## Percutaneous Tibial Nerve Stimulation

### Description

Percutaneous tibial nerve stimulation (PTNS, also known as posterior tibial nerve stimulation) is a technique of electrical neuromodulation used primarily for treating voiding dysfunction. The tibial nerve is stimulated using a fine-needle electrode inserted slightly above the ankle, and low-voltage electrical current is delivered.

### Related Policies

- Biofeedback as a Treatment of Fecal Incontinence or Constipation
- Biofeedback as a Treatment of Urinary Incontinence in Adults
- Electrical Stimulation for Pain and Other Conditions
- Injectable Bulking Agents for the Treatment of Urinary and Fecal Incontinence
- Pelvic Floor Stimulation as a Treatment of Urinary and Fecal Incontinence
- Sacral Nerve Neuromodulation/Stimulation
- Transanal Radiofrequency Treatment of Fecal Incontinence

### Policy

Percutaneous tibial nerve stimulation is considered **investigational** for all indications, including but not limited to the following:

- Urinary dysfunction, including but not limited to overactive bladder syndrome, neurogenic bladder, urinary frequency, urgency, incontinence, and retention
- Fecal incontinence

### Policy Guidelines

There is a specific CPT code for this procedure:

- **64566**: Posterior tibial neurostimulation, percutaneous needle electrode, single treatment, includes programming

CPT codes for percutaneous implantation of neurostimulator electrodes (i.e., 64553-64565) are not appropriate since PTNS uses percutaneously inserted needles and wires rather than percutaneously implanted electrodes. The stimulation devices used in PTNS and percutaneous neuromodulation therapy (PNT) are not implanted, so CPT code 64590 is also not appropriate.
Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program (FEP)) prohibit Plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

Rationale

Background

Altering the function of the posterior tibial nerve with PTNS is believed to improve voiding function and control. Although the posterior tibial nerve is located near the ankle, it is derived from the lumbar-sacral nerves (L4-S3), which control the bladder detrusor and perineal floor. Voiding dysfunction includes urinary frequency, urgency, incontinence, and nonobstructive retention. Common causes of voiding dysfunction are pelvic floor dysfunction (e.g., from pregnancy, childbirth, surgery), inflammation, medication (e.g., diuretics and anticholinergics), obesity, psychogenic factors, and disease (e.g., multiple sclerosis, spinal cord injury, detrusor hyperreflexia, diabetes with peripheral nerve involvement). The current FDA-cleared indication for PTNS is overactive bladder (OAB), which is defined as the presence of urinary urgency, with or without urgency urinary incontinence, that is usually accompanied by frequency and nocturia and is not associated with urinary tract infections or other known pathology.

The procedure for PTNS consists of the insertion of a needle above the medial malleolus into the posterior tibial nerve followed by the application of low-voltage (10 mA, 1-10 Hz frequency) electrical stimulation that produces sensory and motor responses (i.e., a tickling sensation and plantar flexion or fanning of all toes). Noninvasive PTNS has also been delivered with surface electrodes. The recommended course of treatment is an initial series of 12 weekly office-based treatments followed by an individualized maintenance treatment schedule.

PTNS is less invasive than traditional sacral nerve neuromodulation (see Blue Shield of California Medical Policy: Sacral Nerve Neuromodulation/Stimulation), which has been successfully used in the treatment of urinary dysfunction but requires implantation of a permanent device. In sacral root neuromodulation, an implantable pulse generator that delivers controlled electrical impulses is attached to wire leads that connect to the sacral nerves, most commonly the S3 nerve root that modulates the neural pathways controlling bladder function.

