Percutaneous Tibial Nerve Stimulation

Effective: January 1, 2018

Next Review: May 2018
Last Review: December 2017

IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

Percutaneous tibial nerve stimulation (PTNS) is a technique of electrical neuromodulation for the treatment of voiding dysfunction and fecal incontinence in patients who have failed behavioral and/or pharmacologic therapies.

MEDICAL POLICY CRITERIA

Note:

• Stimulation of the sacral nerve as a treatment of incontinence is discussed in a separate Medical Policy (see Cross References).
• Pelvic floor stimulation as a treatment of urinary incontinence refers to electrical stimulation of the pudendal nerve and is addressed in a separate Medical Policy (see Cross References).

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

A. Urinary dysfunction, including but not limited to overactive bladder syndrome, neurogenic bladder, urinary frequency, urgency, incontinence and retention
B. Fecal incontinence
NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.

CROSS REFERENCES

1. Pelvic Floor Stimulation as a Treatment of Urinary Incontinence, Allied Health, Policy No. 4
2. Biofeedback, Allied Health, Policy No. 32
3. Sacral Nerve Modulation/Stimulation for Pelvic Floor Dysfunction, Surgery, Policy No. 134

BACKGROUND

Percutaneous tibial nerve stimulation (PTNS, also known as posterior tibial nerve stimulation) is a technique of electrical neuromodulation primarily for the treatment of voiding dysfunction in patients who have failed behavioral and/or pharmacologic therapies. The posterior tibial nerve is derived from the lumbar-sacral nerves (L4-S3) which control the bladder detrusor and perineal floor. The goal of PTNS is to alter the function of the posterior tibial nerve to improve voiding function and control. Voiding dysfunction includes urinary frequency, urgency, incontinence, and nonobstructive retention. Urgency symptoms and/or urge incontinence may also be referred to as overactive bladder (OAB). Common causes of voiding dysfunction are pelvic floor dysfunction (from pregnancy, childbirth, surgery, etc.), inflammation, interstitial cystitis, 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).

PTNS was developed as a less-invasive treatment alternative to traditional sacral root neuromodulation which has been successfully used in the treatment of urinary dysfunction, but requires implantation of a permanent device. 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 (10mA, 1-10 Hz frequency) electrical stimulation which 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. PTNS studies have been designed as 30-minute sessions given weekly for 10-12 weeks. Consideration has been given to increasing the frequency of treatments to three times per week to speed achievement of desired outcomes. A shorter initial weekly treatment period might be as effective as the 12 week regimen which being studied. However, an optimal treatment protocol has not been established.

PTNS must be distinguished from acupuncture with electrical stimulation. In electrical acupuncture, needles are also inserted just below the skin, but the placement of needles is based on specific theories regarding energy flow throughout the human body. Thus, in PTNS, the location of stimulation is directly in the posterior tibial nerve rather than using the theories of energy flow that guide placement of stimulation for acupuncture.

REGULATORY STATUS

The Urgent® PC Neuromodulation System (Uroplasty, Inc.) – Formerly called the Stoller Afferent Nerve Stimulator (PerQ SANS System), received U.S. Food and Drug Administration (FDA) 510(k) approval for the treatment of overactive bladder (OAB) and associated symptoms of urinary urgency, urinary frequency, and urge incontinence.
In order to isolate the specific therapeutic effects of posterior tibial nerve stimulation (PTNS) and adequately control for placebo effects and individual patient differences (clinical and demographic, known and unknown), well-designed randomized clinical trials (RCTs) that compare PTNS with the current standard of care and sham treatment are needed. The RCT is the most rigorous and reliable study design for demonstrating a causal relationship between the therapy under investigation and the health outcomes of interest. The RCT study design is important to understand whether an intervention such as PTNS can positively impact the health outcomes of patients with voiding dysfunction.

