Medical Policy

Posterior Tibial Nerve Stimulation (Percutaneous or Transcutaneous)

Policy Number: OCA 3.562
Version Number: 17
Version Effective Date: 12/01/19

Product Applicability

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<tr>
<th>Well Sense Health Plan</th>
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<td>☑ Well Sense Health Plan</td>
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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

Posterior tibial nerve stimulation may include percutaneous tibial nerve stimulation (PTNS) and/or transcutaneous posterior tibial nerve stimulation (TPTNS). The Plan considers percutaneous tibial nerve stimulation (PTNS) medically necessary for the treatment of non-neurogenic overactive bladder syndrome in adult members (regardless of gender) when Plan criteria are met (regardless of gender). The Plan considers TPTNS using neurostimulation placed above the posterior tibial nerve on the surface of the skin (also known as transcutaneous electrical nerve stimulation or TENS) to be experimental and investigational for all Plan members (regardless of age and gender) when used for...
the treatment of overactive bladder, urinary incontinence, and/or fecal incontinence, as specified in
the Limitations and Applicable Coding sections of this policy.

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 indicated. The criteria and prior authorization guidelines for TPTNS/TENS used to treat
overactive bladder, urinary incontinence, and/or fecal incontinence are specified in this policy. Review
the Plan’s Code Look-up Tools available at www.bmchp.org for BMC HealthNet Plan members
(including Senior Care Options members) and at www.wellsense.org for Well Sense Health Plan
members for prior authorization requirements for TENS when treatment is used for other indications
(e.g., pain management).

The Plan’s Medically Necessary medical policy, policy number OCA 3.14, includes the product-specific
definitions of medically necessary treatment and the Plan’s Experimental and Investigational
Treatment medical policy, policy number OCA 3.12, specifies 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 Incontinence or
Constipation, policy number OCA 3.969; Pelvic Floor Stimulation for the Treatment of Incontinence
and/or Overactive Bladder, policy number OCA 3.561; and Sacral Nerve Stimulation (Including
Peripheral Nerve Stimulation Test and Two-Stage Tined Lead Procedure) for Incontinence and Urinary
Conditions, policy number OCA 3.563.

Description of Item or Service

Percutaneous Tibial Nerve Stimulation (PTNS): Also known as peripheral tibial nerve stimulation or
posterior tibial nerve stimulation (although posterior tibial nerve stimulation may also refer to
transcutaneous posterior tibial nerve stimulation), PTNS is a treatment option non-neurogenic
overactive bladder syndrome. PTNS is a minimally invasive procedure involving electrical stimulation
of the posterior tibial nerve by means of a needle percutaneously inserted into the ankle or via surface
electrodes connected to an external generator. Treatment typically involves low voltage current
applied for 30 minutes, once a week (sometimes up to 3 times per week) for a period of 10-12 weeks.
Maintenance sessions are recommended every 2-3 weeks. An example of a PTNS system is the
Urgent® PC Neuromodulation System by Uroplasty, Inc. A member seeking treatment with PTNS
should NOT be offered implantable sacral nerve stimulation (including peripheral nerve stimulation
test and/or two-stage tined lead procedure) for the treatment of non-neurogenic overactive bladder
syndrome. See the Medical Policy Statement section of this policy for medical necessity criteria for
PTNS.

Posterior Tibial Nerve Stimulation: Neuromodulation treatment designed to provide sacral nerve
stimulation through electrical stimulation of the posterior tibial nerve. Posterior tibial nerve
stimulation may include percutaneous tibial nerve stimulation (PTNS) and/or transcutaneous posterior
tibial nerve stimulation (TPTNS).
Transcutaneous Posterior Tibial Nerve Stimulation (TPTNS): Also known as transcutaneous electrical nerve stimulation or TENS, TPTNS is neuromodulation treatment with surface electrodes placed on the skin above the posterior tibial nerve. The criteria and prior authorization guidelines for TPTNS/TENS used to treat overactive bladder, urinary incontinence, and/or fecal incontinence are specified in this policy. Review the Plan’s Code Look-up Tools available at www.bmchp.org for BMC HealthNet Plan members (including Senior Care Options members) and at www.wellsense.org for Well Sense Health Plan members for prior authorization requirements for TENS when treatment is used for other indications (e.g., pain management).