PTNS is not cleared by FDA for treating fecal incontinence; however, the treatment has been proposed for this purpose. The manufacturer recommends a course of treatment for fecal incontinence similar to the one used to treat OAB; an initial course of 12 weekly sessions of tibial nerve stimulation followed by a personalized schedule of follow-up treatments.
Regulatory Status
In July 2005, the Urgent® PC Neuromodulation System (Uroplasty Inc.) received 510(k) marketing clearance from FDA for percutaneous tibial nerve stimulation to treat patients suffering from urinary urgency, urinary frequency, and urge incontinence. In 2010, the cleared indication was changed to “overactive bladder (OAB) and associated symptoms of urinary urgency, urinary frequency, and urge incontinence.” The Urgent PC Neuromodulation System is not FDA-cleared for other indications, such as the treatment of fecal incontinence.

Literature Review
Overactive Bladder
Systematic Reviews
An updated Blue Cross Blue Shield Association Technology Evaluation Center (TEC) Assessment on percutaneous tibial nerve stimulation (PTNS) for treatment of voiding dysfunction was published in December 2013 and concluded that PTNS as treatment for voiding dysfunction meets the TEC criteria for treatment of voiding dysfunction.(1) The Assessment included the 6 randomized controlled trials (RCTs) discussed next and had the following conclusion:

Evidence from randomized placebo-controlled trials supports the clinical efficacy of PTNS applied in the standard 12-week regimen. No concurrently controlled evidence exists from a trial over longer periods of time in maintenance therapy. Although the lack of controlled evidence on maintenance PTNS raises concern whether short-term efficacy is maintained over the long term, the available 12- to 36-month evidence appears consistent with maintained efficacy in relieving symptoms of overactive bladder (OAB) and urinary voiding dysfunction. Adverse event rates, assuming accurate ascertainment, appear limited.

In 2012 and 2013, several other systematic reviews of the literature on PTNS for treating OAB were published.(2-5) Only one of these systematic reviews, however, conducted pooled analyses of study results.(2) This review, by Burton et al, conducted a pooled analysis of data from 4 trials (2 of which were abstracts) comparing PTNS with sham treatment. They found a significantly higher risk of successful treatment with PTNS (risk ratio [RR]= 7.02; 95% confidence interval [CI], 1.69 to 29.17) compared with a control intervention. The confidence interval was wide, indicating a lack of precision in the pooled estimate. The SUmiT trial, discussed next, contributed 220 of 289 patients (76%) in the pooled analysis.

Also in 2012, the Agency for Healthcare Research and Quality (AHRQ) Effective Health Care Program published a comparative effectiveness review on the broader topic of nonsurgical treatments for urinary incontinence in adult women.(6) The review identified 4 reports of RCTs comparing PTNS and no active treatment in patients with OAB. Two of the 4 articles reported 12-week results of the sham-controlled SUmiT trial; one of these included a subgroup of SUmiT participants and was only published as an abstract. The AHRQ report included a pooled analysis of data from 3 studies that found statistically significantly greater improvement in urinary incontinence in the PTNS group compared with the control group (RR=1.9; 95% CI, 1.1 to 3.2). This pooled analysis included a total of 405 patients; 220 in the SUmiT trial, 150 in the SUmiT trial subanalysis and 35 in a trial by Finazzi-Agro et al.(7) A limit of the analysis in the AHRQ review was that the 150 patients in the SUmiT subanalysis were included twice. The AHRQ report did not discuss evidence on the efficacy of PTNS beyond 12 weeks.
Randomized Controlled Trials

Two key RCTs that evaluated percutaneous tibial nerve stimulation for treating patients diagnosed with OAB syndrome have been published. In 2009, Peters et al published an industry-sponsored nonblinded comparison of PTNS and extended-release tolterodine (Detrol LA) in women with OAB syndrome (OrBIT trial).(8) The study included 100 patients (50 per group); more than 90% were women. Study participants were identified at 11 centers between June 2006 and September 2008. Subjects had to have symptoms of OAB, with at least 8 voids per 24 hours; the mean daily voids for those entering the study were 12.3. A total of 87 of the 100 (87%) patients completed the study, and voiding diary data were available for 84 patients, 41 of 50 (82%) in the PTNS group and 43 of 50 (86%) in the tolterodine group.

