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: 15
Version Effective Date: 01/01/18

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 to determine coverage guidelines for Senior Care Options.

Policy Summary

The Plan considers implantable sacral nerve stimulation (SNS), also known as sacral neuromodulation, to be medically necessary when used for the treatment of chronic urinary incontinence, urgency-frequency syndrome, non-obstructive urinary retention, or chronic fecal incontinence and when applicable medical criteria are met for a Plan member (regardless of gender); this also includes peripheral nerve stimulation test and tined lead procedure before the implantation of the permanent sacral nerve stimulation device. All requests for implantable SNS (including initial testing phase and/or...
permanent implantation) to treat fecal incontinence require Plan Medical Director review and approval and applicable Plan medical criteria must be met. SNS (including peripheral nerve stimulation testing and tined lead procedure) for the treatment of other conditions is considered experimental and investigational.

Plan prior authorization is required. It will be determined during the Plan’s prior authorization process if the treatment is considered medically necessary or experimental and investigational for the requested indication. See the Plan’s Medically Necessary medical policy (policy number OCA 3.14) for the product-specific definitions of medically necessary treatment and the Plan’s Experimental and Investigational Treatment medical policy (policy number OCA 3.12) for the product-specific definitions of experimental or investigational treatment. Review the following applicable medical policies for additional Plan clinical guidelines: Biofeedback in an Outpatient Setting to Treat Bladder and/or Bowel Dysfunction (Including Incontinence), policy number OCA 3.969; Pelvic Floor Stimulation for the Treatment of Incontinence, policy number OCA 3.561; and Posterior Tibial Nerve Stimulation, policy number OCA 3.562.

**Description of Item or Service**

**Implantable Sacral Nerve Stimulation (SNS):** Also termed sacral neuromodulation or SNM, the Plan considers implantable SNS to be medically necessary when applicable criteria in the Medical Policy Statement section of this policy are met. Implantable SNS is a minimally invasive, reversible surgery that involves the implantation of four (4) electrodes in contact with one of the three (3) sacral nerves (most commonly the S3 nerve root) that control the muscles required for bladder and bowel function. Examples include the following implanted InterStim™ systems developed by Medtronic, Inc.: InterStim™ Therapy for Urinary Control and InterStim™ Therapy for Bowel Control. 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 implanted device sends mild electrical impulses through two (2) wire leads that are connected to a sacral nerve (usually S3), which influences the bladder, the sphincter, and the pelvic floor muscles. 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. 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 the permanent device for SNS, a patient is required to undergo a trial (initial phase) of temporary stimulation with a peripheral nerve stimulation test (also known as a percutaneous nerve evaluation) and elimination patterns must be documented in a diary. 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. Implantable SNS treatment involves modulation of the neural pathways controlling bladder function or bowel function using a permanently implanted device

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

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to deliver controlled electrical impulses to the sacral nerves (after the initial testing phase is completed, as specified below in item 1 for the peripheral nerve stimulation test or item 2 for the two-stage tined lead procedure):

1. **Peripheral Nerve Stimulation Test (Percutaneous Nerve Evaluation):** A type of test that may be used prior to implantation of the permanent SNS 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.

2. **Two-Stage Tined Lead Procedure:** A type of test that may be done prior to implantation of the permanent SNS 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.

**Wireless Sacral Nerve Stimulation:** A microsize neurostimulator injected into the targeted nerve location through the lumen of a needle to treat an overactive bladder. A small external transmitter attaches to the patient’s underwear and is designed to not come into contact with the patient’s skin. The design eliminates the need for a separate implanted pulse generator and extension wire tunneling, and the device does not require batteries. Examples include the StimGuard wireless SNS and StimWave Freedom Spinal Cord Stimulation System (by Medtronic, Inc.). The Plan considers the use of a wireless sacral nerve stimulator to be experimental and investigational until the clinical utility and clinical validity of the device can be consistently established.

