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:** 13  
**Version Effective Date:** 02/01/16

### Product Applicability

- All Plan Products

- **Well Sense Health Plan**
  - New Hampshire Medicaid
  - NH Health Protection Program

- **Boston Medical Center HealthNet Plan**
  - MassHealth
  - Qualified Health Plans/ConnectorCare/Employer Choice Direct
  - Senior Care Options ◊

**Notes:**

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

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

### Policy Summary

The Plan considers sacral nerve stimulation for the treatment of urinary incontinence, urgency-frequency syndrome, or non-obstructive urinary retention to be medically necessary when medical criteria are met; this also includes peripheral nerve stimulation test and tined lead procedure before the implantation of the permanent sacral nerve stimulation device. Sacral nerve stimulation (including peripheral nerve stimulation testing and tined lead procedure) for the treatment of fecal incontinence is considered experimental and investigational. Prior authorization is required.

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

* Plan refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name Well Sense Health Plan.*
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It will be determined during the Plan’s prior authorization process if the service is considered experimental and investigational for the requested indication. 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, *Pelvic Floor Stimulation for the Treatment of Incontinence* (policy number OCA 3.561), *Posterior Tibial Nerve Stimulation* (policy number OCA 3.562), and *Biofeedback for Urinary Incontinence* (policy number OCA 3.969) for additional Plan guidelines.

**Description of Item or Service**

Prior to implantation of the permanent device, patients undergo an initial testing phase to estimate potential response to treatment. The first type of test that may be used in the initial phase is the peripheral nerve stimulation test (also known as a percutaneous nerve evaluation). The second type of testing that may be used in the initial phase is stage one of a two-stage surgical procedure using a tined lead. Either test may be performed in the outpatient setting under local anesthesia. The results of this test phase are used to determine whether the patient is an appropriate candidate for a permanent sacral nerve stimulation device.

**Peripheral Nerve Stimulation Test (Percutaneous Nerve Evaluation):** A type of test that may be used prior to implantation of the permanent device (i.e., this test is used in the initial testing phase). During the procedure, a test needle is used to identify the appropriate sacral nerve(s). Once identified, a temporary wire lead is inserted through the test needle and left in place for several days. This lead is connected to an external stimulator. Generally, at a minimum, a 50% improvement in one or more of the primary symptoms must be documented before a permanent stimulator can be implanted.

**Two-Stage Tined Lead Procedure:** A type of test that may be done prior to implantation of the permanent device (i.e., this test is used in the initial testing phase). In the first stage, a tined lead is implanted. The tined lead has an insulated electrical conductor with one end electrically connected to a pulse generator. The testing phase can last as long as several weeks, and if patients show a 50% or greater reduction in symptom frequency, the treating physician can proceed to stage two, which is the permanent implantation of the neuromodulation device. The two-staged tined lead procedure is used instead of the peripheral nerve stimulation test or when the stimulation test is inconclusive.

**Sacral Nerve Stimulation (SNS):** Also termed sacral neuromodulation, treatment involves modulation of the neural pathways controlling bladder function using a permanently implanted device to deliver controlled electrical impulses to the sacral nerves (after the initial testing phase is completed, as specified above with the peripheral nerve stimulation test or the two-stage tined lead procedure). The SNS device consists of a pulse generator that delivers electrical impulses through two (2) wire leads that are connected to the sacral nerves, most commonly the S3 nerve root. The external components that control the electrical stimulation consist of a control magnet that the patient uses to turn the device on and off and a console programmer that the physician uses to adjust the settings of the pulse generator.
Medical Policy Statement

The following services are considered medically necessary when applicable Plan criteria are met and
documented in the member’s medical record, as specified below in item 1 (criteria for the initial
testing phase) or item 2 (criteria for permanent implantation):

1 Initial Testing Phase:

Trial period of sacral nerve stimulation (with either peripheral nerve stimulation or a
temporarily implanted lead with stage one of the tined lead procedure) is considered medically
necessary when ALL of the following criteria are met, as specified below in items a through g:

a. The member has been diagnosed with at least ONE (1) of the following symptoms for at
least six (6) months, as specified below in items (1) through (3):

(1) Non-obstructive urinary retention; OR
(2) Urgency-frequency syndrome, OR
(3) Urinary urge incontinence, AND

b. The member has ONE (1) of the following conditions, as specified below in item (1) or item
(2):

