Medical Policy

Pelvic Floor Stimulation for the Treatment of Incontinence

Policy Number: OCA 3.561
Version Number: 13
Version Effective Date: 02/01/16

Product Applicability

<table>
<thead>
<tr>
<th>Well Sense Health Plan</th>
<th>Boston Medical Center HealthNet Plan</th>
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<tbody>
<tr>
<td>New Hampshire Medicaid</td>
<td>MassHealth</td>
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<tr>
<td>NH Health Protection Program</td>
<td>Qualified Health Plans/ConnectorCare/Employer Choice Direct</td>
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<tr>
<td></td>
<td>Senior Care Options ◊</td>
</tr>
</tbody>
</table>

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

Policy Summary

The Plan considers non-implantable pelvic floor electrical stimulation for urinary incontinence to be medically necessary when Plan medical criteria are met. Prior authorization is required. Electrical stimulation of the pelvic floor muscles (pelvic floor stimulation) as a treatment for fecal incontinence is considered experimental and investigational. The Plan considers magnetic stimulation of the pelvic floor muscles (pelvic floor magnetic stimulation) as a treatment for urinary incontinence and/or fecal incontinence to be experimental and investigational. It will be determined during the Plan’s prior authorization process if the service is considered experimental and investigational for the requested use. See the Plan’s policy, Experimental and Investigational Treatment (policy number OCA 3.12), for the product-specific definitions of experimental or investigational treatment. See Plan policies,
Description of Item or Service

**Pelvic Floor Electrical Stimulation (PFES):** Neuromuscular electrical stimulation through the pelvic floor by means of a non-implantable device with the goal of exercising and strengthening pelvic floor muscles. Electrical stimulation is delivered by vaginal probe or anal probe connected to an external generator.

**Pelvic Floor Magnetic Stimulation (also known as Extracorporeal Magnetic Stimulation or EMS):** Noninvasive electromagnetic stimulation of the pelvic floor musculature for the treatment of incontinence. During EMS therapy, a focused, time-varying magnetic field penetrates into the perineum and activates the motor neurons of the pelvic floor muscles. The pelvic muscles contract and relax with each magnetic pulse, thereby strengthening the muscles. The goal of this therapy is the rehabilitation of the pelvic floor musculature to reduce urinary incontinence. The magnetic system does not require an internal electrode; the patient sits fully clothed on a specialized chair with an embedded magnet, with the magnetic fields controlled by a separate power unit. Pelvic static magnetic stimulation may use a device that the individual wears with magnetic discs sewn into the undergarment (rather than a specialized magnetic chair). The Plan considers all magnetic stimulation to be experimental and investigational for the treatment of urinary incontinence and/or fecal incontinence.

Medical Policy Statement

Non-implantable pelvic floor electrical stimulation is considered medically necessary for urinary incontinence when ALL of the following criteria are met and documented in the member’s medical record, as specified below in items 1 through 8:

1. The member has been diagnosed with stress and/or urge urinary incontinence; AND

2. The member has completed a documented trial of pelvic muscle exercise training in which ALL of the following criteria are met, as specified below in items a through c:
   a. The trial lasted at least 12 consecutive weeks in duration; AND
   b. The trial included an ordered plan of exercises designed to increase periurethral strength; AND
   c. No clinically significant improvement in urinary incontinence has occurred with the trial; AND

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3. The member is cognitively intact; AND

4. The member’s urinary incontinence is not related to a neurologic condition; AND

5. The member is 16 years of age or older; AND

6. Before use, the member will be counseled by the treating provider on how to use the device properly; AND

7. The member is willing to comply with the treatment protocol to optimize the function of the device; AND

8. The electrical stimulation device is FDA-approved for the member’s specified indication (stress and/or urge urinary incontinence) for use with individuals of the member’s age and gender.

Limitations

1. The use of electrical stimulation of the pelvic floor muscles (pelvic floor electrical stimulation) is considered experimental and investigational when the urinary incontinence is related to a neurological disease.

2. The use of electrical stimulation of the pelvic floor muscles (pelvic floor stimulation) as a treatment for fecal incontinence is considered experimental and investigational.

3. The use of magnetic stimulation of the pelvic floor muscles (pelvic floor stimulation) as a treatment for urinary incontinence and/or fecal incontinence to be experimental and investigational.

4. The use of pelvic floor electrical stimulation is considered experimental and investigational when used for an indication not specified in the Medical Policy Statement section of this Plan policy and/or Plan criteria are not met.

5. The use of the pelvic floor electrical stimulation is considered experimental and investigational when used with a member who is unwilling or unable to comply with the treatment protocol and/or does not have the cognitive capacity to use the device effectively.