Medical Policy Statement

Posterior tibial nerve stimulation may include percutaneous tibial nerve stimulation (PTNS) and/or transcutaneous posterior tibial nerve stimulation (TPTNS). The Plan considers TPTNS experimental and investigation when used for the treatment of overactive bladder, urinary incontinence, and/or fecal incontinence; Plan prior authorization is required for TPTNS (also known as transcutaneous electrical nerve stimulation or TEN) when used for any of these indications.

The Plan considers percutaneous tibial nerve stimulation (PTNS) medically necessary for the treatment of non-neurogenic urinary overactive bladder syndrome when Plan criteria are met and documented in the member’s medical record by the treating provider (including frequency and effectiveness of treatment), as specified below in items 1 through 8:

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

2. The member is diagnosed with non-neurogenic overactive bladder (OAB) syndrome, the member’s diagnosis and associated symptoms are documented by the treating provider (confirmed with medical history, physical exam, and diagnostic testing that includes urinalysis), and the member has NOT received a course of treatment with PTNS sessions in the past for the treatment of OAB symptoms;□ AND

□ Note: Plan Medical Director review is required for any request for PTNS when a member has received a course of treatment with PTNS sessions in the past (regardless of treating provider and prior dates of service) to determine if PTNS is the most effective treatment option for the member (rather than first-line therapy or a long-term treatment option such as implantable sacral nerve stimulation which has greater accuracy because the sacral nerve is directly stimulated).

3. The member has consistently attempted for at least 8 to 12 weeks ALL of the following first-line behavioral therapies but these conservative treatments have failed to manage the member’s symptoms of OAB, as specified below in items a through d:

Posterior Tibial Nerve Stimulation (Percutaneous or Transcutaneous)

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a. Bladder training; AND

b. Bladder control strategies; AND

c. Pelvic floor muscle training; AND

d. Fluid management; AND

4. The member has failed second-line therapy with a trial of at least 2 anticholinergic agents (antimuscarinics) and Myrbetrig® (mirabegron), with each administered for a minimum of 4 weeks to treat the member’s symptoms of OAB syndrome, unless this pharmacotherapy is NOT tolerated or is contraindicated for the member (with drug treatments/timeframes/effect on OAB symptoms, member tolerance of pharmacologic agents, and/or contraindications for treatment documented in the member’s medical record); AND

5. The device is FDA cleared for use with PTNS (e.g., Urgent PC Neuromodulation System by Uroplasty Inc. or NURO Neuromodulation System by Advanced Uro-Solutions Inc.) on the date of service, and the device is used according to FDA-cleared guidelines; AND

6. Member does NOT have an implanted sacral nerve neurostimulator (e.g., sacral neuromodulation with InterStim™ system by Medtronics, Inc.) and the member’s current treatment plan does NOT include the use of an implantable sacral nerve stimulation device (either the initial testing phase and/or insertion of a permanent implant) for the duration that the PTNS will be administered;Δ AND

Δ Note: PTNS and implantable SNS may NOT be administered concurrently. Review the Plan’s Sacral Nerve Stimulation (Including Peripheral Nerve Stimulation Test and Two-Stage Tined Lead Procedure) for Incontinence and Urinary Conditions, medical policy, policy number OCA 3.563.

7. Each PTNS session will be 30 minutes in duration; AND

8. The member’s first course of treatment is defined as first-time use of PTNS to treat one (1) or more urological symptoms per member regardless of treating provider and date of service. The Plan will authorize PTNS sessions ONLY when it is the member’s first course of treatment with PTNS and ONE (1) of the following applicable treatment frequency criteria must be met, as specified below in items a through c:

Posterior Tibial Nerve Stimulation (Percutaneous or Transcutaneous)

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a. **6 Initial PTNS Sessions for First Course of Treatment:**

   BOTH of the following criteria must be met for the initial 6 PTNS sessions for the first course of treatment, as specified below in item (1) and item (2):

   (1) The treating provider will be **objectively documenting** the degree of improvement (e.g., member voiding diaries) of the member’s symptoms after each PTNS session; AND