(1) Medically refractory to conventional therapy includes BOTH of the following criteria,
as specified below in item (a) and item (b):

(a) Failure with at least six (6) months of behavioral therapy (i.e., fluid restriction,
dietary modification, voiding re-training, and/or pelvic floor physiotherapy); AND

(b) Failure with at least three (3) months of pharmacological therapy; OR

(2) Member cannot tolerate a minimum of six (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

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

d. The member is an appropriate surgical candidate for the implantation; AND

e. The member’s urinary symptom is not related to a neurologic condition; AND
f. Before use, the member will be counseled by the treating provider on how to use the device during the testing and treatment phases, and the provider will inform the member that the device will require periodic replacement; AND

g. The 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.

2. **Permanent Implantation:**

Permanent implantation of a sacral nerve stimulation device is considered medically necessary when BOTH of the following criteria are met, as specified below in item a and item b:

a. The member meets all the criteria for the peripheral nerve stimulation test or stage one of the tined lead procedure (to estimate potential response to SNS), as specified above; AND

b. Member has experienced a 50% or greater relief of incontinence symptoms during the percutaneous trial or stage one of the tined lead test as measured by voiding diaries.

**Limitations**

1. The Plan considers implantable sacral nerve stimulation (including associated testing) for the treatment of fecal incontinence, chronic constipation, chronic pelvic pain, or other indication not specified in the Medical Policy Statement section of this policy to be experimental and investigational.

2. The use of implantable sacral nerve stimulation (including associated testing) in an individual under the age of 16 years, pregnant woman, diabetic member, or a member with interstitial cystitis, pelvic pain, multiple sclerosis, or stress incontinence has not been adequately studied to determine safety and efficacy and is therefore considered experimental and investigational.

3. The use of implantable sacral nerve stimulation (including associated testing) is contraindicated in a member with a mechanical obstruction such as benign prostatic hypertrophy, cancer, or urethral stricture, and/or in a member who is receiving any form of diathermy.

4. The use of implantable sacral nerve stimulation (including associated testing) is experimental and investigational when the urinary incontinence is related to a neurological disease.

5. The use of the implantable sacral nerve stimulation (including associated testing) 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 remote control to optimize device function during the testing and treatment phases.

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

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6. The use of a wireless sacral nerve stimulator (e.g., StimGuard) for the relief of an overactive bladder or for any other indication has not been adequately studied to determine safety and efficacy and is therefore considered experimental and investigational.

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).

**Urgency/Frequency Syndrome:** A syndrome in adults characterized by frequent urination of at least seven (7) times per day that is associated with a strong desire to void (urgency).

**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

**Urinary Retention:** A condition where the bladder overfills without causing the sensation of the need to urinate. Non-obstructive urinary retention is caused by a lack of coordination between the bladder and detrusor sphincter mechanisms or a weak or non-existent bladder contraction.

Applicable Coding

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

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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.

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 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 Plan reimbursement policies for Plan billing guidelines.

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<thead>
<tr>
<th>CPT Codes</th>
<th>Description: Codes Covered When Medically Necessary</th>
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</thead>
<tbody>
<tr>
<td>64561</td>
<td>Percutaneous implantation of neurostimulator electrode array; sacral nerve (transoraminal placement) including image guidance, if performed</td>
</tr>
<tr>
<td></td>
<td>(Plan note: Percutaneous trial/temporary stimulation to estimate potential response to SNS)</td>
</tr>
<tr>
<td>64581</td>
<td>Incision for implantation of neurostimulator electrode array; sacral nerve (transoraminal placement)</td>
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<tr>
<td>64585</td>
<td>Revision or removal of peripheral neurostimulator electrode array</td>
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<tr>
<td>64590</td>
<td>Insertion or replacement of peripheral or gastric neurostimulator pulse generator or receiver, direct or inductive coupling</td>
</tr>
<tr>
<td>64595</td>
<td>Revision or removal of peripheral or gastric neurostimulator pulse generator or receiver</td>
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<tr>
<th>HCPCS Codes</th>
<th>Description: Codes Covered When Medically Necessary</th>
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<tbody>
<tr>
<td>A4290</td>
<td>Sacral nerve stimulation test lead, each</td>
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<tr>
<td>E0745</td>
<td>Neuromuscular stimulator, electronic shock unit</td>
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<tr>
<td>L8680</td>
<td>Implantable neurostimulator electrode, each</td>
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<tr>
<td>L8681</td>
<td>Patient programmer (external) for use with implantable programmable neurostimulator pulse generator, replacement only</td>
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<tr>
<td>L8682</td>
<td>Implantable neurostimulator radiofrequency receiver</td>
</tr>
<tr>
<td>L8683</td>
<td>Radiofrequency transmitter (external) for use with implantable neurostimulator radiofrequency receiver</td>
</tr>
<tr>
<td>L8684</td>
<td>Radiofrequency transmitter (external) for use with implantable sacral root</td>
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</table>