6. The use of a pelvic electrical stimulator is considered experimental and investigational when the device is not FDA approved for the member’s specified indication, age, and gender.

7. Electrical stimulation of the pelvic floor muscles is contraindicated when a member has at least ONE (1) of the following conditions, as specified below in items a through g:
Pelvic Floor Stimulation for the Treatment of Incontinence

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a. Complete denervation of the pelvic floor; OR
b. Dementia; OR
c. Demand cardiac (heart) pacemaker; OR
d. Unstable or serious cardiac arrhythmia; OR
e. Pregnancy or attempting pregnancy; OR
f. Active genitourinary tract infection; OR
g. Unstable seizure disorder.

8. The Plan requires Medical Director review to determine the medical necessity of a request for pelvic floor electrical stimulation for a member less than 16 years of age. (See the Plan’s policy, Medically Necessary, policy number OCA 3.14, for the product-specific definitions of medically necessary treatment.)

Definitions

Overactive Bladder: Problem with bladder storage function that causes a sudden urge to urinate. The urge may be difficult to suppress, and overactive bladder can lead to the involuntary loss of urine (incontinence).

Urinary Incontinence: The unintentional loss of urine and/or the inability to retain urine due to the loss of bladder control. The major types of urinary incontinence are listed below, as specified in items 1 through 5:

1. Mixed Incontinence: Urine loss caused by a combination of stress and urge incontinence and is most common in women
2. Overflow: Urine loss that occurs when the amount of urine produced exceeds the bladder’s holding capacity that can occur as a result of bladder obstruction or injury and in men as a result of an enlarged prostate
3. Stress Incontinence: Urine loss caused by increased intra-abdominal pressure that occurs during exercise, coughing, laughing, sneezing, and in men who have had prostate surgery
4. Total: Uncontrolled or continuous urinary leakage caused by neurological dysfunction, surgery, or anatomical defects
5. **Urge Incontinence:** Urine loss caused by involuntary bladder contractions that occurs more often in adults

### Applicable Coding

The Plan uses and adopts up-to-date Current Procedural Terminology (CPT) codes from the American Medical Association (AMA), International Statistical Classification of Diseases and Related Health Problems, 10th revision (ICD-10) diagnosis codes developed by the World Health Organization and adapted in the United Stated by the National Center for Health Statistics (NCHS) of the Centers for Disease Control under the U.S. Department of Health and Human Services, and the Health Care Common Procedure Coding System (HCPCS) established and maintained by the Centers for Medicare & Medicaid Services (CMS). Because the AMA, NCHS, and CMS may update codes more frequently or at different intervals than Plan policy updates, the list of applicable codes included in this Plan policy is for informational purposes only, may not be all inclusive, and is subject to change without prior notification. Whether a code is listed in the Applicable Coding section of this Plan policy does not constitute or imply member coverage or provider reimbursement. Providers are responsible for reporting all services using the most up-to-date industry-standard procedure and diagnosis codes as published by the AMA, NCHS, and CMS at the time of the service.

Providers are responsible for obtaining prior authorization for the services specified in the Medical Policy Statement section and Limitation section of this Plan policy, even if an applicable code appropriately describing the service that is the subject of this Plan policy is not included in the Applicable Coding section of this Plan policy. Coverage for services is subject to benefit eligibility under the member’s benefit plan. Please refer to the member’s benefits document in effect at the time of the service to determine coverage or non-coverage as it applies to an individual member. See the Plan’s reimbursement policies for the necessary billing guidelines, including codes that require modifiers; reimbursement policies are available at [www.bmchp.org](http://www.bmchp.org) for services rendered to members enrolled in a BMC HealthNet Plan product and reimbursement policies applicable for services rendered to Well Sense Health Plan members are available at [www.wellsense.org](http://www.wellsense.org).

<table>
<thead>
<tr>
<th>CPT Codes</th>
<th>Description: Codes Covered When Medically Necessary</th>
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<tbody>
<tr>
<td>97014</td>
<td>Application of a modality to 1 or more areas; electrical stimulation (unattended)</td>
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<td></td>
<td>Note: Supervised. The application of a modality that does not require direct, one-on-one, patient contact by the provider.</td>
</tr>
<tr>
<td>97032</td>
<td>Application of a modality to 1 or more areas; electrical stimulation (manual), each 15 minutes</td>
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<td></td>
<td>Note: Constant attendance. The application of a modality that requires direct, one-on-one, patient contact by the provider.</td>
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<thead>
<tr>
<th>HCPCS Codes</th>
<th>Description: Codes Covered When Medically Necessary</th>
</tr>
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<tbody>
<tr>
<td>E0740</td>
<td>Incontinence treatment system, pelvic floor stimulator, monitor, sensor and/or trainer</td>
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</tbody>
</table>