**Medical Policy Statement**

The initial testing phase of sacral nerve stimulation (SNS) and the permanent implantation of a sacral nerve stimulation device (e.g., InterStim™ system by Medtronic, Inc.) are considered medically necessary when applicable Plan criteria are met for a Plan member (regardless of gender) and documented in the member’s medical record. Applicable medical necessity criteria are based on the indication for treatment and phase of treatment, as specified below in EITHER item A (Sacral Nerve Stimulation to Treat Urinary Conditions) or item B for (Sacral Nerve Stimulation to Treat Chronic Fecal Incontinence):
A. Sacral Nerve Stimulation (SNS) to Treat Urinary Conditions:

The Plan considers the use of an implantable SNS to treat chronic urinary incontinence, urgency-frequency syndrome, and/or non-obstructive urinary retention to be medically necessary when applicable medical criteria are met for a Plan member based on the phase of treatment, as specified below 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 of the following criteria are met, as specified below in items a through g:

a. The member is has been experiencing at least ONE (1) of the following urinary symptoms for at least six (6) months (with or without a clinical diagnosis of overactive bladder), as specified below in items (1) through (3):

   (1) Non-obstructive urinary retention; OR
   (2) Urgency-frequency syndrome (as defined in the Definitions section of this policy); OR
   (3) Urinary urge incontinence; AND

b. The member’s urinary symptoms are NOT related to a neurologic condition; AND

c. The member’s conservative treatment (before the request for the initial testing phase of implanted SNS) meets ONE (1) of the following criteria, as specified below in item (1) or item (2):

   (1) Member is medically refractory to conservative therapy and BOTH of the following criteria are met, as specified below in item (a) and item (b):

      (a) Failure with at least six (6) months of behavioral therapy (i.e., fluid management, dietary modification, voiding re-training, and/or pelvic floor physiotherapy); AND
      (b) Failure with at least three (3) months of pharmacological therapy, including EITHER of the following treatment protocols, as specified below in item i or item ii:

         i. A trial of at least two (2) different anti-cholinergic drugs; OR
         ii. A trial of one (1) anti-cholinergic drug and one (1) beta-3 adrenergic receptor agonist (mirabegron); OR

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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

d. The member is 18 years of age or older on the date of service; AND

e. The member is an appropriate surgical candidate for the implantation; 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 of SNS:

Permanent implantation of a SNS 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

f. 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; OR

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

The Plan considers the use of implanted SNS to treat fecal incontinence to be medically necessary after review and approval of a Plan Medical Director and when ALL applicable medical criteria are met for a member based on the phase of treatment, as specified below 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 of the following criteria are met, as specified below in items a through i:
a. The member is has been experiencing chronic fecal incontinence with greater than 2 incontinent episodes on average per week for at least six (6) months in duration or for at least 12 months after vaginal childbirth; AND

b. The member’s fecal incontinence is not related to a neurologic condition; AND

c. If the member has medical history of chronic inflammatory bowel disease (IBD), IBD does NOT involve the anorectum; AND

d. The member’s conservative treatment (before the request for the initial testing phase of implanted sacral nerve stimulation) meets ONE (1) of the following criteria, as specified below in item (1) or item (2):

(1) Member is medically refractory to conservative therapy and BOTH of the following criteria are met, as specified below 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

e. The member is 18 years of age or older on the date of service; AND

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

g. 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

h. 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; AND

i. Plan Medical Director has approved the treatment for fecal incontinence for the Plan member; OR

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2. **Permanent Implantation of SNS:**

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 of the following criteria are met, as specified below in items a through c:

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 elimination journals; AND

c. Plan Medical Director has approved the treatment for fecal incontinence for the Plan member.

**Limitations**

1. **Contraindications for Sacral Nerve Stimulation (SNS):**

The use of implantable SNS (including associated testing) is contraindicated in a member when at least ONE (1) of the following criteria is met, as specified below in items a through e:

a. Member has chronic inflammatory bowel disease involving the anorectum, mechanical obstruction, or malformation in the applicable anatomical area (e.g., benign prostatic hypertrophy, cancer, urethral stricture, congenital anorectal malformation, defects of the external anal sphincter over 60 degrees, visible sequelae of pelvic radiation, active anal abscesses, fistulae); OR

b. Member is receiving any form of diathermy or is expected to receive diathermy during the duration of treatment with sacral nerve stimulation; OR

c. Member has a pacemaker or implantable defibrillator; OR

d. Member is pregnancy or plans to become pregnancy during the duration of treatment with sacral nerve stimulation; OR

e. A member who has had rectal surgery in the previous 12 months, or in the case of cancer, the patient has had rectal surgery in the past 24 months.
2. **Experimental and Investigational Indications for Sacral Nerve Stimulation (SNS):**

The Plan considers ANY of the following uses of SNS to be experimental and investigational, as specified below in items a through e:

a. The Plan considers implantable SNS (including associated testing) to be experimental and investigational when used for the treatment of chronic constipation, chronic pelvic pain, stress incontinence, and/or another indication not specified in the Medical Policy Statement section of this policy.