**NON-NEUROGENIC URINARY INCONTINENCE INCLUDING OVERACTIVE BLADDER**

**Systematic Reviews and Technology Assessments**

In 2014, BCBSA published an updated TEC assessment which concluded that PTNS met the TEC criteria for treatment of voiding dysfunction. The Assessment included six RCTs which are described in more detail in the RCT section of this policy. The 2014 assessment concluded that the RCT evidence supports the short-term efficacy of PTNS compared with a placebo when applied during a standard 12-week regimen.

This conclusion was based upon two short-term sham controlled trials and four RCTs which compared PTNS to active intervention, which included antimuscarinics, ES, or Kegel exercises. Only one of these trials was noted as being of “high” quality, while four were noted as being of “poor” quality due to various limitations which included lack of blinding, significant dropout rates, no sham control group, suboptimal administration of comparison medication, and small sample sizes in six RCTs.

Evidence is still lacking regarding the efficacy of PTNS past a 12-week regimen; however, 12- to 36-month evidence appears consistent in direction with 12-week data outcomes. This conclusion is based upon data provided by two extension studies regarding PTNS maintenance effects. Responders were followed for 12 months in one study and 36 months in another; however, patients in the control groups were not followed past 12 weeks, limiting comparison between groups. In addition, there was a high drop-out rate in both extension studies which limited the ability to control for placebo affects or draw conclusions about the long-term efficacy of PTNS treatment.

In 2013, the National Institute for Clinical Excellence (NICE) published a technology assessment for management of urinary incontinence in women. The authors concluded that although PTNS was offered as a conservative treatment for OAB, there is limited evidence it is effective. Additional studies must establish cost-effectiveness and/or study groups of patients who are not eligible or who did not have good outcomes from botulinum toxin A, percutaneous sacral nerve stimulation or OAB drug treatment.

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. The review identified four reports of RCTs comparing PTNS with no active treatment in patients with OAB. Two of the four 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 other two studies consisted of the Finazzo-Agro et al. RCT which reported outcomes at four weeks and the Schriner and
colleagues et al. RCT\[5\] which reported outcomes at 12 weeks. The AHRQ report included a pooled analysis of data from three studies that found statistically significantly greater improvement in urinary incontinence in the PTNS compared to 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 sub-analysis and 35 in the Finazzo-Agro trial. A limitation of the analysis was that the 150 patients in the SUmiT sub-analysis were included twice. The authors did not discuss evidence on the efficacy of PTNS beyond 12 weeks.

In addition, several systematic reviews (SRs) and meta-analysis have been published regarding the use of PTNS as a treatment for OAB, reporting a positive success rate of 37-82%\[12\], 54-93%\[13\], 37-100%\[14\] and 36.7-80%\[15\], when compared to placebo or medication. Some of the trials included in these reviews are RCTs addressed separately within this policy or were non-randomized, observational studies. All studies used in each of the reviews were limited by short-term follow-up of 12 weeks and relatively small sample size\[12,16,17\] between 16 and 32 patients. Although the authors reported promising results for use of PTNS in patients with OAB, many stated that larger, long-term, RCTs are needed.\[13-17\]

**Randomized Controlled Trials**

Boudaoud (2015) reported on 20 children with OAB who were randomized to 12 weeks of treatment with PTNS (n=11) or a sham intervention (n=9).\[18\] At the end of the treatment period, there were no statistically significant differences between groups on outcomes, including the proportion of patients with “good” versus “poor” urinary scores (p=0.65). (A 13-point scale was used; a “poor score” was defined as a decrease of 3 or fewer points post-treatment and a “good” score was a decrease of four to six points.)

Preyer (2015) published a non-blinded study comparing 12 weeks of PTNS versus tolderodine in 36 women with OAB.\[19\] Post-treatment, there were no significant differences between groups on the reduction of incontinence episodes in 24 hours (p=0.89) or quality of life (p=0.07).

The following is a summary of the six RCTs analyzed in the 2014 BCBSA TEC assessment cited above.