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

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

<table>
<thead>
<tr>
<th>Item</th>
<th>Description</th>
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<tbody>
<tr>
<td>L8685</td>
<td>Implantable neurostimulator pulse generator, single array, rechargeable, includes extension</td>
</tr>
<tr>
<td>L8686</td>
<td>Implantable neurostimulator pulse generator, single array, nonrechargeable, includes extension</td>
</tr>
<tr>
<td>L8687</td>
<td>Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension</td>
</tr>
<tr>
<td>L8688</td>
<td>Implantable neurostimulator pulse generator, dual array, nonrechargeable, includes extension</td>
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<tr>
<td>L8689</td>
<td>External recharging system for battery (internal) for use with implantable neurostimulator, replacement only</td>
</tr>
<tr>
<td>L8695</td>
<td>External recharging system for battery (external) for use with implantable neurostimulator, replacement only</td>
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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.

The American Urological Association provides a list of behavioral modification techniques for urinary incontinence that includes: self-monitoring (bladder diary), scheduled voiding, delayed voiding, double voiding, pelvic floor muscle training and exercise (including pelvic floor relaxation and Kegel exercises), active use of pelvic floor muscles for urethral occlusion and urge suppression (urge strategies), urge control techniques (distraction, self-assertions), normal voiding techniques, biofeedback, electrical stimulation, fluid management, caffeine reduction, dietary changes (avoiding bladder irritants), weight loss, and other lifestyle changes. Additional treatment options for urinary incontinence include physical therapy, collagen injections, pharmacological interventions, and/or reconstructive surgery. First-line treatment consists of the non-invasive therapies, followed by electrical stimulation (e.g., non-implantable pelvic floor electrical stimulation) before surgical intervention is considered.

First-line treatment for an overactive bladder includes non-invasive behavioral therapies, such as bladder training, fluid management, and pelvic floor muscle training. When symptoms are not adequately improved with first-line treatment, second-line treatment includes combined behavioral and pharmacologic therapies to alleviate symptoms, since the combination of behavioral and pharmacologic therapies is more effective than either alone. Neuromodulation may be offered as third-line options, depending on the severity of the symptoms and the extent to which they interfere.

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with quality of life. These third-line options bridge the treatment gap between conservative therapies for overactive bladder and irreversible surgical procedures. Neuromodulation with electrical stimulation of an overactive bladder targets the sacral nerve plexus, which regulates control of the bladder and pelvic floor muscles. Two (2) types of neuromodulation are currently available for an overactive bladder: sacral nerve stimulation (SNS) delivered by a permanent implantable device and posterior/percutaneous tibial nerve stimulation delivered by an external device as a minimally invasive alternative to SNS.

Sacral nerve stimulation (SNS) is intended as an alternative to surgery for urge incontinence, non-obstructive urinary retention, and urge-frequency syndrome that has failed standard medical management. SNS is a minimally invasive, reversible surgery that involves the implantation of four electrodes in contact with one of the three sacral nerves (usually S3) that control the muscles required for urination. A small pulse generator is implanted into subcutaneous lower abdominal tissue or upper buttock area, and an electrical current is applied to the electrodes via wire leads connected to the pulse generator. The device sends mild electrical impulses through a lead that is connected to a sacral nerve, which influences the bladder, the sphincter and the pelvic floor muscles. The physician can adjust the stimulator to optimal settings with a programmer, and the patient can turn the device on and off by using a magnet over the lower abdomen. Prior to implantation of a permanent SNS, a patient is required to undergo a trial of temporary stimulation and voiding patterns must be documented in a diary.