b. The use of implantable SNS (including associated testing) is considered experimental and investigational when used for a member under 16 years of age (on the date of service) and/or a diabetic member.

c. The use of implantable SNS (including associated testing) is considered experimental and investigational when the member’s symptoms are related to a neurological disease (e.g., multiple sclerosis, neurogenic detrusor overactivity, peripheral neuropathy, or spinal cord injury).

d. The use of the implantable SNS (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.

e. The use of a wireless sacral nerve stimulator (e.g., StimGuard) is considered experimental and investigational for any indication. Wireless sacral nerve stimulators have been proposed as a treatment alternative to implantable SNS, but the safety and efficacy of the wireless devices have not been adequately studied.

3. **Plan Medical Director Review Required:**

Plan Medical Director review is required for ANY of the following, as specified below in item a or item b:

a. Plan Medical Director review is required for the use of implantable sacral nerve stimulation (SNS) for members age 16 or 17 on the date of service (including associated testing). The use of implantable SNS (including associated testing) is considered experimental and investigational when used for a member under 16 years of age on the date of service.

b. All requests for implantable SNS (including initial testing phase and/or permanent implantation) to treat fecal incontinence require Plan Medical Director review and approval. In addition, ALL applicable criteria in item B of the Medical Policy Statement section (Sacral Nerve Stimulation to Treat Chronic Fecal Incontinence) must be met and documented in the member’s medical record. While clinical studies have demonstrated the clinical efficacy of Sacral Nerve Stimulation (Including Peripheral Nerve Stimulation Test and Two-Stage Tined Lead Procedure) for Incontinence and Urinary Conditions.
implantable SNS for the treatment of fecal incontinence, adverse events are common and reoperation rates are estimated at 20 percent.

**Definitions**

**Detrusor Hyperactivity/Detrusor Hyperreflexia/Detrusor Overactivity:** Phasic increases in detrusor pressure cause a sudden and sometimes overwhelming urge to urinate even when the bladder isn’t full (causing clinical manifestations of overactive bladder). These involuntary contractions of the detrusor urinae muscle during the filling phase with or without detrusor overactivity urinary incontinence. Detrusor overactivity may be categorized as phasic (waves of involuntary contractions with or without leakage), terminal (single involuntary detrusor contraction that cannot be suppressed and results in urinary incontinence), neurogenic (caused by neurological condition) or idiopathic (no defined cause).

**Fecal Incontinence:** Uncontrolled passage of feces, liquid, or flatus over at least one (1) month’s duration in an individual of at least four (4) years of age who had previously achieved control. Fecal incontinence may be caused by damage to the anal sphincter (e.g., damage as a result of vaginal childbirth or surgery), diarrhea, fecal impaction, medical conditions that cause the inability to expand and store fecal matter (e.g., inflammatory bowel disease, Crohn’s disease, or injury). Fecal incontinence is more common in women, due mainly to muscular and neural damage that may occur during vaginal delivery.

**Functional Urinary Incontinence:** All forms of involuntary urination without any structural anatomical or neurological deficit.

**Inflammatory bowel disease (IBD):** IBD is a term for two (2) conditions, Crohn’s disease and ulcerative colitis. IBD is characterized by chronic inflammation of the gastrointestinal (GI) tract. Prolonged inflammation results in damage to the GI tract. Crohn’s disease can affect any part of the GI tract (from the mouth to the anus), but most often it affects the portion of the small intestine with patches of damaged areas. Ulcerative colitis occurs in the large intestine and the rectum, with continuous areas damaged usually starting at the rectum and spreading into the colon. Symptoms of ID include persistent diarrhea, abdominal pain, rectal bleeding/bloody stools, weight loss, and fatigue. The cause of IBD is unknown, but IBD is related to an inappropriate response of the immune system which a related genetic component. (Source: CDC.)

**Interstitial Cystitis:** Clinical syndrome characterized by urinary frequency, urgency, and pelvic pain occurring in the daytime and nighttime. The diagnostic criteria, etiology, clinical and urinary markers, and treatment associated with the clinical syndrome have not have not been consistently adopted.

**Neurogenic Bladder:** Urinary bladder dysfunction due to neurologic dysfunction as a result of trauma, disease, or injury.
**Organic Urinary Incontinence:** Rare form of urinary incontinence caused by anatomical malformations such as abnormally located terminal portion of the ureter or malformed urethra.

