. Surgeon has discussed risks and complications of proposed surgery and various surgical techniques, surgeon's own complication rates, impact on fertility, procedures for preservation of fertility, and has obtained member's informed consent; AND
- d. If hormone therapy is a required criterion for a gender affirmation surgery (as specified below in the procedure-specific criteria), medical records must document member compliance with the prescribed regimen and clinical response over the course of hormone therapy; AND
- e. Member's treating surgeon has documented that there are no contraindications to the planned surgery, verified significant medical conditions are stable, and agrees with the plan of care; AND

2. Procedure-Specific Criteria:

Procedure-specific criteria must be met for ANY procedure listed in items a through h:

a. Chest Procedures:

- (1) Bilateral augmentation mammoplasty (with implantation of breast prostheses or lipofilling) when the member has had 12 continuous months of clinician-supervised

hormone therapy (unless hormone therapy is medically contraindicated for the member), and the hormone therapy has not resulted in sufficient breast development as self-reported by the member to the treating provider; OR

- (2) Bilateral breast reduction, mastectomy, and/or chest reconstruction is requested; OR

b. Feminizing Genital Surgery:

ALL guidelines must be met in items (1) through (4):

- (1) ANY of the procedures in items (a) through (g) will be performed:
 - (a) Clitoroplasty/neoclitoroplasty;
 - (b) Labiaplasty/neolabiaplasty;
 - (c) Orchiectomy;
 - (d) Penectomy;
 - (e) Urethroplasty and urethra-meatoplasty;
 - (f) Vaginoplasty (also known as neovaginoplasty); e.g., penile inversion vaginoplasty, colovaginoplasty, peritoneal pulldown vaginoplasty;
 - (g) Vulvoplasty/neovulvoplasty; AND
- (2) Member has been assessed by 2 independently licensed health professionals, one of whom must be a licensed qualified behavioral health professional (referenced above in item A) and the other a clinician familiar with the member's health, with each assessment resulting in a diagnosis of gender dysphoria meeting DSM-5 criteria. The initial diagnosis (from one professional) must have been present for at least 6 months; AND
- (3) Member has had 12 continuous months of living as the gender that is congruent with the member's identity. Exceptions may be provided on a case-by-case basis should the request for prior authorization document that compliance with this requirement would jeopardize the health, safety, and/or well-being of the member; AND
- (4) The member has had 12 continuous months of clinician-supervised hormone therapy appropriate to the member's gender goals, unless hormone therapy is medically contraindicated; OR

c. Masculinizing Genital Surgery:

ALL guidelines must be met in items (1) through (4):

- (1) ANY of the procedures listed in items (a) through (i) will be performed:
 - (a) Hysterectomy;
 - (b) Metoidioplasty;
 - (c) Oophorectomy;
 - (d) Phalloplasty with implantation of penile prosthesis;
 - (e) Salpingectomy;
 - (f) Scrotoplasty with insertion of testicular implants;
 - (g) Urethroplasty;
 - (h) Vaginectomy;
 - (i) Vulvectomy; AND
- (2) Member has been assessed by 2 independently licensed health professionals, one of whom must be a licensed qualified behavioral health professional (referenced above in item A) and the other a clinician familiar with the member's health, with each assessment resulting in a diagnosis of gender dysphoria meeting DSM-5 criteria. The initial diagnosis (from 1 professional) must have been present for at least 6 months; AND
- (3) Member has had 12 continuous months of living as the gender that is congruent with the member's identity. Exceptions may be provided on a case-by-case basis should the request for PA document that compliance with this requirement would jeopardize the health, safety, or well-being of the member; AND
- (4) Member has had 12 continuous months of clinician-supervised hormone therapy appropriate to the member's gender goals, unless hormone therapy is medically contraindicated; OR

d. Facial Feminization or Facial Masculinization Surgical Procedures:

ONE (1) or more of the procedures listed in items (1) through (12) will be performed:

- (1) Blepharoplasty (eyelid surgery) ONLY in conjunction with other medically necessary facial feminization or facial masculinization procedures;
- (2) Brow reconstruction/brow lift;
- (3) Cheek augmentation;
- (4) Forehead contouring (including forehead reshaping or forehead reduction);
- (5) Genioplasty (chin augmentation, chin reconstruction, or chin reduction/narrowing);
- (6) Scalp/hairline advancement;
- (7) Lateral canthopexy;
- (8) Surgical lip lift;
- (9) Lysis intranasal synechiae;
- (10) Mandibuloplasty;
- (11) Osteoplasty;
- (12) Rhinoplasty and septoplasty;
- (13) Rhytidectomy (facelift surgery) of the forehead, cheek, and/or neck (platysmaplasty);
- (14) Suction-assisted lipectomy in conjunction with medically necessary facial procedures; AND/OR
- (15) Tracheoplasty/tracheal shave; OR

e. Hair Removal with Laser or Electrolysis:

Electrolysis and/or laser treatments for face and neck hair removal is performed by a licensed and qualified treating clinician and ALL criteria are met in items (1) through (5):

- (1) A licensed qualified health professional recommends hair removal of the face and/or neck as part of the member's medically necessary treatment for gender dysphoria; AND

- (2) A letter from the clinician performing the hair removal is submitted to the Plan and includes attestation of the medical necessity of hair removal and a summary of the member's care as it relates to gender dysphoria treatment; AND
 - (3) Documentation submitted to the Plan includes the area size and location(s) for permanent hair removal, the type of hair removal treatment (laser or electrolysis), and the expected timeframe and number of treatments requested. The Plan will authorize medically necessary requests for electrolysis and/or laser ablation treatments for medically necessary permanent hair removal of the face and/or neck for up to 12 calendar months from the date of the authorization request. Additional treatments require a separate Plan authorization; AND
 - (4) Clinician performing the hair removal has discussed risks and complications of the proposed procedure, including the clinician's own complication rates, and has obtained informed consent from the member; AND
 - (5) Member has had 12 continuous months of clinician-supervised hormone therapy appropriate to the member's gender goals unless hormone therapy is medically;
OR
- f. Hair removal for standard pre-operative preparation for genital gender affirmation surgery:

Electrolysis and/or laser treatments for hair removal is performed by a licensed and qualified treating provider and ALL criteria are met in items (1) through (4):

- (1) Permanent hair removal is required as part of the standard pre-operative preparation for genital affirming surgery(ies) and is recommended by the treating surgeon, with documentation verifying that hair removal is medically necessary; AND
- (2) A letter from the clinician performing the hair removal is submitted to the Plan and includes attestation of the medical necessity of hair removal and a summary of the member's care as it relates to gender dysphoria treatment; AND
- (3) Documentation submitted to the Plan includes the area size and location(s) for permanent hair removal, the type of hair removal treatment (laser or electrolysis), expected timeframe and number of treatments requested, and the estimated date of the genital gender affirmation surgical procedure(s). The Plan will authorize medically necessary requests for electrolysis and/or laser ablation treatments for medically necessary pre-operative permanent hair removal as standard preparation for genital gender affirmation surgery for up to 18 calendar months from the date of the authorization request. Additional treatments require a separate Plan authorization; AND

(4) Clinician performing the hair removal has discussed risks and complications of the proposed procedure, including the clinician's own complication rates, and has obtained informed consent from the member; OR

g. Gender Affirmation Procedures NOT Requiring Medically Necessary Permanent Hair Removal of Graft Site:

The Plan will authorize medically necessary requests for gender affirmation surgery(ies) up to 12 calendar months from the date of the authorization request; OR

h. Genital Gender Affirmation Procedures Requiring Medically Necessary Permanent Hair Removal of Graft Site:

The Plan will authorize medically necessary requests for genital gender affirmation procedure(s) that require pre-operative permanent hair removal as standard preparation for surgery up to 18 calendar months from the date of the authorization request.

II. The following requests require Plan Medical Director review:

- A. Permanent hair removal in preparation for planned genital gender affirmation procedure if the procedure has not yet been authorized by the Plan.
- B. Hair removal when documentation from the member's surgeon and/or qualified licensed health provider(s) is within 13-18 calendar months of the prior authorization request and permanent hair removal is NOT a medically necessary component of pre-operative preparation for genital gender affirmation procedure(s). Additional documentation must be submitted to the Plan to report the extenuating circumstances that necessitate an extension of the standard 12 calendar month time limit.
- C. Gender affirmation surgery for a member who does NOT meet DSM-5 definitive diagnosis of persistent gender dysphoria (e.g., non-binary members who do not meet traditional diagnostic criteria for gender dysphoria).
- D. Gender affirmation services for a member unable to live in the chosen gender role full-time. This includes members who identify as genders other than male or female. Treating provider must submit documentation indicating why it would be clinically inappropriate to require the member to meet this criterion and why this requirement should be waived.
- E. Gender affirmation surgery and/or permanent hair removal for a member age 17 or younger on the date of service. The Plan Medical Director will review the current version of WPATH Standards of Care and member's clinical situation, including but not limited to the amount of time the adolescent member has been living in the gender congruent role, treatment timeframe with hormone therapy, age of the member, and the requested intervention. Adolescent

members may be eligible for interventions when adolescents and their parents (or guardian) make informed decisions about treatment, and the service is a covered benefit for the Plan member. Informed consent by a parent or guardian for treatment of an adolescent member may not apply if the adolescent member is emancipated at the time the service is rendered (as determined by state requirements).

- F. Surgical revision of a previously performed gender affirmation surgery.
- G. Laparoscopic prostatectomy as a component of gender affirmation surgical procedure(s).
- H. Post-operative lodging is NOT routinely covered by the Plan; Plan Medical Director review is required.

Limitations and Exclusions

- A. External review will be available to the members enrolled in Qualified Health Plans, ConnectorCare, or Employer Choice Direct products when the Plan determines that coverage for treatment of gender dysphoria is NOT medically necessary or the Plan considers the treatment experimental or investigational. The external review for Qualified Health Plans, ConnectorCare, or Employer Choice Direct products will be based upon the Massachusetts definition of medical necessity. (Source: The Commonwealth of Massachusetts, Health Policy Commission, Memo: External Review for Denials of Coverage for Medical and/or Surgical Treatment of Gender Dysphoria, July 2, 2015.)
- B. Hair removal is ONLY covered when criteria are met in the Clinical Criteria section for the method of hair removal (i.e., electrolysis and/or laser hair removal). Any other method of hair removal or indication for treatment is NOT covered.
- C. The Plan considers any services or surgical procedures used to reverse gender affirmation surgery to NOT be medically necessary.
- D. The following procedures/services in items 1 through 17 are NOT covered for the treatment of gender dysphoria:
 - 1. Blepharoplasty (eyelid surgery) NOT in conjunction with other facial feminization or facial masculinization procedures used for the treatment of gender dysphoria; OR
 - 2. Body contouring procedures, including abdominoplasty, liposuction, lipofilling, and/or suction-assisted lipectomy UNLESS the treatment is listed as medically necessary in the Clinical Criteria section (e.g., facial procedures for the treatment of gender dysphoria) and ALL applicable clinical review criteria are met for the gender affirmation surgical procedure; OR
 - 3. Calf augmentation (calf implants); OR

4. Collagen injections; OR
5. Facial feminization surgery, facial masculinization surgery, facial bone reduction, or facial implants or injections UNLESS the treatment is specified as medically necessary in the Clinical Criteria section and applicable clinical review criteria are met for the facial feminizing or facial masculinizing gender affirmation surgical procedure; OR
6. Gluteal augmentation (gluteal implants and/or lipofilling); OR
7. Hair transplantation or hair reconstruction (see the Clinical Criteria section for guidelines for hairline advancement surgery); OR
8. Laryngoplasty (technique to alter the voice tract and adjust vocal range); OR
9. Lip reduction or lip enhancement (see the Clinical Criteria section for guidelines related to lip lift); OR
10. Osteoplasty UNLESS clinical review criteria are met for the facial feminization or facial masculinization gender affirmation surgical procedure in the Clinical Criteria section); OR
11. Otoplasty (surgical reshaping of the outer ear); OR
12. Pectoral augmentation (pectoral implants); OR
13. Removal of redundant skin including but NOT limited to panniculectomy and/or abdominoplasty when used for the treatment of gender dysphoria UNLESS the procedure is listed as medically necessary in the Clinical Criteria section and applicable criteria are met; OR

Note: Review the Plan's medical necessity guidelines included in the *Panniculectomy and Related Redundant Skin Surgery* medical policy, policy number OCA 3.722.

14. Silicone injections of the breast; OR
15. Skin resurfacing treatments including but NOT limited to chemical peels and/or dermabrasion; OR
16. Tattooing; OR
17. Vocal cord surgery (laryngoplasty, cricothyroid approximation or shortening of the vocal cords).

- E. Reimbursement for travel expenses is NOT covered by the Plan unless the Plan’s product-specific criteria are met, as specified in the Non-Emergency Transportation Services medical policy applicable for the member’s product, policy number OCA 3.191.

Variations

The Plan uses guidance from the Centers for Medicare & Medicaid Services (CMS) for medical necessity and coverage determinations for the Plan’s Senior Care Options (SCO) members and New Hampshire 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. At the time of the Plan’s most recent policy review, NCD 140.9 states CMS has determined that no NCD is appropriate at this time for gender affirmation surgery for Medicare beneficiaries with gender dysphoria. LCA A53793 includes billing, coding, and treatment guidelines for gender affirmation services for gender dysphoria. 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.

Applicable Coding

The Plan utilizes up-to-date, industry-standard Current Procedural Terminology (CPT) codes, Health Care Common Procedure Coding System (HCPCS) codes, and International Statistical Classification of Diseases and Related Health Problems, 10th revision (ICD-10) diagnosis codes in the Plan’s medical policies. Since these codes may be updated at different intervals than the medical policy review cycle, the list of applicable codes included in a policy is informational only and may not be all inclusive. Applicable codes are subject to change without prior notification and do not guarantee member coverage or provider reimbursement. Review the Plan’s reimbursement policies for Plan billing guidelines. Providers are responsible for obtaining prior authorization for the services specified in the Clinical Criteria section and Limitations and Exclusions section of a medical policy, even if an applicable code appropriately describing the service is not included in the policy’s Applicable Coding section. Providers are expected to report all services using the most up-to-date, industry-standard procedures and diagnosis codes at the time of the service.

ICD-10 Codes	<p>Description: The following primary diagnosis codes apply to gender dysphoria and require prior authorization when billed with a medically necessary procedure code covered by the Plan for gender affirmation surgeries and/or hair removal.</p> <p>Each gender affirmation surgery requires Plan prior authorization for ALL diagnosis and procedure codes, even if coding is not included in this Applicable Coding section. See the member’s applicable benefit document to determine coverage of services. Plan Medical Director review is required for each gender affirmation surgery when the member has a diagnosis of gender incongruence (without a diagnosis of gender dysphoria) for individual consideration.</p>
F64.0-F64.9	Gender identity disorders
Z87.890	History of sex reassignment surgery

CPT Codes	Description: Services considered medically necessary for the treatment of gender dysphoria if Plan clinical review criteria are met (when billed with a primary ICD-10 diagnosis code listed above). Prior authorization is required.
11960	Insertion of tissue expander(s) for other than breast, including subsequent expansion
11970	Replacement of tissue expander with permanent prosthesis
11971	Removal of tissue expander(s) without insertion of prosthesis
14040	Adjacent tissue transfer or rearrangement, forehead, cheeks, chin, mouth, neck, axillae, genitalia, hands and/or feet; defect 10 sq cm or less
14041	Adjacent tissue transfer or rearrangement, forehead, cheeks, chin, mouth, neck, axillae, genitalia, hands and/or feet; defect 10.1 sq cm to 30.0 sq cm
15769	Grafting of autologous soft tissue, other, harvested by direct excision (e.g., fat, dermis, fascia)
15771	Grafting of autologous fat harvested by liposuction technique to trunk, breasts, scalp, arms and/or legs; 50 cc or less injectate
15772	Grafting of autologous fat harvested by liposuction technique to trunk, breasts, scalp, arms and/or legs; each additional 50 cc injectate, or part thereof (List separately in addition to code for primary procedure)
15820	Blepharoplasty, lower eyelid
15821	Blepharoplasty, lower eyelid; with extensive herniated fat pad
15822	Blepharoplasty, upper eyelid
15823	Blepharoplasty, upper eyelid; with excessive skin weighting down lid
15824	Rhytidectomy; forehead Plan note: Code is NOT payable for the MassHealth and QHP products.
15825	Rhytidectomy; neck with platysmal tightening (platysmal flap, P-flap) Plan note: Code is NOT payable for the MassHealth and QHP products.
15826	Rhytidectomy; glabellar frown lines Plan note: Code is NOT payable for MassHealth and QHP products.
15828	Rhytidectomy; cheek, chin, and neck Plan note: Code is NOT payable for MassHealth and QHP products.
15876	Suction assisted lipectomy; head and neck
19301	Mastectomy partial (e.g., lumpectomy, tylectomy, quadrantectomy, segmentectomy)
19303	Mastectomy, simple, complete
19318	Breast reduction
19325	Breast augmentation with implant Plan note: Breast reconstruction for male-to-female members with persistent, well-documented gender dysphoria may include the medically necessary surgical removal of breast implants and/or the replacement of breast implants after implant explantation (including when the implant was initially inserted as a component of a gender affirmation surgery); review the criteria in the <i>Breast Reconstruction</i> medical policy, policy number OCA 3.43, rather than the criteria included in this policy for Plan prior authorization guidelines for these surgical procedures.
19350	Nipple/areola reconstruction
21120	Genioplasty; augmentation (autograft, allograft, prosthetic material)

21121	Genioplasty; sliding osteotomy, single piece
21122	Genioplasty; sliding osteotomies, 2 or more osteotomies (e.g., wedge excision or bone wedge reversal for asymmetrical chin)
21123	Genioplasty; sliding, augmentation with interpositional bone grafts (includes obtaining autografts)
21125	Augmentation, mandibular body or angle; prosthetic material
21127	Augmentation, mandibular body or angle; with bone graft, onlay or interpositional (includes obtaining autograft)
21137	Reduction forehead; contouring only
21138	Reduction forehead; contouring and application of prosthetic material or bone graft (includes obtaining autograft)
21139	Reduction forehead; contouring and setback of anterior frontal sinus wall
21141	Reconstruction midface, LeFort I; single piece, segment movement in any direction (e.g., for Long Face Syndrome), without bone graft
21142	Reconstruction midface, LeFort I; 2 pieces, segment movement in any direction, without bone graft
21143	Reconstruction midface, LeFort I; 3 or more pieces, segment movement in any direction, without bone graft
21145	Reconstruction midface, LeFort I; single piece, segment movement in any direction, requiring bone grafts (includes obtaining autografts)
21146	Reconstruction midface, LeFort I; 2 pieces, segment movement in any direction, requiring bone grafts (includes obtaining autografts) (e.g., ungrafted unilateral alveolar cleft)
21147	Reconstruction midface, LeFort I; 3 or more pieces, segment movement in any direction, requiring bone grafts (includes obtaining autografts) (e.g., ungrafted bilateral alveolar cleft or multiple osteotomies)
21150	Reconstruction midface, LeFort II; anterior intrusion (e.g., Treacher-Collins Syndrome)
21151	Reconstruction midface, LeFort II; any direction, requiring bone grafts (includes obtaining autografts)
21154	Reconstruction midface, LeFort III (extracranial), any type, requiring bone grafts (includes obtaining autografts); without LeFort I
21155	Reconstruction midface, LeFort III (extracranial), any type, requiring bone grafts (includes obtaining autografts); with LeFort I
21159	Reconstruction midface, LeFort III (extra and intracranial) with forehead advancement (e.g., mono bloc), requiring bone grafts (includes obtaining autografts); without LeFort I
21160	Reconstruction midface, LeFort III (extra and intracranial) with forehead advancement (e.g., mono bloc), requiring bone grafts (includes obtaining autografts); with LeFort I
21172	Reconstruction superior-lateral orbital rim and lower forehead, advancement or alteration, with or without grafts (includes obtaining autografts)
21175	Reconstruction, bifrontal, superior-lateral orbital rims and lower forehead, advancement or alteration (e.g., plagiocephaly, trigonocephaly, brachycephaly), with or without grafts (includes obtaining autografts)
21179	Reconstruction, entire or majority of forehead and/or supraorbital rims; with grafts (allograft or prosthetic material)
21180	Reconstruction, entire or majority of forehead and/or supraorbital rims; with autograft (includes obtaining grafts)
21188	Reconstruction midface, osteotomies (other than LeFort type) and bone grafts (includes obtaining autografts)

21196	Reconstruction of mandibular rami and/or body, sagittal split; with internal rigid fixation
21208	Osteoplasty, facial bones; augmentation (autograft, allograft, or prosthetic implant)
21209	Osteoplasty, facial bones; reduction
21210	Graft, bone; nasal, maxillary or malar areas (includes obtaining graft)
21230	Graft; rib cartilage, autogenous, to face, chin, nose or ear (includes obtaining graft)
21244	Reconstruction of mandible, extraoral, with transosteal bone plate (e.g., mandibular staple bone plate)
21245	Reconstruction of mandible or maxilla, subperiosteal implant; partial
21246	Reconstruction of mandible or maxilla, subperiosteal implant; complete
21248	Reconstruction of mandible or maxilla, endosteal implant (e.g., blade, cylinder); partial
21249	Reconstruction of mandible or maxilla, endosteal implant (e.g., blade, cylinder); complete
21270	Malar augmentation, prosthetic material
21282	Lateral canthopexy
30400	Rhinoplasty, primary; lateral and alar cartilages and/or elevation of nasal tip
30410	Rhinoplasty, primary; complete, external parts including bony pyramid, lateral and alar cartilages, and/or elevation of nasal tip
30420	Rhinoplasty, primary; including major septal repair
30430	Rhinoplasty, secondary; minor revision (small amount of nasal tip work)
30435	Rhinoplasty, secondary; intermediate revision (bony work with osteotomies)
30450	Rhinoplasty, secondary; major revision (nasal tip work and osteotomies)
30460	Rhinoplasty for nasal deformity secondary to congenital cleft lip and/or palate, including columellar lengthening; tip only
30462	Rhinoplasty for nasal deformity secondary to congenital cleft lip and/or palate, including columellar lengthening; tip, septum and osteotomies
30465	Repair of nasal vestibular stenosis (e.g., spreader grafting, lateral nasal wall reconstruction)
30520	Septoplasty or submucous resection, with or without cartilage scoring, contouring or replacement with graft
30560	Lysis intranasal synechia
31599	Unlisted procedure, trachea, bronchi
31750	Tracheoplasty; cervical Plan note: Code used for trachea shaving for male-to-female transition.
40799	Unlisted procedure, lips Plan note: Code used for lip lift.
49329	Peritoneal Flap, Unlisted
53410	Urethroplasty, 1-stage reconstruction of male anterior urethra
53415	Urethroplasty, transpubic or perineal, 1-stage, for reconstruction or repair of prostatic or membranous urethra
53420	Urethroplasty, 2-stage reconstruction or repair of prostatic or membranous urethra; first stage
53425	Urethroplasty, 2-stage reconstruction or repair of prostatic or membranous urethra; second stage
53430	Urethroplasty, reconstruction of female urethra
53450	Urethromeatoplasty, with mucosal advancement
54120	Amputation of penis; partial

54125	Amputation of penis; complete
54400	Insertion of penile prosthesis; non-inflatable (semi-rigid)
54401	Insertion of penile prosthesis; inflatable (self-contained)
54405	Insertion of multi-component inflatable penile prosthesis, including placement of pump, cylinders, and reservoir
54520	Orchiectomy, simple (including subcapsular), with or without testicular prosthesis, scrotal or inguinal approach
54660	Insertion of testicular prosthesis (separate procedure)
54690	Laparoscopy, surgical; orchiectomy
55175	Scrotoplasty; simple
55180	Scrotoplasty; complicated
55970	Intersex surgery; male to female Plan note: Series of staged procedures to remove penis and create vagina.
55980	Intersex surgery; female to male Plan note: Series of staged procedures to remove or close vagina and for penis and testicles.
56620	Vulvectomy simple; partial
56625	Vulvectomy simple; complete
56800	Plastic repair of introitus
56805	Clitoroplasty for intersex state
56810	Perineoplasty, repair of perineum, non-obstetrical (separate procedure)
57106	Vaginectomy, partial removal of vaginal wall
57107	Vaginectomy, partial removal of vaginal wall; with removal of paravaginal tissue (radical vaginectomy)
57110	Vaginectomy, complete removal of vaginal wall
57111	Vaginectomy, complete removal of vaginal wall; with removal of paravaginal tissue (radical vaginectomy)
57291	Construction of artificial vagina; without graft
57292	Construction of artificial vagina; with graft
57335	Vaginoplasty for intersex state
58150	Total abdominal hysterectomy (corpus and cervix), with or without removal of tube(s), with or without removal of ovary(s)
58180	Supracervical abdominal hysterectomy (subtotal hysterectomy) with or without removal of tube(s), with or without removal of ovary(s)
58260	Vaginal hysterectomy, for uterus 250g or less
58262	Vaginal hysterectomy, for uterus 250g or less; with removal of tube(s), and/or ovary(s)
58275	Vaginal hysterectomy, with total or partial vaginectomy
58290	Vaginal hysterectomy, for uterus greater than 250g
58291	Vaginal hysterectomy, for uterus greater than 250g; with removal of tube(s) and/or ovary(s)
58541	Laparoscopy, surgical, supracervical hysterectomy, for uterus 250g or less
58542	Laparoscopy, surgical, supracervical hysterectomy, for uterus 250g or less; with removal of tube(s) and/or ovary(s)
58543	Laparoscopy, surgical, supracervical hysterectomy, for uterus greater than 250g

58544	Laparoscopy, surgical, supracervical hysterectomy, for uterus greater than 250g; with removal of tube(s) and/or ovary(s)
58550	Laparoscopy, surgical, with vaginal hysterectomy, for uterus 250g or less
58552	Laparoscopy, surgical, with vaginal hysterectomy, for uterus 250 grams or less; with removal of tube(s) and/or ovary(s)
58553	Laparoscopy, surgical with vaginal hysterectomy, for uterus greater than 250g
58554	Laparoscopy, surgical, with vaginal hysterectomy, for uterus greater than 250 grams; with removal of tube(s) and/or ovary(s)
58570	Laparoscopy, surgical, with total hysterectomy, for uterus 250g or less
58571	Laparoscopy, surgical, with total hysterectomy, for uterus 250 g or less; with removal of tube(s) and/or ovary(s)
58572	Laparoscopy, surgical, with total hysterectomy, for uterus greater than 250g
58573	Laparoscopy, surgical, with total hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s)
58661	Laparoscopy, surgical; with lysis of adhesions (salpingolysis, ovariolysis) (separate procedure); with removal of adnexal structures (partial or total oophorectomy and/or salpingectomy)
58720	Salpingo-oophorectomy, complete or partial, unilateral or bilateral (separate procedure)
58940	Oophorectomy, partial or total, unilateral or bilateral
67900	Repair of brow ptosis (supraciliary, mid-forehead or coronal approach)

HCCPS Code	Description: Service is considered medically necessary for the treatment of gender dysphoria if Plan criteria are met and is billed with a primary ICD-10 diagnosis code listed above. Prior authorization is required.
L8600	Implantable breast prosthesis, silicone or equal

CPT Codes	Description: The following services require Plan Medical Director review and approval when used for the treatment of gender dysphoria (and billed with a primary ICD-10 diagnosis code listed above). Prior authorization is required.
19316	Mastopexy
19380	Revision of reconstructed breast (e.g., significant removal of tissue, re-advancement and/or re-inset of flaps in autologous reconstruction or significant capsular revision combined with soft tissue excision in implant-based reconstruction)
31587	Laryngoplasty, cricoid split, without graft placement
55866	Laparoscopy, surgical prostatectomy, retropubic radical, including nerve sparing, includes robotic assistance, when performed
57295	Revision (including removal) of prosthetic vaginal graft; vaginal approach
57296	Revision (including removal) of prosthetic vaginal graft; open abdominal approach
57426	Revision (including removal) of prosthetic vaginal graft, laparoscopic approach

CPT Codes	Description: Coverage guidelines based on the indication for treatment and type of service provided (when billed with a primary ICD-10 diagnosis code listed above for gender dysphoria). Prior authorization is required.
17380	Electrolysis epilation, each 30 minutes
17999	Unlisted procedure, skin, mucous membrane and subcutaneous tissue

	Plan note: Code used when billing for laser ablation for hair removal on a skin graft donor site for a genital gender affirmation surgery.
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CPT Codes	Description: Services NOT considered medically necessary for the treatment of gender dysphoria (and billed with a primary ICD-10 diagnosis code listed above). Prior authorization is required.
11950	Subcutaneous injection of filling material (e.g., collagen); 1 cc or less
11951	Subcutaneous injection of filling material (e.g., collagen); 1.1 to 5.0 cc
11952	Subcutaneous injection of filling material (e.g., collagen); 5.1 to 10 cc or less
11954	Subcutaneous injection of filling material (e.g., collagen); over 10 cc
15775	Punch graft for hair transplant; 1-15 punch grafts
15776	Punch graft for hair transplant; more than 15 punch grafts
15780	Dermabrasion; total face (e.g., for acne scarring, fine wrinkling, rhytids, general keratosis)
15781	Dermabrasion; segmental, face
15782	Dermabrasion; regional, other than face
15783	Dermabrasion; superficial, any site (e.g., tattoo removal)
15786	Abrasion; single lesion (e.g., keratosis, scar)
15787	Abrasion; each additional 4 lesions or less (List separately in addition to code for primary procedure)
15788	Chemical peel, facial; epidermal
15789	Chemical peel, facial; dermal
15792	Chemical peel, nonfacial; epidermal
15793	Chemical peel, nonfacial; dermal
15830	Excision, excessive skin and subcutaneous tissue (including lipectomy); abdomen, infraumbilical panniculectomy
15832	Excision, excessive skin and subcutaneous tissue (including lipectomy); thigh
15833	Excision, excessive skin and subcutaneous tissue (including lipectomy); leg
15834	Excision, excessive skin and subcutaneous tissue (including lipectomy); hip
15835	Excision, excessive skin and subcutaneous tissue (including lipectomy); buttock
15836	Excision, excessive skin and subcutaneous tissue (including lipectomy); arm
15837	Excision, excessive skin and subcutaneous tissue (including lipectomy); forearm or hand
15838	Excision, excessive skin and subcutaneous tissue (including lipectomy); submental fat pad
15839	Excision, excessive skin and subcutaneous tissue (including lipectomy); other area
15847	Excision, excessive skin and subcutaneous tissue (includes lipectomy), abdomen (e.g., abdominoplasty) (includes umbilical transposition and fascial plication)
15877	Suction assisted lipectomy; trunk
15878	Suction assisted lipectomy; upper extremity
15879	Suction assisted lipectomy; lower extremity

References

American Academy of Child & Adolescent Psychiatry (AACAP). Adelson SL; AACAP Committee on Quality Issues (CQI): Walter HJ, Bukstein OG, Bellonci C, Beson RS, Chisman A, Farchione TR, Hamilton J, Keable H, Kinlan J, Quiterio N, Schoettle U, Siegel M, Stock S; Medicus J. Practice Parameter on Gay, Lesbian, or Bisexual Sexual Orientation, Gender Nonconformity, and Gender Discordance in Children and Adolescents. *J Am Acad Child Adolesc Psychiatry*. 2012 Sep;51(9):957-74. doi: 10.1016/j.jaac.2012.07.004. PMID: 22917211.