The primary outcome was the noninferiority of PTNS in the mean reduction in the number of voids per 24 hours after 12 weeks of treatment. Noninferiority was defined as no more than a 20% difference in the mean void reduction. Study findings showed noninferiority of PTNS based on results for 84 patients. The decrease in number (standard deviation [SD]) of voids per day was 2.4 (4.0) in the PTNS group and 2.5 (3.9) in the tolterodine group.

The study also reported a number of secondary outcomes, and findings on these were mixed. There were no statistically significant differences in the PTNS and tolterodine groups for other symptoms recorded in the voiding diary; this includes mean change in episodes of nocturia (-0.7 and -0.6, respectively), episodes of moderate to severe urgency per day (-2.2 and -2.9, respectively), and episodes of urge incontinence per day (-1.0 and -1.7, respectively). In other secondary outcomes, 35 of 44 patients (79.5%) in the PTNS group and 23 of 42 (54.8%) in the tolterodine group reported symptom improvement or cure. This difference was statistically significant (p=0.01), favoring the PTNS group. However, the proportion of patients reporting symptom improvement (excluding the 3 patients reporting that they were cured) did not differ significantly between groups, 34 of 44 (77.3%) of those receiving PTNS and 21 of 42 (50%) receiving tolterodine. For the adverse event data, responses were obtained in person for the PTNS group in conjunction with their weekly treatment sessions and over the phone for the medication group, using standard checklists. It is not clear how response to treatment or quality-of-life data were collected. Limitations of the OrBIT trial included the lack of blinding of patients and providers and the lack of comparative data beyond the end of the initial 12-week treatment period. Moreover, there was no sham or placebo group to mitigate the potential bias due to subjective outcomes. In addition, the authors did not clearly define criteria for "improvement" or "cure", a key secondary outcome, and did not report the extent of compliance with medical therapy and used different methods of data collection in the 2 groups for adverse event outcomes and possibly also for other self-report outcomes.

In 2010, MacDiarmid et al reported 1-year follow-up data for patients from the OrBIT trial who had been assigned to the PTNS group and had responded to the initial course of treatment, defined as reporting symptom improvement at 12 weeks.(9) Thirty-three of the 35 responders were included. They received a mean (SD) of 12.1 (4.9) additional treatments between the 12-week and 12-month visits, and there was a median of 17 days between treatments. Data were available for 32 of the 33 (97%) participants at 6 months and 25 of the 33 (76%) participants at 12 months. The mean (SD) reduction in number of voids per day from baseline (the original primary outcome of the study) was 3.2 (3.7) at 6 months and 2.8 (3.7) at 12 months. Other voiding diary outcomes at 12 months, based on 25 responses, were mean changes in nocturia episodes of -0.8, in episodes of moderate to severe urgency per day of -3.7, and in episodes of urge incontinence per day of -1.6. As previously noted, this analysis was limited in that no data
from the tolterodine group were available to compare long-term outcomes. Another limitation was not all patients in the PTNS group were included in the follow-up analysis, only PTNS responders were eligible. A potential bias is that the initial subjective outcome measure may be subject to the placebo effect. Moreover, patients in the PTNS group who responded to initial treatment may be particularly susceptible to a placebo response and/or may represent those with the best treatment response. Thus, these individuals may also be susceptible to a placebo response during maintenance treatments, especially treatments offered on an as-needed basis.

The second key RCT on OAB syndrome, also industry-sponsored, was published by Peters et al in 2010. This study, known as the SUmiT trial, had a sham-comparison group. Before conducting the trial, the researchers performed a pilot study in healthy volunteers to determine the adequacy of a sham PTNS intervention. Findings were that 10 of 30 volunteers (33%) correctly identified the sham procedure. This percentage is below the 50% that could be expected by chance; the investigators concluded that the procedure was a feasible sham. The SUmiT trial included patients with OAB syndrome. Eligibility criteria included a score of at least 4 on the Overactive Bladder Questionnaire short form for urgency, self-report bladder symptoms lasting at least 3 months, and having failed conservative care. Data were collected from 23 centers in the United States. A total of 220 patients were randomly assigned, 110 to the PTNS group and 110 to the sham group. Both groups received 12 weekly 30-minute intervention sessions. In the sham group, a blunt (placebo) instrument was used to simulate the location and sensation of needle electrode insertion in active treatment. An inactive PTNS surface electrode was used and also 2 active transcutaneous electrical nerve stimulation (TENS) surface electrodes. The TENS unit was used to deliver low-level sensation to simulate the PTNS intervention. The 12-week course of treatment was completed by 103 of 110 (94%) in the PTNS group and 105 of 110 (95%) in the sham group.