**Overactive Bladder (OAB):** Symptom-based clinical diagnosis characterized by urinary urgency (hallmark symptom), urinary frequency (usually present) and nocturia (usually present), and with or without urgency urinary incontinence. A diagnosis of OAB requires exclusion of infection and other pathologic conditions. First-line treatment includes lifestyle interventions, pelvic floor exercises, bladder training, and antimuscarinic agents. If conservative therapy fails, second-line treatments may include sacral nerve stimulation (neuromodulation) or surgical interventions such as augmentation cystoplasty or urinary diversion.

**Pathological Urinary Incontinence:** Organic and functional (or psychosomatic) causes of urinary incontinence.

**Pelvic Floor Muscle Training (PFMT):** Training used as a first-line conservative therapy to treat women with urgency urinary incontinence, stress urinary incontinence, and/or mixed urinary incontinence. PFMT utilizes pelvic floor muscles to increase urethral pressure and is believed to inhibit detrusor muscle contractions. PFMT (e.g., Kegel exercises) may be a self-directed regimen or a clinician-guided program and may or may not include biofeedback.

**Physiological Urinary Incontinence:** Urinary incontinence is regarded as normal in the first few years of life and is classified as pathological only after the fifth (5th) year of life has been completed (i.e., up to the child’s sixth birthday). The range of normal continence development is very wide and can extend beyond the age of five (5) for “late developers.”

**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) and may be a symptom of an overactive bladder.

**Urinary Incontinence:** The unintentional loss of urine and/or the inability to retain urine due to the loss of bladder control and may be a symptom of an overactive bladder. 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**

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 States 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 Plan reimbursement policies for Plan billing guidelines.

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<th>CPT Codes</th>
<th>Description: Codes Covered When Medically Necessary</th>
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<tbody>
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<td>64561</td>
<td>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.</td>
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<td>64581</td>
<td>Incision for implantation of neurostimulator electrode array; sacral nerve (transforaminal placement)</td>
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<td>64585</td>
<td>Revision or removal of peripheral neurostimulator electrode array</td>
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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

<table>
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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 life style 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 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. Implantable SNS (also known as sacral neuromodulation or SNM) is intended as an alternative to surgery for urge incontinence, non-obstructive urinary retention, and urge-frequency syndrome that has failed standard medical management (e.g., the implanted InterStim™ system developed by Medtronic, Inc. for the treatment of urinary retention and the symptoms of overactive bladder, including urinary urge incontinence and significant symptoms of urgency-frequency alone or in combination, in patients who have failed or could not tolerate more conservative treatments).

Fecal incontinence is also a frequent and debilitating condition affecting a reported 7 to 15 percent of community-dwelling U.S. adults (e.g., nursing home residents), but the true incidence may be much higher due to underreporting of the condition. The Food and Drug Administration (FDA) cleared the InterStim™ Therapy (developed by Medtronic, Inc.) device for the application of fecal incontinence on March 14, 2011. According to the American Society of Colon and Rectal Surgeons, “sacral neuromodulation (SNM) is thought to modulate rectal sensation by activating or deactivating chemical mediating receptors, stimulating the afferent pathway, and changing brain activity relevant to the continence mechanism. SNM has been consistently shown to result in a reduction in frequency of fecal incontinence episodes.” (Source: Paquette et al. 2015.) 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 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.

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.

At the time of the Plan’s most recent policy review, the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) 230.18 includes medically necessary indications for the use of sacral nerve stimulation for the treatment of urinary urge incontinence, urgency-frequency syndrome, and urinary retention. For CMS to cover the treatment, the beneficiary must meet medical criteria and be able to demonstrate adequate ability to record voiding diary data such that clinical results of the implant procedure can be properly evaluated. According to CMS, sacral nerve stimulation involves both a temporary test stimulation to determine if an implantable stimulator would be effective and a permanent implantation in appropriate candidates. Both the test and the permanent implantation are covered. The following summary of limitations for CMS coverage apply for sacral nerve stimulation: Patient is refractory to conventional therapy and is an appropriate surgical candidate; patient has stress incontinence, urinary obstruction, and specific neurologic diseases; and patient has had a successful and documented test stimulation (demonstrating 50% or greater improvement through test stimulation) in order to support subsequent implantation. See NCD 230.18 for the detailed clinical criteria. Verify CMS medical criteria for sacral nerve stimulation for the specified indication in the applicable NCD or local coverage determination (LCD) and coverage guidelines in effect on the date of the prior authorization request for a Senior Care Options member.