American Academy of Child & Adolescent Psychiatry (AACAP). AACAP Sexual Orientation and Gender Identity Issues Committee. Conversion Therapy Policy (Lack of Evidence). 2018 Feb.

American Academy of Pediatrics (AAP). Levine DA, the Committee on Adolescence. Office-Based Care for Lesbian, Gay, Bisexual, Transgender, and Questioning Youth. *Pediatrics*. 2013 Jul;132(1):e297-313. doi:10.1542/peds.2013-1283. PMID: 23796737.

American Academy of Pediatrics (AAP). Rafferty J; Committee on Psychosocial Aspects of Child and Family Health; Committee on Adolescence; Section on Lesbian, Gay, Bisexual, and Transgender Health and Wellness. Ensuring Comprehensive Care and Support for Transgender and Gender-Diverse Children and Adolescents. *Pediatrics*. 2018 Oct;142(4). pii: e20182162. doi: 10.1542/peds.2018-2162. Epub 2018 Sep 17. PMID: 30224363.

American College of Obstetricians and Gynecologists (ACOG). Committee Opinion Number 512. Healthcare for Transgender Individuals. 2011 Dec. *Obstet Gynecol*. 2011 Dec;118(6):1454-1458. doi: 10.1097/AOG.0b013e31823ed1c1. PMID: 22105293.

American College of Obstetricians and Gynecologists (ACOG). Committee Opinion Number 685. Care for Transgender Adolescents. *Obstet Gynecol*. 2017 Jan;129(1):e11-16. doi: 10.1097/AOG.0000000000001861. PMID: 28002311.

American College of Pediatricians (ACPeds). Position Statement. Gender Dysphoria in Children. 2018 Nov.

American Medical Association (AMA). Policies on Lesbian, Gay, Bisexual, Transgender & Queer (LGBTQ) issues.

American Psychiatric Association (APA). Byne W, Bradley S, Coleman E, Eyler AE, Green R, Menvielle EJ, Meyer-Bahlburg HFL, Pleak RR, Tompkins DA; APA Task Force on Treatment of Gender Identity Disorder. Report of the APA Task Force on Treatment of Gender Identity Disorder. *Arch Sex Behav*. 2012 Aug;41(4):759-96. doi: 10.1007/s10508-012-9975-x. PMID: 22736225.

American Psychiatric Association (APA). Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition. APA. Arlington, VA. 2013:451-9.

American Psychiatric Association (APA). Parekh R. Help with Gender Dysphoria. 2016 Feb.

American Psychiatric Association (APA). Parekh R. What is Gender Dysphoria? 2016 Feb.

American Psychological Association (APA). APA Task Force on Guidelines for Psychological Practice with Transgender and Gender Nonconforming People; Dickey LM, Singh AA, Bockting WO, Chang S, Ducheny K, Edwards-Leeper L, Ehrbar RD, Fuhrmann MF, Hendricks ML, Magalhaes E. Guidelines for

Psychological Practice with Transgender and Gender Nonconfirming People. *American Psychologist*. 2015 Dec;70(9):832-64. doi: 10.1037/a0039906. PMID: 26653312.

American Psychological Association (APA). APA Task Force; Schneider MS, Bockting WO, Ehrbar RD, Lawrence AA, Rachlin K, Zucker KJ. Report of the APA Task Force on Gender Identity and Gender Variance. 2009.

American Psychological Association (APA). Bockting W. The Psychology of Transgender. 2015 Nov 19.

American Psychological Association (APA). Transgender, Gender Identity, & Gender Expression Non-Discrimination Resolution. 2008 Aug.

American Psychological Association (APA). Transgender People, Gender Identity and Gender Expression. What does transgender mean? 2014.

Beek TF, Cohen-Kettenis PT, Bouman WP, de Vries ALC, Steensma TD, Witcomb GL, Arcelus J, Richards C, De Cuypere G, Kreukels BP. Gender Incongruence of Childhood: Clinical Utility and Stakeholder Agreement with the World Health Organization's Proposed ICD-11 Criteria. *PLoS One*. 2017 Jan 12;12(1):e0168522. doi: 10.1371/journal.pone.0168522. eCollection 2017. PMID: 28081569.

Beek TF, Cohen-Kettenis PT, Kreukels BP. Gender incongruence/gender dysphoria and its classification history. *Int Rev Psychiatry*. 2016;28(1):5-12. doi: 10.3109/09540261.2015.1091293. Epub 2015 Nov 19. PMID: 26782319.

Bekeny JC, Zolper EG, Fan KL, Del Corral G. Breast augmentation for transfeminine patients: methods, complications, and outcomes. *Gland Surg*. 2020 Jun;9(3):788-796. doi: 10.21037/gs.2020.03.18. PMID: 32775269.

Bradford NJ, Rider GN, Spencer KG. Hair removal and psychological well-being in transfeminine adults: associations with gender dysphoria and gender euphoria. *J Dermatolog Treat*. 2021 Sep;32(6):635-42. doi: 10.1080/09546634.2019.1687823. Epub 2019 Nov 22. PMID: 31668100.

Bradley SJ, Zucker KJ. Gender identity disorder: a review of the past 10 years. *J Am Acad Child Adolesc Psychiatry*. *J Am Acad Child Adolesc Psychiatry*. 1997 Jul;36(7):872-80. doi: 10.1097/00004583-199707000-00008. PMID: 9204664.

Centers for Disease Control and Prevention (CDC). Lesbian, Gay, Bisexual, and Transgender Health Resources.

Center of Excellence for Transgender Health. Deutsch MB. Guidelines for the Primary and Gender-Affirming Care of Transgender and Gender Nonbinary People. 2016 Jun 17.

Centers for Medicare & Medicaid Services (CMS). Local Coverage Article (LCA) A53793. Billing and Coding: Gender Reassignment Services for Gender Dysphoria. 2015 Oct 1. Revision Effective Date 2021 Jan 1.

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

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

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

Centers for Medicare & Medicaid Services (CMS). National Coverage Determination (NCD) 140.9. Gender Dysphoria and Gender Reassignment Surgery. 2017 Apr 4.

Chung KC. Operative Techniques in Plastic Surgery. First Edition. 2018. Lippincott Williams & Wilkins. ISBN: 978-1-49-633950-8.

Commonwealth of Massachusetts. Executive Office of Health and Human Services (EOHHS). MassHealth Guidelines for Medical Necessity Determination for Gender Affirming Surgery. MNG-GAS-0921. 2021 Sep 1.

Commonwealth of Massachusetts. Executive Office of Health and Human Services (EOHHS). MassHealth Guidelines for Medical Necessity Determination for Hair Removal. MNG-HR-0921. 2021 Sep 1.

Commonwealth of Massachusetts. Executive Office of Health and Human Services (EOHHS). MassHealth Provider Bulletins.

Commonwealth of Massachusetts. Executive Office of Health and Human Services (EOHHS). MassHealth Provider Manuals.

Commonwealth of Massachusetts. Executive Office of Health and Human Services (EOHHS). MassHealth Transmittal Letters.

Commonwealth of Massachusetts. Massachusetts Law about Emancipation of Minors.

Dittrich R, Binder H, Cupisti S, Hoffmann I, Beckmann MW, Mueller A. Endocrine Treatment of Male-to-Female Transsexuals Using Gonadotropin-Releasing Hormone Agonist. *Exp Clin Endocrinol Diabetes*. 2005 Dec;113(10):586-92. doi: 10.1055/s-2005-865900. PMID: 16320157.

Dubov A, Fraenkel L. Facial Feminization Surgery: The Ethics of Gatekeeping in Transgender Health. *Amer J Bioethics*. 2018 Dec;18(12):3-9. doi: 10.1080/15265161.2018.1531159.

Endocrine Society. Corrigendum for "Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline." *J Clin Endocrinol Metab.* 2018 Feb 1;103(2):699. doi.org/10.1210/jc.2017-02548. PMID: 29244095.

Endocrine Society. Hembree WC, Cohen-Kettenis PT, Gooren L, Hannema SE, Meyer WJ, Murad MH, Rosenthal SM, Safer JD, Tangpricha V, T'Sjoen GG. Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline. *J Clin Endocrinol Metab.* 2017 Nov 1;102(11):3869-3903. doi: 10.1210/jc.2017-01658. Erratum in: *J Clin Endocrinol Metab.* 2018 Feb 1;103(2):699. *J Clin Endocrinol Metab.* 2018 Jul 1;103(7):2758-59. PMID: 28945902.

Feldman J, Deutsch MB. Primary care of transgender individuals. UpToDate. Updated 2019 Oct 18.

Fernandez JD, Tannock LR. Metabolic Effects of Hormone Therapy in Transgender Patients. *Endocr Pract.* 2016 Apr;22(4):383-8. doi: 10.4158/EP15950.OR. Epub 2015 Nov 17. PMID: 26574790.

Ferrando CU, Zhao LC, Nikolavsky D. Transgender surgery: Female to male. UpToDate. Updated 2022 Apr.

Hadj-Moussa M, Agarwal S, Ohl DA, Kuzon WM Jr. Masculinizing Genital Gender Confirmation Surgery. *Sex Med Rev.* 2019 Jan;7(1):141-155. doi: 10.1016/j.sxmr.2018.06.004. Epub 2018 Aug 16. PMID: 30122339.

Hancock AB, Krissing J, Owen K. Voice perceptions and quality of life of transgender people. *J Voice.* 2011 Sep;25(5):553-8. doi: 10.1016/j.jvoice.2010.07.013. Epub 2010 Nov 4. *J Voice.* 2011. PMID: 21051199.
Hayes. Health Technology Assessment. Sex Reassignment Surgery for the Treatment of Gender Dysphoria. Dallas, TX: Hayes; 2017 Aug 1. Annual Review 2021 Jul 27.

Horbach SE, Bouman MB, Smit JM, Özer M, Buncamper ME, Mullender MG. Outcome of Vaginoplasty in Male-to-Female Transgenders: A Systematic Review of Surgical Techniques. *J Sex Med.* 2015 Jun;12(6):1499-512. doi: 10.1111/jsm.12868. Epub 2015 Mar 26. PMID: 25817066.

The Joint Commission. Advancing Effective Communication, Cultural Competence, and Patient- and Family-Centered Care for the Lesbian, Gay, Bisexual, and Transgender (LGBT) Community. A Field Guide. 2014 Apr 3.

Kailas M, Lu HMS, Rothman EF, Safer JD. Prevalence and Types of Gender-Affirming Surgery Among a Sample of Transgender Endocrinology Patients Prior to State Expansion of Insurance Coverage. *Endocr Pract.* 2017 Jul;23(7):780-786. doi: 10.4158/EP161727.OR. Epub 2017 Apr 27. PMID: 28448757.

Lee J, Lee S. Facial Contouring Surgery-Mandibuloplasty: Genioplasty and Mandible Angle Correction. *Plast Reconstr Surg Glob Open.* 2017 Oct;5(10):e1296. doi:10.1097/GOX.0000000000001296. PMID: 29184722.

Mañero I, Labanca T, Triviño JM. Aesthetic Refinements after Radial Free Flap Phalloplasty: Optimizing the Donor Site and the Phallus. *Plast Reconstr Surg Glob Open*. 2017 Dec 28;5(12):e1611. doi: 10.1097/GOX.0000000000001611. eCollection 2017 Dec. PMID: 29632786.

Marks DH, Hagigeorges D, Manatis-Lornell AJ, Dommasch E, Senna MM. J Cosmet Dermatol. Excess hair, hair removal methods, and barriers to care in gender minority patients: A survey study. *J Cosmet Dermatol*. 2020 Jun;19(6):1494-1498. doi: 10.1111/jocd.13164. Epub 2019 Sep 25. 2020. PMID: 31553137.

Morrison SD, Capitán-Cañadas F, Sánchez-García A, Ludwig DC, Massie JP, Nolan IT, Swanson M, Rodríguez-Conesa M, Friedrich JB, Cederna PS, Bellinga RJ, Simon D, Capitán L, Satterwhite T. Prospective Quality-of-Life Outcomes after Facial Feminization Surgery: An International Multicenter Study. *Plastic and Reconstructive Surgery*: 2020 June;145(6):1499-509. doi: 10.1097/PRS.0000000000006837. PMID: 32459779.

National Center for Transgender Equality. *Transgender Rights Toolkit: A Legal Guide for Trans People and Their Allies (Transgender Parents)*, Lambda. 2015 Jan 14.

National LGBT Health Education Center. A Program of the Fenway Institute. *Collecting Sexual Orientation and Gender Identity Data*.

National LGBT Health Education Center. A Program of the Fenway Institute. *Sexual Orientation and Gender Identity Questions: Information for Patients*.

National LGBT Health Education Center. A Program of the Fenway Institute. *Understanding the Health Needs of LGBT People*.

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

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

New Hampshire Legal Aid. *Legal Information, Referrals, and Pro Se Assistance. Emancipation*.

Nuttbrock L, Hwahng S, Bockting W, Rosenblum A, Mason M, Macri M, Becker J. Psychiatric impact of gender-related abuse across the life course of male-to-female transgender persons. *J Sex Res*. 2010 Jan;47(1):12-23. doi: 10.1080/00224490903062258. PMID: 19568976.

Olson-Kennedy J, Forcier M. Management of transgender and gender-diverse children and adolescents. *UpToDate*. 2022 Apr.

Reed GM, Drescher J, Krueger RB, Atalla E, Cochran SD, First MB, Cohen-Kettenis PT, Arango-de Montis I, Parish SJ, Cottler S, Briken P, Saxena S. Disorders related to sexuality and gender identity in the ICD-11: revising the ICD-10 classification based on current scientific evidence, best clinical practices, and human rights considerations. *World Psychiatry*. 2016 Oct;15(3):205-221. doi: 10.1002/wps.20354. Erratum in: *World Psychiatry*. 2017 Jun;16(2):220. PMID: 27717275.

Salgado CJ, AlQattan H, Nugent A, Gerth D, Kassira W, McGee CS, Wo L. Feminizing the Face: Combination of Frontal Bone Reduction and Reduction Rhinoplasty. *Case Rep Surg*. 2018 Jul 2;2018:1947807. doi: 10.1155/2018/1947807. eCollection 2018. PMID: 30057846.

Salgado CJ, Nugent AG, Satterwaite T, Carruthers KH, Joumblat NR. Gender Reassignment: Feminization and Masculinization of the Neck. *Clin Plast Surg*. 2018 Oct;45(4):635-45. doi: 10.1016/j.cps.2018.06.006. Epub 2018 Aug 10. PMID: 30268248.

Schwarz K, Fontanari AMV, Schneider MA, Borba Soll BM, da Silva DC, Spritzer PM, Kazumi Yamaguti Dorfman ME, Kuhl G, Costa AB, Cielo CA, Villas Bôas AP, Lobato MIR. Laryngeal surgical treatment in transgender women: A systematic review and meta-analysis. *Laryngoscope* 2017 Nov;127(11):2596-603. Epub 2017 Jul 3 doi: 10.1002/lary.26692. PMID: 28671273.

Seal LJ, Franklin S, Richards C, Shishkareva A, Sinclair C, Barrett J. Predictive Markers for Mammoplasty and a Comparison of Side Effect Profiles in Transwomen Taking Various Hormonal Regimens. *J Clin Endocrinol Metab*. 2012 Dec;97(12):4422-8. doi: 10.1210/jc.2012-2030. Epub 2012 Oct 9. PMID: 23055547.

Society for Adolescent Health and Medicine (SAHM). Reitman DS, Austin B, Belkind U, Chaffee T, Hoffman ND, Moore E, Morris R, Olson J, Ryan C. Recommendations for promoting the health and well-being of lesbian, gay, bisexual, and transgender adolescents: a position paper of the SAHM. *J Adolesc Health*. 2013 Apr;52(4):506-10. doi: 10.1016/j.jadohealth.2013.01.015. PMID: 23521897.

Soll BM, Robles-García R, Brandelli-Costa A, Mori D, Mueller A, Vaitses-Fontanari AM, Cardoso-da-Silva D, Schwarz K, Abel-Schneider M, Saadeh A, Lobato MI. Gender incongruence: a comparative study using ICD-10 and DSM-5 diagnostic criteria. *Braz J Psychiatry*. 2017 Oct 2;40(2):174-80. doi: 10.1590/1516-4446-2016-2224. Print Apr-June 2018. PMID: 28977069.

Spack NP, Edwards-Leeper L, Feldman HA, Leibowitz S, Mandel F, Diamond DA, Vance SR. Children and adolescents with gender identity disorder referred to a pediatric medical center. *Pediatrics*. 2012 Mar;129(3):418-25. doi: 10.1542/peds.2011-0907. Epub 2012 Feb 20. PMID: 22351896.

Tangpricha V, den Heijer M. Oestrogen and anti-androgen therapy for transgender women. *Lancet Diabetes Endocrinol*. 2017 Apr;5(4):291-300. doi: 10.1016/S2213-8587(16)30319-9. Epub 2016 Dec 2. PMID: 27916515.

Tangpricha V, Safer JD. Transgender men: Evaluation and management. *UpToDate*. 2022 Apr.

Tangpricha V, Safer JD. Transgender women: Evaluation and management. *UpToDate*. 2022 Apr.

Thomas JP, Macmillan C. Feminization laryngoplasty: assessment of surgical pitch elevation. *Eur Arch Otorhinolaryngol*. 2013 Sep;270(10):2695-700. doi: 10.1007/s00405-013-2511-3. Epub 2013 Apr 30. PMID: 23632870.

Unger CA. Hormone therapy for transgender patients. *Transl Androl Urol*. 2016 Dec;5(6):877–84. doi: 10.21037/tau.2016.09.04. PMID: 28078219.

Vance SR, Ehrensaft D, Rosenthal SM. Psychological and Medical Care of Gender Nonconforming Youth. *Pediatrics*. 2014 Dec;134(6):1184–92. doi: 10.1542/peds.2014-0772. Epub 2014 Nov 17. PMID: 25404716.

Wierckx K, Gooren L, T'sjoen G. Clinical Review: Breast Development in Trans Women Receiving Cross-Sex Hormones. *J Sex Med*. 2014 May;11(5):1240–7. doi: 10.1111/jsm.12487. Epub 2014 Mar 12. PMID: 24618412.

The World Professional Association for Transgender Health (WPATH). Position Statement on Medical Necessity of Treatment, Sex Reassignment, and Insurance Coverage in the U.S.A. 2016 Dec 21.

The World Professional Association for Transgender Health (WPATH). Standards of Care for the Health of Transsexual, Transgender, and Gender-Nonconforming People. 7th Version.

Zhang WR, Garrett GL, Arron ST, Garcia MM. Laser hair removal for genital gender affirming surgery. *Transl Androl Urol*. 2016 Jun;5(3):381–7. doi: 10.21037/tau.2016.03.27. PMID: 27298787.

Zucker KJ. The DSM diagnostic criteria for gender identity disorder in children. *Arch Sex Behav*. 2010 Apr;39(2):477–98. doi: 10.1007/s10508-009-9540-4. PMID: 19842027.

Next Review Date

04/01/23

Authorizing Entity

MPCTAC

Appendix

Appendix: Policy History

Disclaimer Information:

Plan refers to Boston Medical Center Health Plan, Inc. which operates under the trade name WellSense Health Plan. 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.

Appendix: Policy History

Original Approval Date	Original Effective Date* and Version Number	Policy Owner	Original Policy Approved by
Regulatory Approval: N/A Internal Approval: 03/18/15: Medical Policy, Criteria, and Technology Assessment Committee (MPCTAC) 04/08/15: Quality Improvement Committee (QIC)	07/01/15 Version 1	Medical Policy Manager as Chair of MPCTAC	MPCTAC and QIC

*Effective Date for QHP Commercial Product: 01/01/12

*Effective Date for NH Medicaid Product: 07/01/17

*Effective Date for Senior Care Options Product: 01/01/16

*Effective Date for NH Medicare Advantage HMO Product: 01/01/22

Policy title *Gender Reassignment Surgery* from 01/01/16 to 05/31/18. Policy title changed to *Gender Affirmation Surgeries* from 06/01/18 to 12/31/21. Policy title changed to *Gender Affirmation Services* as 01/01/22.

Policy Revisions History			
Review Date	Summary of Revisions	Revision Effective Date and Version Number	Approved by
09/01/15	Review for effective date 01/01/16. Updated criteria in the Medical Policy Statement and Limitations sections. Removed requirement for 18 months of treatment for gender dysphoria. Added guidelines on external review for services denied by the Plan when members are enrolled in Qualified Health Plans, ConnectorCare, and/or Employer Choice Direct products. Update the Summary, Clinical Background Information, Definitions, and References sections and the list of applicable products.	01/01/16 Version 2	09/16/15: MPCTAC 10/14/15: QIC
11/25/15	Review for effective date 01/01/16. Updated language in the Applicable Coding section.	01/01/16 Version 3	11/25/15: MPCTAC (electronic vote) 12/09/15: QIC
04/01/16	Review for effective date 08/01/16. Revised the Definitions, Clinical Background Information, References, and Reference to Applicable Laws and Regulations sections. Removed ICD9 codes, added CPT code 17380 as applicable code, and added a Plan not in the Applicable Coding section.	08/01/16 Version 4	04/20/16: MPCTAC 05/23/16: QIC

Policy Revisions History			
	Revised criteria in the Medical Policy Statement and Limitations sections.		
07/05/16	Review for effective date 10/01/16. Revised criteria in the Medical Policy Statement and Limitations section. Revised the applicable code list and added Plan notes to codes. Updated Summary and References sections.	10/01/16 Version 5	07/05/16: MPCTAC (electronic vote) 07/13/16: QIC
09/01/16	Review for effective date 10/01/16. Added reference to the CMS Decision Memo for Gender Dysphoria and Gender Reassignment Surgery (CAG-00446N) effective 08/30/16 in the Clinical Background Information and References sections. CMS industry-wide update with no change to criteria and/or the applicable code list for Plan members (including members enrolled in a SCO product).	10/01/16 Version 6	Not applicable because industry-wide update of CMS guidelines with no change to criteria and/or the applicable code list
09/28/16	Review for effective date 11/01/16. Administrative changes made to clarify language related to gender. Revised Definitions section.	11/01/16 Version 7	09/30/16: MPCTAC (electronic vote) 10/12/16: QIC
06/01/17	Review for effective date 07/01/17. Added the NH Medicaid product as applicable new product for this policy as of 07/01/17 with the necessary administrative changes made to the Medical Policy Statement, Summary, Definitions, Clinical Background Information, References, and Reference to Applicable Laws and Regulations sections. NH Medicaid criteria added in product-specific Medical Policy Statement section and product-specific Limitations section.	07/01/17 Version 8	06/21/17: MPCTAC
05/01/17	Review for effective date 08/01/17. Criteria for MA products were revised in the Medical Policy Statement section in 05/17 (with adequate provider notification); new criteria are effective 08/01/17 for MA products. Administrative changes made to the Summary, Definitions, and References sections.	08/01/17 Version 9	05/17/17: MPCTAC
06/01/17	Review for effective date 08/01/17. Administrative change made to combine criteria in the Medical Policy Statement sections and in the Limitations sections for all MA products and NH Medicaid product (since all criteria are consistent among Plan products as of 08/01/17). Administrative change made to the Limitations section to be consistent with the Applicable Coding section.	08/01/17 Version 10	06/21/17: MPCTAC
03/01/18	Review for effective date 06/01/18. Revised policy title. Administrative changes made to the Policy	06/01/18 Version 11	03/21/18: MPCTAC

Policy Revisions History			
	Summary, Description of Item or Service, Definitions, Clinical Background Information, References, and Other Applicable Policies sections. Criteria revised in the Medical Policy Statement and Limitations sections. Coding updated and Plan notes revised in the Applicable Coding section.		
05/01/19	Review for effective date 08/01/19. Administrative changes made to the Policy Summary, Description of Item or Service, Clinical Background Information, References, Other Applicable Policies, and Reference to Applicable Laws and Regulations sections. Criteria updated in the Medical Policy Statement and Limitations sections. Coding updated in the Applicable Coding section.	08/01/19 Version 12	05/15/19: MPCTAC
12/01/19	Review for effective date 01/01/20. Industry-wide update to coding (as a code deletion) included in the Applicable Coding section.	01/01/20 Version 13	Not applicable because industry-wide code changes
04/01/20	Review for effective date 08/01/20. Administrative changes made to the Definitions, References, and Reference to Applicable Laws and Regulations sections. Criteria revised in the Medical Policy Statement and Limitations sections. Coding updated in the Applicable Coding section.	08/01/20 Version 14	04/15/20: MPCTAC
12/01/20	Review for effective date 01/01/21. Industry-wide updates to coding in the Applicable Coding section. Administrative changes made to the Limitations and Other Applicable Policies sections.	01/01/21 Version 15	Not applicable because industry-wide code changes; 12/16/20: MPCTAC review
01/01/21	Review for effective date 02/01/21. Revised criteria in the Medical Policy Statement section.	02/01/21 Version 16	01/22/21: MPCTAC (electronic vote)
04/01/21	Review for effective date 07/01/21. Revised criteria in the Medical Policy Statement and Limitations sections. Administrative changes made to the Policy Summary, Description of Item or Service, Definitions, Clinical Background Information, and References sections. Updated the applicable code list.	07/01/21 Version 17	04/21/21: MPCTAC
10/01/21	Review for effective date 01/01/22. Adopted new medical policy template; removed administrative sections, Medical Policy Statement section renamed Clinical Criteria section, and Limitations section renamed Limitations and Exclusions section. Administrative changes made	01/01/22 Version 18 Version 18 replaced with version 19 as of	10/20/21: MPCTAC

Policy Revisions History			
	to the Policy Summary and References sections. Criteria revised in the Clinical Criteria and Limitations and Exclusions sections. Coding revised in the Applicable Coding section.	01/01/22 and version 18 not implemented	
11/01/21	Review for effective date 01/01/22. Administrative changes made to the Policy Summary, Clinical Criteria, Limitations, and Applicable Coding sections. Criteria and coding for voice therapy used for the treatment of gender dysphoria moved from the Plan's speech therapy medical policies to this policy with Plan notification (rather than prior authorization) required when applicable coding guidelines followed. Revised policy title.	01/01/22 Version 19 Version 19 replaced version 18 as of 01/01/22 and all revisions in version 18 adopted	11/30/21: MPCTAC (electronic vote)
05/01/22	Review for effective date 08/01/22. Administrative changes made to the Policy Summary, Clinical Criteria, Limitations, References and Applicable Coding sections. Added CPT codes 49329 and 53450. Non-material changes made to Clinical Criteria and Limitations and Exclusions sections.	08/01/22 Version 20	05/11/22: MPCTAC (electronic vote)
08/01/22	Review for effective date 11/01/22. Administrative changes made to Policy Summary, Clinical Criteria, and Applicable Coding sections. Removed coding and criteria for voice therapy when used for the treatment of gender dysphoria; prior authorization requests for voice therapy must be submitted to AIM Specialty Health as of 11/01/22.	11/01/22 Version 21 Version 21 NOT implemented; Version 20 effective 08/01/22 to 11/30/22	08/26/22: MPCTAC (electronic vote)
09/01/22	Review for effective date 12/01/22. The effective date of AIM Specialty Health's management of outpatient rehabilitation services changed from 11/01/22 to 12/01/22. Administrative changes made to Policy Summary, Clinical Criteria, and Applicable Coding sections. Removed coding and criteria for voice therapy when used for the treatment of gender dysphoria; prior authorization requests for voice therapy must be submitted to AIM for dates of service on or after 12/01/22.	12/01/22 Version 22	09/23/22: MPCTAC (electronic vote)



Medical Policy – Policy with InterQual Criteria Retired and AIM Criteria Adopted as of 12/01/22

Occupational Therapy in the Outpatient Setting

Policy Number: OCA 3.543

Version Number: 26

Policy Retired Date: 12/01/22

Impacted Products

- All Products**
- NH Medicaid
- NH Medicare Advantage
- MA MassHealth ACO
- MA MassHealth MCO
- MA Qualified Health Plans/Employer Choice Direct
- MA Senior Care Options

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

Policy Summary

The Plan considers outpatient occupational therapy (OT) medically necessary, including habilitative services and/or rehabilitative services, when AIM clinical appropriateness guidelines are met for an adult or pediatric member or are required EPSDT services for a member age 20 or younger on the date of service. Prior authorization from AIM Specialty Health is required for outpatient OT after the initial evaluation. OT must be provided within the scope of practice of the treating professional and/or paraprofessional and follow all applicable state licensing and supervisory requirements.