Pelvic Floor Stimulation for the Treatment of Incontinence

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**ICD-9 Codes** | Description: One of the following primary ICD-9 or ICD-10 diagnosis codes is required when billing for a covered CPT code or HCPCS code for this service.
---|---
625.6 | Stress incontinence, female
788.30 | Urinary incontinence, unspecified
788.31 | Urge incontinence
788.32 | Stress incontinence, male
788.33 | Mixed Incontinence, (male) (female)
788.34 | Incontinence without sensory awareness
788.35 | Post-void dribbling
788.37 | Continuous leakage
788.38 | Overflow incontinence
788.39 | Other urinary incontinence

**ICD-10 Codes** | Description: One of the following primary ICD-10 diagnosis codes or one of the ICD-9 diagnosis codes listed above is required when billing for a covered CPT code or HCPCS code for this service.
---|---
N39.3 | Stress incontinence (female) (male)
N39.41 | Other specified urinary incontinence; urge incontinence
N39.42 | Other specified urinary incontinence; incontinence without sensory awareness
N39.43 | Other specified urinary incontinence; post void dribbling
N39.45 | Other specified urinary incontinence; continuous leakage
N39.46 | Other specified urinary incontinence; mixed incontinence (urge and stress incontinence)
N39.490 | Other specified urinary incontinence; overflow incontinence
N39.498 | Other specified urinary incontinence (reflex incontinence) (total incontinence)
R32 | Unspecified urinary incontinence

**Clinical Background Information**

Urinary incontinence, or the unintentional loss of urine, is a major problem in the United States that can negatively impact the quality of life predominately in women and the elderly populations. Incontinence has several causes; women are most likely to develop urinary incontinence either during pregnancy and childbirth, or after the hormonal changes of menopause due to weakened muscles of the pelvis. Older men can become incontinent as the result of prostate surgery. Other possible risk factors for the development of urinary incontinence include pelvic trauma, hysterectomy, recurrent urinary tract infections, spinal cord damage, advanced age, caffeine, and medications such as diuretics, sedatives, beta-blockers, over-the-counter cold remedies and diet tablets.

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First line treatment options for urinary incontinence include pharmacotherapy, followed by minimally invasive treatment options that may include intravesical injection of Botox, sacral nerve stimulation, and/or posterior tibial nerve stimulation. When non-invasive treatment is unsuccessful, surgical interventions may include reconstructive surgery, placement of slings, placement of compression devices, cystoplasty, and/or urinary diversion.

Pelvic floor electrical stimulation (PFES) is intended as a possible alternative to surgery for urinary incontinence that fails to respond to pelvic exercises. PFES involves placing electrodes vaginally, anally, percutaneously, or transurethrally. Electrical current is applied to the electrodes via a wire connected to the external stimulator device. Treatment regimens performed in an outpatient setting vary from 20-minute sessions twice a week to daily sessions. PFES enhances the beneficial effects of Kegel exercises by always exercising the correct muscles without active participation of the patient. The treatment is used to strengthen and tone the sphincter and pelvic floor muscles and improve the patient’s muscle awareness. Possible side effects include vaginal irritation, occasional episodes of pain, tingling of the thigh, vaginal infection, urinary tract infection, and/or local reaction to the electrode gel. Other proposed treatment options for urinary incontinence include sacral nerve stimulation and posterior tibial nerve stimulation.

Magnetic stimulators and several electrical stimulators and have been cleared by the U.S. Food and Drug Administration (FDA) for the treatment of incontinence. The current clinical evidence is insufficient to reach conclusions about the efficacy of pelvic floor electrical stimulation as a treatment for fecal incontinence. Additional data from large, well-designed, long-term randomized trials are also needed to establish the efficacy of magnetic stimulation of the pelvic floor muscles for the treatment of urinary incontinence and/or fecal incontinence.