   (2) Each of the 6 initial PTNS sessions will occur **once a week** for 6 consecutive weeks; OR

   Note: The treating provider must verify with the member BEFORE authorized PTNS sessions begin that the member will comply with the treatment plan (e.g., documentation of symptoms with voiding diaries) and the member will attend ALL weekly PTNS sessions; an alternative treatment plan must be utilized if the member cannot adhere to the weekly schedule of authorized PTNS sessions. Plan Medical Director review is required if PTNS sessions will be administered more than once a week.

b. **PTNS Sessions Number 7 Through 12 for First Course of Treatment:**

   BOTH of the following criteria must be met for PTNS session number 7 through 12 for the first course of treatment, as specified below in item (1) and item (2):

   (1) The treating provider has objectively documented the degree of improvement (e.g., member voiding diaries) of the member’s symptoms after each of the initial sessions 1 through 6 and will continue to **objectively document** improvement after each of the PTNS sessions number 7 through 12; AND

   (2) Each of PTNS sessions number 7 through 12 will occur **once a week** for ALL consecutive weeks; OR

   Note: The treating provider must verify with the member BEFORE authorized PTNS sessions begin that the member will comply with the treatment plan (e.g., documentation of symptoms with voiding diaries) and the member will attend ALL weekly PTNS sessions; an alternative treatment plan must be utilized if the member cannot adhere to the weekly schedule of authorized PTNS sessions. Plan Medical Director review is required if PTNS sessions will be administered more than once a week.
c. **PTNS After Initial 12 Sessions for First Course of Treatment**

After the initial 12 sessions of PTNS for the member’s first course of treatment (i.e., initial 12-week treatment regimen outlined above), PTNS sessions must meet ALL of the following criteria, as specified below in items (1) through (3):

1. The additional PTNS sessions will occur **no more frequently than monthly** for the first 6 months of treatment (with the first 6 months of treatment defined as 6 consecutive calendar months from the date of the initial PTNS session for the member regardless of treating provider); AND

2. The treating provider has **objectively documented** (e.g., member voiding diaries) that the member has consistently experienced **50% or greater improvement in voiding symptoms for at least 48 hours** after each PTNS session – if this improvement threshold is not met or not documented, the PTNS treatment will be immediately discontinued (even if additional PTNS sessions are authorized by the Plan); AND

3. The PTNS sessions do not exceed 6 consecutive calendar months from the initial PTNS session for the member (regardless of treating provider). ~

~ Note: The Plan will **NOT** approve more than 6 sessions of PTNS per prior authorization request. Plan Medical Director review is required when the total duration of PTNS sessions is **longer than 6 consecutive calendar months** per member to determine if PTNS is the most effective treatment option for the member (rather than additional first-line therapy or a long-term treatment option such as implantable sacral nerve stimulation which has greater accuracy because the sacral nerve is directly stimulated). The treating provider must verify with the member BEFORE authorized PTNS sessions begin that the member will comply with the treatment plan (e.g., documentation of symptoms with voiding diaries) and the member will attend ALL PTNS sessions; an alternative treatment plan must be utilized if the member cannot adhere to the schedule of authorized PTNS sessions.

Limitations

1. **Plan Medical Director Review:**

   Plan Medical Director review is required for ANY of the following conditions, as specified below in items a through e:

   a. **Request for percutaneous tibial nerve stimulation (PTNS) that does NOT meet all applicable medical necessity criteria (and indications for treatment) outlined in the Medical Policy Statement section, including PTNS for a member 17 years of age or younger on the date of service; OR**

   ~ Posterior Tibial Nerve Stimulation (Percutaneous or Transcutaneous)
b. Request for PTNS after the initial 12 sessions when that the member has NOT experienced 50% or greater improvement in voiding symptoms for at least 48 hours; the efficacy of continued treatment with PTNS has NOT been established if the initial 12-week course of PTNS has failed to adequately manage the member’s urological symptoms; OR

c. Request for PTNS for a member whose sessions will exceed 6 consecutive calendar months from the member’s initial PTNS session (regardless of treating provider and dates of service) to determine if PTNS remains the most effective treatment option for the member (rather than first-line therapy or a long-term treatment option such as implantable sacral nerve stimulation which has greater accuracy because the sacral nerve is directly stimulated); OR

d. Request for PTNS sessions more frequently than once a week for the first 12 consecutive weeks of treatment; OR

e. Request for PTNS for a member who has received a course of treatment with PTNS sessions in the past for the treatment of any urological symptom(s). The member’s first course of treatment is defined as first-time use of PTNS to treat one (1) or more urological symptoms per member regardless of treating provider and date of service.