Clinical Criteria

No medical policy criteria.

Limitations and Exclusions

None.

Variations

The Plan uses guidance from the Centers for Medicare & Medicaid Services (CMS) for medical necessity and coverage determinations for NH Medicare Advantage members, including but not limited to national coverage determinations (NCDs), local coverage determinations (LCDs), local coverage articles (LCAs), and documentation included in Medicare manuals. At the time of the Plan's

most recent policy review, LCD L34427 includes medically necessary indications for occupational therapy. Verify CMS guidelines in effect on the date of the prior authorization request. When there is no guidance from CMS on the requested service, Plan-adopted clinical review criteria will be used to determine the medical necessity of the service.

Applicable Coding

The Plan utilizes up-to-date, industry-standard Current Procedural Terminology (CPT) codes, Health Care Common Procedure Coding System (HCPCS) codes, and International Statistical Classification of Diseases and Related Health Problems, 10th revision (ICD-10) diagnosis codes in the Plan's medical policies. The list of applicable codes included in this policy is informational only and may not be all inclusive. Applicable codes are subject to change without prior notification and do not guarantee member coverage or provider reimbursement. Review the Plan's reimbursement policies for Plan billing guidelines. Providers are responsible for obtaining prior authorization from AIM for occupational therapy, even if an applicable code appropriately describing the service is not included in this policy's Applicable Coding section. Providers are expected to report all services using the most up-to-date, industry-standard procedures and diagnosis codes at the time of the service.

CPT Codes	Code Descriptions
97010	Application of a modality to 1 or more areas; hot or cold packs
97012	Application of a modality to 1 or more areas; traction, mechanical
97014	Application of a modality to 1 or more areas; electrical stimulation (unattended)
97016	Application of a modality to 1 or more areas; vasopneumatic devices
97018	Application of a modality to 1 or more areas; paraffin bath
97022	Application of a modality to 1 or more areas; whirlpool
97024	Application of a modality to 1 or more areas; diathermy (e.g., microwave)
97026	Application of a modality to 1 or more areas; infrared
97028	Application of a modality to 1 or more areas; ultraviolet
97032	Application of a modality to 1 or more areas; electrical stimulation (manual), each 15 minutes
97033	Application of a modality to 1 or more areas; iontophoresis, each 15 minutes
97034	Application of a modality to 1 or more areas; contrast baths, each 15 minutes
97035	Application of a modality to 1 or more areas; ultrasound, each 15 minutes
97036	Application of a modality to 1 or more areas; Hubbard tank, each 15 minutes
97110	Therapeutic procedure, 1 or more areas, each 15 minutes; therapeutic exercises to develop strength and endurance, range of motion and flexibility
97112	Therapeutic procedure, 1 or more areas, each 15 minutes; neuromuscular reeducation of movement, balance, coordination, kinesthetic sense, posture, and/or proprioception for sitting and/or standing activities
97113	Therapeutic procedure, 1 or more areas, each 15 minutes; aquatic therapy with therapeutic exercises
97116	Therapeutic procedure, 1 or more areas, each 15 minutes; gait training (includes stair climbing)
97124	Therapeutic procedure, 1 or more areas, each 15 minutes; massage, including effleurage, petrissage and/or tapotement (stroking, compression, percussion)

97129	Therapeutic interventions that focus on cognitive function (e.g., attention, memory, reasoning, executive function, problem solving, and/or pragmatic functioning) and compensatory strategies to manage the performance of an activity (e.g., managing time or schedules, initiating, organizing, and sequencing tasks), direct (one-on-one) patient contact; initial 15 minutes
97130	Therapeutic interventions that focus on cognitive function (e.g., attention, memory, reasoning, executive function, problem solving, and/or pragmatic functioning) and compensatory strategies to manage the performance of an activity (e.g., managing time or schedules, initiating, organizing, and sequencing tasks), direct (one-on-one) patient contact; each additional 15 minutes (List separately in addition to code for primary procedure)
97140	Manual therapy techniques (e.g., mobilization/manipulation, manual lymphatic drainage, manual traction), 1 or more regions, each 15 minutes
97150	Therapeutic procedure(s), group (2 or more individuals)
97168	Re-evaluation of occupational therapy established plan of care, requiring these components: An assessment of changes in patient functional or medical status with revised plan of care; an update to the initial occupational profile to reflect changes in condition or environment that affect future interventions and/or goals; and a revised plan of care. A formal reevaluation is performed when there is a documented change in functional status or a significant change to the plan of care is required. Typically, 30 minutes are spent face-to-face with the patient and/or family.
97530	Therapeutic activities, direct (one-on-one) patient contact (use of dynamic activities to improve functional performance), each 15 minutes
97533	Sensory integrative techniques to enhance sensory processing and promote adaptive responses to environmental demands, direct (one-on-one) patient contact, each 15 minutes
97535	Self-care/home management training (e.g., activities of daily living [ADL] and compensatory training, meal preparation, safety procedures, and instructions in use of assistive technology devices/adaptive equipment) direct one-on-one contact, each 15 minutes
97537	Community/work reintegration training (e.g., shopping, transportation, money management, avocational activities and/or work environment/modification analysis, work task analysis, use of assistive technology device/adaptive equipment), direct one-on-one contact, each 15 minutes by provider, each 15 minutes
97545	Work hardening/conditioning; initial 2 hours
97546	Work hardening/conditioning; each additional hour (List separately in addition to code for primary procedure)
97750	Physical performance test or measurement (e.g., musculoskeletal, functional capacity), with written report, each 15 minutes
97755	Assistive technology assessment (e.g., to restore, augment or compensate for existing function, optimize functional tasks and/or maximize environmental accessibility), direct one-on-one contact, with written report, each 15 minutes
97760	Orthotic(s) management and training (including assessment and fitting when not otherwise reported), upper extremity(ies), lower extremity(ies) and/or trunk, initial orthotic(s) encounter, each 15 minutes
97761	Prosthetic training, upper and/or lower extremity(ies), initial prosthetic(s) encounter each 15 minutes

97763	Orthotic(s)/prosthetic(s) management and/or training, upper extremity(ies), lower extremity(ies), and/or trunk, subsequent orthotic(s)/prosthetic(s) encounter, each 15 minutes
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References

American Academy of Pediatrics (AAP). 2020 Recommendations for Preventive Pediatric Health Care. Committee on Practice and Ambulatory Medicine and Bright Futures Periodicity Schedule Workgroup. Pediatrics. 2020 Mar;145(3):e20200013. doi: 10.1542/peds.2020-0013.

American Occupational Therapy Association (AOTA). Guidelines for Supervision, Roles, and Responsibilities During the Delivery of Occupational Therapy Services. Am J Occup Ther. 2020 Nov-Dec;74(3):7413410020. doi: 10.5014/ajot.2020.74S3004.

American Occupational Therapy Association (AOTA). Occupational Therapy Using a Sensory Integration-Based Approach with Adult Populations.

American Occupational Therapy Association (AOTA). Practice Guidelines.

American Occupational Therapy Association (AOTA). Scope of Practice: Questions & Answers.

Centers for Medicare & Medicaid Services (CMS). Early and Periodic Screening, Diagnostic and Treatment (EPSDT). Medicaid.gov.

Centers for Medicare & Medicaid Services (CMS). EPSDT – A Guide for States: Coverage in the Medicaid Benefit for Children and Adolescents. 2014 Jun.

Centers for Medicare & Medicaid Services (CMS). Local Coverage Article (LCA). Billing and Coding: Outpatient Physical and Occupational Therapy Services A56566. 2019 Dec 19. Revision Effective Date 2020 Oct 1. National Government Services, Inc.

Centers for Medicare & Medicaid Services (CMS). Local Coverage Determination (LCD). Outpatient Physical and Occupational Therapy Services L33631. 2015 Oct 1. Revision Effective Date 2020 Jan 1. National Government Services, Inc.

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

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

Hayes. Health Technology Assessment. Cognitive Rehabilitation Therapy for Traumatic Brain Injury (TBI). Dallas, TX: Hayes; 2017 Sep 26. Annual Review 2021 Feb 8.

Hayes. Health Technology Assessment. Occupational Therapy for Attention-Deficit/Hyperactivity Disorder (ADHD). Dallas, TX: Hayes; 2017 Mar 16. Annual Review 2021 May 12.

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

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

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

New Hampshire Medicaid. Therapies. Physical, Occupational, Speech. Provider Manual. Volume II. 2017 Dec 1.

New Hampshire Office of Professional Licensure and Certification. Office of Licensed Allied Health Professionals. Laws and Administrative Rules Governing Licensed Allied Health Professionals.

Next Review Date

Not applicable

Retired Date

12/01/22

Authorizing Entity

MPCTAC

Appendix

Appendix: Policy History

Disclaimer Information:

Plan refers to Boston Medical Center Health Plan, Inc. which operates under the trade name WellSense Health Plan. 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.

Appendix: Policy History

Original Approval Date	Original Effective Date* and Version	Policy Owner	Original Policy Approved by
Regulatory Approval: N/A Internal Approval: 09/16/05	10/16/05 Version 1	Director of Medical Policy as Chair of Medical Policy, Criteria, and Technology Assessment Committee (MPCTAC)	Quality and Clinical Management Committee (Q&CMC)

*Effective Date for NH Medicaid Product: 01/01/13

*Effective Date for NH Medicare Advantage HMO Product: 01/01/22

Policy retired and service managed by AIM Specialty Health as of 12/01/22

Policy Revisions History			
Review Date	Summary of Revisions	Revision Effective Date and Version Number	Approved by
02/07/06	Added definitions for modality and visit. Defined coverage for visits, evaluations and units billed.	Version 2	02/07/06: Q&CMC
07/06/06	Removed verbiage regarding reimbursement for evaluation and modality services.	Version 3	07/06/06: Q&CMC
03/27/07	Policy archived.	Not applicable	Not specified
10/14/08	Policy reviewed and clinical criteria updated, effective date of revised policy is 12/16/08.	12/16/08 Version 4	11/10/08: MPCTAC 12/16/08: Quality Improvement Committee (QIC)
09/22/09	No changes.	Version 5	09/22/09: MPCTAC 10/28/09: QIC
10/01/10	Updated template and references, no changes to criteria	Version 6	10/20/10: MPCTAC 11/22/10: QIC
10/01/11	Added Commercial benefit limitations, updated references and coding.	Version 7	10/19/11: MPCTAC 11/29/11: QIC
08/01/12	Off cycle review for the NH Medicaid product, revised Summary statement, reformatted Medical Policy Statement, revised Applicable Coding introductory paragraph, updated code list, revised limitations, deleted references to contracts and EOCs that are not applicable.	Version 8	08/13/12: MPCTAC 09/06/12: QIC
11/01/12	Review for effective date 03/01/13. Updated references and revised Summary section.	03/01/13 Version 9	11/21/12: MPCTAC 12/20/12: QIC

	Moved medical criteria from Summary section to Clinical Guidelines Statement section. Moved services not considered medically necessary from the Clinical Guidelines Statement section to the Limitations section. Updated applicable coding list and references. Removed duplicate text in the Clinical Background Information section. Referenced Plan reimbursement policy 4.609 for occupational therapy reimbursement guidelines. Updated language in introductory paragraph of Applicable Coding section. Removed "Guideline" from title.		
08/14/13 and 08/15/13	Off cycle review for the NH Medicaid product and merged policy format. Incorporate policy revisions dated 11/01/12 (as specified above) for the NH Medicaid product; these policy revisions were approved by MPCTAC on 11/21/12 and QIC on 12/20/12 for applicable Plan products.	Version 10	08/14/13: MPCTAC (electronic vote) 08/15/13: QIC
11/01/13, 12/01/13, 01/01/14, and 02/01/14	Review for effective date 05/01/14. Updated code definitions, introductory paragraph in Applicable Coding section, and the applicable code lists for the MA products and the NH Medicaid product. Updated references. Removed prior authorization waiver for the first 32 units of OT for the NH Medicaid product. Add criterion in the Medical Policy Statement sections for the MA products and NH Medicaid product requiring an updated physician prescription and supporting clinical documentation after 20 OT visits per treatment episode. Revised Limitations.	05/01/14 Version 11	02/11/14: MPCTAC 02/18/14: QIC
09/08/14	For NH Medicaid product only, waived prior authorization of first eight (8) 15-minute treatment units per member per servicing provider per calendar year.	10/01/14 Version 11 Addendum A	09/17/14: MPCTAC 09/30/14: QIC
11/04/14 and 11/19/14	Review for effective date 01/11/15. Summary and Medical Policy Statement sections updated with guidelines specified in version 11, addendum A. Policy renumbered OCA 3.543 to include occupational therapy in the outpatient setting for NH Medicaid members age 21 or older. Summary, Limitations, and References sections updated. (OT services formerly included in policy number OCA 3.53 for all adult and pediatric members.) Change in review calendar.	01/11/15 Version 12	11/06/14: MPCTAC (electronic vote) 11/11/14: QIC (electronic vote) 11/19/14: MPCTAC 12/10/14: QIC

12/03/15	Review for effective date 01/01/16. Updated template and Summary section. Administrative changes made to the Medical Policy Statement section and Limitations sections without changing criteria. Revised language in the Applicable Coding section. Added definitions.	01/01/16 Version 13	12/03/15: MPCTAC (electronic vote) 12/09/15: QIC
12/01/16	Review for effective date 02/01/17. Industry-wide revisions of applicable codes. Clarified existing criteria in the Medical Policy Statement section.	02/01/17 Version 14	12/21/16: MPCTAC 01/11/17: QIC
12/01/17	Review for effective 01/01/18. Industry-wide updates to codes included in the Applicable Coding section. Annual review of policy with administrative changes made to the Definitions and Reference sections.	01/01/18 Version 15	12/20/17: MPCTAC
02/01/18	Review for effective date 03/01/18. Administrative changes made to the Policy Summary and Limitations sections.	03/01/18 Version 16	02/21/18: MPCTAC
11/01/18	Review for effective date 12/01/18. Administrative changes made to the Policy Summary, Medical Policy Statement, Limitations, Definitions, Applicable Coding, References, Other Applicable Policies, and Reference to Applicable Laws and Regulations sections.	12/01/18 Version 17	11/21/18: MPCTAC
03/01/19	Review for effective date 07/01/19. Criteria and prior authorization guidelines revised in the Medical Policy Statement section. Administrative changes made to the Limitations and Reference to Applicable Laws and Regulations sections.	07/01/19 Version 18	03/20/19: MPCTAC
12/01/19	Review for effective date 01/01/20. Industry-wide updates to codes included in the Applicable Coding section.	01/01/20 Version 19	Not applicable because industry-wide code changes
11/01/19	Review for effective date 02/01/20. Revised criteria in the Medical Policy Statement and Limitations sections. Administrative changes made to the References Reference to Applicable Laws and Regulations sections.	02/01/20 Version 20 Renumbered to version 20 to implement industry-wide code updates effective 01/01/20 in version 19	11/20/19: MPCTAC

12/01/19	Review for effective 02/01/20. Industry-wide updates to codes effective 01/01/20 included in the Applicable Coding section of the policy version 20 effective 02/01/20.	02/01/20 Version 21	Not applicable because industry-wide code changes
12/01/19	Review for effective date 03/01/20. Revised in the Medical Policy Statement section the definition of a servicing OT provider for the prior authorization waiver.	03/01/20 Version 22	12/18/19: MPCTAC
11/01/20	Review for effective date 12/01/20. Updated the References section. Administrative change made to the Applicable Coding section.	12/01/20 Version 23	11/18/20: MPCTAC
11/01/21	Review for effective date 12/01/21. Adopted new medical policy template; removed administrative sections, Medical Policy Statement section renamed Clinical Criteria section, and Limitations section renamed Limitations and Exclusions section. Added NH Medicare Advantage HMO as an applicable product effective 01/01/22. Administrative changes made to the Policy Summary and References sections. Criteria revised in the Clinical Criteria and Limitations and Exclusions sections. Medical policy criteria retired and InterQual criteria will continue to be used to determine medical necessity.	12/01/21 Version 24	11/17/21: MPCTAC
08/01/22	Review for effective date 11/01/22. Administrative changes made to the Policy Summary and Applicable Coding sections. InterQual medical necessity criteria and medical policy guidelines in the Clinical Criteria and Limitations and Exclusions sections retired on 11/01/22. AIM criteria adopted for outpatient OT on 11/01/22. Plan prior authorization waivers removed after 10/31/22. AIM prior authorization is required for outpatient OT after the initial evaluation as of 11/01/22, even when applicable codes are not listed in this Plan policy.	11/01/22 Version 25 Version 25 NOT implemented; Version 24 effective 12/01/21 to 11/30/22	08/26/22: MPCTAC (electronic vote)
09/01/22	Review for policy retired date 12/01/22. The effective date of AIM Specialty Health's management of outpatient rehabilitation services changed from 11/01/22 to 12/01/22. Administrative changes made to the Policy Summary and Applicable Coding sections. InterQual medical necessity criteria and medical policy guidelines in the Clinical Criteria and Limitations and Exclusions sections retired on	12/01/22 Version 26	09/23/22: MPCTAC (electronic vote)

	<p>12/01/22. AIM criteria adopted for outpatient OT for dates of service on or after 12/01/22. Plan prior authorization waivers removed after 11/30/22. AIM prior authorization is required for outpatient OT after the initial evaluation as of 12/01/22, even when applicable codes are not listed in this Plan policy.</p>		
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Medical Policy – Policy Retired and AIM Criteria Adopted as of 12/01/22

Pelvic Floor Stimulation for the Treatment of Incontinence and/or Overactive Bladder

Policy Number: OCA 3.561

Version Number: 26

Policy Retired Date: 12/01/22

Impacted Products

- All Products**
- NH Medicaid
- NH Medicare Advantage
- MA MassHealth ACO
- MA MassHealth MCO
- MA Qualified Health Plans/Employer Choice Direct
- MA Senior Care Options

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

Policy Summary

AIM Specialty Health’s clinical appropriateness criteria will be used to determine if non-implantable pelvic floor stimulation is considered medically necessary for the treatment of overactive bladder, urinary incontinence and/or fecal incontinence; this includes pelvic floor electrical stimulation (PFES) and/or pelvic floor magnetic stimulation. Prior authorization from AIM is required.

Clinical Criteria

No medical policy criteria.

Limitations and Exclusions

None.

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 NH 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. At the time of the Plan’s most recent policy review, CMS NCD 230.8 8 includes medically necessary indications for the use of a non-implantable pelvic floor electrical stimulator. No

CMS clinical criteria were identified for pelvic floor magnetic stimulation for urinary incontinence or fecal incontinence or the use of pelvic floor electrical stimulation (PFES) for fecal incontinence. 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.

Applicable Coding

The Plan utilizes up-to-date, industry-standard Current Procedural Terminology (CPT) codes, Health Care Common Procedure Coding System (HCPCS) codes, and International Statistical Classification of Diseases and Related Health Problems, 10th revision (ICD-10) diagnosis codes in the Plan's medical policies. The list of applicable codes included in a policy is informational only and may not be all inclusive. Applicable codes are subject to change without prior notification and do not guarantee member coverage or provider reimbursement. Review the Plan's reimbursement policies for Plan billing guidelines. Providers are responsible for obtaining prior authorization for this services, even if an applicable code appropriately describing the service is not included in this policy's Applicable Coding section. Providers are expected to report all services using the most up-to-date, industry-standard procedures and diagnosis codes at the time of the service.

CPT/HCPCS Codes	Code Descriptions
97014	Application of a modality to 1 or more areas; electrical stimulation (unattended) Note: Supervised. The application of a modality that does not require direct, one-on-one, patient contact by the provider. Plan note: Code is NOT payable for the Senior Care Options and NH Medicare Advantage HMO products.
97032	Application of a modality to 1 or more areas; electrical stimulation (manual), each 15 minutes
E0740	Non-implanted pelvic floor electrical stimulator, complete system
G0283	Electrical stimulation (unattended), to one or more areas for indication(s) other than wound care, as part of a therapy plan of care

References

Abdelbary AM, El-Dessoukey AA, Massoud AM, Moussa AS, Zayed AS, Elsheikh MG, Ghoneima W, Abdella R, Yousef M. Combined Vaginal Pelvic Floor Electrical Stimulation (PFS) and Local Vaginal Estrogen for Treatment of Overactive Bladder (OAB) in Perimenopausal Females. Randomized Controlled Trial (RCT). *Urology*. 2015 Sep;86(3):482-6. doi: 10.1016/j.urology.2015.06.007. Epub 2015 Jun 30. PMID: 26135813.

Abrams P, Andersson KE, Birder L, Brubaker L, Cardozo L, Chapple C, Cottenden A, Davila W, de Ridder D, Dmochowski R, Drake M, Dubeau C, Fry C, Hanno P, Smith JH, Herschorn S, Hosker G, Kelleher C, Koelbl H, Khoury S, Madoff R, Milsom I, Moore K, Newman D, Nitti V, Norton C, Nygaard I, Payne C, Smith A, Staskin D, Tekgul S, Thuroff J, Tubaro A, Vodusek D, Wein A, Wyndaele JJ; Members of Committees; Fourth International Consultation on Incontinence. Fourth international

consultation on incontinence recommendations of the International Scientific Committee: Evaluation and treatment of urinary incontinence, pelvic organ prolapse, and fecal incontinence. *Neurourol Urodyn*. 2010;29(1):213-40. doi: 10.1002/nau.20870. PMID: 20025020.

American College of Gastroenterology (ACG). Guidelines.

The American College of Obstetricians and Gynecologists (ACOG). Clinical Guidance.

The American College of Obstetricians and Gynecologists (ACOG). ACOG Practice Bulletin No. 155. Urinary Incontinence in Women. 2015. Reaffirmed 2018. *Obstet Gynecol*. 2015 Nov;126(5):e66-81. doi: 10.1097/AOG.0000000000001148. PMID: 26488524.

The American College of Obstetricians and Gynecologists (ACOG). ACOG Practice Bulletin No. 210. Fecal Incontinence. *Obstet Gynecol*. 2019 Apr;133(4):837-39. doi: 10.1097/AOG.0000000000003188. PMID: 30913191.

The American College of Obstetricians and Gynecologists (ACOG), American Urogynecologic Society (AUGS). ACOG Committee on Gynecologic Practice. Evaluation of Uncomplicated Stress Urinary Incontinence in Women Before Surgical Treatment. Committee Opinion Number 603. 2014 Jun. Reaffirmed 2017.

The American College of Obstetricians and Gynecologists (ACOG). Urinary Incontinence. Patient Resources.

American College of Physicians (ACP). Clinical Guidelines & Recommendations.

American College of Physicians (ACP). Gaseem A, Dallas P, Forcica MA, Starkey M, Denberg TD, Shekelle P. Clinical Guidelines Committee of the ACP. Nonsurgical management of urinary incontinence in women: a clinical practice guideline from the ACP. *Ann Intern Med*. 2014 Sep 16;161(6):429-40. doi: 10.7326/M13-2410. PMID: 25222388.

American Gastroenterological Association (AGA). Bharucha AE, Pemberton JH, Locke GR. American Gastroenterological Association technical review on constipation. *Gastroenterology*. 2013 Jan;144(1):218-38. doi: 10.1053/j.gastro.2012.10.028. PMID: 23261065.

American Gastroenterological Association (AGA). Clinical Guidelines.

American Society of Colon and Rectal Surgeons (ASCRS). Paquette IM, Varma MG, Kaiser AM, Steele SR, Rafferty JF. The ASCRS' Clinical Practice Guideline for the Treatment of Fecal Incontinence. *Dis Colon Rectum*. 2015 Jul;58(7):623-36. doi: 10.1097/DCR.0000000000000397. PMID: 26200676.

American Society of Colon and Rectal Surgeons (ASCRS). Paquette IM, Varma M, Ternent C, Melton-Meaux G, Rafferty J, Feingold D, Steele SR. The ASCRS' Clinical Practice Guideline for the Evaluation

and Management of Constipation. *Dis Colon Rectum* 2016; 59: 479–92. doi: 10.1097/DCR.0000000000000599. PMID: 27145304.

American Urogynecologic Society (AUGS). Clinical Guidance Documents.

American Urological Association (AUA). Guidelines & Policies.

American Urological Association (AUA) and Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction (SUFU). Lightner DJ, Gomelsky A, Souter L, Vasavada SP. Diagnosis and Treatment of Overactive Bladder (Non-Neurogenic) in Adults: AUA/SUFU Guideline Amendment 2019. *J Urol*. 2019 Sep;202(3):558–63. doi: 10.1097/JU.0000000000000309. Epub 2019 Aug 8. PMID: 31039103.

Anderson CA, Omar MI, Campbell SE, Hunter KF, Cody JD, Glazener CM. Conservative management for postprostatectomy urinary incontinence. *Cochrane Database Syst Rev*. 2015 Jan 20;1:CD001843. doi: 10.1002/14651858.CD001843.pub5. PMID: 25602133.

Aydin S, Arioglu Aydin Ç, Batmaz G, Dansuk R. Effect of vaginal electrical stimulation on female sexual functions: a randomized study. *J Sex Med*. 2015 Feb;12(2):463–9. doi: 10.1111/jsm.12788. Epub 2014 Dec 3. PMID: 25470078.

Berghmans B, Hendriks E, Bernards A, de Bie R, Omar MI. Electrical stimulation with non-implanted electrodes for urinary incontinence in men. *Cochrane Database Syst Rev*. 2013 Jun 6;(6):CD001202. doi: 10.1002/14651858.CD001202.pub5. PMID: 23740763.

Canadian Urological Association. Bettez M, Tu LM, Carlson K, Corcos J, Gajewski J, Jolivet M, Bailly G. 2012 Update: Guidelines for Adult Urinary Incontinence Collaborative Consensus Document for the Canadian Urological Association. *Can Urol Assoc J*. 2012 Oct;6(5):354–63. doi: 10.5489/cuaj.12248. PMID: 23093627.

Centers for Medicare & Medicaid Services (CMS). Local Coverage Determination (LCD) Posterior Tibial Nerve Stimulation for Voiding Dysfunction L33396. National Government Services, Inc. 2015 Oct 1. Revision Effective Date 2019 Oct 24.

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

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

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

Centers for Medicare & Medicaid Services (CMS). National Coverage Determination (NCD) for Biofeedback Therapy for the Treatment of Urinary Incontinence 30.1.1. Effective 2001 Jul 1.

Centers for Medicare & Medicaid Services (CMS). National Coverage Determination (NCD) for Bladder Stimulators (Pacemakers) 230.16. 1996 Oct 7.

Centers for Medicare & Medicaid Services (CMS). National Coverage Determination (NCD) for Non-Implantable Pelvic Floor Electrical Stimulator 230.8. Effective 2006 Jun 19.

Centers for Medicare & Medicaid Services (CMS). National Coverage Determination (NCD) for Sacral Nerve Stimulation for Urinary Incontinence (230.18). Effective 2002 Jan 1.