Peters (2009) published an industry-sponsored non-blinded comparison of PTNS and extended-release tolterodine (Detrol LA) for treatment of overactive bladder syndrome (the OrBIT trial).\[20\] The study included 100 patients, over 90% women, with at least eight voids per 24 hours (mean 12.3). The primary outcome was the non-inferiority of PTNS in the mean reduction in the number of voids per 24 hours after 12 weeks of treatment. Non-inferiority was defined as no more than a 20% difference in the mean void reduction.

A total of 87 of the 100 (87%) patients completed the study and voiding diary data were available for only 84 patients, 41 of 50 (82%) in the PTNS group and 43 of 50 (86%) in the tolterodine group. Study findings showed non-inferiority of PTNS, with a decrease in voids per day of 2.4 in the PTNS group and 2.5 in the tolterodine group. The study reported mixed findings for a number of secondary outcomes, some of which were based on patient reports. There were no statistically significant differences in the PTNS and tolterodine groups for other symptoms recorded in the voiding diary. This finding includes episodes of nocturia (-0.7 and -0.6, respectively) and 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). There
was a statistically significant difference in the proportion of patients reporting improvement or cure in symptoms in favor of the PTNS group (79.5 vs. 54.8%).

Limitations of this study include the following:

- Lack of blinding of patient and providers;
- Lack of comparative data beyond the end of the initial 12-week treatment period;
- Lack of a sham/placebo group both to mitigate the potential bias due to subjective outcomes and to evaluate whether either treatment is better than placebo;
- Data were not reported for compliance with medication therapy;
- The authors did not clearly define criteria for “improvement” or “cure”; and
- Different methods of data collection in the 2 groups for adverse event outcomes and possibly also for other self-report outcomes; specifically, The PTNS group was assessed in person while the medication group was assess by telephone.

MacDiarmid (2010) reported one-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. Thirty-three of the 35 responders were included. They received a mean of 12.1 (SD=4.9) 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 six months and 25 of the 33 (76%) participants at 12 months. The mean reduction in number of voids per day from baseline (the original primary outcome of the study) was 3.2 (SD=3.7) at six months and 2.8 (SD=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 noted above, this analysis was limited in that no data from the tolterodine group were available to compare long-term outcomes. Additionally, not all patients in the PTNS group were included in the follow-up analysis; only PTNS responders were eligible. Therefore, a potential bias is that the initial subjective outcome measure may be subject to the placebo effect. 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. It is important that long-term response data from RCTs reflect the patient population at the beginning of the study. In addition, since subjects were not counseled on fluid management, it is unknown if subject fluid management habits influenced results. The authors note that, “with an average overactive bladder (OAB) symptom duration of more than 10 years, subjects may have already learned fluid management as a means to mediate OAB symptoms.” Due to these significant study design flaws, the data in this study are unreliable and do not permit conclusion about long-term efficacy.

The SUmiT trial was a randomized, sham-controlled trial that included 220 OAB patients with a score of at least 4 on the overactive bladder questionnaire (OAB-q) short form for urgency, self-report bladder symptoms lasting at least three months, and having failed conservative care. Patients were randomized at a 1:1 ratio to either active or sham PTNS. 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 two active 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 (p<0.001). Intention-to-treat analysis was used for the primary endpoint only. Several secondary outcomes also favored the PTNS group. The mean reduction in a symptom severity score (a lower score indicates less severity) was 36.7 (SD=21.5) in the PTNS group and 29.2 (SD=20.0) in the sham group (p=0.01). Similarly, the mean reduction in a quality of life scale, the SF-36 (a higher score indicates higher quality of life), was 34.2 (SD=21.3) in the PTNS group and 20.6 (SD=20.6) in the sham group (p=0.006).