2. **Contraindications for Percutaneous Tibial Nerve Stimulation (PTNS):**

Contraindications for PTNS include ANY of the following, as specified below in items a through h:

a. Member with neurogenic overactive bladder syndrome/neurogenic lower urinary tract dysfunction; OR

b. Member with pacemaker or implantable defibrillator; OR

c. Member prone to excessive bleeding; OR

d. Member with nerve damage that could impact either percutaneous tibial nerve or pelvic floor function; OR

e. Member who is pregnant or planning to become pregnant during the duration of the treatment; OR

f. Member with active infection in the area of the percutaneous puncture; OR

g. Member unable to tolerate needle stick (e.g., phobia to needles); OR

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Posterior Tibial Nerve Stimulation (Percutaneous or Transcutaneous)

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h. Member with an implanted sacral nerve neurostimulator, member who has initiated the initial testing phase for implantable sacral nerve stimulation (SNS), or a member whose current treatment plan will include the use of implantable SNS (either the initial testing phase and/or insertion of a permanent implant). PTNS and implantable SNS may NOT be administered concurrently. Review the Plan’s Sacral Nerve Stimulation (Including Peripheral Nerve Stimulation Test and Two-Stage Tined Lead Procedure) for Incontinence and Urinary Conditions medical policy, policy number OCA 3.563.

3. Experimental and Investigational:

The Plan considers transcutaneous posterior tibial nerve stimulation (TPTNS) experimental and investigation when used for the treatment of overactive bladder, urinary incontinence, and/or fecal incontinence because there is insufficient scientific evidence to support the effectiveness of this treatment for these indications. TPTNS is also known as transcutaneous electrical nerve stimulation or TENS. Review the Plan’s Code Look-up Tools available at www.bmchp.org for BMC HealthNet Plan members (including Senior Care Options members) and at www.wellsense.org for Well Sense Health Plan members for prior authorization requirements when TENS is used for other indications (e.g., pain management).

Definitions

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

**Non-Neurologic Overactive Bladder (OAB):** Clinical diagnosis of overactive bladder (OAB) with symptoms not related to a neurological condition.

**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, 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).

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

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). Since 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.

<table>
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<tr>
<th>CPT Code</th>
<th>Description: Code Considered Medically Necessary for Percutaneous Tibial Nerve Stimulation (PTNS) for Non-Neurogenic Overactive Bladder Syndrome</th>
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<tr>
<td>64566</td>
<td>Posterior tibial neurostimulation, percutaneous needle electrode, single treatment, includes programming</td>
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Plan note: See the Medical Policy Statement and Limitations sections of this policy for applicable medical necessity criteria.

Posterior Tibial Nerve Stimulation (Percutaneous or Transcutaneous)