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

Chêne G, Mansoor A, Jacquetin B, Mellier G, Douvier S, Sergent F, Aubard Y, Seffert P. Female urinary incontinence and intravaginal electrical stimulation: an observational prospective study. *Eur J Obstet Gynecol Reprod Biol.* 2013 Sep;170(1):275–80. doi: 10.1016/j.ejogrb.2013.06.011. Epub 2013 Jul 5. PMID: 23830965.

Chughtai B, Lee R, Sandhu J, Te A, Kaplan S. Conservative Treatment for Postprostatectomy Incontinence. *Rev Urol.* 2013;15(2):61–6. PMID: 24082844.

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

Commonwealth of Massachusetts. MassHealth Provider Bulletins.

Commonwealth of Massachusetts. MassHealth Provider Manuals.

Commonwealth of Massachusetts. MassHealth Transmittal Letters.

Correia, GN, Pereira, VS, Hirakawa, HS, Driusso, P. Effects of surface and intravaginal electrical stimulation in the treatment of women with stress urinary incontinence: randomized controlled trial. *Eur J Obstet Gynecol Reprod Biol.* 2014 Feb;173:113–8. doi: 10.1016/j.ejogrb.2013.11.023. Epub 2013 Dec 4. PMID: 24382548.

Dumoulin C, Hay-Smith EJC, Mac Habée-Séguin G. Pelvic floor muscle training versus no treatment, or inactive control treatments, for urinary incontinence in women. *Cochrane Database Syst Rev.* 2014 May 14;(5):CD005654. doi: 10.1002/14651858.CD005654.pub3. PMID: 24823491.

European Association of Urology (EAU). Blok B, Castro-Diaz D, Del Popolo G, Groen J, Hamid R, Karsenty G, Kessler TM, Pannek J, Ecclestone H, Musco S, Padilla-Fernández B, Sartori A, 't Hoen LA. EAU Guidelines. *Neuro-Urology.* 2020 Mar. Edn. presented at the EAU Annual Congress Amsterdam 2022. ISBN 978-94-92671-16-5.

European Association of Urology (EAU). Gacci M, Sakalis VI, Karavitakis M, Cornu JN, Gratzke C, Hermann TRW, Kyriazis I, Malde S, Mamoulakis C, Rieken M, Schouten N, Smith EJ, Speakman MJ,

Tikkinen KAO, Gravas S. EAU Guidelines on Male Urinary Incontinence. *Rev Incon*. 2022 Oct 1;82(4):387–98. doi: 10.1016/j.euro.2022.05.0122.

European Association of Urology (EAU). Nambiar AK, Arlandis S, Bo K, Cobussen-Boekhorst H, Costantini E, de Heide M, Farag F, Groen J, Karavitakis M, Lapitan MC, Manso M, Monagas Arteaga S, Nic An Riogh A, O'Connor E, Omar MI, Peyronnet B, Phe V, Sakalis VI, Sihra N, Tzelves L, van Poelgeest-Pomfret ML, van den Bos TWL, van der Vaart H, Harding CK. EAU Guidelines on the Diagnosis and Management of Female Non-Neurogenic Lower Urinary Tract Symptoms. Part 1: Diagnostics, Overactive Bladder, Stress Urinary Incontinence, and Mixed Urinary Incontinence. *European Urology*. 2022 Jul;82(1):60–70. doi: 10.1016/j.eururo.2022.01.045.

European Association of Urology (EAU). Nambiar AK, Bosch R, Cruz F, Lemack GE, Thiruchelvam N, Tubaro A, Bedretidnova DA, Ambühl D, Farag F, Lombardo R, Schneider MP, Burkhard FC. EAU Guidelines on Assessment and Nonsurgical Management of Urinary Incontinence. *Eur Urol*. 2018 Apr;73(4):596–609. doi: 10.1016/j.eururo.2017.12.031. Epub 2018 Feb 3. PMID: 29398262.

European Society for Pediatric Gastroenterology, Hepatology, and Nutrition (ESPGHAN), North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition (NASPGHAN). Tabbers MM, DiLorenzo C, Berger MY, Faure BC, Langendam MW, Nurko S, Staiano A, Vandenplas Y, Benninga MA. Clinical Guideline. Evaluation and Treatment of Functional Constipation in Infants and Children: Evidence-Based Recommendations from ESPGHAN and NASPGHAN. *J Pediatr Gastroenterol Nutr*. 2014 Feb;58(2):258–74. doi: 10.1097/MPG.0000000000000266. PMID: 24345831.

Faiena I, Patel N, Parihar JS, Calabrese M, Tunuguntla H. Conservative Management of Urinary Incontinence in Women. *Rev Urol*. 2015;17(3):129–39. PMID: 26543427.

Fernández-Cuadros ME, Nieto-Blasco J, Geanini-Yagüez A, Ciprián-Nieto D, Padilla-Fernández B, Lorenzo-Gómez MF. Male Urinary Incontinence: Associated Risk Factors and Electromyography Biofeedback Results in Quality of Life. *Am J Mens Health*. 2016 Nov;10(6):NP127–35. Epub 2015 Jun 30. doi: 10.1177/1557988315590653. PMID: 26130728.

Fritel X, Fauconnier A, Bader G, Cosson M, Debodinance P, Deffieux X, Denys P, Dompeyre P, Faltin D, Fatton B, Haab F, Hermieux JF, Kerdraon J, Mares P, Mellier G, Michel-Laaengh N, Nadeau C, Robain G, de Tayrac R, Jacquelin B; French College of Gynecologists and Obstetricians. Diagnosis and management of adult female stress urinary incontinence: guidelines for clinical practice from the French College of Gynecologists and Obstetricians. *Eur J Obstet Gynecol Reprod Biol*. 2010 Jul;151(1):14–9. doi: 10.1016/j.ejogrb.2010.02.041. Epub 2010 Mar 16. PMID: 20236751.

Fürst MC, Mendonça RR, Rodrigues AO, Matos LL, Pompeo AC, Bezerra CA. Long-term results of a clinical trial comparing isolated vaginal stimulation with combined treatment for women with stress incontinence. *Einstein (Sao Paulo)*. 2014 Apr;12(2):168–74. doi: 10.1590/s1679-45082014ao2866. PMID: 25003921.

Ghaderi F, Oskouei AE. Physiotherapy for Women with Stress Urinary Incontinence: A Review Article. *J Phys Ther Sci*. 2014 Sep;26(9):1493–9. doi: 10.1589/jpts.26.1493. Epub 2014 Sep 17. PMID: 25276044.

Gilling PJ, Wilson LC, Westenberg AM, McAllister WJ, Kennett KM, Frampton CM, Bell DF, Wrigley PM, Fraundorfer MR. A double-blind randomized controlled trial of electromagnetic stimulation of the pelvic floor vs. sham therapy in the treatment of women with stress urinary incontinence. *BJU Int*. 2009 May;103(10):1386–90. Epub 2009 Jan 14. doi: 10.1111/j.1464-410X.2008.08329.x. Epub 2009 Jan 14. PMID: 19154474.

Goode PS, Burgio KL, Johnson TM 2nd, Clay OJ, Roth DL, Markland AD, Burkhardt JH, Issa MM, Lloyd LK. Behavioral therapy with or without biofeedback and pelvic floor electrical stimulation for persistent postprostatectomy incontinence: a randomized controlled trial. *JAMA*. 2011 Jan 12;305(2):151–9. doi: 10.1001/jama.2010.1972. PMID: 21224456.

Gungor Ugurlucan F, Onal M, Aslan E, Ayyildiz Erkan H, Kizilkaya Beji N, Yalcin O. Comparison of the effects of electrical stimulation and posterior tibial nerve stimulation in the treatment of overactive bladder syndrome. *Gynecol Obstet Invest*. 2013;75(1):46–52. doi: 10.1159/000343756. Epub 2012 Nov 16. PMID: 23171636.

Guralnick ML, Kelly H, Engelke H, Koduri S, O'Connor RC. InTone: a novel pelvic floor rehabilitation device for urinary incontinence. *Int Urogynecol J*. 2015 Jan;26(1):99–106. doi: 10.1007/s00192-014-2476-9. Epub 2014 Jul 30. PMID: 25074260.

Hersh L, Salzman B. Clinical management of urinary incontinence in women. *Am Fam Physician*. 2013 May;87(9):634–40. Erratum in: *Am Fam Physician*. 2013 May 1;87(9):634–40. PMID: 23668526.

International Urogynecological Association (IUGA), International Continence Society (ICS). Haylen BT, de Ridder D, Freeman RM, Swift SE, Berghmans B, Lee J, Monga A, Petri E, Rizk DE, Sand PK, Schaer GN. An IUGA/ICS joint report on the terminology for female pelvic floor dysfunction. *Int Urogynecol J*. 2010 Jan;21(1):5–26. doi: 10.1007/s00192-009-0976-9. Epub 2009 Nov 25. PMID: 19937315.

Joussain C, Denys P. Electrical management of neurogenic lower urinary tract disorders. *Ann Phys Rehabil Med*. 2015 Sep;58(4):245–250. doi: 10.1016/j.rehab.2015.07.005. Epub 2015 Aug 25. PMID: 26321622.

Lim R, Liong ML, Leong WS, Khan NA, Yuen KH. Magnetic stimulation for stress urinary incontinence: study protocol for a randomized controlled trial. *Trials*. 2015 Jun 21;16:279. doi: 10.1186/s13063-015-0803-1. PMID: 26093910.

Maher RM, Caulfield B. A novel externally applied neuromuscular stimulator for the treatment of stress urinary incontinence in women—a pilot study. *Neuromodulation*. 2013 Nov-Dec;16(6):590–4; discussion 594. doi: 10.1111/j.1525-1403.2012.00509.x. Epub 2012 Sep 25. PMID: 23009698.

Mariotti G, Salciccia S, Innocenzi M, Gentilucci A, Fasulo A, Gentile V, Sciarra A. Recovery of Urinary Continence After Radical Prostatectomy Using Early vs. Late Pelvic Floor Electrical Stimulation and Biofeedback-associated Treatment. *Urology*. 2015 Jul;86(1):115-20. doi: 10.1016/j.urology.2015.02.064. PMID: 26142594.

Maternik M, Krzeminska K, Zurowska A. The management of childhood urinary incontinence. *Pediatr Nephrol*. 2015 Jan;30(1):41-50. doi: 10.1007/s00467-014-2791-x. Epub 2014 Mar 11. PMID: 24615564.

Morin F, Akhavizadegan H, Kavanagh A, Moore K. Dysfunctional voiding: Challenges of disease transition from childhood to adulthood. *Can Urol Assoc J*. 2018 Apr;12(4 Suppl 1):S42-7. doi: 10.5489/cuaj.5230. PMID: 29681274.

Moroni RM, Magnani PS, Haddad JM, Castro Rde A, Brito LG. Conservative Treatment of Stress Urinary Incontinence: A Systematic Review with Meta-analysis of Randomized Controlled Trials. *Rev Bras Ginecol Obstet*. 2016 Feb;38(2):97-111. doi: 10.1055/s-0035-1571252. Epub 2016 Jan 29. PMID: 26883864.

National Institute for Health and Care Excellence (NICE). Lower urinary tract symptoms in men: management. Clinical Guideline CG97. 2010 May 23. Last Updated 2015 Jun 3.

National Institute for Health and Care Excellence (NICE). Urinary incontinence in neurological disease: assessment and management. Clinical Guideline CG148. 2012 Aug 8.

National Institute for Health and Care Excellence (NICE). Urinary incontinence and pelvic organ prolapse in women: management. NICE Guideline NG123. 2019 Apr 2. Last Updated 2019 Jun 24.

Nepple KG, Cooper CS. Management of bladder dysfunction in children. *UpToDate*. 2021 Jun 22.

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

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

Santos JD, Lopes RI, Koyle MA. Bladder and bowel dysfunction in children: An update on the diagnosis and treatment of a common, but underdiagnosed pediatric problem. *Can Urol Assoc J*. 2017 Jan-Feb;11(1-2Suppl1):S64-72. doi: 10.5489/cuaj.4411. PMID: 28265323.

Schreiner L, Santos TG, Souza AB, Nygaard CC, Silva Filho IG. Electrical stimulation for urinary incontinence in women: a systematic review. *Int Braz J Urol*. 2013 Jul-Aug;39(4):454-64. doi: 10.1590/S1677-5538.IBJU.2013.04.02. PMID: 24054395.

Terlikowski R, Dobrzycka B, Kinalski M, Kuryliszyn-Moskal A, Terlikowski SJ. Transvaginal electrical stimulation with surface-EMG biofeedback in managing stress urinary incontinence in women of premenopausal age: a double-blind, placebo-controlled, randomized clinical trial. *Int Urogynecol J*. 2013 Oct;24(10):1631-8. doi: 10.1007/s00192-013-2071-5. Epub 2013 Feb 27. PMID: 23443345.

Tugtepe H, Thomas DT, Ergun R, Kalyoncu A, Kaynak A, Kastarli C, Dagli TE. The effectiveness of transcutaneous electrical neural stimulation therapy in patients with urinary incontinence resistant to initial medical treatment or biofeedback. *J Pediatr Urol*. 2015 Jun;11(3):137.e1-5. doi: 10.1016/j.jpuro.2014.10.016. Epub 2015 Mar 12. PMID: 25824876.

U.S. Food and Drug Administration (FDA). Clinical Investigations of Devices Indicated for the Treatment of Urinary Incontinence – Guidance for Industry and FDA Staff. 2011 Mar 8.

U. S. Food and Drug Administration (FDA). Medical Devices. 510(k) Clearances.

U. S. Food and Drug Administration (FDA). Medical Devices. Device Registration and Listing.

Wald A. Diagnosis and Management of Fecal Incontinence. *Curr Gastroenterol Rep*. 2018 Mar 26;20(3):9. doi: 10.1007/s11894-018-0614-0. PMID: 29582182.

Wallis MC, Davies EA, Thalib L, Griffiths S. Pelvic static magnetic stimulation to control urinary incontinence in older women: a randomized controlled trial. *Clin Med Res*. 2012 Feb;10(1):7-14. doi: 10.3121/cmr.2011.1008. Epub 2011 Aug 4. PMID: 21817123.

Yamanishi T, Mizuno T, Watanabe M, Honda M, Yoshida K. Randomized, placebo controlled study of electrical stimulation with pelvic floor muscle training for severe urinary incontinence after radical prostatectomy. *J Urol*. 2010 Nov;184(5):2007-12. doi: 10.1016/j.juro.2010.06.103. Epub 2010 Sep 20. PMID: 20850831.

Zhu YP, Yao XD, Zhang SL, Dai B, Ye DW. Pelvic floor electrical stimulation for postprostatectomy urinary incontinence: a meta-analysis. *Urology* 2012 Mar;79(3):552-5. doi: 10.1016/j.urology.2011.10.005. PMID: 22386394.

Next Review Date

Not applicable

Retired Date

12/01/22

Authorizing Entity

MPCTAC

Appendix

Appendix: Policy History

Disclaimer Information:

Plan refers to Boston Medical Center Health Plan, Inc. which operates under the trade name WellSense Health Plan. 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.

Appendix: Policy History

Original Approval Date	Original Effective Date and Version	Policy Owner	Original Policy Approved by
Regulatory Approval: N/A Internal Approval: 10/03/06	12/03/06 Version 1	Director of Medical Policy as Chair of Medical Policy, Criteria, and Technology Assessment Committee (MPCTAC)	Quality and Clinical Management Committee (Q&CMC)

*Effective Date for QHP Commercial Product: 01/01/12

*Effective Date for New Hampshire Medicaid Product: 01/01/13

*Effective Date for Senior Care Options Product: 01/01/16

*Effective Date for New Hampshire Medicare Advantage HMO Product: 01/01/22

This policy replaced *Pelvic Floor/Sacral Nerve Stimulation for Urinary Incontinence* medical policy, policy number OCA 3.56, as of 05/01/13 for criteria related to pelvic floor stimulation for the treatment of incontinence. The policy was titled *Non-Implantable Pelvic Floor Electrical Stimulation for Urinary Incontinence* from 05/01/13 to 01/31/16. The policy title was *Pelvic Floor Stimulation for the Treatment of Incontinence* from 02/01/16 to 02/28/19. Effective 03/01/19, the policy title has been changed to *Pelvic Floor Stimulation for the Treatment of Incontinence and/or Overactive Bladder*. Policy retired and service managed by AIM Specialty Health as of 12/01/22.

Policy Revisions History			
Review Date	Summary of Revisions	Revision Effective Date and Version Number	Approved by
09/11/07	Updated template, added coding, approved by MPCTAC.	Version 2	09/11/07: MPCTAC 09/25/07: Utilization Management Committee (UMC) 10/15/07: Quality Improvement Committee (QIC)
09/09/08	No changes.	Version 3	09/09/08: MPCTAC 09/30/08: UMC 10/22/08: QIC
09/22/09	Updated references, no changes to criteria.	Version 4	09/22/09: MPCTAC 10/28/09: QIC
09/01/10	Updated template and references, no changes to criteria.	Version 5	10/20/10: MPCTAC 11/22/10: QIC
10/01/11	Updated limitations to include that sacral nerve stimulation for the treatment of fecal incontinence and posterior tibial nerve stimulation for the treatment of symptoms	Version 6	10/19/11: MPCTAC 11/29/11: QIC

Pelvic Floor Stimulation for the Treatment of Incontinence and/or Overactive Bladder

	associated with overactive bladder are considered experimental and investigational. Updated references and coding.		
07/20/12	Off cycle review for Well Sense Health Plan: Updated title, revised Summary statement, added posterior tibial stimulation to Description of Item or Service, reformatted Medical Policy Statement, updated Definitions, revised language in Applicable Coding section, updated code list.	Version 7	08/13/12: MPCTAC 09/13/12: QIC
12/01/12	Separated pelvic floor electrical stimulation, sacral nerve stimulation, and posterior tibial nerve stimulation into three separate policies; policy formerly titled <i>Pelvic Floor/Sacral Nerve Stimulation for Urinary Incontinence</i> (formerly policy number OCA: 3.65). Revised title and re-numbered policy. Updated language in Summary, Description of Item or Service, Definitions, Applicable Coding, and Clinical Background Information sections. Referenced <i>Posterior Tibial Nerve Stimulation, Sacral Nerve Stimulation (Including Peripheral Nerve Stimulation Test and Two-Stage Tined Lead Procedure) for Incontinence and Urinary Conditions, Biofeedback for Urinary Incontinence, Experimental and Investigation Treatment, and Medically Necessary</i> policies. Reformatted and added criteria in Medical Policy Statement section, updated and added references, and added limitations. Revised applicable code list.	Version 8	12/19/12: MPCTAC 01/31/13: QIC
12/01/13	Review for effective date 02/01/14. Updated references.	02/01/14 Version 9	12/18/13: MPCTAC 01/21/14: QIC
12/01/14	Review for effective date 05/01/15. Updated references. Added ICD9/ICD10 diagnosis codes for urinary incontinence to the Applicable Coding section. Updated introductory paragraph in the Applicable Coding section.	05/01/15 Version 10	12/17/14: MPCTAC 01/14/15: QIC
10/01/15	Review for effective date 12/01/15. Updated template with list of applicable products and corresponding notes.	12/01/15 Version 11	10/21/15: MPCTAC 11/11/15: QIC
10/21/15	Review for effective date 02/01/16. Updated Summary, Description of Item or Service, Definitions, Clinical Background Information, and References sections. Updated criteria in the Medical Policy Statement and Limitations sections. Revised the title of the policy.	02/01/16 Version 12	10/21/15: MPCTAC 11/11/15: QIC

11/25/15	Review for effective date 02/01/16. Revised language in the Applicable Coding section. Plan note added to HCPCS code G0283.	02/01/16 Version 13	11/25/15: MPCTAC (electronic vote) 12/09/15: QIC
10/01/16	Review for effective date 12/01/16. Updated Summary, Definitions, Clinical Background Information, References, and References to Applicable Laws and Regulations sections. Administrative changes made to the Medical Policy Statement and Limitations sections; no change to criteria. Removed ICD-9 diagnosis codes and Plan notes added to applicable codes.	12/01/16 Version 14	10/19/16: MPCTAC 11/09/16: QIC
12/01/16	Industry-wide change to applicable code description (HCPCS code E0740) effective 01/01/17.	01/01/17 Version 15	Not applicable because industry-wide change in code description.
10/01/17	Review for effective date 01/01/18. Revised criteria in the Medical Policy Statement and Limitations sections (designating service experimental and investigational for the treatment of urinary incontinence and/or fecal incontinence). Administrative changes made to the Policy Summary, Description of Item or Service, Definitions, Clinical Background Information, References, and Other Applicable Policies sections. Plan notes updated in the Applicable Coding section and revised code list; diagnosis codes added for fecal incontinence and applicable procedure codes considered experimental and investigational for specified indications.	01/01/18 Version 16	10/18/17: MPCTAC
10/01/18	Review for effective date 11/01/18. Administrative changes made to the Policy Summary, References, and Other Applicable Policies sections. Administrative change made to the Applicable Coding section (using ICD-10 diagnosis code range rather than individual diagnosis codes without changing the code list).	11/01/18 Version 17	10/17/18: MPCTAC
12/01/18	Review for effective date 03/01/19. Revised the policy title. Administrative changes made to the Policy Summary, Description of Item or Service, Definitions, and References sections. Criteria updated in the Medical Policy Statement and Limitations sections. Revised the diagnosis codes and Plan notes in the Applicable Coding section.	03/01/19 Version 18	12/19/18: MPCTAC
07/01/19	Review for effective date 08/01/19. Updated the Plan notes in the Applicable Coding section.	08/01/19 Version 19	07/17/19: MPCTAC

09/01/19	Review for effective date 10/01/19. Administrative changes made to the Other Applicable Policies, References, and Reference to Applicable Laws and Regulations sections.	10/01/19 Version 20	09/18/19: MPCTAC
09/01/20	Review for effective date 10/01/20. Administrative changes made to the References and Other Applicable Policies sections.	10/01/20 Version 21	09/16/20: MPCTAC
05/01/21	Review for effective date 06/01/21. Plan note revised in the Applicable Coding section. Administrative changes made to the Policy Summary, Description of Item or Service, Medical Policy Statement, and Limitations sections.	06/01/21 Version 22	05/19/21: MPCTAC
10/01/21	Review for effective date 11/01/21. Adopted new medical policy template; removed administrative sections and the Medical Policy Statement section renamed the Clinical Criteria section. Added NH Medicare Advantage HMO as an applicable product effective 01/01/22. Administrative changes made to the Policy Summary, Clinical Criteria, Applicable Coding, and References sections. Removed the Limitations section.	11/01/21 Version 23	10/20/21: MPCTAC
08/01/22	Review for effective date 09/01/22. Administrative changes made to the Clinical Criteria and References sections.	09/01/22 Version 24	08/26/22: MPCTAC (electronic vote)
08/01/22	Review for policy retired date 11/01/22. Administrative changes made to the Policy Summary and Applicable Coding sections. Medical policy criteria revised in the Clinical Criteria and Limitations and Exclusions sections. Service will be managed by AIM Specialty Health as of 11/01/22 with AIM prior authorization required.	11/01/22 Version 25 Version 25 NOT implemented; Version 24 effective 09/01/22 to 11/30/22	08/26/22: MPCTAC (electronic vote)
09/01/22	Review for policy retired date 12/01/22. The effective date of AIM Specialty Health's management this service changed from 11/01/22 to 12/01/22. Administrative changes made to the Policy Summary and Applicable Coding sections. Medical policy criteria revised in the Clinical Criteria and Limitations and Exclusions sections.	12/01/22 Version 26	09/23/22: MPCTAC (electronic vote)



Medical Policy – Policy with InterQual Criteria Retired and AIM Criteria Adopted as of 12/01/22

Physical Therapy in the Outpatient Setting

Policy Number: OCA 3.544

Version Number: 26

Policy Retired Date: 12/01/22

Impacted Products

- All Products**
- NH Medicaid
- NH Medicare Advantage
- MA MassHealth ACO
- MA MassHealth MCO
- MA Qualified Health Plans/Employer Choice Direct
- MA Senior Care Options

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

Policy Summary

The Plan considers outpatient physical therapy (PT) medically necessary, including habilitative services and/or rehabilitative services, when AIM clinical appropriateness guidelines are met for an adult or pediatric member or are required EPSDT services for a member age 20 or younger on the date of service. Prior authorization from AIM Specialty Health is required for outpatient PT after the initial evaluation. PT must be provided within the scope of practice of the treating professional and/or paraprofessional and follow all applicable state licensing and supervisory requirements.

Clinical Criteria

No medical policy criteria.

Limitations and Exclusions

None.

Variations

The Plan uses guidance from the Centers for Medicare & Medicaid Services (CMS) for medical necessity and coverage determinations for NH Medicare Advantage members, including but not limited to national coverage determinations (NCDs), local coverage determinations (LCDs), local coverage articles (LCAs), and documentation included in Medicare manuals. At the time of the Plan's

most recent policy review, no applicable clinical guidelines were found from CMS. Verify CMS criteria in effect for the requested service on the date of the prior authorization request for a SCO or NH Medicare Advantage HMO member. When there is no guidance from CMS for the requested service for the specified indication on the date of the prior authorization request, Plan-adopted clinical review criteria will be used to determine the medical necessity of the service.

Applicable Coding

The Plan utilizes up-to-date, industry-standard Current Procedural Terminology (CPT) codes, Health Care Common Procedure Coding System (HCPCS) codes, and International Statistical Classification of Diseases and Related Health Problems, 10th revision (ICD-10) diagnosis codes in the Plan's medical policies. The list of applicable codes included in this policy is informational only and may not be all inclusive. Applicable codes are subject to change without prior notification and do not guarantee member coverage or provider reimbursement. Review the Plan's reimbursement policies for Plan billing guidelines. Providers are responsible for obtaining prior authorization from AIM for physical therapy, even if an applicable code appropriately describing the service is not included in this policy's Applicable Coding section. Providers are expected to report all services using the most up-to-date, industry-standard procedures and diagnosis codes at the time of the service.

CPT Codes	Code Descriptions
97010	Application of a modality to 1 or more areas; hot or cold packs
97012	Application of a modality to 1 or more areas; traction, mechanical
97014	Application of a modality to 1 or more areas; electrical stimulation (unattended)
97016	Application of a modality to 1 or more areas; vasopneumatic devices
97018	Application of a modality to 1 or more areas; paraffin bath
97022	Application of a modality to 1 or more areas; whirlpool
97024	Application of a modality to 1 or more areas; diathermy (e.g., microwave)
97026	Application of a modality to 1 or more areas; infrared
97028	Application of a modality to 1 or more areas; ultraviolet
97032	Application of a modality to 1 or more areas; electrical stimulation (manual), each 15 minutes
97033	Application of a modality to 1 or more areas; iontophoresis, each 15 minutes
97034	Application of a modality to 1 or more areas; contrast baths, each 15 minutes
97035	Application of a modality to 1 or more areas; ultrasound, each 15 minutes
97036	Application of a modality to 1 or more areas; Hubbard tank, each 15 minutes
97110	Therapeutic procedure, 1 or more areas, each 15 minutes; therapeutic exercises to develop strength and endurance, range of motion and flexibility
97112	Therapeutic procedure, 1 or more areas, each 15 minutes; neuromuscular reeducation of movement, balance, coordination, kinesthetic sense, posture, and/or proprioception for sitting and/or standing activities
97113	Therapeutic procedure, 1 or more areas, each 15 minutes; aquatic therapy with therapeutic exercises
97116	Therapeutic procedure, 1 or more areas, each 15 minutes; gait training (includes stair climbing)

97124	Therapeutic procedure, 1 or more areas, each 15 minutes; massage, including effleurage, petrissage and/or tapotement (stroking, compression, percussion)
97129	Therapeutic interventions that focus on cognitive function (e.g., attention, memory, reasoning, executive function, problem solving, and/or pragmatic functioning) and compensatory strategies to manage the performance of an activity (e.g., managing time or schedules, initiating, organizing, and sequencing tasks), direct (one-on-one) patient contact; initial 15 minutes
97130	Therapeutic interventions that focus on cognitive function (e.g., attention, memory, reasoning, executive function, problem solving, and/or pragmatic functioning) and compensatory strategies to manage the performance of an activity (e.g., managing time or schedules, initiating, organizing, and sequencing tasks), direct (one-on-one) patient contact; each additional 15 minutes (List separately in addition to code for primary procedure)
97140	Manual therapy techniques (e.g., mobilization/manipulation, manual lymphatic drainage, manual traction), 1 or more regions, each 15 minutes
97150	Therapeutic procedure(s), group (2 or more individuals)
97164	Re-evaluation of physical therapy established plan of care, requiring these components: An examination including a review of history and use of standardized tests and measures is required; and revised plan of care using a standardized patient assessment instrument and/or measurable assessment of functional outcome. Typically, 20 minutes are spent face-to-face with the patient and/or family.
97530	Therapeutic activities, direct (one-on-one) patient contact by the provider (use of dynamic activities to improve functional performance), each 15 minutes
97533	Sensory integrative techniques to enhance sensory processing and promote adaptive responses to environmental demands, direct (one-on-one) patient contact, each 15 minutes
97535	Self-care/home management training (e.g., activities of daily living (ADL) and compensatory training, meal preparation, safety procedures, and instructions in use of assistive technology devices/adaptive equipment) direct one-on-one contact, each 15 minutes
97537	Community/work reintegration training (e.g., shopping, transportation, money management, avocational activities and/or work environment/modification analysis, work task analysis, use of assistive technology device/adaptive equipment), direct one-on-one contact, each 15 minutes
97545	Work hardening/conditioning; initial 2 hours
97546	Work hardening/conditioning; each additional hour (List separately in addition to code for primary procedure)
97750	Physical performance test or measurement (e.g., musculoskeletal, functional capacity), with written report, each 15 minutes
97755	Assistive technology assessment (e.g., to restore, augment or compensate for existing function, optimize functional tasks and/or maximize environmental accessibility), direct one-on-one contact, with written report, each 15 minutes
97760	Orthotic(s) management and training (including assessment and fitting when not otherwise reported), upper extremity(ies), lower extremity(ies) and/or trunk, initial orthotic(s) encounter, each 15 minutes

97761	Prosthetic training, upper and/or lower extremity(ies), initial prosthetic(s) encounter, each 15 minutes
97763	Orthotic(s)/prosthetic(s) management and/or training, upper extremity(ies), lower extremity(ies), and/or trunk, subsequent orthotic(s)/prosthetic(s) encounter, each 15 minutes

References

American Association of Acupuncture and Oriental Medicine (AAAOM). AAAOM Position Statement on Trigger Point Dry Needling (TPDN) and Intramuscular Manual Therapy (IMT).