For the four voiding diary variables used, there was a statistically significant difference between groups favoring PTNS. The mean change from baseline in the number of voids per day was -2.4 (SD=2.5) in the PTNS group and -1.5 (SD=2.4) in the sham group (difference between groups 0.9 voids per day, p=0.01). The mean change in nocturia episodes was -0.7 (SD=1.2) in the PTNS group and -0.3 (SD=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 less than 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 one episode per day, p less than 0.002). (Standard deviations were not reported for the latter two outcomes.)

Advantages of the SUmiT trial were that it included a sham comparison and the primary endpoint analysis was intention to treat. 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 to sham treatment; however, the clinical significance of the difference between the PTNS and sham groups was unclear e.g., on average, there was one 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.

Results from a long-term extension of the SUmiT study were published in 2012.[9] Fifty patients were included and were prescribed a fixed schedule 14 week tapering protocol followed by a personal treatment plan. Only 29 patients (58%) completed the study and of those who did, 77% showed a moderate or marked improvement in OAB symptoms. Like the OrBIT trial extension, the STEP (Sustained Therapeutic Effects of Percutaneous Tibial Nerve Stimulation) study only included patients assigned to the PTNS group who responded to treatment and did not include additional follow-up of initial non-responders or comparative data from patients assigned to the sham-control group. Given this design, it is unlikely that the study results adequately resolve outstanding issues. It is critically important that long-term response rates reflect the patient population at the beginning of the study, not just those considered
successes at 12 weeks. Other methodological limitations include the addition of an external intervention in the form of a personalized treatment plan which may have biased outcomes. In addition, the high loss-to-follow-up rate severely limited the reliability of any conclusion regarding the long-term utility of PTNS treatment for patients with OAB.

Finazzi-Agro and colleagues studied the effect of more frequent treatment sessions for a reduced initial period.\[3\] Patients, who had urge incontinence and detrusor overactivity on urodynamic testing, were randomized to 30-minute PTNS (n=18) or sham treatment (n=17) sessions three times a week for four weeks. One patient dropped out of the PTNS group and 2 dropped out of the sham group. The primary outcome, percent responders at four weeks (defined as at least 50% reduction in incontinent episodes), was attained by 12/17 (71%) in the PTNS group and 0/15 (0%) in the sham group. The study did not conduct intention-to-treat analysis, was not double-blind, and did not report follow-up data beyond four weeks.

Schreiner and colleagues randomized 51 women above 60 years old 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).\[5\] 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 and this study was also limited by small sample size.

Gungor Ugurlucan (2013) published findings of an RCT comparing transvaginal electrical stimulation (ES) (n=38) and PTNS (n=21) in women with OAB.\[6\] The ES protocol consisted of 20-minute treatments three times a week for 6-8 weeks. PTNS was performed with an Urgent PC device used for 12 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<0.05 level in mean change in urgency episodes, nocturia or incontinence episodes. For example, the mean number of urgency episodes was 2.9 (SD: 4.1) at baseline and 1.6 (SD: 0.5) after treatment in the ES group and 2.0 (SD: 3.1) at baseline and 1.3 (SD: 0.5) after treatment in the PTNS group, p=0.54. There was a statistically significant difference in daytime frequency. The mean daytime frequency was 7.8 (SD: 2.7) at baseline and 5.8 (SD: 1.9) after treatment in the ES group and 7.6 (SD: 2.6) at baseline and 7.4 (SD: 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.

Vecchioli-Scaldazza and colleagues studied 40 women with OAB in a randomized controlled crossover study to evaluate the effectiveness of solifenacin succinate (SS) versus PTNS.\[7\] Group A received SS and then PTNS and group B received PTNS and then SS. The primary efficacy outcome was reduction in the number of voids in a 24-hour period and outcomes were measured through voiding diaries, quality of life surveys and perception of urgency ratings both before and after each treatment. In addition, a global impression score was completed at the end of the study. Only 30 of the 40 subjects (75%) completed the study. Improved outcomes were observed in both groups, however greater improvement in voided volume and greater effectiveness overall was found in PTNS compared to SS. However, much of the reported improvements were based upon subjective data, which limit conclusions regarding the superiority of PTNS over SS. In addition, authors did not compare the efficacy of PTNS to
medication. Other study limitations include a lack of blinding and uncertainty regarding the clinical significance of these findings.