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<th>CPT Codes</th>
<th>Description: Codes Considered Experimental and Investigational for Transcutaneous Posterior Tibial Nerve Stimulation (TPTNS)/Transcutaneous Electrical Nerve Stimulation (TENS) When Used to Treat Overactive Bladder, Urinary Incontinence, and/or Fecal Incontinence (and Billed with a Related Primary Diagnosis Code)</th>
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</thead>
</table>
| 97014     | Application of a modality to 1 or more areas; electrical stimulation (unattended) | Plan notes:  
1. CPT code 97014 is NOT a payable code for the Senior Care Options product. See HCPCS code G0283. This code is ONLY payable for the Well Sense Health Plan products.  
2. Review the Limitations section of this policy for Plan guidelines on the use of TPTS/TENS to treat overactive bladder, urinary incontinence, and/or fecal incontinence.  
3. This code is also considered experimental and investigational when it is used to bill for non-implantable pelvic floor electrical stimulation (PFES) for the treatment of overactive bladder, urinary incontinence, and/or fecal incontinence, as stated in the Plan’s Pelvic Floor Stimulation for the Treatment of Incontinence medical policy, policy number OCA 3.561.  
4. See the Plan’s CPT Code Look-up Tool for prior authorization guidelines and all applicable medical policies for this CPT code when it is billed with a primary diagnosis NOT related to overactive bladder, urinary incontinence, and/or fecal incontinence; the look-up tool is available at www.bmchp.org for BMC HealthNet Plan and Senior Care Options members and posted at www.wellsense.org for Well Sense Health Plan members. |
| 97032     | Application of a modality to 1 or more areas; electrical stimulation (manual), each 15 minutes | Plan notes:  
1. Review the Limitations section of this policy for Plan guidelines on the use of TPTS/TENS to treat overactive bladder, urinary incontinence, and/or fecal incontinence.  
2. This code is also considered experimental and investigational when it is used to bill for non-implantable pelvic floor electrical stimulation (PFES) for the treatment of overactive bladder, urinary incontinence, and/or fecal incontinence, as stated in the Plan’s Pelvic Floor Stimulation for the Treatment of Incontinence and/or Overactive Bladder medical policy, policy number OCA 3.561.  
3. See the Plan’s CPT Code Look-up Tool for prior authorization guidelines and all applicable medical policies for this CPT code when it is billed with a primary diagnosis NOT related to overactive bladder, urinary incontinence, and/or fecal incontinence; the look-up tool is available at www.bmchp.org for BMC |

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HCPCS Code | Description: Code Considered Experimental and Investigational for Transcutaneous Posterior Tibial Nerve Stimulation (TPTNS)/Transcutaneous Electrical Nerve Stimulation (TENS) When Used to Treat Overactive Bladder, Urinary Incontinence, and/or Fecal Incontinence (and Billed with a Related Primary Diagnosis Code)

G0283 | Electrical stimulation (unattended), to one or more areas for indication(s) other than wound care, as part of a therapy plan of care

Plan notes:
1. Review the Limitations section of this policy for Plan guidelines on the use of TPTS/TENS to treat overactive bladder, urinary incontinence, and/or fecal incontinence.
2. This code is also considered experimental and investigational when it is used to bill for non-implantable pelvic floor electrical stimulation (PFES) for the treatment of overactive bladder, urinary incontinence, and/or fecal incontinence, as stated in the Plan’s Pelvic Floor Stimulation for the Treatment of Incontinence and/or Overactive Bladder medical policy, policy number OCA 3.561.
3. See the Plan’s CPT Code Look-up Tool for prior authorization guidelines and all applicable medical policies for this CPT code when it is billed with a primary diagnosis NOT related to overactive bladder, urinary incontinence, and/or fecal incontinence; the look-up tool is available at www.bmchp.org for BMC HealthNet Plan and Senior Care Options members and posted at www.wellsense.org for Well Sense Health Plan members.

ICD-10 Diagnosis Codes | Description: One (1) of the Following Primary ICD-10 Diagnosis Codes is Required When Billing with a CPT Code or HCPCS Code for TPTNS/TENS Used to Treat Overactive Bladder, Urinary Incontinence and/or Fecal Incontinence

N32.81 | Overactive bladder
N32.9 | Bladder disorder, unspecified
N39.3 | Stress incontinence (female)(male)
N39.41-N39.43 | Other specified urinary incontinence
N39.45-N39.46 | Other specified urinary incontinence
N39.490 | Other specified urinary incontinence; overflow incontinence
N39.498 | Other specified urinary incontinence (reflex incontinence) (total incontinence)
R15.0-R15.9 | Fecal incontinence
R32 | Unspecified urinary incontinence
R33.0-R33.9 | Retention of urine
R35.0 | Frequency of micturition
R39.14 | Feeling of incomplete bladder emptying

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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. Overactive bladder affects more than 10 to 15% of adult women, with 5 to 10% experiencing urge urinary incontinence monthly or more often. 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.

Treatment options for urinary incontinence include behavioral strategies, Kegel exercises, physical therapy, collagen injections, pharmacological interventions, and temporary electric stimulation before reconstructive surgery 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 percutaneous tibial nerve stimulation delivered by an external device as a minimally invasive alternative to SNS.