The primary study outcome was response to treatment based on a single-item global response assessment (GRA) variable at 13 weeks. Possible responses were that symptoms were markedly worse, moderately worse, mildly worse, the same, slightly improved, moderately improved, or markedly improved. The proportion of patients who responded to treatment based on the GRA (i.e., answered that symptoms were moderately or markedly improved) was 60 of 110 (54.5%) in the PTNS group and 23 of 110 (20.9%) in the sham group; this difference was statistically significant (p<0.001). Intention-to-treat (ITT) analysis was used for the primary end point only. Several secondary outcomes also favored the PTNS group. The mean (SD) reduction in a symptom severity score (a lower score indicates less severity) was 36.7 (21.5) in the PTNS group and 29.2 (20.0) in the sham group (p=0.01). Similarly, the mean (SD) reduction in a quality-of-life scale, the 36-Item Short-Form Health Survey (a higher score indicates higher quality of life), was 34.2 (21.3) in the PTNS group and 20.6 (20.6) in the sham group (p=0.006).

For the 4 voiding diary variables used, there was a statistically significant difference between groups favoring PTNS. The mean (SD) change from baseline in the number of voids per day was -2.4 (2.5) in the PTNS group and -1.5 (2.4) in the sham group (difference between groups, 0.9 voids per day; p=0.01). The mean (SD) change in nocturia episodes was -0.7 (1.2) in the PTNS group and -0.3 (1.4) in the sham group (difference between groups, 0.4 nighttime voids; p=0.04). The mean change in moderate to severe urgency per day was -3.7 in the PTNS group and -2.0 in the sham group (difference between groups, 1.7 episodes; p<0.001). Finally, the mean change in urge incontinence episodes was -1.3 in the PTNS group and -0.3 in the sham group (difference between groups, 1 episode per day; p<0.002). (Standard deviations were not reported for the latter 2 outcomes.)
Advantages of the SUmiT trial were that it included a sham comparison and the primary end point analysis was ITT. A limitation was that the primary outcome, the GRA, was a single-item subjective measure. For the more objective measures, the voiding diary variables, there was statistically significantly greater benefit with PTNS compared with sham treatment; however, the clinical significance of the difference between the PTNS and sham groups was unclear (e.g., on average, there was 1 fewer episode of urge incontinence a day in the PTNS group). In addition, as in the OrBIT trial, the SUmiT trial only reported comparative data immediately following the initial course of treatment; the study did not evaluate the long-term effectiveness of PTNS. Unlike medication which can be taken on an ongoing basis, PTNS involves an initial 12-week course of treatment followed by maintenance therapy, which to date has not been well defined. Therefore, the assumption cannot be made that short-term treatment effects will be maintained.