Other Randomized Controlled Trials

Several other RCTs have been published which were not included in the 2010 and 2014 TEC assessments; however, both are limited by short-term follow-up as none reported on the efficacy of PTNS beyond 12 weeks.

Raheem and colleagues reported on 28 patients with refractory monosymptomatic nocturnal enuresis in a randomized control study comparing PTNS treatment to placebo.\[21\] The treatment group received a weekly session of PTNS for 12 weeks and a follow-up assessment was also made at three months post-treatment. Consistent with the 2010 TEC assessment conclusions, short-term treatment effects were observed in patients who received PTNS compared to the placebo group, however response rates decreased from 78.6% to 42.9% at the three-month follow-up. The decrease in response rates also support the TEC assessment conclusion that efficacy of long-term treatment effect of PTNS has not been established.

Sancaktar and colleagues evaluated 40 women with severe overactive bladder without any prior treatment who were randomized into medication alone and combination treatment groups.\[22\] All subjects received 4 mgs of tolterodine daily and 20 subjects also received Stoller afferent neuro-stimulation (SANS), a form of PTNS, for 12 weeks. Subjects completed a IIQ-7 questionnaire and a seven-day voiding diary at baseline and after treatment and results were compared. Of the 38 women completing the study, severity of symptoms were reduced in both groups, although a more significant decrease was observed in the combination group. This study is limited by small sample size and relatively short term follow-up.

NEUROGENIC BLADDER

Systematic Reviews

Schneider (2015) published a systematic review of literature on tibial nerve stimulation (transcutaneous and percutaneous) for treating neurogenic lower urinary tract dysfunction.\[23\] Sixteen studies were identified; four RCTs, nine prospective cohort studies, two retrospective case series and one case report. Sample sizes of the included studies were generally small; most included fewer than 50 patients and none had a sample size larger than 100 patients. Three of the four RCTs used transcutaneous tibial nerve stimulation and the fourth study, which was conducted in Iran, stated that PTNS was used but did not specify the device. The four RCTs included different study populations; women with neurogenic bladder (n=1), men with neurogenic overactive bladder (n=1), multiple sclerosis patients (n=1) and Parkinson disease patients (n=1). Comparison interventions were tolterodine, pelvic floor muscle training, lower limb stretching and sham (1 study each). Pooled analyses were not conducted and the systematic review mainly discussed intermediate outcomes e.g., maximum cystometric capacity and maximum detrusor pressure. In the articles reporting on RCT results, none reported statistically significant between-group differences in clinical outcome variables e.g., number of episodes of urgency, frequency or nocturia.

Randomized Controlled Trials

Monteiro (2014) published an RCT evaluating PTNS for neurogenic OAB in 24 adult men with no prior symptoms who were between six months and three years post-stroke.\[24\] Patients were randomized to six 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, eight patients (67%) in the PTNS group and nine 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. However, the study was limited by small-sample size. Additional studies with larger sample sizes are needed before conclusions can be drawn about the efficacy of PTNS for treatment of neurogenic bladder.

LOWER URINARY TRACT SYMPTOMS

A SR by Zecca (2016) evaluated PTNS for the treatment of lower urinary symptoms in patients with multiple sclerosis.[25] The review included randomized controlled studies, case-control studies and prospective cohort studies. A total of seven studies were included with a total of 313 multiple sclerosis patients. The review concluded that the current data is limited but PTNS seems effective and safe.

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.

Systematic Reviews and technology Assessments

In 2015, NICE published a technology assessment for guidance on percutaneous tibial nerve stimulation for faecal incontinence.[26] This included one nonrandomized comparative study and six case series. The guidance’s limited evidence showed PTNS effective for a limited number of patients short-term. The authors stated PTNS should only be used under certain circumstance.