American College of Physicians (ACP), American Pain Society (APS). Chou R, Qaseem A, Snow V, Casey D, Cross JT Jr, Shekelle P, Owens DK; Clinical Efficacy Assessment Subcommittee of the ACP; ACP; APS Low Back Pain Guidelines Panel. Diagnosis and treatment of low back pain: a joint clinical practice guideline from the ACP and the APS. *Ann Intern Med.* 2007 Oct 2;147(7):478-91. Erratum in: *Ann Intern Med.* 2008 Feb 5;148(3):247-8. PMID: 17909209.

American College of Physicians (ACP). Qaseem A, Wilt TJ, McLean RM, Forciea MA; Clinical Guidelines Committee of the ACP. Noninvasive Treatments for Acute, Subacute, and Chronic Low Back Pain: A Clinical Practice Guideline from the ACP. *Ann Intern Med.* 2017 Apr 4;166(7):514-30. doi: 10.7326/M16-2367. Epub 2017 Feb 14. PMID: 28192789.

American Heart Association/American Stroke Association. Winstein CJ, Stein J, Arena R, Bates B, Cherney LR, Cramer SC, Deruyter F, Eng JJ, Fisher B, Harvey RL, Lang CE, MacKay-Lyons M, Ottenbacher KJ, Pugh S, Reeves MJ, Richards LG, Stiers W, Zorowitz RD; American Heart Association Stroke Council, Council on Cardiovascular and Stroke Nursing, Council on Clinical Cardiology, and Council on Quality of Care and Outcomes Research. Guidelines for Adult Stroke Rehabilitation and Recovery: A Guideline for Healthcare Professionals From the American Heart Association/American Stroke Association. *Stroke.* 2016 Jun;47(6):e98-e169. doi: 10.1161/STR.0000000000000098. Epub 2016 May 4. Review. Erratum in: *Stroke.* 2017 Feb;48(2):e78. *Stroke.* 2017 Dec;48(12):e369. PMID: 27145936.

American Pain Society (APS). Guideline Summaries.

American Physical Therapy Association (APTA). APTA Clinical Practice Guidelines Development Manual.

American Physical Therapy Association (APTA). Balance and Falls.

American Physical Therapy Association (APTA). Clinical Practice Guidelines (CPGs) Developed by APTA.

American Physical Therapy Association (APTA). Coding and Billing.

American Physical Therapy Association (APTA). Direction and Supervision of the Physical Therapist Assistant.

American Physical Therapy Association (APTA). Dry Needling.

American Physical Therapy Association (APTA). Ethics and Professionalism. Code of Ethics for the Physical Therapist, Standards of Ethical Conduct for the PTA, Value-Based Behaviors for the PTA, Core Values for the PT and PTA, Standards of Practice for Physical Therapy.

American Physical Therapy Association (APTA). Guide to Physical Therapist Practice. Guide 3.0. 2016.

American Physical Therapy Association (APTA). Physical Therapy Documentation of Patient/Client Management.

American Physical Therapy Association (APTA). Supervision and Teamwork.

American Society of Anesthesiologists (ASA), American Society of Regional Anesthesia and Pain Medicine (ASRA). Rosenquist RW, Benzon HT, Connis RT, De Leon-Casasola OA, Glass D, Korevaar WC, Cynwyd B, Mekhail NA, Merrill DG, Nickinovich DG, Rathmell JP, Nai-Mei Sang C, Simon DL; ASA Task Force on Chronic Pain Management. Practice guidelines for chronic pain management: an updated report by the ASA Task Force on Chronic Pain Management and the ASRA. *Anesthesiology*. 2010 Apr;112(4):810-33. doi: 10.1097/ALN.0b013e3181c43103. PMID: 20124882.

Centers for Medicare & Medicaid Services (CMS). Early and Periodic Screening, Diagnostic and Treatment (EPSDT). Medicaid.gov.

Centers for Medicare & Medicaid Services (CMS). EPSDT – A Guide for States: Coverage in the Medicaid Benefit for Children and Adolescents. 2014 Jun.

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 & Medicaid Services (CMS). National Coverage Determination (NCD) Neuromuscular Electrical Stimulation (NMES) 160.12. Version 2. 2006 Oct 1.

Cruickshank TM, Reyes AR, Ziman MR. A systematic review and meta-analysis of strength training in individuals with multiple sclerosis or Parkinson disease. *Medicine (Baltimore)*. 2015 Jan;94(4):e411. doi: 10.1097/MD.0000000000000411. PMID: 25634170.

Hayes. Health Technology Assessment. Cognitive Rehabilitation Therapy for Traumatic Brain Injury (TBI). Dallas, TX: Hayes; 2017 Sep 26. Annual Review 2021 Feb 8.

Madsen M, Larsen K, Madsen IK, Søre H, Hansen TB. Late group-based rehabilitation has no advantages compared with supervised home-exercises after total knee arthroplasty. *Dan Med J*. 2013 Apr;60(4):A4607. PMID: 23651717.

Monticone M, Ferrante S, Rocca B, Baiardi P, Farra FD, Foti C. Effect of a long-lasting multidisciplinary program on disability and fear-avoidance behaviors in patients with chronic low back pain: results of a randomized controlled trial. *Clin J Pain*. 2013 Nov;29(11):929-38. doi: 10.1097/AJP.0b013e31827fef7e. PMID: 23328343.

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

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

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

New Hampshire Medicaid. Therapies. Physical, Occupational, Speech. Provider Manual. Volume II. 2017 Dec 1.

New Hampshire Office of Professional Licensure and Certification. Office of Licensed Allied Health Professionals. Laws and Administrative Rules Governing Licensed Allied Health Professionals.

Parikh SS, Baxi N, Padavan SA. Musculoskeletal medicine. In: Sackheim KA, editor. *Rehab Clinical Pocket Guide*. New York, NY: Springer; 2013:357-426.

Reid MC, Eccleston C, Pillemer K. Management of chronic pain in older adults. *BMJ*. 2015 Feb 13;350:h532. doi: 10.1136/bmj.h532. PMID: 25680884.

Schaufele MK, Tate JL. Lumbar degenerative disease. In: Frontera WR, Silver JK, Rizzo TD Jr, editors. *Essentials of Physical Medicine and Rehabilitation: Musculoskeletal Disorders, Pain, and Rehabilitation*. 3rd ed. Philadelphia, PA: Elsevier Saunders; 2015:225-32.

Stanos SP, Tybursky MD, Harden RN. Chronic pain. In: Cifu DX, et al., editors. *Braddom's Physical Medicine and Rehabilitation*. 5th ed. Elsevier; 2016:809-33.

Next Review Date

Not applicable

Retired Date

12/01/22

Authorizing Entity

MPCTAC

Appendix

Appendix: Policy History

Disclaimer Information:

Plan refers to Boston Medical Center Health Plan, Inc. which operates under the trade name WellSense Health Plan. 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.

Appendix: Policy History

Original Approval Date	Original Effective Date* and Version	Policy Owner	Original Policy Approved by
Regulatory Approval: N/A Internal Approval: 09/16/05	09/16/05 Version 1	Director of Medical Policy as Chair of Medical Policy, Criteria, and Technology Assessment Committee (MPCTAC)	Quality and Clinical Management Committee (Q&CMC)

*Effective Date for NH Medicaid Product: 01/01/13

*Effective Date for NH Medicare Advantage HMO Product: 01/01/22

Physical Therapy policy renumbered OCA 3.544 for physical therapy provided to NH Medicaid members age 21 or older in the outpatient setting as of 01/11/15. (Policy formerly numbered OCA 3.54 for physical therapy in the outpatient setting for all adult and pediatric NH Medicaid members from 01/01/13 to 01/10/15.) Policy title changed to *Physical Therapy in the Outpatient Setting* as of 12/01/21.

Policy Revisions History			
Review Date	Summary of Revisions	Revision Effective Date and Version Number	Approved by
02/07/06	Added definitions for modality and visit. Defined coverage for visits, evaluations and units billed.	Version 2	02/07/06: Q&CMC
07/06/06	Removed verbiage regarding reimbursement for evaluation and modality services.	Version 3	07/06/06: Q&CMC
03/27/07	Policy archived.	Not applicable	Not specified
10/14/08	Reviewed policy and updated clinical criteria, effective date of the revised policy is 12/16/08.	12/16/08 Version 4	11/10/08: MPTAC 12/16/08: Quality Improvement Committee (QIC)
09/22/09	No changes.	Version 5	09/22/09: MPCTAC 10/28/09: QIC
10/01/10	Updated template and references.	Version 6	10/20/10: MPCTAC 11/22/10: QIC
10/01/11	Added Commercial benefit limitations, updated coding and references.	Version 7	10/19/11: MPCTAC 11/29/11: QIC
08/01/12	Off cycle review for WellSense New Hampshire Medicaid product, revised Summary statement, reformatted Medical Policy Statement, revised Applicable Coding introductory paragraph,	Version 8	08/13/12: MPCTAC 09/06/12: QIC

	updated code list, revised Limitations section, and revised references.		
11/01/12	Review for effective date 03/01/13. Updated references. Revised Summary section. Clarified text in Medical Policy Statement section. Revised language in introductory paragraph in Applicable Coding section and updated applicable code list. Clinical criteria moved from Clinical Background and Summary sections to Medical Policy Statement section. Moved services not considered medically necessary from the Medical Policy Statement section to the Limitations section. Removed duplicate text from Clinical Background Information section. Referenced Plan reimbursement policy 4.609 for physical therapy reimbursement guidelines. Removed "Guideline" from title.	03/01/13 Version 9	11/21/12: MPCTAC 12/20/12: QIC
08/14/13 and 08/15/13:	Off cycle review for the NH Medicaid product and merged policy format. Incorporate policy revisions dated 11/01/12 (as specified above) for the NH Medicaid product; these policy revisions were approved by MPCTAC on 11/21/12 and QIC on 12/20/12 for applicable Plan products.	Version 10	08/14/13: MPCTAC (electronic vote) 08/15/13: QIC
11/01/13, 12/01/13, 01/01/14, and 02/01/14	Review for effective date 05/01/14. Updated code definitions, introductory paragraph in Applicable Coding section, and the applicable code lists for the MA products and the NH Medicaid product. Updated references. Removed prior authorization waiver for the first 32 units of PT for the NH Medicaid product. Add criterion in the Medical Policy Statement sections for the MA products and NH Medicaid product requiring an updated physician prescription and supporting clinical documentation after 20 OT visits per treatment episode. Revised Limitations sections.	05/01/14 Version 11	02/11/14: MPCTAC 02/18/14: QIC
09/08/14	For NH Medicaid product only, waived prior authorization of first eight (8) 15-minute treatment units per member per servicing provider per calendar year.	10/01/14 Version 11 Addendum A	09/17/14: MPCTAC 09/30/14: QIC
11/04/14 and 11/19/14	Review for effective date 01/11/15. Summary and Medical Policy Statement sections updated with guidelines specified in version 11, addendum A. Policy renumbered OCA 3.544 to include physical therapy in the outpatient setting for NH Medicaid members age 21 or older on the date of	01/11/15 Version 12	11/06/14: MPCTAC (electronic vote) 11/11/14: QIC (electronic vote) 11/19/14: MPCTAC 12/10/14: QIC

	service. Revised Limitations section. (PT services formerly included in policy number OCA 3.54 for all adult and pediatric members.) Revised review calendar.		
11/01/15	Review for effective date 01/01/16. Updated template, Summary section, and References section. Administrative changes made to the Medical Policy Statement and Limitations section without changing criteria. Revised language in the Applicable Coding section. Added definitions.	01/01/16 Version 13	12/03/15: MPCTAC (electronic vote) 12/09/15: QIC
12/01/16	Review for effective date 02/01/17. Industry-wide revisions of applicable codes. Clarified existing criteria in the Medical Policy Statement section.	02/01/17 Version 14	12/21/16: MPCTAC 01/11/17: QIC
12/01/17	Review for effective 01/01/18. Industry-wide updates to codes included in the Applicable Coding section. Annual review of policy with administrative changes made to the Definitions and Reference sections.	01/01/18 Version 15	12/20/17: MPCTAC
02/01/18	Review for effective date 03/01/18. Administrative changes made to the Policy Summary and Limitations sections.	03/01/18 Version 16	02/21/18: MPCTAC
11/01/18	Review for effective date 12/01/18. Administrative changes made to the Policy Summary, Medical Policy Statement, Limitations, Definitions, References, Other Applicable Policies, and Reference to Applicable Laws and Regulations sections.	12/01/18 Version 17	11/21/18: MPCTAC
03/01/19	Review for effective date 07/01/19. Administrative changes made to the Limitations and Reference to Applicable Laws and Regulations sections. Criteria revised in the Medical Policy Statement section.	07/01/19 Version 18	03/20/19: MPCTAC
12/01/19	Review for effective date 01/01/20. Industry-wide updates to codes included in the Applicable Coding section.	01/01/20 Version 19	Not applicable because industry-wide code changes
11/01/19	Review for effective date 02/01/20. Administrative changes made to the References and Reference to Applicable Laws and Regulations sections. Revised criteria in the Medical Policy Statement and Limitations sections.	02/01/20 Version 20 Renumbered to version 20 to implement industry-wide code updates effective 01/01/20	11/20/19: MPCTAC

		included in version 19	
12/01/19	Review for effective 02/01/20. Industry-wide updates to codes effective 01/01/20 included in the Applicable Coding section of the policy version 20 effective 02/01/20.	02/01/20 Version 21	12/18/19: MPCTAC
12/01/19	Review for effective date 03/01/20. Revised in the Medical Policy Statement section the definition of a servicing PT provider for the prior authorization waiver.	03/01/20 Version 22	12/18/19: MPCTAC
11/01/20	Review for effective date 12/01/20. Updated the References section. Administrative change made to the Applicable Coding section.	12/01/20 Version 23	11/18/20: MPCTAC
11/01/21	Review for effective date 12/01/21. Adopted new medical policy template; removed administrative sections, Medical Policy Statement section renamed Clinical Criteria section, and Limitations section renamed Limitations and Exclusions section. Administrative changes made to the Policy Summary, Applicable Coding, and References sections. Medical policy criteria retired and InterQual criteria will continue to be used to determine the medical necessity of services. Revised policy title because policy applies to adult and pediatric members as of 12/01/21.	12/01/21 Version 24	11/17/21: MPCTAC
08/01/22	Review for policy retired date 11/01/22. Administrative changes made to the Policy Summary and Applicable Coding sections. InterQual medical necessity criteria and medical policy guidelines in the Clinical Criteria and Limitations and Exclusions sections retired on 11/01/22. AIM criteria adopted for outpatient PT on 11/01/22. Plan prior authorization waivers removed after 10/31/22. AIM prior authorization is required for outpatient PT after the initial evaluation as of 11/01/22, even when applicable codes are not listed in this Plan policy.	11/01/22 Version 25 Version 25 NOT implemented; Version 24 effective 12/01/21 to 11/30/22	08/26/22: MPCTAC (electronic vote)
09/01/22	Review for policy retired date 12/01/22. The effective date of AIM Specialty Health's management of outpatient rehabilitation services changed from 11/01/22 to 12/01/22. Administrative changes made to the Policy Summary and Applicable Coding sections. InterQual medical necessity criteria and medical policy guidelines in the Clinical Criteria and	12/01/22 Version 26	09/23/22: MPCTAC (electronic vote)

	<p>Limitations and Exclusions sections retired as of 12/01/22. AIM criteria adopted for outpatient PT for dates of service on or after 12/01/22. Plan prior authorization waivers removed after 11/30/22. AIM prior authorization is required for outpatient PT after the initial evaluation as of 12/01/22, even when applicable codes are not listed in this Plan policy.</p>		
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Medical Policy

Sacral Nerve Stimulation (Including Peripheral Nerve Stimulation Test and Two-Stage Tined Lead Procedure) for Incontinence and Urinary Conditions

Policy Number: OCA 3.563

Version Number: 21

Version Effective Date: 12/01/22

Impacted Products

- All Products**
- NH Medicaid
- NH Medicare Advantage
- MA MassHealth ACO
- MA MassHealth MCO
- MA Qualified Health Plans/Employer Choice Direct
- MA Senior Care Options

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

Policy Summary

The Plan considers implantable sacral nerve stimulation (SNS), also known as sacral neuromodulation, to be medically necessary when applicable medical criteria are met; this includes peripheral nerve stimulation test and tined lead procedure before the implantation of the permanent SNS device. Plan prior authorization is required.

Clinical Criteria

Sacral nerve stimulation (SNS) initial testing or permanent implantation of a SNS device (e.g., InterStim™ system by Medtronic, Inc.) is considered medically necessary when applicable Plan criteria are met in EITHER item I or item II:

I. Medical Necessity Criteria:

A. Sacral Nerve Stimulation (SNS) to Treat Urinary Conditions:

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Applicable criteria must be met based on the phase of treatment in EITHER item 1 (Initial Testing Phase) or item 2 (Permanent Implantation):

1. Initial Testing Phase for Implanted SNS:

Trial period of implantable SNS (with either peripheral nerve stimulation or a temporarily implanted lead with stage one of the tined lead procedure) is considered medically necessary when ALL criteria are met in items a through f:

- a. Member is experiencing at least ONE (1) of the urinary symptoms in items (1) through (3) for at least 6 months:
 - (1) Non-obstructive urinary retention; OR
 - (2) Urgency-frequency syndrome; OR
 - (3) Urinary urge incontinence; AND
- b. Member's urinary symptoms are NOT related to a neurologic condition; AND
- c. Member's conservative treatment meets ONE (1) of the criteria in item (1) or item (2):
 - (1) Member is medically refractory to conservative therapy and has failed 6 months of behavioral therapy and 3 months of pharmacological therapy (which included a trial of at least 2 anti-cholinergic agents or a trial of 1 anti-cholinergic agent and 1 beta 3 adrenergic receptor agonist); OR
 - (2) Member cannot tolerate a minimum of 6 consecutive months of conservative treatment due to a significant disability (e.g., frequency or severity impacts ability to work or participate in activities outside of the home); AND
- d. Member is 18 years of age or older on the date of service; AND
- e. Member is willing to comply with the treatment protocol and has the cognitive capacity to use the remote control to optimize device function during the testing and treatment phases; AND
- f. Member's current treatment plan does NOT include the use of percutaneous tibial nerve stimulation (PTNS) for non-neurogenic urinary overactive bladder symptoms; OR

2. Permanent Implantation of SNS:

Permanent implantation of a SNS device is considered medically necessary when BOTH criteria are met in item a and item b:

- a. Member meets all the criteria listed above for the peripheral nerve stimulation test or stage one of the tined lead procedure (to estimate potential response to SNS); AND
- b. Member has experienced a 50% or greater relief of incontinence or primary symptoms for at least 48 hours during the percutaneous trial or stage one of the tined lead test as measured by voiding diaries; OR

B. Sacral Nerve Stimulation (SNS) to Treat Chronic Fecal Incontinence:

Applicable criteria must be met based on the phase of treatment in EITHER item 1 (Initial Testing Phase) or item 2 (Permanent Implantation):

1. Initial Testing Phase of Implanted SNS:

Trial period of implantable SNS (with either peripheral nerve stimulation or a temporarily implanted lead with stage one of the tined lead procedure) is considered medically necessary to treat fecal incontinence after review and approval of a Plan Medical Director and when ALL criteria are met in items a through f:

- a. Member has chronic fecal incontinence with greater than 2 incontinent episodes on average per week for at least 6 months in duration or for at least 12 months after vaginal childbirth; AND
- b. Member's fecal incontinence is NOT related to a neurologic condition; AND
- c. Member's conservative treatment (before the request for the initial testing phase of implanted sacral nerve stimulation) meets ONE (1) of the criteria in item (1) or item (2):
 - (1) Member is medically refractory to conservative therapy and BOTH criteria are met in item (a) and item (b):
 - (a) Failure of behavioral therapy (e.g., dietary modification, pelvic floor retraining); AND
 - (b) Failure of pharmacological therapy; AND
 - (2) Member cannot tolerate conservative treatment due to a significant disability (e.g., frequency or severity impacts ability to work or participate in activities outside of the home); AND

- d. If the member has medical history of chronic inflammatory bowel disease (IBD), IBD does NOT involve the anorectum; AND
- e. Member is 18 years of age or older on the date of service; AND
- f. Member is willing to comply with the treatment protocol and has the cognitive capacity to use the remote control to optimize device function during the testing and treatment phases; OR

C. Permanent Implantation of SNS:

- 1. Permanent implantation of a SNS device for the treatment of fecal incontinence is considered medically necessary after review and approval of a Plan Medical Director and when ALL criteria are met in items a and b:
 - a. Member meets all the criteria above for the peripheral nerve stimulation test or stage one of the tined lead procedure (to estimate potential response to SNS); AND
 - b. Member has experienced a 50% or greater relief of incontinence symptoms for at least 48 hours during the percutaneous trial or stage one of the tined lead test as measured by elimination journals.

II. Plan Medical Director review is required for any of the following requests:

- A. The use of an implantable sacral nerve stimulation (SNS) for members age 16 or 17 on the date of service; OR
- B. All requests for implantable SNS (including initial testing phase and/or permanent implantation) to treat fecal incontinence; in addition, ALL applicable criteria in item IB above (Sacral Nerve Stimulation to Treat Chronic Fecal Incontinence) must be met and documented in the member's medical record.

Limitations and Exclusions

- A. Contraindications for the use of implantable SNS (including associated testing) include any of the following conditions for the member:
 - 1. Chronic inflammatory bowel disease involving the anorectum mechanical obstruction, or malformation in the applicable anatomical area; OR
 - 2. Receiving any form of diathermy or is expected to receive diathermy during the duration of treatment with sacral nerve stimulation; OR
 - 3. Member has a pacemaker or implantable defibrillator; OR

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4. Pregnant or plans to become pregnant during the duration of treatment with sacral nerve stimulation; OR
 5. History of rectal surgery in the previous 12 months, or in the case of cancer, the member has had rectal surgery in the past 24 months.
- B. The Plan considers ANY uses of SNS (including associated testing) listed in items 1 through 3 to be experimental and investigational or NOT medically necessary due to limited evidence demonstrating the clinical utility and clinical validity of SNS for these indications or conditions:
1. Member is unwilling or unable to comply with the treatment protocol and/or does not have the cognitive capacity to use the remote control to optimize device function during the testing and treatment phases; OR
 2. The use of a wireless sacral nerve stimulator (e.g., StimGuard) because the safety and efficacy of the wireless devices have not been adequately studied; OR
 3. The use of implantable SNS (including associated testing) is considered experimental and investigational when used for a member age 15 or younger on the date of service.

The use of posterior tibial nerve stimulation, including percutaneous tibial nerve stimulation (PTNS) and/or transcutaneous posterior tibial nerve stimulation (TPTNS) with a member who has an implantable SNS device or has initiated the initial testing phase of an implantable SNS. Posterior tibial nerve stimulation may NOT be administered concurrently with SNS. Review the Plan's *Posterior Tibial Nerve Stimulation (Percutaneous or Transcutaneous)* medical policy, policy number OCA 3.562 for applicable medical necessity criteria for these services.

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 New Hampshire 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. At the time of the Plan's most recent policy review, NCD 23.18 includes medical necessity criteria for the use of sacral nerve stimulation (SNS) for the treatment of urinary urge incontinence, urgency-frequency syndrome, and urinary retention. 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.

Applicable Coding

The Plan utilizes up-to-date, industry-standard Current Procedural Terminology (CPT) codes, Health Care Common Procedure Coding System (HCPCS) codes, and International Statistical Classification

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of Diseases and Related Health Problems, 10th revision (ICD-10) diagnosis codes in the Plan's medical policies. Since these codes may be updated at different intervals than the medical policy review cycle, the list of applicable codes included in a policy is informational only and may not be all inclusive. Applicable codes are subject to change without prior notification and do not guarantee member coverage or provider reimbursement. Review the Plan's reimbursement policies for Plan billing guidelines. Providers are responsible for obtaining prior authorization for the services specified in the Clinical Criteria section and Limitations and Exclusions section of a medical policy, even if an applicable code appropriately describing the service is not included in the policy's Applicable Coding section. Providers are expected to report all services using the most up-to-date, industry-standard procedures and diagnosis codes at the time of the service.

CPT Codes	Description: Codes covered when medically necessary
64561	Percutaneous implantation of neurostimulator electrode array; sacral nerve (transforaminal placement) including image guidance, if performed Plan note: Percutaneous trial/temporary stimulation to estimate potential response to SNS.
64581	Open implantation of neurostimulator electrode array; sacral nerve (transforaminal placement)
64585	Revision or removal of peripheral neurostimulator electrode array
64590	Insertion or replacement of peripheral or gastric neurostimulator pulse generator or receiver, direct or inductive coupling
64595	Revision or removal of peripheral or gastric neurostimulator pulse generator or receiver

HCPCS Codes	Description: Codes covered when medically necessary
A4290	Sacral nerve stimulation test lead, each
E0745	Neuromuscular stimulator, electronic shock unit
L8680	Implantable neurostimulator electrode, each Plan note: Code is NOT payable for the Senior Care Options and WellSense Medicare Advantage HMO products.
L8681	Patient programmer (external) for use with implantable programmable neurostimulator pulse generator, replacement only
L8682	Implantable neurostimulator radiofrequency receiver
L8683	Radiofrequency transmitter (external) for use with implantable neurostimulator radiofrequency receiver
L8684	Radiofrequency transmitter (external) for use with implantable sacral root neurostimulator receiver for bowel and bladder management, replacement
L8685	Implantable neurostimulator pulse generator, single array, rechargeable, includes extension Plan note: Code is NOT payable for the Senior Care Options and WellSense Medicare Advantage HMO products.
L8686	Implantable neurostimulator pulse generator, single array, nonrechargeable, includes extension

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	Plan note: Code is NOT payable for the Senior Care Options and WellSense Medicare Advantage HMO products.
L8687	Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension Plan note: Code is NOT payable for the Senior Care Options and WellSense Medicare Advantage HMO products.
L8688	Implantable neurostimulator pulse generator, dual array, nonrechargeable, includes extension Plan note: Code is NOT payable for the Senior Care Options and WellSense Medicare Advantage HMO products.
L8689	External recharging system for battery (internal) for use with implantable neurostimulator, replacement only
L8695	External recharging system for battery (external) for use with implantable neurostimulator, replacement only

ICD-10 Diagnosis Codes	Description: One (1) of the following ICD-10 diagnosis codes is required when billing with a CPT code or HCPCS code for SNS
N32.81	Overactive bladder
N32.9	Bladder disorder, unspecified
N39.3	Stress incontinence (female)(male)
N39.41-N39.43	Other specified urinary incontinence
N39.45-N39.46	Other specified urinary incontinence
N39.490	Other specified urinary incontinence; overflow incontinence
N39.498	Other specified urinary incontinence (reflex incontinence) (total incontinence)
R15.0-R15.9	Fecal incontinence
R32	Unspecified urinary incontinence
R33.0-R33.9	Retention of urine
R35.0	Frequency of micturition
R39.14	Feeling of incomplete bladder emptying
R39.15	Urgency of urination

References

Abrams P, Andersson KE, Birder L, Brubaker L, Cardozo L, Chapple C, Cottenden A, Davila W, de Ridder D, Dmochowski R, Drake M, Dubeau C, Fry C, Hanno P, Smith JH, Herschorn S, Hosker G, Kelleher C, Koelbl H, Khoury S, Madoff R, Milsom I, Moore K, Newman D, Nitti V, Norton C, Nygaard I, Payne C, Smith A, Staskin D, Tekgul S, Thuroff J, Tubaro A, Vodusek D, Wein A, Wyndaele JJ; Members of Committees; Fourth International Consultation on Incontinence. Fourth international consultation on incontinence recommendations of the International Scientific Committee: Evaluation and treatment of urinary incontinence, pelvic organ prolapse, and fecal incontinence. *Neurourol Urodyn.* 2010;29(1):213-40. doi: 10.1002/nau.20870. PMID: 20025020.