As with the OrBIT trial, there was a SUmiT extension study including only those patients who had been assigned to the PTNS group and initially responded to treatment. That is, the extension study did not collect additional follow-up data from patients in the PTNS group who failed to meet the 12-week primary effectiveness end point or from patients assigned to the sham-control group. Among the 110 patients assigned to the PTNS group, 60 were initial responders and 50 of these entered the extension study. Data were available on 34 patients at 24 months and 29 patients at 36 months. After enrolling in the extension study, patients underwent a 14-week transitional protocol consisting of 2 treatments with a 14-day interval, 2 treatments with a 21-day interval and then 1 treatment after another 28 days. Following this 14-week period, a personal treatment plan was developed for each patient. PTNS treatments were delivered based on the patient’s reporting of symptoms; patients knew that PTNS sessions were available to them as needed when their symptoms increased. Between 6 and 36 months, patients received a median of 1.1 PTNS treatments per month. In a per-protocol analysis, compared with baseline, 28 of 29 patients (97%) who completed the 36-month follow-up met the primary efficacy end point of moderate or marked improvement in overall bladder symptoms on the GRA. In addition, compared with baseline, all voiding diary measures were significantly improved in this group of patients at every 6-month follow-up. As mentioned previously in the discussion of the OrBIT extension study, the SUmiT extension study was limited by a lack of follow-up data on the control group and a lack of follow-up data on all participants in the treatment group.

Several other RCTs have been published; none reported on the efficacy of PTNS beyond 12 weeks. Three trials used a parallel group design. In 2010, Finazzi-Agro et al from Italy conducted a double-blind RCT that included 35 female patients who had urge incontinence and detrusor overactivity on urodynamic testing. Patients were randomly assigned to 30-minute PTNS sessions 3 times per week for 4 weeks (n=18) or sham treatment (n=17). One patient dropped from the PTNS group and 2 dropped from the sham group; analysis was not ITT. The primary outcome, percent responders at 4 weeks (defined as at least 50% reduction in incontinent episodes) was attained by 12 of 17 (71%) in the PTNS group and 0 of 15 (0%) in the sham group. Also in 2010, Schreiner et al in Brazil randomized 51 women older than 60 years who complained of urge urinary incontinence to 12 weeks of conservative treatment (Kegel exercises and bladder training) alone (n=26) or conservative treatment plus 12 weekly sessions of PTNS (n=25). The response rate at 12 weeks, defined as a reduction of at least 50% in the number of incontinence episodes reported by the patient in a bladder diary, was 76% in the PTNS group and 27% in the conservative treatment only group (p=0.001). Blinding was not discussed.

In 2012, Gungor Ugurlucan et al in Turkey published findings of an RCT comparing transvaginal electrical stimulation (ES) (n=38) and PTNS (n=21) in women with OAB.
The ES protocol consisted of 20-minute treatments 3 times a week for 6 to 8 weeks. PTNS was performed with an Urgent PC device used for twelve 30-minute weekly sessions. A total of 52 of 59 (88%) patients completed the study. The authors assessed numerous outcome variables and did not specify primary outcomes or adjust p values for multiple comparisons. Four bladder diary variables were reported. From baseline to the end of the treatment period, the groups did not differ significantly at the p less than 0.05 level in mean change in urgency episodes, nocturia or incontinence episodes. For example, the mean number (SD) of urgency episodes was 2.9 (4.1) at baseline and 1.6 (0.5) after treatment in the ES group and 2.0 (3.1) at baseline and 1.3 (0.5) after treatment in the PTNS group (p=0.54). There was a statistically significant difference in daytime frequency. The mean (SD) daytime frequency was 7.8 (2.7) at baseline and 5.8 (1.9) after treatment in the ES group and 7.6 (2.6) at baseline and 7.4 (2.9) in the PTNS group (p=0.03). The authors reported that a significantly higher proportion of patients in the ES group described themselves as cured, but they did not provide proportions or p values.

One randomized trial, published in 2013, used a crossover design. This study, by Vecchioli-Scaldazza et al in Italy, included 40 women with OAB.(16) The treatments were PTNS (twice weekly for 6 weeks) and medication (oral solifenacin succinate 5 mg/d for 40 days), given in random order, with a 6-week wash-out period between treatments. Group A received medication first and group B received PTNS first. The primary efficacy outcome was reduction in the number of voids in a 24-hour period. Thirty of the 40 patients (75%) completed the study. The number of daily voids significantly decreased after each treatment compared with before treatment. In group A, the mean number (SD) of daily voids premedication was 11.6 (1.6) and postmedication was 10.0 (2.1) (p=0.004). The mean number of voids pre-PTNS was 11.5 (1.1) and post-PTNS, 8.5 (2.3) (p<0.001). In group B, the mean number (SD) of voids premedication was 11.4 (1.4) and postmedication, 10.4 (1.8) (p=0.008). The mean number (SD) of voids pre-PTNS was 11.4 (1.4) and post-PTNS, 9.4 (1.9) (p<0.001). In addition, secondary outcomes including nocturia, urge incontinence and voided volume significantly improved after each treatment compared with pretreatment values. The authors did not directly compare the efficacy of medication and PTNS.