Two SRs of the literature on tibial nerve stimulation for fecal incontinence have been published; neither conducted pooled analyses of PTNS outcomes compared to a sham or alternative intervention.[27,28] Most recently, in 2015, Edenfeld et al identified 17 studies, 13 case series and 4 RCTs.24 Three of the RCTs evaluated TENS stimulation and 1 used PTNS.[27] Edenfeld stated multiple low-quality studies show improvement in fecal incontinence after PTNS, but more high-quality studies are needed to establish the utility of PTNS.

Horrocks (2014) published a SR of literature on tibial nerve stimulation (percutaneous and transcutaneous) to treat fecal incontinence.[28] The authors included all study designs and identified a total of 12 articles, two RCTs and 10 case series. Six studies evaluated PTNS, five 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 five case series on PTNS and one 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 due to the absence of a control group and did not include data from all published studies.

Randomized Controlled Trials
A larger sham-controlled RCT, known as the CONFIDeNT trial, was published in 2015 by Knowles et al in the U.K. [29] The study was double-blind and multicenter. A total of 227 patients with fecal incontinence sufficiently severe to warrant intervention (per the principal investigator at each site) were randomized to receive PTNS (n=115) or sham stimulation (n=112). Both groups received 12 weekly intervention sessions lasting 30 minutes each. The primary outcome was at least a 50% reduction in the mean number of episodes of fecal incontinence per week compared with baseline. The mean number of episodes was calculated from 2-week bowel diaries. Twelve patients withdrew from the study. After treatment, 39 of 103 (38%) in the PTNS group and 32 of 102 (31%) in the sham group had at least a 50% reduction in the number of fecal incontinence episodes. The difference between groups was not statistically significant (adjusted OR, 1.28; 95% CI, 0.72 to 2.28; p=0.396). There were also no significant differences between the PTNS and sham groups in the proportion of patients achieving more than 25%, more than 75%, or 100% reduction in mean weekly episodes. There was, however, a significantly greater reduction in the absolute mean number of weekly fecal incontinence episodes in the active PTNS group. The mean number of weekly fecal incontinence episodes in the PTNS group was 6.0 at baseline and 3.5 after treatment. This compares to means of 6.9 and 4.8, respectively, in the sham group. The difference between groups was -2.26 (95% CI, -4.18 to -0.35; p=0.021).

Thin (2015) published an RCT assessing the efficacy of PTNS compared to sacral nerve stimulation (SNS) as a treatment of fecal incontinence in 40 patients (39 women). [30] Within-group effect sizes demonstrated a slightly greater benefit with SNS compared to PTNS over a six month follow-up period. Fecal incontinence (FI) episodes (mean, standard deviation) at baseline, three months and six months were 11.4(12.0), 4.0(4.0) and 4.9(6.9) respectively for SNS compared with 10.6(11.2), 5.8(6.9) and 6.3(6.9) for PTNS. Mean Cleveland Clinic Incontinence Score values at baseline, and three and six months were: 16.2(3.0), 11.1(5.2) and 10.4(5.6) for SNS versus 15.1(2.7), 11.7(4.4) and 12.1(5.2) for PTNS. Authors reported a minimum 50% improvement if FI episodes at six months in 11/18 SNS patients and 7/15 PTNS patients; however, it is unclear if these results are statistically or clinically significant. Limitations of this study include the small number of patients included and the lack of sham comparator group.

George (2013) published an RCT evaluating PTNS for fecal incontinence. [31] 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 six 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 six week treatment period. Only one 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 one of eight in the sham group attained the primary end point; however, the difference among groups was not statistically significant, p=0.035. All of the responders reported no weekly episodes of fecal incontinence after treatment. Study limitations include a small sample size and short-term follow-up.

**Nonrandomized Studies**

Kelly and colleagues evaluated women (n=60) with fecal incontinence who underwent PTNS after a failure to respond to biofeedback. [32] The authors concluded that PTNS may have an
effect on bowel related function in two thirds of patients. In addition, PTNS had more of an
effect on bowel related function than pelvic function.