Percutaneous tibial nerve stimulation (PTNS) is a minimally invasive neuromodulation treatment designed to provide sacral nerve stimulation through percutaneous electrical stimulation of the posterior tibial nerve. The procedure consists of insertion of a percutaneous needle above the medial malleolus into a superficial branch of the posterior tibial nerve. Possible problems or complications of this procedure include excessive bleeding and disruption of cardiac pacemakers.

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. Conservative treatment for fecal incontinence includes medication management, pharmacologic therapy (e.g., antidiarrheal agents), dietary modification, bowel training, and biofeedback. Surgical intervention is reserved for patients who have anatomical

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defects, pathologic conditions that can be corrected surgically, and those in whom conservative management has failed.

At the time of the Plan’s most recent policy review, no national coverage determination (NCD) was found from the Centers for Medicare & Medicaid Services (CMS) for posterior tibial nerve stimulation for the treatment of incontinence and/or for any other indication. Local coverage determinations (LCD) L34436 and L33396 were identified for posterior tibial nerve stimulation applicable to Massachusetts, and the service may be considered medically necessary when criteria in the applicable LCD are met. Verify applicable CMS criteria in effect for the specified service and the indication for treatment in an NCD or LCD on the date of the prior authorization request for a Senior Care Options member.

Proposed treatment for urinary incontinence or an overactive bladder 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), NCD 230.18 for sacral nerve stimulation for urinary incontinence, 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. 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


The American Society of Colon and Rectal Surgeons (ASCRS). Paquette IM, Varma MG, Kaiser AM, Steele SR, Rafferty JF. The American Society of Colon and Rectal Surgeons’ clinical practice guideline for

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American Urological Association (AUA). Guidelines & Policies. Accessed at: https://www.auanet.org/guidelines?ContentType=%7C&q=Overactive+Bladder+%28OAB%29&ContentType=%7C&q=Overactive+Bladder+%28OAB%29


Posterior Tibial Nerve Stimulation (Percutaneous or Transcutaneous)


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Policy History

<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>
</tr>
</thead>
<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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<tr>
<td>Internal Approval: 10/03/06</td>
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</table>

*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 Date for the Senior Care Options Product(s): 01/01/16

Notes: Effective 05/01/13, this policy replaced the Pelvic Floor/Sacral Nerve Stimulation for Urinary Incontinence policy, policy number OCA: 3.56, for a service-specific policy for posterior tibial nerve stimulation. Policy title was Posterior Tibial Nerve Stimulation from 05/01/13 to 12/31/18. Effective 01/01/19, policy title changed to Posterior Tibial Nerve Stimulation (Percutaneous or Transcutaneous).

Policy Revisions History

<table>
<thead>
<tr>
<th>Review Date</th>
<th>Summary of Revisions</th>
<th>Revision Effective Date and Version Number</th>
<th>Approved by</th>
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<tbody>
<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: Quality Improvement Committee</td>
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<table>
<thead>
<tr>
<th>Date</th>
<th>Description</th>
<th>Version</th>
<th>Date</th>
<th>Author</th>
</tr>
</thead>
<tbody>
<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>Review for effective date 05/01/13. Separated pelvic floor electrical stimulation, sacral nerve stimulation, and posterior tibial nerve stimulation into three separate policies; policy formerly titled Pelvic Floor/Sacral Nerve Stimulation for Urinary Incontinence (formerly policy number OCA: 3.65). Revised title and re-numbered policy. Updated language in Summary, Description of Item or Service, Medical Policy Statement, Definitions, Applicable Coding, and Clinical Background Information sections. Updated references and revised limitations. Revised applicable code list. Referenced the following policies: Experimental and Investigational Treatment, Non-Implantable Pelvic Floor Electrical Stimulation for Urinary</td>
<td>Version 8</td>
<td>05/01/13 01/31/13: QIC</td>
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</tbody>
</table>

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### Policy Revisions History