Proposed treatment for urinary incontinence, urgency-frequency syndrome, and/or non-obstructive urinary retention may include (but are not limited to) additional services specified in the following NCDs: NCD 30.1.1 for biofeedback therapy; NCD 230.10 for incontinence control devices, including mechanical/hydraulic incontinence control devices and collagen implants; and/or NCD 230.8 for a non-implantable pelvic floor electrical stimulator. According to NCD 230.16, the use of bladder stimulators, spinal cord electrical stimulators, rectal electrical stimulators, and/or bladder wall stimulators are not considered reasonable and necessary for Medicare beneficiaries, and CMS does not reimburse for these devices or for their implantation. At the time of the Plan’s most recent policy review, no NCD was found from CMS for posterior tibial nerve stimulation for the treatment of incontinence and/or for any other indication; LCD L34436 and LCD L33396 were identified for posterior tibial nerve stimulation for incontinence and urinary conditions.
applicable to Massachusetts, and the service may be considered medically necessary when criteria in the applicable LCD are met. No related NCD or LCD was found for the treatment of fecal incontinence. Determine if applicable CMS criteria are in effect for the requested service in an NCD or LCD on the date of the prior authorization request for a Senior Care Options member by evaluating the requested treatment and clinical indication(s) for the service or device.

References


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

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<table>
<thead>
<tr>
<th>Original Approval Date</th>
<th>Original Effective Date* and Version Number</th>
<th>Policy Owner</th>
<th>Original Policy 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)</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 Health Plan New Hampshire Medicaid Product(s): 01/01/13  
*Effective Date for the Senior Care Options Product(s): 01/01/16

(Effective 05/01/13, this policy replaced Pelvic Floor/Sacral Nerve Stimulation for Urinary Incontinence policy, policy number OCA 3.56, for this service.)

<table>
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<tr>
<th>Policy Revisions History</th>
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<tr>
<td><strong>Review Date</strong></td>
<td><strong>Summary of Revisions</strong></td>
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| 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 investigational. Updated references and coding. | Version 6 | 10/19/11: MPCTAC  
11/29/11: QIC |
| 07/20/12 | Off cycle review for Well Sense Health Plan: Updated title, revised Summary statement, added posterior tibial stimulation to | Version 7 | 08/13/12: MPCTAC  
09/13/12: QIC |

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<tr>
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<th>Revisions/Consulting Committees</th>
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<tr>
<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 <em>Pelvic Floor/Sacral Nerve Stimulation for Urinary Incontinence</em> (formerly OCA: 3.65). Revised title and renumbered 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 tined lead procedure, updated references, and added limitations. Revised applicable code list. Referenced the following policies: <em>Experimental and Investigational Treatment, Non-Implantable Pelvic Floor Electrical Stimulation for Urinary Incontinence, Posterior Tibial Nerve Stimulation</em>, and <em>Biofeedback for Urinary Incontinence</em>. Changed name of policy category from “Clinical Coverage Guidelines” to “Medical Policy.”</td>
<td>05/01/13</td>
<td>05/01/13: MPCTAC 01/31/13: QIC</td>
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<td>12/01/13</td>
<td>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.</td>
<td>02/01/14</td>
<td>02/01/14: 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</td>
<td>12/17/14: MPCTAC 01/14/15: QIC</td>
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<td>10/21/15: MPCTAC 11/11/15: QIC</td>
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Sacral Nerve Stimulation (Including Peripheral Nerve Stimulation Test and Two-Stage Tined Lead Procedure) for Incontinence and Urinary Conditions

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## Policy Revisions History

<table>
<thead>
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<tr>
<td>10/01/16</td>
<td>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.</td>
<td>Version 13</td>
<td>10/19/16: MPCTAC 11/09/16: QIC</td>
<td>12/09/15: QIC</td>
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<td>10/01/17</td>
<td>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.</td>
<td>Version 14</td>
<td>10/24/17: MPCTAC (electronic vote)</td>
<td>10/01/17: QIC</td>
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## Last Review Date

10/01/17

## Next Review Date

10/01/18

## Authorizing Entity

MPCTAC

## Other Applicable Policies

Medical Policy - *Biofeedback in an Outpatient Setting to Treat Bladder and/or Bowel Dysfunction (Including 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

Reimbursement Policy - *General Billing and Coding Guidelines*, policy number 4.31

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Reference to Applicable Laws and Regulations


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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