Posterior Tibial Nerve Stimulation

Policy Number: OCA 3.562
Version Number: 13
Version Effective Date: 12/01/16

Product Applicability

- All Plan Products

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

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

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

Policy Summary

The Plan considers posterior tibial nerve stimulation (PTNS) for the treatment of overactive bladder or for any other indication to be experimental and investigational for a Plan member (regardless of gender). (Posterior tibial nerve stimulation is also known as peripheral tibial nerve stimulation or percutaneous tibial nerve stimulation.) Prior authorization is required. It will be determined during the Plan’s prior authorization process if the service is considered experimental and investigational for the requested use. See the Plan’s policy, Experimental and Investigational Treatment (policy number OCA 3.12), for the product-specific definitions of experimental or investigational treatment. See Plan policies, Pelvic Floor Stimulation for the Treatment of Incontinence (policy number OCA 3.561), 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), for additional Plan guidelines.

**Description of Item or Service**

**Posterior Tibial Nerve Stimulation (PTNS):** Also known as peripheral tibial nerve stimulation or percutaneous tibial nerve stimulation, treatment involves 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. An example of a PTNS system is the Urgent® PC Neuromodulation System by Uroplasty, Inc.

**Medical Policy Statement**

The Plan considers posterior tibial nerve stimulation for the treatment of symptoms associated with overactive bladder or for any other indication to be experimental and investigational for a Plan member (regardless of gender).

**Limitations**

The Plan considers this service experimental and investigational.

**Definitions**

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

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

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

**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 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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<thead>
<tr>
<th>CPT Code</th>
<th>Description: Code Considered Experimental and Investigational</th>
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<tbody>
<tr>
<td>64566</td>
<td>Posterior tibial neurostimulation, percutaneous needle electrode, single treatment, includes programming</td>
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</table>

**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 posterior/percutaneous tibial nerve stimulation delivered by an external device as a minimally invasive alternative to SNS.

*Plan refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name Well Sense Health Plan.*
Posterior tibial nerve stimulation (PTNS), also called peripheral tibial nerve stimulation or percutaneous tibial nerve stimulation, is proposed as a treatment option for urological disorders, including urinary incontinence, overactive bladder, pelvic floor dysfunction, chronic prostatitis and fecal incontinence. Treatments typically involve low voltage current applied for 30 minutes, 1-3 times per week for a period of 10-12 weeks. Maintenance sessions are recommended every 2-3 weeks. PTNS may be regarded as an intermediate therapy between pelvic muscle exercise and sacral nerve stimulation. The use of PTNS is considered experimental and investigational because there is insufficient scientific evidence to support the effectiveness of PTNS for these indications. Other proposed treatment options for urinary incontinence include sacral nerve stimulation and pelvic floor electrical stimulation. PTNS has also been proposed for treatment of fecal incontinence, but clinical validity and clinical utility of this treatment for fecal incontinence has not been documented.

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. 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


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<tr>
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<th>Original Effective Date* and Version Number</th>
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<tr>
<td>Regulatory Approval: N/A</td>
<td>12/03/06 Version 1</td>
<td>Medical Policy Manager as Chair of Medical Policy, Criteria, and Technology Assessment Committee (MPCTAC) and member of Quality Improvement Committee (QIC)</td>
<td>Quality and Clinical Management Committee (Q&amp;CMC)</td>
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<td>Internal Approval: 10/03/06</td>
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*Effective Date for the BMC HealthNet Plan Commercial Product(s): 01/01/12
*Effective Date for the Well Sense 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.)

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<th>Review Date</th>
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<td>09/11/07</td>
<td>Updated template and added coding.</td>
<td>Version 2</td>
<td>09/11/07: MPCTAC 09/25/07: Utilization Management Committee (UMC) 10/15/07: QIC</td>
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<td>No changes.</td>
<td>Version 3</td>
<td>09/09/08: MPCTAC</td>
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<td>Version 4</td>
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<td>10/22/08: QIC</td>
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<td>09/01/10</td>
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<td>Version 5</td>
<td>10/20/10: MPCTAC</td>
<td>11/22/10: QIC</td>
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<td>10/01/11</td>
<td>Updated limitations to include that sacral nerve stimulation for the treatment of fecal incontinence and posterior tibial nerve stimulation for the treatment of symptoms associated with overactive bladder are considered experimental and investigational. Updated references and coding.</td>
<td>Version 6</td>
<td>10/19/11: MPCTAC</td>
<td>11/29/11: QIC</td>
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<td>07/20/12</td>
<td>Off cycle review for Well Sense Health Plan: Updated title, revised Summary statement, added posterior tibial stimulation to Description of Item or Service, reformatted Medical Policy Statement, updated Definitions, revised language in Applicable Coding section, updated code list.</td>
<td>Version 7</td>
<td>08/13/12: MPCTAC</td>
<td>09/13/12: QIC</td>
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<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 <em>Pelvic Floor/Sacral Nerve Stimulation for Urinary Incontinence</em> (formerly policy number OCA: 3.65). Revised title and re-numbered policy. Updated language in Summary, Description of Item or Service, Medical Policy Statement, Definitions, Applicable Coding, and Clinical Background Information sections. Updated references and revised limitations. Revised applicable code list. Referenced the following policies: <em>Experimental and Investigational Treatment, Non-Implantable Pelvic Floor Electrical Stimulation for Urinary Incontinence, Sacral Nerve Stimulation (Including Peripheral Nerve Stimulation)</em></td>
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<td>05/01/13 01/31/13: QIC</td>
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### Policy Revisions History

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<td>12/01/15</td>
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<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>MPCTAC (electronic vote) 12/09/15: QIC</td>
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<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>MPCTAC 10/19/16: QIC</td>
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**Last Review Date**

10/01/16

**Next Review Date**

10/01/17

**Authorizing Entity**

QIC

**Other Applicable Policies**

Medical Policy - *Biofeedback for 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

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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.