Neurogenic Bladder

An RCT evaluating PTNS for neurogenic OAB in men was published by Monteiro et al in 2014.(17) Twenty-four adult men with no prior urinary symptoms who were between 6 months and 3 years post-stroke were randomized to 6 weeks of PTNS twice a week or a control group that received general advice and stretching exercises. Sessions in both groups lasted 30 minutes. The proportion of patients experiencing urinary urgency, urge incontinence, and nocturnal enuresis did not differ significantly between groups immediately after treatment or at the 12-month follow-up. For example, after treatment, 8 patients (67%) in the PTNS group and 9 patients (75%) in the control group reported urge incontinence, p=0.65. Rates of nocturia did not differ between groups after treatment, but there was a significant difference at 12 months, favoring PTNS. Advantages of this study were a placebo treatment and longer-term follow-up. Findings were mostly negative, but additional studies with larger sample sizes are needed before conclusions can be drawn about the efficacy of PTNS for treatment of neurogenic bladder.

Fecal Incontinence

The Urgent PC Neuromodulation System is not FDA-cleared for the treatment of fecal incontinence. The company’s website states that the treatment can be used for this condition and that the recommended initial course of treatment includes 12 weekly sessions.
In 2014, Horrocks et al. published a systematic review of literature on tibial nerve stimulation (percutaneous and transcutaneous) to treat fecal incontinence. The authors included all study designs and identified a total of 12 articles, 2 RCTS and 10 case series. Six studies evaluated PTNS, 5 evaluated transcutaneous tibial nerve stimulation (TTNS), and 1 of the RCTS compared the 2 treatments. The other RCT compared TTNS with a sham treatment. Three of the 5 case series on PTNS and 1 RCT reported the outcome, 50% or greater reduction in the number of fecal incontinence episodes per week immediately after treatment. In these studies, a median of 71% of patients (range, 63%-82%) reported at least a 50% reduction in episodes. However, this analysis is limited because it lacks a control group and did not include data from all published studies.

The single RCT to date evaluating PTNS for fecal incontinence was published in 2013 by George et al in the U.K. Thirty patients (28 women) who had failed conservative therapy for fecal incontinence were randomized to PTNS (n=11), TTNS (n=11) or sham transcutaneous stimulation (n=9). Patients in all groups received a total of 12 treatments given twice-weekly sessions for 6 weeks. (This differs from the PTNS manufacturer's recommended course of 12 weekly treatments). The primary study end point was at least a 50% reduction in the mean number of incontinence episodes per week at the end of the 6-week treatment period. Only 1 patient did not complete the study, and data were analyzed on an ITT basis. Nine of 11 patients in the PTNS group, 5 of 11 in the TTNS group, and 1 of 8 in the sham group attained the primary end point; the difference among groups was not statistically significant, p=0.035. All of the responders reported no weekly episodes of fecal incontinence after treatment. The study is limited by the small sample size and short-term follow-up.

Ongoing Clinical Trials
A search of clinicaltrials.gov on November 17, 2014 identified the following relevant ongoing RCTS on PTNS:

Comparison of PTNS and Biofeedback for Fecal Incontinence (NCT01882101): This RCT, sponsored by the Seoul National University Hospital, is randomizing patients with 2 or more weekly episodes of fecal incontinence to 6 weeks of PTNS or EMG biofeedback. The primary outcome is change in the number of weekly episodes of fecal incontinence. The investigators plan to enroll 50 patients. As of November 2014, the study has not yet started enrolling patients.