The Plan considers sacral nerve stimulation for the treatment of fecal incontinence to be experimental and investigational because study results demonstrate conflicting findings on the safety and effectiveness of this treatment. The Food and Drug Administration (FDA) cleared the Interstim Therapy (Medtronic, Inc., O’Fallon, IL) device for the application of fecal incontinence on March 14, 2011, subject to a five (5) year post-approval study. The post-approval study will be called the InterStim Sacral Nerve Stimulation Therapy for Bowel Control: Fecal Incontinence Post Approval Study (FI-PAS). The primary objective is to continue evaluation of incontinent episodes per week at yearly intervals through five (5) years post-implant. Both device and therapy adverse events will be tracked during this ongoing study period (which is limited to individuals age 18 and older). The adverse event occurrence is high for sacral nerve stimulation for fecal incontinence and the careful selection of individuals for this treatment is extremely important. Potential adverse effects (e.g., complications) associated with the use of the device include the following: Adverse change in voiding function (bowel and/or bladder) including diarrhea, constipation, urinary retention, defecation urgency, micturition urgency, incontinence, and frequent bowel movements; changes in sensation of stimulation which has been described as uncomfortable (jolting or shocking) by some patients including muscle spasms, vaginal pain, vulvovaginal discomfort, scrotal pain, paralysis, and paraesthesia; potential for nerve injury; allergic or immune system response to the implanted materials that could result in device rejections; pain at neurostimulator and/or lead site including skin irritation, skin ulcer, infection, wound dehiscence, erythema, erosion of the neurostimulator, seroma, hemorrhage, and hematoma; and malfunction of the components of the InterStim Therapy System including neurostimulator programming error, lead migration/dislodgement, lead fracture, erosion of the lead into the colon with perforation, neurostimulator battery depletion, extension fracture, neurostimulator migration.

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Caution must be taken if sacral nerve stimulation is used in conjunction with cardiac pacemakers, cardiac defibrillators, electrocautery, ultrasonic equipment, radiation therapy, and magnetic resonance imaging. No serious side effects have been reported but adverse events can include possible lead migration, technical problems, infection, inflammation, and pain. Hospitalization is not required for SNS implantation and the procedure is usually done in the outpatient setting.

References


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Leong RK, De Wachter SG, Nieman FH et al. 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; 30(7):1249-52.


http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm249208.htm


<table>
<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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<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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<td>Internal Approval: 10/03/06</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.)

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<table>
<thead>
<tr>
<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 and added coding.</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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<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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<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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<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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<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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<td>12/01/12</td>
<td>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 Pelvic Floor/Sacral Nerve Stimulation for Urinary Incontinence (formerly OCA: 3.65). Revised title and renumbered policy. Updated language in Summary, Description of Item or Service, Definitions, Applicable Coding, and Clinical</td>
<td>Version 8</td>
<td>05/01/13 01/31/13: QIC</td>
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## Policy Revisions History

<table>
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<th>Date</th>
<th>Description</th>
<th>Version</th>
<th>Revision Date</th>
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<tr>
<td>12/01/13:</td>
<td>Review for effective date 02/01/14. Reformed Description of Item or Service section. Reformed Medical Policy Statement section without changing criteria. Updated code definitions without changing applicable code list. Updated references.</td>
<td>02/01/14 Version 9</td>
<td>12/18/13: MPCTAC 01/21/14: QIC</td>
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<td>12/01/14</td>
<td>Review for effective date 02/01/15. Updated references.</td>
<td>02/01/15 Version 10</td>
<td>12/17/14: MPCTAC 01/14/15: QIC</td>
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<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 Version 11</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. Revised limitations. Updated References, Definitions, and Clinical Background Information sections.</td>
<td>02/01/16 Version 12</td>
<td>10/21/15: MPCTAC 11/11/15: QIC</td>
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<td>11/25/15</td>
<td>Review for effective date 02/01/16. Revised language in the Applicable Coding section.</td>
<td>02/01/16 Version 13</td>
<td>11/25/15: MPCTAC (electronic vote) 12/09/15: 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 - Pelvic Floor Stimulation for the Treatment of Incontinence, policy number OCA 3.561
Medical Policy - Posterior Tibial Nerve Stimulation, policy number OCA 3.562

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.