Altomare DF, Giuratrabocchetta S, Knowles CH, Muñoz Duyos A, Robert-Yap J, Matzel KE; European SNS Outcome Study Group. Long-term outcomes of sacral nerve stimulation for fecal incontinence. *Br J Surg*. 2015 Mar;102(4):407-15. doi: 10.1002/bjs.9740. Epub 2015 Feb 2. PMID: 25644687.

American College of Gastroenterology (ACG). Guidelines.

American College of Gastroenterology (ACG). Rao SS, ACG Practice Parameters Committee. Diagnosis and management of fecal incontinence. *Am J Gastroenterol*. 2004 Aug;99(8):1585-604. doi: 10.1111/j.1572-0241.2004.40105.x. PMID: 15307881.

The American College of Obstetricians and Gynecologists (ACOG). Clinical Guidance.

The American College of Obstetricians and Gynecologists (ACOG). ACOG Practice Bulletin No. 155. Urinary Incontinence in Women. *Obstet Gynecol*. 2015 Nov;126(5):e66-81. doi: 10.1097/AOG.0000000000001148. PMID: 26488524.

The American College of Obstetricians and Gynecologists (ACOG). ACOG Practice Bulletin No. 210. Fecal Incontinence. *Obstet Gynecol*. 2019 Apr;133(4):837-9. doi: 10.1097/AOG.0000000000003188. PMID: 30913191.

The American College of Obstetricians and Gynecologists (ACOG), American Urogynecologic Society (AUGS). ACOG Committee on Gynecologic Practice. Evaluation of Uncomplicated Stress Urinary Incontinence in Women Before Surgical Treatment. Committee Opinion Number 603. 2014 Jun. Reaffirmed 2017.

The American College of Obstetricians and Gynecologists (ACOG). Urinary Incontinence. Patient Resources.

American College of Physicians (ACP). Clinical Guidelines & Recommendations.

American College of Physicians (ACP). Qaseem A, Dallas P, Forciea MA, Starkey M, Denberg TD, Shekelle P. Clinical Guidelines Committee of the ACP. Nonsurgical management of urinary incontinence in women: a clinical practice guideline from the ACP. *Ann Intern Med*. 2014 Sep 16;161(6):429-40. doi: 10.7326/M13-2410. PMID: 25222388.

American Gastroenterological Association (AGA). Bharucha AE, Pemberton JH, Locke GR. American Gastroenterological Association technical review on constipation. *Gastroenterology*. 2013 Jan;144(1):218-38. doi: 10.1053/j.gastro.2012.10.028. PMID: 23261065.

American Gastroenterological Association (AGA). Clinical Guidelines.

The American Society of Colon and Rectal Surgeons (ASCRS). Clinical Practice Guidelines.

The American Society of Colon and Rectal Surgeons (ASCRS). Paquette IM, Varma MG, Kaiser AM, Steele SR, Rafferty JF. The American Society of Colon and Rectal Surgeons' clinical practice guideline for the treatment of fecal incontinence. *Dis Colon Rectum*. 2015 Jul;58(7):623-36. doi: 10.1097/DCR.0000000000000397. PMID: 26200676.

American Urogynecologic Society (AUGS). Clinical Guidance Documents.

American Urological Association (AUA). Guidelines & Policies.

American Urological Association (AUA) and Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction (SUFU). Lightner DJ, Gomelsky A, Souter L, Vasavada SP. Diagnosis and Treatment of Overactive Bladder (Non-Neurogenic) in Adults: AUA/SUFU Guideline Amendment 2019. *J Urol*. 2019 Sep;202(3):558-63. doi: 10.1097/JU.0000000000000309. Epub 2019 Aug 8. PMID: 31039103.

American Urological Association (AUA) and Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction (SUFU). Kobashi KC, Albo ME, Dmochowski RR, Ginsberg DA, Goldman HB, Gomelsky A, Kraus SR, Sandhu JS, Shepler T, Treadwell JR, Vasavada S, Lemack GE. Surgical Treatment of Female Stress Urinary Incontinence (SUI): AUA/SUFU Guideline. *J Urol*. 2017 Oct;198(4):875-883. doi: 10.1016/j.juro.2017.06.061. Epub 2017 Jun 15. PMID: 28625508.

Amundsen CL, Richter HE, Menefee SA, Komesu YM, Arya LA, Gregory WT, Myers DL, Zyczynski HM, Vasavada S, Nolen TL, Wallace D, Meikle SF. OnabotulinumtoxinA vs Sacral Neuromodulation on Refractory Urgency Urinary Incontinence in Women: A Randomized Clinical Trial. *JAMA*. 2016 Oct 4;316(13):1366-1374. doi: 10.1001/jama.2016.14617. PMID: 27701661.

Angioli R, Montera R, Plotti F, Aloisi A, Montone E, Zullo MA. Success rates, quality of life, and feasibility of sacral nerve stimulation in elderly patients: 1-year follow-up. *Int Urogynecol J*. 2013 May;24(5):789-94. doi: 10.1007/s00192-012-1928-3. Epub 2012 Sep 8. PMID: 22961496.

Banakhar M, Hassouna M. Percutaneous Nerve Evaluation Test Versus Staged Test Trials for Sacral Neuromodulation: Sensitivity, Specificity, and Predictive Values of Each Technique. *Int Neurourol J*. 2016 Sep;20(3):250-254. doi: 10.5213/inj.1630498.249. PMID: 27706006.

Barnett G, Ockrim J. Re: Cost of neuromodulation therapies for overactive bladder: percutaneous tibial nerve stimulation versus sacral nerve stimulation: M. Martinson, S. MacDiarmid and E. Black *J Urol* 2013;189:210-6. *J Urol*. 2013 Oct;190(4):1444-5. doi: 10.1016/j.juro.2013.04.131. Epub 2013 Jul 22. PMID: 23886880.

Brégeon J, Neunlist M, Bossard C, Biraud C, Mandy B, Coron E, Bourreille A, Meurette G. Improvement of Refractory Ulcerative Proctitis With Sacral Nerve Stimulation. *J Clin Gastroenterol*. 2015 Nov/Dec;49(10):853-7. doi: 10.1097/MCG.0000000000000331. PMID: 25930972.

Bielefeldt K. Adverse events of sacral neuromodulation for fecal incontinence reported to the federal drug administration. *World J Gastrointest Pharmacol Ther.* 2016 May 6;7(2):294–305. doi: 10.4292/wjgpt.v7.i2.294. PMID: 27158546.

Bragg R, Hebel D, Vouri SM, Pitlick JM. Mirabegron: a Beta-3 agonist for overactive bladder. *Consult Pharm.* 2014 Dec;29(12):823–37. doi: 10.4140/TCP.n.2014.823. PMID: 25521658.

Canadian Urological Association. Bettez M, Tu LM, Carlson K, Corcos J, Gajewski J, Jolivet M, Bailly G. 2012 Update: Guidelines for Adult Urinary Incontinence Collaborative Consensus Document for the Canadian Urological Association. *Can Urol Assoc J.* 2012 Oct;6(5):354–63. doi: 10.5489/cuaj.12248. PMID: 23093627.

Carrington EV, Evers J, Grossi U, Dinning PG, Scott SM, O'Connell PR, Jones JF, Knowles CH. A systematic review of sacral nerve stimulation mechanisms in the treatment of fecal incontinence and constipation. *Neurogastroenterol Motil.* 2014 Sep;26(9):1222–37. doi: 10.1111/nmo.12388. PMID: 25167953.

Centers of Disease Control and Prevention (CDC). Inflammatory bowel disease (IBD). 2017 Mar 14.

Centers for Medicare & Medicaid Services (CMS). Local Coverage Determination (LCD) Posterior Tibial Nerve Stimulation for Voiding Dysfunction L33396. National Government Services, Inc. 2015 Oct 1. Revision Effective Date 2019 Oct 24.

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

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

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

Centers for Medicare & Medicaid Services (CMS). National Coverage Determination (NCD) for Bladder Stimulators (Pacemakers) 230.16. 1996 Oct 7.

Centers for Medicare & Medicaid Services (CMS). National Coverage Determination (NCD) for Incontinence Control Devices 230.10. 1996 Oct 7.

Centers for Medicare & Medicaid Services (CMS). National Coverage Determination (NCD) for Non-Implantable Pelvic Floor Electrical Stimulator 230.8. Effective 2006 Jun 19.

Centers for Medicare & Medicaid Services (CMS). National Coverage Determination (NCD) for Sacral Nerve Stimulation for Urinary Incontinence 230.18. Effective 2002 Jan 1.

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

Sacral Nerve Stimulation (Including Peripheral Nerve Stimulation Test and Two-Stage Tined Lead Procedure)
for Incontinence and Urinary Conditions

Chiarioni G, Palsson OS, Asteria CR, Whitehead WE. Neuromodulation for fecal incontinence: An effective surgical intervention. *World J Gastroenterol*. 2013 Nov 7;19(41):7048–54. doi: 10.3748/wjg.v19.i41.7048. PMID: 24222947.

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

Commonwealth of Massachusetts. MassHealth Provider Bulletins.

Commonwealth of Massachusetts. MassHealth Provider Manuals.

Commonwealth of Massachusetts. MassHealth Transmittal Letters.

Dinning PG, Hunt L, Patton V, Zhang T, Szczesniak M, Gebiski V, Jones M, Stewart P, Lubowski DZ, Cook IJ. Treatment efficacy of sacral nerve stimulation in slow transit constipation: a two-phase, double-blind randomized controlled crossover study. *Am J Gastroenterol*. 2015 May;110(5):733–40. doi: 10.1038/ajg.2015.101. Epub 2015 Apr 21. PMID: 25895520.

El-Gazzaz G, Zutshi M, Salcedo L, Hammel J, Rackley R, Hull T. Sacral neuromodulation for the treatment of fecal incontinence and urinary incontinence in female patients: long-term follow-up. *Int J Colorectal Dis*. 2009 Dec;24(12):1377–81. doi: 10.1007/s00384-009-0745-8. Epub 2009 Jun 2. PMID: 19488765.

European Association of Urology (EAU). Blok B, Castro-Diaz D, Del Popolo G, Groen J, Hamid R, Karsenty G, Kessler TM, Pannek J, Ecclestone H, Musco S, Padilla-Fernández B, Sartori A, 't Hoen LA. EAU Guidelines. *Neuro-Urology*. 2020 Mar. Edn. presented at the EAU Annual Congress Amsterdam 2022. ISBN 978-94-92671-16-5.

European Association of Urology (EAU). Gacci M, Sakalis VI, Karavitakis M, Cornu JN, Gratzke C, Hermann TRW, Kyriazis I, Malde S, Mamoulakis C, Rieken M, Schouten N, Smith EJ, Speakman MJ, Tikkinen KAO, Gravas S. EAU Guidelines on Male Urinary Incontinence. *Rev Incon*. 2022 Oct 1;82(4):387–98. doi: 10.1016/j.euro.2022.05.0122.

European Association of Urology (EAU). Nambiar AK, Arlandis S, Bo K, Cobussen-Boekhorst H, Costantini E, de Heide M, Farag F, Groen J, Karavitakis M, Lapitan MC, Manso M, Monagas Arteaga S, Nic An Riogh A, O'Connor E, Omar MI, Peyronnet B, Phe V, Sakalis VI, Sihra N, Tzelvels L, van Poelgeest-Pomfret ML, van den Bos TWL, van der Vaart H, Harding CK. EAU Guidelines on the Diagnosis and Management of Female Non-Neurogenic Lower Urinary Tract Symptoms. Part 1: Diagnostics, Overactive Bladder, Stress Urinary Incontinence, and Mixed Urinary Incontinence. *European Urology*. 2022 Jul;82(1):60–70. doi: 10.1016/j.eururo.2022.01.045.

European Association of Urology (EAU). Nambiar AK, Bosch R, Cruz F, Lemack GE, Thiruchelvam N, Tubaro A, Bedretdinova DA, Ambühl D, Farag F, Lombardo R, Schneider MP, Burkhard FC. EAU

Guidelines on Assessment and Nonsurgical Management of Urinary Incontinence. *Eur Urol*. 2018 Apr;73(4):596-609. doi: 10.1016/j.eururo.2017.12.031. Epub 2018 Feb 3. PMID: 29398262.

European Society for Pediatric Gastroenterology, Hepatology, and Nutrition (ESPGHAN), North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition (NASPGHAN). Tabbers MM, DiLorenzo C, Berger MY, Faure BC, Langendam MW, Nurko S, Staiano A, Vandenplas Y, Benninga MA. Clinical Guideline. Evaluation and Treatment of Functional Constipation in Infants and Children: Evidence-Based Recommendations from ESPGHAN and NASPGHAN. *JPGN*. 2014 Feb;58(2):258-74. doi: 10.1097/MPG.0000000000000266.

Fritel X, Fauconnier A, Bader G, Cosson M, Debodinance P, Deffieux X, Denys P, Dompeyre P, Faltin D, Fotton B, Haab F, Hermieux JF, Kerdraon J, Mares P, Mellier G, Michel-Laaengh N, Nadeau C, Robain G, de Tayrac R, Jacquelin B; French College of Gynecologists and Obstetricians. Diagnosis and management of adult female stress urinary incontinence: guidelines for clinical practice from the French College of Gynecologists and Obstetricians. *Eur J Obstet Gynecol Reprod Biol*. 2010 Jul;151(1):14-9. doi: 10.1016/j.ejogrb.2010.02.041. Epub 2010 Mar 16. PMID: 20236751.

George AT, Kalmar K, Panerese A, Dudding TC, Nicholls RJ, Vaizey CJ. Long-term outcomes of sacral nerve stimulation for fecal incontinence. *Dis Colon Rectum*. 2012 Mar;55(3):302-6. doi: 10.1097/DCR.0b013e3182401ecd. PMID: 22469797.

Gorissen KJ, Bloemendaal AL, Prapasrivorakul S, Gosselink MP, Jones OM, Cunningham C, Lindsey I, Hompes R. Dynamic Article: Permanent Sacral Nerve Stimulation Under Local Anesthesia: Feasibility, Best Practice, and Patient Satisfaction. *Dis Colon Rectum*. 2015 Dec;58(12):1182-5. doi: 10.1097/DCR.0000000000000489. PMID: 26544816.

Groen J, Blok BF, Bosch JL. Sacral neuromodulation as treatment for refractory idiopathic urge urinary incontinence: 5-year results of a longitudinal study in 60 women. *J Urol*. 2011 Sep;186(3):954-9. doi: 10.1016/j.juro.2011.04.059. Epub 2011 Jul 24. PMID: 21791355.

Hayes. Clinical Assessment. Sacral Nerve Stimulation for Treatment of Non-obstructive Urinary Retention. Dallas, TX: Hayes; 2022 Feb 11.

Hayes. Evolving Evidence Review. Axonics Sacral Neuromodulation (Axonics Inc) for the Management of Urinary Dysfunction. Dallas, TX: Hayes; 2021 Sep 1.

Hotouras A, Murphy J, Allison M, Curry A, Williams NS, Knowles CH, Chan CL. Prospective clinical audit of two neuromodulatory treatments for fecal incontinence: sacral nerve stimulation (SNS) and percutaneous tibial nerve stimulation (PTNS). *Surg Today*. 2014 Nov;44(11):2124-30. doi: 10.1007/s00595-014-0898-0. Epub 2014 May 5. PMID: 24792064.

Hotouras A, Murphy J, Thin NN, Allison M, Horrocks E, Williams NS, Knowles CH, Chan CL. Outcome of sacral nerve stimulation for fecal incontinence in patients refractory to percutaneous tibial nerve

stimulation. *Dis Colon Rectum*. 2013 Jul;56(7):915-20. doi: 10.1097/DCR.0b013e31827f0697. PMID: 23739200.

Hull T, Giese C, Wexner SD, Mellgren A, Devroede G, Madoff RD, Stromberg K, Collier JA; SNS Study Group. Long-term durability of sacral nerve stimulation therapy for chronic fecal incontinence. *Dis Colon Rectum*. 2013 Feb;56(2):234-45. doi: 10.1097/DCR.0b013e318276b24c. PMID: 23303153.

Jelovsek JE, Reddy J. Surgical management of stress urinary incontinence in women: Choosing a primary surgical procedure. *UpToDate*. 2020 Apr 13. Updated: 2022 Apr 07.

Johnson BL 3rd, Abodeely A, Ferguson MA, Davis BR, Rafferty JF, Paquette IM. Is sacral neuromodulation here to stay? Clinical outcomes of a new treatment for fecal incontinence. *J Gastrointest Surg*. 2015 Jan;19(1):15-9; discussion 19-20. doi: 10.1007/s11605-014-2611-4. Epub 2014 Aug 13. PMID: 25115325.

Knowles CH, Thin N, Gill K, Bhan C, Grimmer K, Lunniss PJ, Williams NS, Scott SM. Prospective randomized double-blind study of temporary sacral nerve stimulation in patients with rectal evacuatory dysfunction and rectal hyposensitivity. *Ann Surg*. 2012 Apr;255(4):643-9. doi: 10.1097/SLA.0b013e318247d49f. PMID: 22418005.

Leong RK, De Wachter SG, Nieman FH, de Bie RA, van Kerrebroeck PE. PNE versus 1st stage tined lead procedure: a direct comparison to select the most sensitive test method to identify patients suitable for sacral neuromodulation therapy. *Neurourol Urodyn*. 2011 Sep;30(7):1249-52. doi: 10.1002/nau.20979. Epub 2011 Mar 14. PMID: 21404317.

Leroi AM, Lenne X, Dervaux B, Chartier-Kastler E, Mauroy B, Normand LL, Grise P, Faucheron JL, Parc Y, Lehur PA, Mion F, Damon H, Barth X, Leriche A, Saussine C, Guy L, Haab F, Bresler L, Sarramon JP, Bensadoun H, Rullier E, Slim K, Sielezneff I, Mourey E, Ballanger P, Michot F. Outcome and cost analysis of sacral nerve modulation for treating urinary and/or fecal incontinence. *Ann Surg*. 2011 Apr;253(4):720-32. doi: 10.1097/SLA.0b013e318210f1f4. PMID: 21475012.

Liberman D, Valiquette L. Concerns regarding sacral neuromodulation as a treatment option for medical-refractory overactive bladder. *Can Urol Assoc J*. 2011 Aug; 5(4):285-7. doi: 10.5489/cuaj.11043. PMID: 21801689.

Maeda Y, Kamm MA, Vaizey CJ, Matzel KE, Johansson C, Rosen H, Baeten CG, Laurberg S. Long-term outcome of sacral neuromodulation for chronic refractory constipation. *Tech Coloproctol*. 2017 Apr;21(4):277-286. doi: 10.1007/s10151-017-1613-0. Epub 2017 Apr 20. PMID: 28429130.

Martellucci J, Naldini G, Carriero A. Sacral nerve modulation in the treatment of chronic pelvic pain. *Int J Colorectal Dis*. 2012 Jul;27(7):921-6. doi: 10.1007/s00384-011-1394-2. Epub 2011 Dec 29. PMID: 22203519.

Martellucci J, Valeri A. Colonic electrical stimulation for the treatment of slow-transit constipation: a preliminary pilot study. *Surg Endosc.* 2014 Feb;28(2):691-7. doi: 10.1007/s00464-013-3192-0. Epub 2013 Sep 19. PMID: 24048815.

Maternik M, Krzeminska K, Zurowska A. The management of childhood urinary incontinence. *Pediatr Nephrol.* 2015 Jan;30(1):41-50. doi: 10.1007/s00467-014-2791-x. Epub 2014 Mar 11. PMID: 24615564.

Medtronic. Healthcare Professionals. InterStim™ System.

Mehmood S, Altaweel WM. Long-term outcome of sacral neuromodulation in patients with idiopathic nonobstructive urinary retention: Single-center experience. *Urol Ann.* 2017 Jul-Sep;9(3):244-248. doi: 10.4103/UA.UA_165_16. PMID: 28794590.

Mellgren A, Wexner SD, Collier JA, Devroede G, Lerew DR, Madoff RD, Hull T. Long-term efficacy and safety of sacral nerve stimulation for fecal incontinence. *Dis Colon Rectum.* 2011 Sep;54(9):1065-75. doi: 10.1097/DCR.0b013e31822155e9. PMID: 21825885.

Meyer I, Richter HE. An Evidence-Based Approach to the Evaluation, Diagnostic Assessment and Treatment of Fecal Incontinence in Women. *Curr Obstet Gynecol Rep.* Author manuscript; available in PMC 2014 Dec 8. Published in final edited form as: *Curr Obstet Gynecol Rep.* 2014 Sep;3(3):155-64. doi: 10.1007/s13669-014-0085-8. PMID: 25505643.

Monga AK, Tracey MR, Subbaroyan J. A systematic review of clinical studies of electrical stimulation for treatment of lower urinary tract dysfunction. *Int Urogynecol J.* 2012 Aug;23(8):993-1005. doi: 10.1007/s00192-012-1691-5. Epub 2012 Mar 17. PMID: 22426872.

Moya P, Arroyo A, Lacueva J, Candela F, Soriano-Irigaray L, López A, Gómez MA, Galindo I, Calpena R. Sacral nerve stimulation in the treatment of severe faecal incontinence: long-term clinical, manometric and quality of life results. *Tech Coloproctol.* 2014 Feb;18(2):179-85. doi: 10.1007/s10151-013-1022-y. Epub 2013 Apr 27. PMID: 23624794.

National Institute for Health and Care Excellence (NICE). Faecal incontinence in adults: management. Clinical Guideline CG49. 2007 Jun 27.

National Institute for Health and Care Excellence (NICE). Lower urinary tract symptoms in men: management. Clinical Guideline CG97. 2010 May 23. Last Updated 2015 Jun 3.

National Institute for Health and Care Excellence (NICE). Urinary incontinence in neurological disease: assessment and management. Clinical Guideline CG148. 2012 Aug 8.

National Institute for Health and Care Excellence (NICE). Urinary incontinence and pelvic organ prolapse in women: management. NICE Guideline NG123. 2019 Apr 2. Last Updated 2019 Jun 24.

Nepple KG, Cooper CS. Management of bladder dysfunction in children. *UpToDate.* 2021 Jun 22.

Sacral Nerve Stimulation (Including Peripheral Nerve Stimulation Test and Two-Stage Tined Lead Procedure)
for Incontinence and Urinary Conditions

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

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

Noblett KL, Cadish LA. Sacral nerve stimulation for the treatment of refractory voiding and bowel dysfunction. *Am J Obstet Gynecol*. 2014 Feb;210(2):99-106. doi: 10.1016/j.ajog.2013.07.025. Epub 2013 Jul 27. PMID: 23899452.

Noblett K, Siegel S, Mangel J, Griebing TL, Sutherland SE, Bird ET, Comiter C, Culkin D, Bennett J, Zylstra S, Kan F, Berg KC. Results of a prospective, multicenter study evaluating quality of life, safety, and efficacy of sacral neuromodulation at twelve months in subjects with symptoms of overactive bladder. *Neurourol Urodyn*. 2016 Feb;35(2):246-51. doi: 10.1002/nau.22707. Epub 2014 Dec 24. PMID: 25546568.

Pilkington SA, Emmett C, Knowles CH, Mason J, Yiannakou Y; NIHR CapaCiTY working group; Pelvic floor Society. Surgery for constipation: systematic review and practice recommendations: Results V: Sacral Nerve Stimulation. *Colorectal Dis*. 2017 Sep;19 Suppl 3:92-100. doi: 10.1111/codi.13780. PMID: 28960926.

Sanford MT, Suskind AM. Neuromodulation in neurogenic bladder. *Transl Androl Urol*. 2016 Feb;5(1):117-26. doi: 10.3978/j.issn.2223-4683.2015.12.01. PMID: 26904417.

Schober MS, Sulkowski JP, Lu PL, Minneci PC, Deans KJ, Teich S, Alpert SA. Sacral nerve stimulation for pediatric lower urinary tract dysfunction: development of a standardized pathway with objective urodynamic outcomes. *J Urol*. 2015 Dec;194(6):1721-6. doi: 10.1016/j.juro.2015.06.090. Epub 2015 Jun 30. PMID: 26141849.

Siegel S, Noblett K, Mangel J, Griebing TL, Sutherland SE, Bird ET, Comiter C, Culkin D, Bennett J, Zylstra S, Berg KC, Kan F, Irwin CP. Results of a prospective, randomized, multicenter study evaluating sacral neuromodulation with InterStim therapy compared with standard medical therapy at 6-months in subjects with mild symptoms of overactive bladder. *Neurourol Urodyn*. 2015 Mar;34(3):224-30. doi: 10.1002/nau.22544. Epub 2014 Jan 10. PMID: 24415559.

Sukhu T, Kennelly MJ, Kurpad R. Sacral neuromodulation in overactive bladder: a review and current perspectives. *Res Rep Urol*. 2016 Oct 26;8:193-199. doi: 10.2147/RRU.S89544. eCollection 2016.. PMID: 27822462.

Sulkowski JP, Nacion KM, Deans KJ, Minneci PC, Levitt MA, Mousa HM, Alpert SA, Teich S. Sacral nerve stimulation: a promising therapy for fecal and urinary incontinence and constipation in children. *J Pediatr Surg*. 2015 Oct;50(10):1644-7. doi:10.1016/j.jpedsurg.2015.03.043. Epub 2015 Mar 26. PMID: 25858097.

Tan E, Ngo NT, Darzi A, Shenouda M, Tekkis PP. Meta-analysis: sacral nerve stimulation versus conservative therapy in the treatment of fecal incontinence. *Int J Colorectal Dis.* 2011 Mar;26(3):275-94. doi: 10.1007/s00384-010-1119-y. Epub 2011 Jan 29. PMID: 21279370.

Thaha MA, Abukar AA, Thin NN, Ramsanahie A, Knowles CH. Sacral nerve stimulation for faecal incontinence and constipation in adults. *Cochrane Database Syst Rev.* 2015 Aug 24;(8):CD004464. doi: 10.1002/14651858.CD004464.pub3. PMID: 26299888.

Thin NN, Horrocks EJ, Hotouras A, Palit S, Thaha MA, Chan CL, Matzel KE, Knowles CH. Systematic review of the clinical effectiveness of neuromodulation in the treatment of faecal incontinence. *Br J Surg.* 2013 Oct;100(11):1430-47. doi: 10.1002/bjs.9226. PMID: 24037562.

Tirlapur SA, Vlismas A, Ball E, Khan KS. Nerve stimulation for chronic pelvic pain and bladder pain syndrome: a systematic review. *Acta Obstet Gynecol Scand.* 2013 Aug;92(8):881-7. doi: 10.1111/aogs.12184. Epub 2013 Jun 22. PMID: 23710833.

Tutolo M, Ammirati E, Heesakkers J, Kessler TM, Peters KM, Rashid T, Sievert KD, Spinelli M, Novara G, Van der Aa F, De Ridder D. Efficacy and Safety of Sacral and Percutaneous Tibial Neuromodulation in Non-neurogenic Lower Urinary Tract Dysfunction and Chronic Pelvic Pain: A Systematic Review of the Literature. *Eur Urol.* 2018 Mar;73(3):406-418. doi: 10.1016/j.eururo.2017.11.002. Epub 2018 Jan 12. PMID: 29336927.

U.S. Food and Drug Administration (FDA). Clinical Investigations of Devices Indicated for the Treatment of Urinary Incontinence – Guidance for Industry and FDA Staff. 2011 Mar 8.

U. S. Food and Drug Administration (FDA). Medical Devices. 510(k) Clearances.

U. S. Food and Drug Administration (FDA). Medical Devices. Device Registration and Listing.

U.S. Food and Drug Administration (FDA). Summary of Safety and Effectiveness Data (SSED). Implantable Electrical Stimulator for Incontinence. Medtronic® InterStim® Therapy System. Premarket Approval Application (PMA) Number P080025. 2011 Mar 14.

Valentini FA, Marti BG, Robain G, Nelson PP. Phasic or terminal detrusor overactivity in women: age, urodynamic findings and sphincter behavior relationships. *Int Braz J Urol.* 2011 Nov-Dec;37(6):773-80. doi.org/10.1590/S1677-55382011000600014. PMID: 22233983.

van der Wilt AA, van Wunnik BP, Sturkenboom R, Han-Geurts IJ, Melenhorst J, Benninga MA, Baeten CG, Breukink SO. Sacral neuromodulation in children and adolescents with chronic constipation refractory to conservative treatment. *Int J Colorectal Dis.* 2016 Aug;31(8):1459-66. doi: 10.1007/s00384-016-2604-8. Epub 2016 Jun 13. PMID: 27294660.