Summary of Evidence
Percutaneous tibial nerve stimulation (PTNS, also known as posterior tibial nerve stimulation) is a technique of electrical neuromodulation used primarily for treating voiding dysfunction. The available randomized controlled trials (RCTs) report short-term (up to 12 weeks) improvements on measures of urinary incontinence and overactive bladder. Up to 36 months of data are available for some patients enrolled in RCTs who responded to an initial course of treatment, but not on other RCT participants. There is a lack of control data beyond 12 weeks to control for a possible placebo response. Moreover, there was a high dropout rate in long-term follow-up. The optimal maintenance regimen after an initial 12-week course is unclear. Systematic reviews of the evidence have found short-term improvements with PTNS and have not identified long-term comparative studies. Clinical input obtained in 2012 was mixed regarding whether PTNS for voiding dysfunction should be considered medically necessary. In addition, there is insufficient evidence that PTNS is effective for other conditions such as fecal incontinence. Based on this evidence and clinical input, PTNS is considered investigational for all indications.
Supplemental Information

Practice Guidelines and Position Statements

In 2014, the American Urological Association and the Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction published a guideline on diagnosis and treatment of nonneurogenic OAB in adults. The guideline included a statement that clinicians may offer PTNS as a third-line treatment option in carefully selected patients. The statement was rated as grade C, indicating that the balance of benefits and risks/burdens are uncertain. (This is a revised version of a 2012 guideline; the statement on PTNS did not change).

The 2005 (reaffirmed 2013) American College of Obstetricians and Gynecologists practice bulletin on treatment of urinary incontinence in women did not address PTNS or other types of nerve stimulation.

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

References


**Documentation Required for Clinical Review**

- No records required

**Coding**

This Policy relates only to the services or supplies described herein. Benefits may vary according to benefit design; therefore, contract language should be reviewed before applying the terms of the Policy. Inclusion or exclusion of a procedure, diagnosis or
device code(s) does not constitute or imply member coverage or provider reimbursement.

IE

The following services are considered investigational and therefore not covered for any indication.

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<th>Type</th>
<th>Code</th>
<th>Description</th>
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<td>CPT®</td>
<td>64566</td>
<td>Posterior tibial neurostimulation, percutaneous needle electrode, single treatment, includes programming</td>
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<td>64999</td>
<td>Unlisted procedure, nervous system</td>
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<td>97014</td>
<td>Application of a modality to 1 or more areas; electrical stimulation (unattended)</td>
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<td>97032</td>
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Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

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<tr>
<td>2/27/2015</td>
<td>Policy title change from Urinary Incontinence Outpatient Treatment</td>
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<td>BCBSA Medical Policy adoption</td>
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<td></td>
<td>Policy revision with position change</td>
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Definitions of Decision Determinations

Medically Necessary: A treatment, procedure or drug is medically necessary only when it has been established as safe and effective for the particular symptoms or diagnosis, is not investigational or experimental, is not being provided primarily for the convenience
of the patient or the provider, and is provided at the most appropriate level to treat the condition.

**Investigational/Experimental:** A treatment, procedure or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

**Split Evaluation:** Blue Shield of California / Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a Split Evaluation, where a treatment, procedure or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

**Prior Authorization Requirements**

This service (or procedure) is considered medically necessary in certain instances and investigational in others (refer to policy for details).

For instances when the indication is medically necessary, clinical evidence is required to determine medical necessity.

For instances when the indication is investigational, you may submit additional information to the Prior Authorization Department.

Within five days before the actual date of service, the Provider MUST confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should also be directed to the Prior Authorization Department. Please call 1-800-541-6652 or visit the Provider Portal www.blueshieldca.com/provider.

The materials provided to you are guidelines used by this plan to authorize, modify, or deny care for persons with similar illness or conditions. Specific care and treatment may vary depending on individual need and the benefits covered under your contract. These Policies are subject to change as new information becomes available.