A small, comparative cohort study comparing the use of sacral nerve stimulation (n=10) to
PTNS (n=9) for the treatment of fecal incontinence in men was published in 2016.[33] Anal
continence was evaluated using the Wexner continence grading system and quality of life was
measured. Both of the treatments improved incontinence and quality of life but there was no
significant difference between groups for both measures.

PRACTICE GUIDELINE SUMMARY

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE (NICE)

Urinary Incontinence in Women

NICE published a 2013 updated guideline for management of women with urinary
incontinence.[10] The guideline stated there is insufficient evidence to recommend the use of
percutaneous posterior tibial nerve stimulation routinely for OAB. The authors stated PTNS
may be offered only after a multidisciplinary team (MDT) review, failed drug treatment and
urodynamic testing.

Fecal Incontinence in Adults

Nice published a 2007 guideline for the management of faecal Incontinence in adults stating
“People with faecal incontinence should be offered sacral nerve stimulation on the basis of
their response to percutaneous nerve evaluation during specialist assessment, which is
predictive of therapy success.”[34]

Fecal Incontinence

Nice published a 2011 guidance on percutaneous tibial nerve stimulation for faecal
incontinence. The limited evidence showed PTNS as a safe treatment for faecal
incontinence.[26] PTNS was only effective for a limited number of patients short-term. The
authors stated PTNS should only be used under certain circumstance.

Over Active Bladder

Nice published a 2010 guidance on percutaneous posterior tibial nerve stimulation for overactive bladder syndrome stating current evidence on PTNS for OAB is effective in the
short and medium term.[35] There were no major concerns and the recommendation was PTNS
may be used if appropriate processes are in place.

AMERICAN UROLOGICAL ASSOCIATION[36]

In 2014, the American Urological Association (AUA) and the Society of Urodynamics published
a guideline on the diagnosis and treatment of overactive bladder in adults. The following
recommendation was made as a third-line treatment option:

“Clinicians may offer peripheral tibial nerve stimulation (PTNS) (also known as posterior
tibial nerve stimulation) as third-line treatment in a carefully selected patient population.”

This statement was based on a grade C, which states the following: the balance of benefits
and risks/burdens are uncertain.
There is not enough research to show that percutaneous tibial nerve stimulation (PTNS) improves health outcomes for any indication, including but not limited to urinary dysfunction and fecal incontinence. No clinical guidelines based on research recommend PTNS. Therefore, PTNS is considered investigational for all indications, including but not limited to urinary dysfunction and fecal incontinence.

REFERENCES

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10. NICE. Urinary incontinence in women: management National Instititue of Health and Care Excellance (NICE); 2013.
11. Shamliyan, T, Wyman, J, Kane, RL. Nonsurgical Treatments for Urinary Incontinence in Adult Women: Diagnosis and Comparative Effectiveness [Internet]. AHRQ Comparative Effectiveness Reviews. 2012 Apr Comparative Effectiveness;11(12):EHC074-EF. PMID: 22624162


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**CODES**

CPT codes for percutaneous implantation of neurostimulator electrodes (i.e., 64553, 64555, 64561, 64590) are not appropriate since PTNS uses percutaneously temporarily inserted needles and wires rather than percutaneously implanted electrodes that are left in place.

<table>
<thead>
<tr>
<th>Codes</th>
<th>Number</th>
<th>Description</th>
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<tbody>
<tr>
<td>CPT</td>
<td>64999</td>
<td>Unlisted procedure, nervous system</td>
</tr>
<tr>
<td></td>
<td>64566</td>
<td>Posterior tibial neurostimulation, percutaneous needle electrode, single treatment, includes programming</td>
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<tr>
<td>HCPCS</td>
<td>L8680</td>
<td>Implantable neurostimulator electrode, each</td>
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</tbody>
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*Date of Origin: August 2006*