Van Kerrebroeck PE, Marcelissen TA. Sacral neuromodulation for lower urinary tract dysfunction. 2012 Aug;30(4):445-50. doi: 10.1007/s00345-011-0780-2. Epub 2011 Oct 12. PMID: 21989816.

Sacral Nerve Stimulation (Including Peripheral Nerve Stimulation Test and Two-Stage Tined Lead Procedure) for Incontinence and Urinary Conditions

Wald A. Diagnosis and Management of Fecal Incontinence. *Curr Gastroenterol Rep*. 2018 Mar 26;20(3):9. doi: 10.1007/s11894-018-0614-0. PMID: 29582182.

Wein AJ, Kavoussi LR, Partin AW, Peters CA. *Campbell-Walsh Urology*. 11th Edition. Elsevier. 2015 Nov 5.

Wexner SD, Collier JA, Devroede G, Hull T, McCallum R, Chan M, Ayscue JM, Shobeiri AS, Margolin D, England M, Kaufman H, Snape WJ, Mutlu E, Chua H, Pettit P, Nagle D, Madoff RD, Lerew DR, Mellgren A. Sacral nerve stimulation for fecal incontinence: results of a 120-patient prospective multicenter study. *Ann Surg*. 2010 Mar;251(3):441-9. doi: 10.1097/SLA.0b013e3181cf8ed0. PMID: 20160636.

Whitehead WE, Rao SS, Lowry A, Nagle D, Varma M, Bitar KN, Bharucha AE, Hamilton FA. Treatment of fecal incontinence: state of the science summary for the National Institute of Diabetes and Digestive and Kidney Diseases workshop. *Am J Gastroenterol*. 2015 Jan;110(1):138-46; quiz 147. doi: 10.1038/ajg.2014.303. Epub 2014 Oct 21. PMID: 25331348.

Zerbib F, Siproudhis L, Lehur PA, Germain C, Mion F, Leroi AM, Coffin B, Le Sidaner A, Vitton V, Bouyssou-Cellier C, Chene G; CONSTIMOD study investigators. Randomized clinical trial of sacral nerve stimulation for refractory constipation. *Br J Surg*. 2017 Feb;104(3):205-213. doi: 10.1002/bjs.10326. Epub 2016 Oct 25. PMID: 27779312.

Next Review Date

09/01/23

Authorizing Entity

MPCTAC

Appendix

Appendix: Policy History

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

Sacral Nerve Stimulation (Including Peripheral Nerve Stimulation Test and Two-Stage Tined Lead Procedure)
for Incontinence and Urinary Conditions

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.

Appendix: Policy History

Original Approval Date	Original Effective Date* and Version Number	Policy Owner	Original Policy Approved by
Regulatory Approval: N/A Internal Approval: 10/03/06	12/03/06 Version 1	Director of Medical Policy as Chair of Medical Policy, Criteria, and Technology Assessment Committee (MPCTAC)	Quality and Clinical Management Committee (Q&CMC)

*Effective Date for QHP Commercial Product: 01/01/12

*Effective Date for New Hampshire Medicaid Product: 01/01/13

*Effective Date for Senior Care Options Product: 01/01/16

*Effective Date for New Hampshire Medicare Advantage HMO Product: 01/01/22

Note: Effective 05/01/13, this policy replaced *Pelvic Floor/Sacral Nerve Stimulation for Urinary Incontinence* policy, policy number OCA 3.56, to include the medical necessity criteria for implantable sacral nerve stimulation and the policy title was changed to *Sacral Nerve Stimulation (Including Peripheral Nerve Stimulation Test and Two-Stage Tined Lead Procedure) for Incontinence and Urinary Conditions*.

Policy Revisions History			
Review Date	Summary of Revisions	Revision Effective Date and Version Number	Approved by
09/11/07	Updated template and added coding.	Version 2	09/11/07: MPCTAC 09/25/07: Utilization Management Committee (UMC) 10/15/07: Quality Improvement Committee (QIC)
09/09/08	No changes.	Version 3	09/09/08: MPCTAC 09/30/08: UMC 10/22/08: QIC
09/22/09	Updated references. No changes to criteria.	Version 4	09/22/09: MPCTAC 10/28/09: QIC
09/01/10	Updated template and references. No changes to criteria.	Version 5	10/20/10: MPCTAC 11/22/10: QIC
10/01/11	Updated limitations to include that sacral nerve stimulation for the treatment of fecal incontinence and posterior tibial nerve stimulation for the treatment of symptoms associated with overactive bladder are considered experimental and	Version 6	10/19/11: MPCTAC 11/29/11: QIC

Sacral Nerve Stimulation (Including Peripheral Nerve Stimulation Test and Two-Stage Tined Lead Procedure)
for Incontinence and Urinary Conditions

Policy Revisions History			
	investigational. Updated references and coding.		
07/20/12	Off cycle review for Well Sense Health Plan: Updated title, revised Summary statement, added posterior tibial stimulation to Description of Item or Service, reformatted Medical Policy Statement, updated Definitions, revised language in Applicable Coding section, updated code list.	Version 7	08/13/12: MPCTAC 09/13/12: QIC
12/01/12	Review for effective date 05/0/13. Separated pelvic floor electrical stimulation, implantable sacral nerve stimulation, and posterior tibial nerve stimulation into three separate policies; policy formerly titled <i>Pelvic Floor/Sacral Nerve Stimulation for Urinary Incontinence</i> (formerly OCA: 3.65). Revised title and re-numbered policy. Updated language in Summary, Description of Item or Service, Definitions, Applicable Coding, and Clinical Background Information sections. Reformatted criteria in Medical Policy Statement section and added criteria for peripheral nerve stimulation test and two-stage timed lead procedure, updated references, and added limitations. Revised applicable code list. Referenced the following policies: <i>Experimental and Investigational Treatment, Non-Implantable Pelvic Floor Electrical Stimulation for Urinary Incontinence, Posterior Tibial Nerve Stimulation, and Biofeedback for Urinary Incontinence</i> . Changed name of policy category from "Clinical Coverage Guidelines" to "Medical Policy."	05/01/13 Version 8	12/19/12: MPCTAC 01/31/13: QIC
12/01/13:	Review for effective date 02/01/14. Revised Description of Item or Service section. Reformatted Medical Policy Statement section without changing criteria. Updated code definitions without changing applicable code list. Updated references.	02/01/14 Version 9	12/18/13: MPCTAC 01/21/14: QIC
12/01/14	Review for effective date 02/01/15. Updated references.	02/01/15 Version 10	12/17/14: MPCTAC 01/14/15: QIC

Sacral Nerve Stimulation (Including Peripheral Nerve Stimulation Test and Two-Stage Timed Lead Procedure)
for Incontinence and Urinary Conditions

Policy Revisions History			
10/01/15	Review for effective date 12/01/15. Updated template with list of applicable products and corresponding notes.	12/01/15 Version 11	10/21/15: MPCTAC 11/11/15: QIC
10/21/15	Review for effective date 02/01/16. Revised limitations. Updated References, Definitions, and Clinical Background Information sections.	02/01/16 Version 12	10/21/15: MPCTAC 11/11/15: QIC
11/25/15	Review for effective date 02/01/16. Revised language in the Applicable Coding section.	02/01/16 Version 13	11/25/15: MPCTAC (electronic vote) 12/09/15: QIC
10/01/16	Review for effective date 12/01/16. Administrative changes made to the Summary, Medical Policy Statement, Definitions, Clinical Background Information, References, and References to Applicable Laws and Regulations sections. No change to criteria or applicable code list.	12/01/16 Version 14	10/19/16: MPCTAC 11/09/16: QIC
10/01/17	Review for effective date 01/01/18. Administrative changes made to the Policy Summary, Description of Item or Service, Definitions, Clinical Background Information, References, and Other Applicable Policies sections. Criteria revised in the Medical Policy Statement and Limitations sections.	01/01/18 Version 15	10/24/17: MPCTAC (electronic vote)
10/01/18	Review for effective date 01/01/19. Administrative changes made to the Policy Summary, Description of Item or Service, Definitions, Clinical Background Information, References, and Other Applicable Policies sections. Revised criteria in the Medical Policy Statement and Limitations sections.	01/01/19 Version 16	10/17/18: MPCTAC
09/01/19	Review for effective date 10/01/19. Administrative changes made to the Clinical Background Information, References, Other Applicable Policies, and Reference to Applicable Laws and Regulations sections. Revised Plan notes in the Applicable Coding section.	10/01/19 Version 17	09/18/19: MPCTAC
09/01/20	Review for effective date 10/01/20. Administrative changes made to the References and Other Applicable Policies sections.	10/01/20 Version 18	09/16/20: MPCTAC

Policy Revisions History			
10/01/21	Review for effective date 01/01/22. Adopted new medical policy template; removed administrative sections, Medical Policy Statement section renamed Clinical Criteria section, and Limitations section renamed Limitations and Exclusions section. Added NH Medicare Advantage HMO as an applicable product effective 01/01/22. Administrative changes made to the Policy Summary, Limitations and Exclusions, Applicable Coding, and References sections. Criteria revised in the Clinical Criteria section.	01/01/22 Version 19 Not implemented - replaced with Version 20	10/20/21: MPCTAC
12/01/21	Review for effective date 01/01/22. Industry-wide code description change in the Applicable Coding section. Revisions approved in version 19 implemented.	01/01/22 Version 20	Not applicable because industry-wide code description change; 12/15/21: MPCTAC review
09/01/22	Review for effective date 12/01/22. Administrative changes to Policy Summary, Clinical Criteria, Limitations and Exclusions, and References sections. ICD-10 diagnosis codes for fecal or urinary incontinence added to be billed in combination with CPT/HCPCS procedure codes in the Applicable Coding section.	12/01/22 Version 21	09/23/22: MPCTAC (electronic vote)



Medical Policy – Policy with InterQual Criteria Retired and AIM Criteria Adopted as of 12/01/22

Speech Therapy, Language Therapy, Voice Therapy, or Auditory Rehabilitation in the Outpatient Setting

Policy Number: OCA 3.542

Version Number: 33

Policy Retired Date: 12/01/22

Impacted Products

- All Products**
- NH Medicaid
- NH Medicare Advantage
- MA MassHealth ACO
- MA MassHealth MCO
- MA Qualified Health Plans/Employer Choice Direct
- MA Senior Care Options

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

Policy Summary

The Plan considers outpatient speech therapy (i.e., speech and language therapy, swallowing therapy, feeding therapy, aural or auditory rehabilitation, and/or voice therapy) medically necessary, including habilitative services and/or rehabilitative services, when AIM clinical appropriateness guidelines are met for an adult or pediatric member or are required EPSDT services for a member age 20 or younger on the date of service. Prior authorization from AIM Specialty Health is required for outpatient speech therapy (ST) after the initial evaluation. ST must be provided within the scope of practice of the treating professional and/or paraprofessional and follow all applicable state licensing and supervisory requirements.

Clinical Criteria

No medical policy criteria.

Limitations and Exclusions

None.

Variations

The Plan uses guidance from the Centers for Medicare & Medicaid Services (CMS) for medical necessity and coverage determinations for Plan's New Hampshire 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. At the time of the Plan's most recent policy review, no applicable clinical guidelines were found from CMS. Verify CMS criteria in effect for the requested service on the date of the prior authorization request for a NH Medicare Advantage HMO member. When there is no guidance from CMS for the requested service for the specified indication on the date of the prior authorization request, Plan-adopted clinical review criteria will be used to determine the medical necessity of the service.

Applicable Coding

The Plan utilizes up-to-date, industry-standard Current Procedural Terminology (CPT) codes, Health Care Common Procedure Coding System (HCPCS) codes, and International Statistical Classification of Diseases and Related Health Problems, 10th revision (ICD-10) diagnosis codes in the Plan's medical policies. The list of applicable codes included in this policy is informational only and may not be all inclusive. Applicable codes are subject to change without prior notification and do not guarantee member coverage or provider reimbursement. Review the Plan's reimbursement policies for Plan billing guidelines. Providers are responsible for obtaining prior authorization from AIM for speech therapy, even if an applicable code appropriately describing the service is not included in this policy's Applicable Coding section. Providers are expected to report all services using the most up-to-date, industry-standard procedures and diagnosis codes at the time of the service.

CPT Codes	Code Descriptions
92507	Treatment of speech, language, voice, communication, and/or auditory processing disorder; individual
92508	Treatment of speech, language, voice, communication, and/or auditory processing disorder; group, two or more individuals
92526	Treatment of swallowing dysfunction and/or oral function for feeding
92606	Therapeutic services for use of non-speech-generating device with programming
92609	Therapeutic services for use of speech-generating device with programming
97129	Therapeutic interventions that focus on cognitive function (e.g., attention, memory, reasoning, executive function, problem solving, and/or pragmatic functioning) and compensatory strategies to manage the performance of an activity (e.g., managing time or schedules, initiating, organizing, and sequencing tasks), direct (one-on-one) patient contact; initial 15 minutes
97130	Therapeutic interventions that focus on cognitive function (e.g., attention, memory, reasoning, executive function, problem solving, and/or pragmatic functioning) and compensatory strategies to manage the performance of an activity (e.g., managing time or schedules, initiating, organizing, and sequencing tasks), direct (one-on-one) patient contact; each additional 15 minutes (List separately in addition to code for primary procedure)

References

American Academy of Otolaryngology - Head and Neck Surgery Foundation (AAO-HNSF). Clinical Practice Guidelines.

American Academy of Otolaryngology - Head and Neck Surgery Foundation (AAO-HNSF). Schwartz S, Cohen S, Dailey S, Rosenfeld R, Deutsch E, Gillespie B, Granieri E, Hapner E, Kimball E, Krouse H, McMurray S, Medina S, O'Brien K, Ouellette D, Messinger-Rapport B, Stachler R, Strode S, Thompson D, Stemple J, Willging P, Cowley T, McCoy, Bernad P, Patel M. Clinical practice guideline: hoarseness (dysphonia). *Otolaryngol Head Neck Surg*. 2009 Sep;141(3S2):S1-31. doi: 10.1016/j.otohns.2009.06.744. PMID: 19729111.

American Academy of Otolaryngology - Head and Neck Surgery Foundation (AAO-HNSF). Stachler RJ, Francis DO, Schwartz SR, Damask CC, Digoy GP, Krouse HJ, McCoy SJ, Ouellette DR, Patel RR, Reavis CCW, Smith LJ, Smith M, Strode SW, Woo P, Nnacheta LC. Clinical Practice Guideline: Hoarseness (Dysphonia) (Update). *Otolaryngol Head Neck Surg*. 2018 Mar;158(1_suppl):S1-S42. doi: 10.1177/0194599817751030. PMID: 29494321.

American Speech-Language-Hearing Association (ASHA). Adult Speech and Language.

American Speech-Language-Hearing Association (ASHA). Cognitive-Communication. ASHA Policy Documents.

American Speech-Language-Hearing Association (ASHA). Scope of Practice in Speech-Language Pathology.

American Speech-Language-Hearing Association (ASHA). Speech-Language Pathology Medical Review Guidelines.

American Speech-Language-Hearing Association (ASHA). Stuttering.

American Speech-Language-Hearing Association (ASHA). Swallowing and Feeding Disorders.

Bahar-Fuchs A, Clare L, Woods B. Cognitive training and cognitive rehabilitation for persons with mild to moderate dementia of the Alzheimer's or vascular type: a review. *Alzheimers Res Ther*. 2013;5(4):35. doi: 10.1186/alzrt189. PMID: 23924584.

Centers for Medicare & Medicaid Services (CMS). Local Coverage Determination (LCD) L33580. Speech-Language Pathology. 2015 Oct 1. National Governmental Services, Inc. 2015 Dec 19. Revision Effective Date 2019 Dec 19.

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

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

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

Centers for Medicare & Medicaid Services (CMS). National Coverage Determination (NCD) 170.3. Speech-Language Pathology Services for the Treatment of Dysphagia. 2006 Oct 1.

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

Hauser RA. What is the Lee Silverman Voice Treatment (LSVT) program for Parkinson disease (PD)? Medscape. 2019 Aug 29.

Hayes. Health Technology Assessment. Cognitive Rehabilitation Therapy for Traumatic Brain Injury (TBI). Dallas, TX: Hayes; 2017 Sep 26. Annual Review 2021 Feb 8.

Hayes. Health Technology Assessment. Lee Silverman Voice Treatment (LSVT) LOUD for Speech and Voice Problems in Parkinson Disease. Dallas, TX: Hayes; 2020 Nov 9.

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

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

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

New Hampshire Medicaid. Therapies. Physical, Occupational, Speech. Provider Manual. Volume II. 2017 Dec 1.

New Hampshire Office of Professional Licensure and Certification. Office of Licensed Allied Health Professionals. Laws and Administrative Rules Governing Licensed Allied Health Professionals.

Next Review Date

Not applicable

Retired Date

12/01/22

Authorizing Entity

MPCTAC

Appendix

Appendix: Policy History

Disclaimer Information:

Plan refers to Boston Medical Center Health Plan, Inc. which operates under the trade name WellSense Health Plan. 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.

Appendix: Policy History

Original Approval Date	Original Effective Date* and Version	Policy Owner	Original Policy Approved by
Regulatory Approval: N/A Internal Approval: 03/16/11: Medical Policy, Criteria, and Technology Assessment Committee (MPCTAC) 04/27/11: Quality Improvement Committee (QIC)	07/01/11 Version 1	Director of Medical Policy as Chair of Medical Policy, Criteria, and Technology Assessment Committee (MPCTAC)	MPCTAC and QIC

* Effective Date for NH Medicaid Product: 01/01/13

* Effective Date for NH Medicare Advantage HMO Product: 01/01/22

Policy Revisions History			
Review Date	Summary of Revisions	Revision Effective Date and Version Number	Approved by
03/19/12	Updated references.	Version 2	03/21/12: MPCTAC 04/25/12: QIC
08/01/12	Off cycle review. Revised Summary statement, reformatted Medical Policy Statement, revised Applicable Coding introductory paragraph, updated code list, revised Limitations, and updated references.	Version 3	08/13/12: MPCTAC 09/06/12: QIC
11/01/12	Review for effective date 03/01/13. Updated references. Revised title so policy applies to members age 22 or older (rather than members over the age of 21). Added language in Summary section to clarify text. Referenced Plan reimbursement policy 4.609 for therapy reimbursement guidelines. Reorganized clinical criteria in Medical Policy Statement section and referenced InterQual® criteria. Revised applicable code list.	03/01/13 Version 4	11/21/12: MPCTAC 12/20/12: QIC
08/14/13 and 08/15/13	Off cycle review. Incorporate policy revisions dated 11/01/12 (as specified above) for the New Hampshire Medicaid product; these policy revisions were approved by MPCTAC on 11/21/12 and QIC on 12/20/12 for applicable Plan		08/14/13: MPCTAC (via electronic vote) 08/15/13: QIC

	products. Additional review of policy conducted.		
11/01/13, 12/01/13, 01/01/14, and 02/01/14	Review for effective date 05/01/14. Revised Applicable Coding section by updating code definitions and Plan notes, introductory paragraph, and applicable codes for the Massachusetts and New Hampshire products. Reformatted Limitations section without changing criteria. Updated references.	05/01/14 Version 5	02/11/14: MPCTAC 02/18/14: QIC
09/08/14	For New Hampshire products only, waive prior authorization of first 2 treatment sessions per member per servicing provider per calendar year.	10/01/14 Version 11 Addendum A	09/17/14: MPCTAC 09/30/14: QIC
11/04/14 and 11/19/14	Review for effective date 01/11/15. Summary and Medical Policy Statement sections updated with guidelines specified in version 11, addendum A. Policy renumbered OCA 3.542 to include speech therapy (and associated therapies) for members age 21 or older in the outpatient setting for Well Sense Health Plan members. Revised language in the Applicable Coding section without changing the applicable code list. Age range changed from age 22 or older to age 21 or older for adult Well Sense members; ST services for adult members formerly in policy number OCA 3.551. Revised review calendar.	01/11/15 Version 12	11/06/14: MPCTAC (electronic vote) 11/11/14: QIC (electronic vote) 11/19/14: MPCTAC 12/10/14: QIC
12/03/15	Review for effective date 01/01/16. Updated template and Summary section. Administrative changes made to the Medical Policy Statement and Limitations sections without changing criteria. Revised language in the Applicable Coding section. Added definitions.	01/01/16 Version 13	12/03/15: MPCTAC (electronic vote) 12/09/15: QIC
12/01/16	Review for effective date 02/01/17. Clarified existing criteria in the Medical Policy Statement section. Updated references.	02/01/17 Version 14	12/21/16: MPCTAC 01/11/17: QIC
05/01/17	Review for effective date 08/01/17. Removed CPT code 92524 from the applicable code list because it is an initial evaluation code for voice and resonance.	08/01/17 Version 15	05/17/17: MPCTAC
12/01/17	Review for effective date 01/01/17. Updated Policy Summary section.	01/01/17 Version 16	12/20/17: MPCTAC
12/01/17	Review for effective date 01/01/18. Industry-wide updates to codes included in the Applicable Coding section. Annual review of policy with administrative changes made to the	01/01/18 Version 17	12/20/17: MPCTAC

	Medical Policy Statement, Definitions, and Reference sections.		
02/01/18	Review for effective date 03/01/18. Administrative changes made to the Policy Summary and Limitations sections.	03/01/18 Version 18	02/21/18: MPCTAC
11/01/18	Review for effective date 12/01/18. Administrative changes made to the Limitations, Definitions, References, Other Applicable Policies, and Reference to Applicable Laws and Regulations sections.	12/01/18 Version 19	11/21/18: MPCTAC
03/01/19	Review for effective date 07/01/19. Administrative changes made to the Limitations and Reference to Applicable Laws and Regulations sections. Criteria revised in the Medical Policy Statement section.	07/01/19 Version 20	03/20/19: MPCTAC
05/01/19	Review for effective date 08/01/19. Revised criteria in the Medical Policy Statement section. Administrative changes made to the References and Reference to Applicable Laws and Regulations sections.	05/15/19 Version 21	05/15/19: MPCTAC
12/01/19	Review for effective date 01/01/20. Industry-wide code deletion required revision to coding in the Applicable Coding section.	01/01/20 Version 22	Not applicable because industry-wide code changes.
11/01/19	Review for effective date 02/01/20. Administrative changes made to the Policy Summary, References and Reference to Applicable Laws and Regulations sections. Criteria revised in the Medical Policy Statement and Limitations sections.	02/01/20 Version 23 Renumbered to Version 23 to implement industry-wide code updates effective 01/01/20 in Version 22	11/20/19: MPCTAC
12/01/19	Review for effective 02/01/20. Industry-wide code deletion required revision to coding in the Applicable Coding section of the policy version 23 effective 02/01/20.	02/01/20 Version 24	Not applicable because industry-wide code changes.
12/01/19	Review for effective date 03/01/20. Revised in the Medical Policy Statement section the definition of a servicing ST provider for the prior authorization waiver.	03/01/20 Version 25	12/18/19: MPCTAC
11/01/20	Review for effective date 02/01/21. Administrative changes made to the Definitions, Applicable Coding, and References sections. Revised criteria in the Medical Policy Statement section.	02/01/21 Version 26	11/18/20: MPCTAC

05/01/21	Review for effective date 08/01/21. Administrative changes made to the Policy Summary, Medical Policy Statement, Limitations, Definitions, and References sections. Codes added to the Applicable Coding section.	08/01/21 Version 27	05/19/21: MPCTAC
10/01/21	Review for effective date 01/01/22. Adopted new medical policy template; removed administrative sections, Medical Policy Statement section renamed Clinical Criteria section, and Limitations section renamed Limitations and Exclusions section. Administrative changes made to the Policy Summary, Limitations and Exclusions, Applicable Coding, and References sections. Added New Hampshire Medicare Advantage HMO as an applicable product effective 01/01/22. Added gender dysphoria as a medically necessary indication for voice therapy in the Criteria section.	01/01/22 Version 28	10/20/21: MPCTAC
02/01/22	Review for effective date 02/01/22. Administrative changes made to the Policy Summary. Revised policy title because policy will apply to adult and pediatric members. Adopted InterQual criteria to determine medical necessity and retired medical policy criteria. Gender dysphoria specified as a medically necessary indication for voice therapy in the <i>Gender Affirmation Services</i> medical policy, OCA 3.11, as of 01/01/22.	02/01/22 Version 29	11/17/21: MPCTAC
05/01/22	Review for effective date 06/01/22. Administrative changes made to the Policy Summary, Clinical Criteria, Limitations and Exclusions, and Applicable Coding sections.	06/01/22 Version 30	05/11/22: MPCTAC (electronic vote)
05/01/22	Review for effective date 08/01/22. Revised code list in the Applicable Coding section.	08/01/22 Version 31	05/11/22: MPCTAC
08/01/22	Review for policy retired date 11/01/22. Administrative changes made to the Policy Summary and Applicable Coding sections. InterQual medical necessity criteria and medical policy guidelines in the Clinical Criteria and Limitations and Exclusions sections retired on 11/01/22. AIM criteria adopted for outpatient ST on 11/01/22. Plan prior authorization waivers removed after 10/31/22. AIM prior authorization is required for outpatient ST after	11/01/22 Version 32 Version 32 NOT implemented; Version 31 effective 08/01/22 to 11/30/22	08/26/22: MPCTAC (electronic vote)

	the initial evaluation as of 11/01/22, even when applicable codes are not listed in this Plan policy.		
09/01/22	Review for policy retired date 12/01/22. The effective date of AIM Specialty Health's management of outpatient rehabilitation services changed from 11/01/22 to 12/01/22. Administrative changes made to the Policy Summary and Applicable Coding sections. InterQual medical necessity criteria and medical policy guidelines in the Clinical Criteria and Limitations and Exclusions sections retired as of 12/01/22. AIM criteria adopted for outpatient ST for dates of service on or after 12/01/22. Plan prior authorization waivers removed after 11/30/22. AIM prior authorization is required for outpatient ST after the initial evaluation as of 12/01/22, even when applicable codes are not listed in this Plan policy.	12/01/22 Version 33	09/23/22: MPCTAC (electronic vote)

Temporomandibular Joint Disorder Treatment

Policy Number: OCA 3.968

Version Number: 23

Version Effective Date: 11/01/22

Impacted Products

- All Products**
- NH Medicaid
- NH Medicare Advantage
- MA MassHealth ACO
- MA MassHealth MCO
- MA Qualified Health Plans/Employer Choice Direct
- MA Senior Care Options

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

Policy Summary

The Plan considers medical and/or surgical (non-dental) treatment of a temporomandibular joint (TMJ) disorders to be medically necessary ONLY when the disorders are caused by, or results from a specific medical condition. Examples of specific medical conditions include jaw fractures and/or dislocations and degenerative arthritis. Plan prior authorization is required. Separate coverage is outlined in the member's benefit documents for dental services (if dental services are covered for the Plan member). This medical policy ONLY includes guidelines for TMJ disorders related to a medical condition for medical and/or surgical (non-dental) treatment.

For dates of service on or after November 1, 2022, the Plan uses AIM clinical appropriateness guidelines to determine the medical necessity of radiology services, musculoskeletal services (i.e., spine surgeries, joint surgeries, and interventional pain management treatments) and genetic testing. AIM manages outpatient rehabilitation services (i.e., physical therapy, occupational therapy, and speech therapy) for Plan members for dates of service on or after December 1, 2022. Prior authorization from AIM Specialty Health is required for these services.

Clinical Criteria

Criteria must be met in item A (medical necessity criteria) or item B (services that require Plan Medical Director review):

A. Criteria must be met in either item 1 or item 2:

1. Initial Medical Evaluation: Prior authorization is REQUIRED for the initial medical evaluation for a TMJ disorder ONLY when conducted by a provider who is NOT a participating oral and maxillofacial surgeon or participating otolaryngologist; OR
2. Treatment after the Initial Evaluation: All medical and/or surgical treatments for TMJ disorders REQUIRE prior authorization after the initial medical evaluation. ALL criteria must be met in items a through c:
 - a. Medical condition eligible for treatment includes ANY of the following:
 - (1) Jaw fracture or jaw dislocation (i.e., current fracture or acute dislocation); OR
 - (2) Degenerative arthritis; AND
 - b. Medical condition is confirmed by diagnostic x-rays or other generally accepted diagnostic procedures used to diagnose a jaw fracture, jaw dislocation, and/or degenerative arthritis, including but not limited to a CT scan, MRI, tomogram, or arthrogram; AND
 - c. Based on the treatment plan determined by the treating provider, the member requires ANY treatment specified in item (1) or item (2):
 - (1) Criteria for Non-Surgical Treatment: Covered first-line, conservative treatment may include diet and behavior modification and ANY combination of treatment listed below in items (a) through (e):
 - (a) Pharmacologic therapy such as anti-inflammatory, muscle relaxants, and/or analgesics (according to guidelines included in the Plan's pharmacy policies and formulary applicable for the member's benefit coverage); OR
 - (b) Occupational therapy, speech therapy, and/or physical therapy; OR
 - (c) Use of mandibular orthopedic repositioning appliances (MORA); OR
 - (d) Therapeutic injections (e.g. local anesthetic or corticosteroids); OR
 - (e) Manipulation for reduction of fracture or dislocation; OR
 - (2) Criteria for Surgical Treatment: ANY criteria must be met in items (a) through (e):
 - (a) Arthrocentesis (e.g., for acute closed lock); OR
 - (b) Arthroscopic surgery (e.g., for arthritis); OR

- (c) Intraoral vertical ramus osteotomy (IVRO) to correct internal derangements; OR
- (d) Open surgical procedure such as open reduction, arthroplasty, condylectomy, meniscus or disc plication, or disc removal; OR
- (e) TMJ arthroplasty will be performed with an FDA-approved prosthetic implant (only) according to the FDA-approved indication for the implantation.