References


Pelvic Floor Stimulation for the Treatment of Incontinence


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Shamliyan T, Wyman J, Kane RL et al. Nonsurgical treatments for urinary incontinence in adult women: diagnosis and comparative effectiveness. Comparative Effectiveness Review No. 36. (Prepared by the Pelvic Floor Stimulation for the Treatment of Incontinence

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<thead>
<tr>
<th>Original Approval Date</th>
<th>Original Effective Date* and Version Number</th>
<th>Policy Owner</th>
<th>Approved by</th>
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<tbody>
<tr>
<td>Regulatory Approval: N/A</td>
<td>12/03/06 Version 1</td>
<td>Medical Policy Manager as Chair of Medical Policy, Criteria, and Technology Assessment Committee (MPCTAC) and member of Quality Improvement Committee (QIC)</td>
<td>Quality and Clinical Management Committee (Q&amp;CMC)</td>
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*Effective Date for the BMC HealthNet Plan Commercial Product(s): 01/01/12
*Effective Date for the Well Sense Heath Plan New Hampshire Medicaid Product(s): 01/01/13

(Effective 05/01/13, this policy replaced Pelvic Floor/Sacral Nerve Stimulation for Urinary Incontinence policy, policy number OCA 3.56, for this service. Effective 02/01/16, policy renamed Pelvic Floor Stimulation for the Pelvic Floor Stimulation for the Treatment of Incontinence

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Pelvic Floor Stimulation for the Treatment of Incontinence; the policy was formerly titled *Non-Implantable Pelvic Floor Electrical Stimulation for Urinary Incontinence.*

### Policy Revisions History

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<thead>
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<th>Review Date</th>
<th>Summary of Revisions</th>
<th>Revision Effective Date and Version Number</th>
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<tr>
<td>09/11/07</td>
<td>Updated template, added coding, approved by MPCTAC.</td>
<td>Version 2</td>
<td>09/11/07: MPCTAC 09/25/07: Utilization Management Committee (UMC) 10/15/07: QIC</td>
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<tr>
<td>09/09/08</td>
<td>No changes.</td>
<td>Version 3</td>
<td>09/09/08: MPCTAC 09/30/08: UMC 10/22/08: QIC</td>
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<tr>
<td>09/22/09</td>
<td>Updated references, no changes to criteria.</td>
<td>Version 4</td>
<td>09/22/09: MPCTAC 10/28/09: QIC</td>
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<tr>
<td>09/01/10</td>
<td>Updated template and references, no changes to criteria.</td>
<td>Version 5</td>
<td>10/20/10: MPCTAC 11/22/10: QIC</td>
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<tr>
<td>10/01/11</td>
<td>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 investigational. Updated references and coding.</td>
<td>Version 6</td>
<td>10/19/11: MPCTAC 11/29/11: QIC</td>
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<tr>
<td>07/20/12</td>
<td>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.</td>
<td>Version 7</td>
<td>08/13/12: MPCTAC 09/13/12: QIC</td>
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<tr>
<td>12/01/12</td>
<td>Separated pelvic floor electrical stimulation, sacral nerve stimulation, and posterior tibial nerve stimulation into three separate policies; policy formerly titled <em>Pelvic Floor/Sacral Nerve Stimulation for Urinary Incontinence</em> (formerly policy number OCA: 3.65). Revised title and re-numbered policy. Updated language in Summary, Description of Item or Service, Definitions, Applicable</td>
<td>Version 8</td>
<td>12/19/12: MPCTAC 01/31/13: QIC</td>
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### Policy Revisions History

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<th>Date</th>
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<th>Effective Date</th>
<th>Review Date(s)</th>
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<tr>
<td>12/01/13</td>
<td>Coding, and Clinical Background Information sections. Referenced <em>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</em>, and <em>Medically Necessary</em> policies. Reformatted and added criteria in Medical Policy Statement section, updated and added references, and added limitations. Revised applicable code list.</td>
<td>02/01/14</td>
<td>12/18/13: MPCTAC 01/21/14: QIC</td>
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<tr>
<td>12/01/14</td>
<td>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.</td>
<td>05/01/15</td>
<td>12/17/14: MPCTAC 01/14/15: QIC</td>
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<tr>
<td>10/01/15</td>
<td>Review for effective date 12/01/15. Updated template with list of applicable products and corresponding notes.</td>
<td>12/01/15</td>
<td>10/21/15: MPCTAC 11/11/15: QIC</td>
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<tr>
<td>10/21/15</td>
<td>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.</td>
<td>02/01/16</td>
<td>10/21/15: MPCTAC 11/11/15: QIC</td>
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### Last Review Date

11/25/15

### Next Review Date

10/01/16

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Authorizing Entity

QIC

Other Applicable Policies

Medical Policy - Biofeedback for Urinary Incontinence (policy number OCA 3.969)
Medical Policy - Experimental and Investigational Treatment, policy number OCA 3.12
Medical Policy - Medically Necessary, policy number OCA 3.14
Medical Policy - Posterior Tibial Nerve Stimulation, policy number OCA 3.562
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

Disclaimer Information: +

Medical Policies are the Plan’s guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member’s benefit document, and when appropriate, coordinates with the Member’s health care Providers to consider the individual Member’s health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan’s service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member’s benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.

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