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

<table>
<thead>
<tr>
<th>Date</th>
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<tr>
<td>12/01/13</td>
<td>Review for effective date 02/01/14. Updated references.</td>
<td>02/01/14</td>
<td>12/18/13</td>
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<td>Version 9</td>
<td>01/21/14</td>
<td>QIC</td>
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<tr>
<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</td>
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<td>Version 10</td>
<td>01/14/15</td>
<td>QIC</td>
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<tr>
<td>10/01/15</td>
<td>Review for effective date 12/01/15. Updated list of applicable products and corresponding notes. Updated Clinical Background Information and References sections.</td>
<td>12/01/15</td>
<td>10/21/15</td>
<td>MPCTAC</td>
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<td>Version 11</td>
<td>11/11/15</td>
<td>QIC</td>
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<tr>
<td>11/25/15</td>
<td>Review for effective date 01/01/16. Revised language in the Applicable Coding section.</td>
<td>01/01/16</td>
<td>11/25/15</td>
<td>MPCTAC (electronic vote)</td>
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<td>Version 12</td>
<td>12/09/15</td>
<td>QIC</td>
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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 the applicable code list.</td>
<td>12/01/16</td>
<td>10/19/16</td>
<td>MPCTAC</td>
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<td></td>
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<td>Version 13</td>
<td>11/09/16</td>
<td>QIC</td>
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<tr>
<td>10/01/17</td>
<td>Review for effective date 11/01/17. Administrative changes made to the Policy Summary, Description of Item or Service, Limitations, Definitions, Clinical Background Information, References, and Other Applicable Policies sections. Percutaneous tibial nerve stimulation (PTNS) remains an experimental and investigational treatment.</td>
<td>11/01/17</td>
<td>10/18/17</td>
<td>MPCTAC</td>
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<td>Version 14</td>
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<td>10/01/18</td>
<td>Review for effective date 01/01/19. Revised policy title. 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 (designating</td>
<td>01/01/19</td>
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<td>MPCTAC</td>
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<td>Version 15</td>
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<td>12/01/18</td>
<td>Review for effective date 03/01/19. Revised code list (including industry-wide code update) and Plan notes in the Applicable Coding section.</td>
<td>03/01/19</td>
<td>Version 16</td>
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<td>09/01/19</td>
<td>Review for effective date 12/01/19. Administrative changes made to the Other Applicable Policies, References, and Reference to Applicable Laws and Regulations sections. Administrative change made to the Plan notes in the Applicable Coding section. Revised criteria in the Limitations section.</td>
<td>12/01/19</td>
<td>Version 17</td>
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</tbody>
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**Last Review Date**

09/01/19

**Next Review Date**

09/01/20

**Authorizing Entity**

MPCTAC

**Other Applicable Policies**

- Medical Policy - *Biofeedback in an Outpatient Setting to Treat Incontinence or Constipation*, 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 and/or Overactive Bladder*, policy number OCA 3.561
- Medical Policy - *Sacral Nerve Stimulation (Including Peripheral Nerve Stimulation Test and Two-Stage Tined Lead Procedure) for Incontinence and Urinary Conditions, and Biofeedback for Urinary Incontinence*, policy number OCA 3.969
- Reimbursement Policy - *General Billing and Coding Guidelines*, policy number 4.31
- Reimbursement Policy - *General Billing and Coding Guidelines*, policy number SCO 4.31

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Reimbursement Policy - *General Billing and Coding Guidelines*, policy number WS 4.31
Reimbursement Policy - *General Clinical Editing and Payment Accuracy Review Guidelines*, policy number 4.108
Reimbursement Policy - *General Clinical Editing and Payment Accuracy Review Guidelines*, policy SCO 4.108
Reimbursement Policy - *General Clinical Editing and Payment Accuracy Review Guidelines*, policy number WS 4.18
Reimbursement Policy - *Non-Participating Provider*, policy number WS 4.5
Reimbursement Policy - *Non-Reimbursed Codes*, policy number 4.38
Reimbursement Policy - *Non-Reimbursed Codes*, policy number WS 4.38
Reimbursement Policy - *Physician and Non Physician Practitioner Services*, policy number 4.608
Reimbursement Policy - *Physician and Non Physician Practitioner Services*, policy number SCO 4.608
Reimbursement Policy - *Physician and Non Physician Practitioner Services*, policy number WS 4.28

**Reference to Applicable Laws and Regulations**


130 CMR. Code of Massachusetts Regulations. Division of Medical Assistance.

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


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

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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.