B. Medical Director review is required for individual consideration when medical necessity criteria are NOT met and/or the disorder may be caused by a medical condition other than a jaw fracture, jaw dislocation, and/or degenerative arthritis.

Limitations and Exclusions

- A. The treatment of TMJ disorders or TMJ syndrome that is NOT related to a medical condition would be considered a dental service rather than a medical benefit.
- B. ANY of the following services is considered NOT medically necessary for the assessment and/or treatment of TMJ disorders or other TMJ-related indications:
 - 1. Treatment of a TMJ disorder that is NOT proven to be caused by or to result in a specific medical condition; OR
 - 2. Acupuncture (unless a covered benefit for the member for the specified indication); OR
 - 3. Arthroscopy of the TMJ for diagnostic purposes only; OR
 - 4. Biofeedback; OR
 - 5. Dental or orthodontic services (including restorations, prostheses procedures, radiographic images, oral/facial photographic images, supplies) for TMJ-related indications and/or to adjust the height of teeth or other way restore occlusion, such as crowns, bridges, braces; OR
 - 6. Devices/appliances such as mechanical stretching devices or devices to maintain range of motion, gain increased range of motion, and/or improve functioning of the TMJ, including but not limited to continuous passive motion (CPM) devices, passive rehabilitation therapy devices, mandibular orthopedic repositioning appliances (MORA); OR
 - 7. Dry needling alone or in combination with a stretching regimen used to reduce pain and increase range of motion in patients with TMJ pain; OR
 - 8. Electrical stimulation techniques such as:

- a. Electrogalvanic stimulation; OR
 - b. Microcurrent electrical therapy (MET); OR
 - c. Percutaneous electrical stimulation (PENS); OR
 - d. Percutaneous neuromodulation therapy (e.g., the Percutaneous Neuromodulation Therapy™ by Vertis Neurosciences system or the Deepwave® Percutaneous Neuromodulation Pain Therapy System by Biowave Corp.); OR
 - e. Transcutaneous electrical nerve stimulation (TENS); OR
- 9. Electromyography (EMG); OR
 - 10. Intra-articular injection of hyaluronic acid (viscosupplementation); OR
 - 11. Iontophoresis using electricity to enhance the percutaneous absorption of a drug or chemical ions (e.g., lidocaine hydrochloride, dexamethasone sodium phosphate); OR
 - 12. Jaw tracking devices, computerized jaw tracking technologies, and associated jaw tracking services using one or more technologies/services (e.g., TENS, 3D imaging/computerized mandibular scans, kinesiography, magnetic recording devices, electronic motion recording methods, and/or range of motion measurements); OR
 - 13. Kinesiography; OR
 - 14. Laser therapy; OR
 - 15. Neuromuscular junction studies, range of motion measurements, and/or muscle testing; OR
 - 16. Phonophoresis using ultrasound to enhance the delivery of topically applied drugs; OR
 - 17. Somatosensory testing (also known as somatosensory evoked potentials test, SEPs, or SSEPs);
OR
 - 18. Thermography (including digital infrared thermal imaging, magnetic resonance thermography and temperature gradient studies); OR
 - 19. Transcranial or lateral skull x-rays; OR
 - 20. Ultrasonic Doppler auscultation/ultrasound imaging/sonogram for diagnosing disorders of the temporomandibular joint; OR

21. Use of a TMJ arthroplasty implant or device not FDA approved or not used according to FDA-approved indications.

Variations

The Plan uses guidance from the Centers for Medicare & Medicaid Services (CMS) for medical necessity and coverage determinations for the Plan’s Senior Care Options (SCO) members and New Hampshire 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. At the time of the Plan’s most recent policy review, no applicable clinical guidelines were found from CMS specifically for temporomandibular joint disorder, but CMS guidelines do exist for services that may be used for the diagnosis or treatment of TMJ. Verify CMS criteria in effect on the date of the prior authorization request. When there is no guidance from CMS for the requested service for the specified indication on the date of the prior authorization request, Plan-adopted clinical review criteria will be used to determine the medical necessity of the service.

Applicable Coding

The Plan utilizes up-to-date, industry-standard Current Procedural Terminology (CPT) codes, Health Care Common Procedure Coding System (HCPCS) codes, and International Statistical Classification of Diseases and Related Health Problems, 10th revision (ICD-10) diagnosis codes in the Plan’s medical policies. Since these codes may be updated at different intervals than the medical policy review cycle, the list of applicable codes included in a policy is informational only and may not be all inclusive. Applicable codes are subject to change without prior notification and do not guarantee member coverage or provider reimbursement. Review the Plan’s reimbursement policies for Plan billing guidelines. Providers are responsible for obtaining prior authorization for the services specified in the Clinical Criteria section and Limitations and Exclusions section of a medical policy, even if an applicable code appropriately describing the service is not included in the policy’s Applicable Coding section. Providers are expected to report all services using the most up-to-date, industry-standard procedures and diagnosis codes at the time of the service.

ICD-10 Diagnosis Codes	Description: Diagnoses Requiring Prior Authorization for Any Treatment
M26.601	Right temporomandibular joint disorder
M26.602	Left temporomandibular joint disorder
M26.603	Bilateral temporomandibular joint disorder
M26.609	Unspecified temporomandibular joint disorder
M26.611	Adhesions and ankylosis of right temporomandibular joint
M26.612	Adhesions and ankylosis of left temporomandibular joint
M26.613	Adhesions and ankylosis of bilateral temporomandibular joint
M26.619	Adhesions and ankylosis of temporomandibular joint, unspecified side

Temporomandibular Joint Disorder Treatment

M26.621	Arthralgia of right temporomandibular joint
M26.622	Arthralgia of left temporomandibular joint
M26.623	Arthralgia of bilateral temporomandibular joint
M26.629	Arthralgia of temporomandibular joint
M26.631	Articular disc disorder of right temporomandibular joint
M26.632	Articular disc disorder of left temporomandibular joint
M26.633	Articular disc disorder of bilateral temporomandibular joint
M26.639	Articular disc disorder of temporomandibular joint, unspecified side
M26.641	Arthritis of right temporomandibular joint
M26.642	Arthritis of left temporomandibular joint
M26.643	Arthritis of bilateral temporomandibular joint
M26.649	Arthritis of unspecified temporomandibular joint
M26.651	Arthropathy of right temporomandibular joint
M26.652	Arthropathy of left temporomandibular joint
M26.653	Arthropathy of bilateral temporomandibular joint
M26.659	Arthropathy of unspecified temporomandibular joint
M26.69	Other specified disorders of temporomandibular joint

References

Abboud WA, Givol N, Yahalom R. Arthroscopic lysis and lavage for internal derangement of the temporomandibular joint. *Ann Maxillofac Surg*. 2015 Jul-Dec;5(2):158-62. doi: 10.4103/2231-0746.175754. PMID: 26981463.

Abboud WA, Yarom N, Yahalom R, Joachim M, Reiter S, Koren O, Elishoov H. Comparison of two physiotherapy programs for rehabilitation after temporomandibular joint arthroscopy. *Int J Oral Maxillofac Surg*. 2018 Jun;47(6):755-61. doi: 10.1016/j.ijom.2017.10.019. Epub 2017 Nov 15. PMID: 29150380.

Abboud W, Nadel S, Yarom N, Yahalom R. Arthroscopy of the Temporomandibular Joint for the Treatment of Chronic Closed Lock. *Isr Med Assoc J*. 2016 Jul;18(7):397-400. PMID: 28471560.

Abboud W, Yahalom R, Leiba M, Greenberg G, Yarom N. Temporomandibular joint involvement in patients with multiple myeloma-a retrospective study. *Int J Oral Maxillofac Surg*. 2016 Dec;45(12):1545-50. doi: 10.1016/j.ijom.2016.06.014. Epub 2016 Jul 1. PMID: 27377681.

Al-Baghdadi M, Durham J, Steele J. Timing interventions in relation to temporomandibular joint closed lock duration: a systematic review of 'locking duration.' *J Oral Rehabil*. 2014 Jan;41(1):24-58. doi: 10.1111/joor.12126. Epub 2014 Jan 7. PMID: 24393132.

Al-Morass EA. Open versus arthroscopic surgery for the management of internal derangement of the temporomandibular joint: a meta-analysis of the literature. *Int J Oral Maxillofac Surg*. 2015 Jun;44(6):763-70. doi: 10.1016/j.ijom.2015.01.024. Epub 2015 Feb 18. PMID: 25701306.

The American Academy of Orofacial Pain (AAOP). Orofacial Pain: Guidelines for Assessment, Diagnosis and Management. Fifth Edition. 2013.

American Association of Oral and Maxillofacial Surgeons (AAOMS). Parameters of Care Version 6: Clinical Practice Guidelines for Oral and Maxillofacial Surgery. 2017.

American Dental Association. Clinical Practice Guidelines.

American Society of Temporomandibular Joint Surgeons (ASTMJS). Guidelines.

American Society of Temporomandibular Joint Surgeons (ASTMJS). Guidelines for diagnosis and management of disorders involving the temporomandibular joint and related musculoskeletal structures. *Cranio*. 2003 Jan;21(1):68-76. PMID: 12555934.

Blasco-Bonora PM, Martín-Pintado-Zugasti A. Effects of myofascial trigger point dry needling in patients with sleep bruxism and temporomandibular disorders: a prospective case series. *Acupunct Med*. 2017 Mar;35(1):69-74. doi: 10.1136/acupmed-2016-011102. Epub 2016 Oct 3. PMID: 27697769.

Butts R, Dunning J, Pavkovich R, Mettillie J, Mourad F. Conservative management of temporomandibular dysfunction: A literature review with implications for clinical practice guidelines (Narrative review part 2). *J Bodyw Mov Ther*. 2017 Jul; 21(3):541-548. doi: 10.1016/j.jbmt.2017.05.021. Epub 2017 Jun 1. PMID: 28750962.

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

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

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

Centers for Medicare & Medicaid Service (CMS). National Coverage Determination (NCD) for Assessing Patient's Suitability for Electrical Nerve Stimulation Therapy 160.7.1. Version 2. 2006 Jun 19.

Centers for Medicare & Medicaid Service (CMS). National Coverage Determination (NCD) for Manipulation 150.1. Effective date not posted.

Centers for Medicare & Medicaid Service (CMS). National Coverage Determination (NCD) for Transcutaneous Electrical Nerve Stimulators (TENS) 280.13. Version 2. 2012 Jun 8.

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

Chebbi R, Khalifa HB, Dhidah M. Temporomandibular joint disorder in systemic sclerosis: a case report. *Pan Afr Med J*. 2016 Nov 16;25:164. doi: 10.11604/pamj.2016.25.164.10432. eCollection 2016.

PMID: 28292126.

Chen YW, Chiu YW, Chen CY, Chuang SK. Botulinum toxin therapy for temporomandibular joint disorders: a systematic review of randomized controlled trials. *Int J Oral Maxillofac Surg.* 2015 Aug;44(8):1018-26. doi: 10.1016/j.ijom.2015.04.003. Epub 2015 Apr 25. PMID: 25920597.

Cömert Kiliç S, Güngörmüs M. Is dextrose prolotherapy superior to placebo for the treatment of temporomandibular joint hypermobility? A randomized clinical trial. *Int J Oral Maxillofac Surg.* 2016 Jul;45(7):813-9. doi: 10.1016/j.ijom.2016.01.006. Epub 2016 Feb 2. PMID: 2684679.

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

Commonwealth of Massachusetts. MassHealth Provider Bulletins.

Commonwealth of Massachusetts. MassHealth Provider Manuals.

Commonwealth of Massachusetts. MassHealth Transmittal Letters.

de Freitas RF, Ferreira MÂ, Barbosa GA, Calderon PS. Counselling and self-management therapies for temporomandibular disorders: a systematic review. *J Oral Rehabil.* 2013 Nov;40(11):864-74. doi: 10.1111/joor.12098. Epub 2013 Sep 18. PMID: 24102692.

de Leeuw R, Klasser GD. *Orofacial Pain: Guidelines for Assessment, Diagnosis, and Management*, Fifth Edition. 2013.

Gauer RL, Semidey MJ. Diagnosis and Treatment of Temporomandibular Disorders. *Am Fam Physician.* 2015 Mar 15; 91(6):378-86. PMID: 25822556.

Gurung T, Singh RK, Mohammad S, Pal US, Mahdi AA, Kumar M. Efficacy of arthrocentesis versus arthrocentesis with sodium hyaluronic acid in temporomandibular joint osteoarthritis: A comparison. *Natl J Maxillofac Surg.* 2017 Jan-Jun;8(1):41-9. doi: 10.4103/njms.NJMS_84_16. PMID: 28761275.

Hayes. Comparative Effectiveness Review. Comparative Effectiveness Review of Dry Needling for Indications Other than Neck or Trapezius Muscle Pain in Adults. Dallas, TX: Hayes; 2017 Jun 22. Annual Review 2021 Jun 30.

Huang IY, Chen CM, Kao YH, Chen CM, Wu CW. Management of long-standing mandibular dislocation. *Int J Oral Maxillofac Surg.* 2011 Aug;40(8):810-4. doi: 10.1016/j.ijom.2011.02.031. Epub 2011 Apr 6. PMID: 21474286.

Huang IY. A simple method to expand the joint space for TMJ surgery. *Int J Oral Maxillofac Surg.* 2011 Sep;40(9):983-4. doi: 10.1016/j.ijom.2011.04.011. Epub 2011 May 23. PMID: 21602029.

Ivorra-Carbonell L, Montiel-Company JM, Almerich-Silla JM, Paredes-Gallardo V, Bellot-Arcis C. Impact of functional mandibular advancement appliances on the temporomandibular joint - a systematic review. *Med Oral Patol Oral Cir Buccal*. 2016 Sep; 21(5):e565-72. doi: 10.4317/medoral.21180. PMID: 27475694.

Korkmaz YT, Altintas NY, Korkmaz FM, Candırlı C, Coskun U, Durmuslar MC. Is Hyaluronic Acid Injection Effective for the Treatment of Temporomandibular Joint Disc Displacement With Reduction? *J Oral Maxillofac Surg*. 2016 Sep;74(9):1728-40. doi: 10.1016/j.joms.2016.03.005. Epub 2016 Mar 15. PMID: 27058964.

Liu F, Steinkeler A. Epidemiology, diagnosis, and treatment of temporomandibular disorders. *Dent Clin North Am*. 2013 Jul;57(3):465-79. doi: 10.1016/j.cden.2013.04.006. PMID: 23809304.

MacIntosh RB, Shivapuja PK, Naqvi R. Scleroderma and the temporomandibular joint: reconstruction in 2 variants. *J Oral Maxillofac Surg*. 2015 Jun;73(6):1199-210. doi: 10.1016/j.joms.2014.12.012. Epub 2014 Dec 17. PMID: 25795177.

Majumdar SK, Krishna S, Chatterjee A, Chakraborty R, Ansari N. Single Injection Technique Prolotherapy for Hypermobility Disorders of TMJ Using 25% Dextrose: A Clinical Study. *J Maxillofac Oral Surg*. 2017 Jun;16(2):226-30. doi: 10.1007/s12663-016-0944-0. Epub 2016 Jul 25. PMID: 28439165.

Manfredini D. *Current Concepts on Temporomandibular Disorders*. Quintessence Publishers 2010.
Manfredini D, Favero L, Michieli M, Salmaso L, Cocilovo F, Guarda-Nardini L. An assessment of the usefulness of jaw kinesiography in monitoring temporomandibular disorders: correlation of treatment-related kinesiographic and pain changes in patients receiving temporomandibular joint injections. *J Am Dent Assoc*. 2013 Apr;144(4):397-405. PMID: 23543694.

Martins WD, Ribas Mde O, Bisinelli J, França BH, Martins G. Recurrent dislocation of the temporomandibular joint: a literature review and two case reports treated with eminectomy. *Cranio*. 2014 Apr; 32(2):110-7. doi: 10.1179/0886963413Z.00000000017. PMID: 24839722.

Mina R, Melson P, Powell S, Rao M, Hinze C, Passo M, Graham TB, Brunner HI. Effectiveness of dexamethasone iontophoresis for temporomandibular joint involvement in juvenile idiopathic arthritis. *Arthritis Care Res (Hoboken)*. 2011 Nov;63(11):1511-6. doi: 10.1002/acr.20600. PMID: 22034112.

Monje-Gil F, Nitzan D, González-García R. Temporomandibular joint arthrocentesis. Review of the literature. *Med Oral Patol Oral Cir Buccal*. 2012 July;17(4): e575-81. PMID: 22322493.

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

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

Niibo P, Pruunsild C, Voog-Oras Ü, Nikopensus T, Jagomägi T, Saag M. Contemporary management of TMJ involvement in JIA patients and its orofacial consequences. *EPMA J*. 2016 Jun 2;7:12. doi: 10.1186/s13167-016-0061-7. eCollection 2016. PMID: 27257443.

O'Connor RC, Fawthrop F, Salha R, Sidebottom AJ. Management of the temporomandibular joint in inflammatory arthritis: Involvement of surgical procedures. *Eur J Rheumatol*. 2017 Jun;4(2):151-6. doi: 10.5152/eurjrheum.2016.035. Epub 2017 Feb 23. PMID: 28638693.

Politi M, Sembronio S, Robiony M, Costa F, Toro C, Undt G. High condylectomy and disc repositioning compared to arthroscopic lysis, lavage, and capsular stretch for the treatment of chronic closed lock of the temporomandibular joint. *Oral Surg Oral Med Oral Pathol Oral Radiol Endod*. 2007 Jan;103(1):27-33. Epub 2006 Jul 27. PMID: 17178490.

Prechel U, Ottl P, Ahlers OM, Neff A. The Treatment of Temporomandibular Joint Dislocation. *Dtsch Arztebl Int*. 2018 Feb 2; 115(5):59-64. doi: 10.3238/arztebl.2018.0059. PMID: 29439762.

Rigon M, Pereira LM, Bortoluzzi MC, Loguercio AD, Ramos AL, Cardoso JR. Arthroscopy for Temporomandibular Disorders. *Cochrane Database Syst Rev*. 2011 May 11 ;(5):CD006385. doi: 10.1002/14651858.CD006385.pub2. PMID: 21563153.

Rodrigues-Bigaton D, Dibai Filho AV, Costa AC, Packer AC, de Castro EM. Accuracy and reliability of infrared thermography in the diagnosis of arthralgia in women with temporomandibular disorder. *J Manipulative Physiol Ther*. 2013 May;36(4):253-8. doi: 10.1016/j.jmpt.2013.04.006. Epub 2013 May 27. PMID: 23719519.

Rodrigues PC, da Mota AS, Pereira JR, Stuginski-Barbosa J. Management of painful temporomandibular joint clicking with different intraoral devices and counseling: a controlled study. *J Appl Oral Sci*. 2015 Sep-Oct;23(5):529-35. doi: 10.1590/1678-775720140438. PMID: 2621948.

Schiffman EL, Velly AM, Look JO, Hodges JS, Swift JQ, Decker KL, Anderson QN, Templeton RB, Lenton PA, Kang W, Friction JR. Effects of four treatment strategies for temporomandibular joint closed lock. *Int J Oral Maxillofac Surg*. 2014 Feb;43(2):217-26. doi: 10.1016/j.ijom.2013.07.744. Epub 2013 Sep 14. PMID: 24042068.

Schiffman E, Ohrbach R. Executive summary of the Diagnostic Criteria for Temporomandibular Disorders for clinical and research applications. *J Am Dent Assoc*. 2016 Jun;147(6):438-45. doi: 10.1016/j.adaj.2016.01.007. PMID: 26922248.

Scrivani SJ, Khawaja SN, Bavia PF. Nonsurgical Management of Pediatric Temporomandibular Joint Dysfunction. *Oral Maxillofac Surg Clin North Am*. 2018 Feb;30(1):35-45. doi: 10.1016/j.coms.2017.08.001. PMID: 29153236.

Shukla D, Muthusekhar MR. Efficacy of low-level laser therapy in temporomandibular disorders: A systematic review. *Natl J Maxillofac Surg*. 2016 Jan-Jun;7(1):62-6. doi: 10.4103/0975-5950.196127.

PMID: 28163481.

U. S. Food & Drug Administration (FDA). Medical Devices. 510(k) Clearances.

U.S. Food & Drug Administration (FDA). 510(k) Summary for the Biowave Deepwave Percutaneous Neuromodulation Pain Therapy System. 2006 Jul 19.

U.S. Food & Drug Administration (FDA). 510(k) Summary of Safety and Effectiveness. Vertis Neuroscience, Inc. Percutaneous Neuromodulation Therapy (PNT)™ Control Unit and Accessories. 2002.

U. S. Food & Drug Administration (FDA). Medical Devices. Device Registration and Listing.

Wieckiewicz M, Boening K, Wiland P, Shiau YY, Paradowska-Stolarz A. Reported concepts for the treatment modalities and pain management of temporomandibular disorders. *J Headache Pain*. 2015;16:106. doi: 10.1186/s10194-015-0586-5. Epub 2015 Dec 7. PMID: 26644030.

Xu GZ, Jia J, Jin L, Li JH, Wang ZY, Cao DY. Low-Level Laser Therapy for Temporomandibular Disorders: A Systematic Review with Meta-Analysis. *Pain Res Manag*. 2018 May 10;2018:4230583. doi: 10.1155/2018/4230583. eCollection 2018. PMID: 29861802.

Zhang C, Wu JY, Deng DL, He BY, Tao Y, Niu YM, Deng MH. Efficacy of splint therapy for the management of temporomandibular disorders: a meta-analysis. *Oncotarget*. 2016 Dec 20;7(51):84043-53. doi: 10.18632/oncotarget.13059. PMID: 27823980.

Next Review Date

07/01/23

Authorizing Entity

MPCTAC

Appendix

Appendix: Policy History

Disclaimer Information:

Plan refers to Boston Medical Center Health Plan, Inc. which operates under the trade name WellSense Health Plan. 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.

Appendix: Policy History

Original Approval Date	Original Effective Date* and Version	Policy Owner	Original Policy Approved by
Regulatory Approval: N/A Internal Approval: 09/09/08: Medical Policy, Criteria, and Technology Assessment Committee (MPCTAC) 09/30/08: Utilization Management Committee (UMC) 10/22/08: Quality Improvement Committee (QIC)	01/01/09 Version 1	Director of Medical Policy as Chair of MPCTAC	MPCTAC, QIC, and UMC

*Effective Date for QHP Commercial Product: 01/01/12

*Effective Date for New Hampshire Medicaid Product: 01/01/13

*Effective Date for Senior Care Options Product: 01/01/16

*Effective Date for New Hampshire Medicare Advantage HMO Product: 01/01/22

Policy Revisions History			
Review Date	Summary of Revisions	Revision Effective Date and Version Number	Approved by
09/22/09	No criteria changes. Updated references.	Version 2	09/22/09: MPCTAC 10/28/09: QIC
09/01/10	No changes to criteria. Updated references and coding.	Version 3	09/15/10: MPCTAC 11/22/10: QIC
09/01/11	Updated limitations and references.	Version 4	09/21/11: MPCTAC 10/26/11: QIC
07/01/12	References updated, revised language in the Applicable Coding section, and deleted four-digit diagnosis code 524.6.	Version 5	07/18/12: MPCTAC 08/22/12: QIC
07/01/13	Review for effective date 11/01/13. Updated references. Added criteria for medical evaluation of TMJ disorders. Reformatted, revised, and added examples in the Medical Policy Statement section. Added definition for temporomandibular joint syndrome. Deleted duplicate text in Clinical Background Information section.	11/01/13 Version 6	07/17/13: MPCTAC 08/15/13: QIC
07/29/12	Off cycle review for WellSense New Hampshire Medicaid product, revised Description of Item or Service section, reformatted the Medical Policy	Version 7	08/03/12: MPCTAC 09/05/12: QIC

	Statement section, and updated the References section.		
01/30/14	Off cycle review for effective date 04/01/14. Added ICD10 diagnosis code equivalents of existing ICD9 diagnosis codes.	Version 8	01/27/14: MPCTAC 01/30/14: QIC
09/01/14	Review for effective date 01/01/15. Revised language in the Limitations section related to benefit coverage. Revised medical criteria in the Medical Policy Statement and Limitations sections. Updated references.	01/01/15 Version 9	09/17/14: MPCTAC 10/08/14: QIC
09/01/15	Annual review for effective date 01/01/16. Revised the list of applicable products, including removing Commonwealth Care, Commonwealth Choice, and Employer Choice from the list of applicable products because the products are no longer available. Revised criteria in the Medical Policy Statement and Limitations sections. Updated Clinical Background Information and References sections.	01/01/16 Version 10	09/16/15: MPCTAC 10/14/15: QIC
11/25/15	Review for effective date 01/14/16. Revised language in the Applicable Coding section.	01/14/16 Version 11	11/25/15: MPCTAC (electronic vote) 12/09/15: QIC
09/01/16 and 09/28/16	Review for effective date 01/01/17. Removed ICD9 diagnosis codes. Updated Summary, Description of Item or Service, Definitions, Clinical Background Information, References, and Reference to Applicable Laws and Regulations sections. Revised criteria in the Medical Policy Statement and Limitations sections. Administrative changes made to clarify language related to gender.	01/01/17 Version 12	09/21/16: MPCTAC 09/30/16: MPCTAC (electronic vote) 10/12/16: QIC
12/05/16	Industry-wide changes to applicable ICD-10 diagnosis codes for temporo-mandibular joint disorder effective 01/01/17.	01/01/17 Version 13	Not applicable because industry-wide revisions to ICD-10 diagnosis codes.
09/01/17	Review for effective date 12/01/17. Revised criteria in the Medical Policy Statement and Limitations sections. Updated the Policy Summary, Definitions, References, Other Applicable Policies, and Reference to Applicable Laws and Regulations sections.	12/01/17 Version 14	09/20/17: MPCTAC
09/01/18	Review for effective date 12/01/18. Updated the Clinical Background Information, References, and Other Applicable Policies sections. Criteria revised in the Medical Policy Statement and Limitations sections.	12/01/18 Version 15	09/19/18: MPCTAC
12/01/18	Review for effective date 01/01/19. Administrative change made to the Limitations	01/01/19 Version 16	12/19/18: MPCTAC

Temporomandibular Joint Disorder Treatment

	section (removing the reference to the NH Health Protection Program).		
09/01/19	Review for effective date 12/01/19. Administrative changes made to the Policy Summary, Definitions, References, and Reference to Applicable Laws and Regulations sections. Revised criteria in the Limitations section.	12/01/19 Version 17	09/18/19: MPCTAC
07/01/20	Review for effective date 10/01/20 to be consistent with implementation date of industry-wide diagnosis code updates made to the Applicable Coding section. Administrative changes made to the Medical Policy Statement, References, and Other Applicable Policies sections.	10/01/20 Version 18	07/15/20: MPCTAC
08/01/21	Review for effective date 09/01/21. Administrative changes made to the Policy Summary, Medical Policy Statement, Limitations, and References sections.	09/01/21 Version 19	08/27/21: MPCTAC (electronic vote)
11/01/21	Review for effective date 12/01/21. Adopted new medical policy template; removed administrative sections, the Medical Policy Statement section renamed the Clinical Criteria section, and the Limitations section renamed the Limitations and Exclusions section. Added WellSense Medicare Advantage HMO as an applicable product effective 01/01/22. Administrative changes made to the Policy Summary, Clinical Criteria, Limitations and Exclusions, Applicable Coding, and References sections.	12/01/21 Version 20	11/17/21: MPCTAC
07/01/22	Review for effective date 08/01/22. Administrative changes made to the Policy Summary, Clinical Criteria, Limitations and Exclusions, Applicable Coding, and References sections.	08/01/22 Version 21	07/25/22: MPCTAC (electronic vote)
08/01/22	Review for effective date 11/01/22. Administrative changes made to the Policy Summary section.	11/01/22 Version 22 Version 22 not implemented and replaced with Version 23 as of 11/01/22	08/26/22: MPCTAC (electronic vote)
09/01/22	Review for effective date 11/01/22. Revised the effective date of AIM's management of outpatient rehabilitation services from 11/01/22 to 12/01/22 in the Policy Summary section.	11/01/22 Version 23	09/23/22: MPCTAC (electronic vote)

	Administrative changes made to the Clinical Criteria section.		
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