RADIOFREQUENCY THERAPY AND TIBIAL NERVE STIMULATION FOR URINARY DISORDERS

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INSTRUCTIONS FOR USE

This Medical Policy provides assistance in interpreting UnitedHealthcare benefit plans. When deciding coverage, the enrollee specific document must be referenced. The terms of an enrollee's document (e.g., Certificate of Coverage (COC) or Summary Plan Description (SPD) and Medicaid State Contracts) may differ greatly from the standard benefit plans upon which this Medical Policy is based. In the event of a conflict, the enrollee’s specific benefit document supersedes this Medical Policy. All reviewers must first identify enrollee eligibility, any federal or state regulatory requirements and the enrollee specific plan benefit coverage prior to use of this Medical Policy. Other Policies and Coverage Determination Guidelines may apply. UnitedHealthcare reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

BENEFIT CONSIDERATIONS

Essential Health Benefits for Individual and Small Group:

For plan years beginning on or after January 1, 2014, the Affordable Care Act of 2010 (ACA) requires fully insured non-grandfathered individual and small group plans (inside and outside of Exchanges) to provide coverage for ten categories of Essential Health Benefits (“EHBs”). Large group plans (both self-funded and fully insured), and small group ASO plans, are not subject to the requirement to offer coverage for EHBs. However, if such plans choose to provide coverage for benefits which are deemed EHBs (such as maternity benefits), the ACA requires all dollar limits on those benefits to be removed on all Grandfathered and Non-Grandfathered plans. The determination of which benefits constitute EHBs is made on a state by state basis. As such, when using this guideline, it is important to refer to the enrollee specific benefit document to determine benefit coverage.
COVERAGE RATIONALE

Percutaneous tibial nerve stimulation is proven and medically necessary for the treatment of overactive bladder syndrome (OAB) including urinary frequency, urgency and urge incontinence.

Percutaneous tibial nerve stimulation is proven and medically necessary for the treatment of urinary frequency, urgency, and urge incontinence in adult patients refractory to standard first-line treatment with pharmacotherapy, when anatomical abnormalities of the lower urinary tract and active urinary tract infections are excluded.

Transurethral radiofrequency energy therapy (Renessa® System) is unproven and not medically necessary for the treatment of urinary incontinence.

There is insufficient evidence to conclude that transurethral radiofrequency therapy is effective for treating urinary incontinence. Analysis and interpretation of published study results are complicated by a high placebo response rate and by the single-blind design of the trials. Further studies incorporating blinded assessment of objective outcomes and longer follow-up are needed, both to confirm the efficacy and safety of this procedure, and to define the patients who are likely to benefit from this procedure.

Transvaginal radiofrequency energy therapy is unproven and not medically necessary for the treatment of urinary incontinence.

There is insufficient evidence to conclude that transvaginal radiofrequency therapy is effective for treating urinary incontinence. Studies report low cure rates and high rates of additional corrective treatment.

APPLICABLE CODES

The Current Procedural Terminology (CPT®) codes and Healthcare Common Procedure Coding System (HCPCS) codes listed in this policy are for reference purposes only. Listing of a service code in this policy does not imply that the service described by this code is a covered or non-covered health service. Coverage is determined by the enrollee specific benefit document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claims payment. Other policies and coverage determination guidelines may apply. This list of codes may not be all inclusive.

<table>
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<th>CPT® Code</th>
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<tr>
<td>53860</td>
<td>Transurethral radiofrequency micro-remodeling of the female bladder neck and proximal urethra for stress urinary incontinence</td>
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<td>53899</td>
<td>Unlisted procedure, urinary system</td>
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<td>64566</td>
<td>Posterior tibial neurostimulation, percutaneous needle electrode, single treatment, includes programming</td>
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DESCRIPTION OF SERVICES

Treatment options for urinary voiding disorders, such as urinary incontinence and overactive bladder (OAB) syndrome, include behavioral strategies, pharmacological interventions, electrical stimulation, and reconstructive surgery. Conservative, non-invasive therapies, such as behavioral and pharmacological interventions, are generally advised before reconstructive surgery is considered. Pharmacotherapy is the first-line treatment for most patients. Urinary voiding disorder therapy that is addressed in this policy includes percutaneous tibial nerve stimulation (PTNS) and radiofrequency therapy (Elser, 2012)
Percutaneous Tibial Nerve Stimulation: Tibial nerve stimulation is an indirect, external method of stimulating the sacral plexus. The first device to use percutaneous tibial nerve stimulation to stimulate the sacral plexus was called PerQ SANS (Stoller Afferent Nerve Stimulator). The device was eventually revised, commercially developed, and introduced as the Urgent PC Neuromodulator (UPC) in 2003. The Urgent PC device produces an adjustable, low voltage electrical impulse that travels to the sacral nerve plexus via the tibial nerve. Percutaneous tibial nerve stimulation has been investigated for the treatment of chronic non-neurogenic urinary voiding dysfunctions (e.g., OAB/urge incontinence) in individuals who have failed conservative treatments. OAB syndrome is defined as urinary urgency, with or without urge incontinence, usually with frequency and nocturia (ECRI, 2012).

Radiofrequency Energy Therapy: Radiofrequency (RF) micro-remodeling for stress incontinence uses RF energy to heat the tissues surrounding the bladder neck and proximal urethra. Application of RF energy stiffens the tissues to prevent the momentary opening associated with stress incontinence. In RF micro-remodeling, RF energy is used to generate temperatures (around 65 to 75 degrees C) that are sufficient to allow for tissue stiffening, but low enough to avoid gross destruction of tissue. Two devices are currently available that deliver RF energy to treat stress incontinence. First, the SURx Transvaginal System is a radiofrequency device that has been specifically designed as a transvaginal treatment of urinary stress incontinence. An incision is made through the vagina lateral to the urethra, exposing the endopelvic fascia. Radiofrequency energy is then applied over the endopelvic fascia, resulting in blanching and shrinkage of the tissue. Second, the Renessa System uses a transurethral probe, inserted through the urethra, to emit low levels of RF energy along small circumferential sites from the bladder neck to the proximal urethral submucosa (ECRI, 2010; Elser, 2012).

CLINICAL EVIDENCE

Percutaneous Tibial Nerve Stimulation (PTNS):
Peters et al. (2010) conducted a multicenter, double-blind, randomized, controlled trial comparing the efficacy of percutaneous tibial nerve stimulation to sham therapy through 12 weeks of therapy. A total of 220 adults with OAB symptoms were randomized to 12 weeks of treatment with weekly percutaneous tibial nerve stimulation or sham therapy. OAB and quality of life (QOL) questionnaires, as well as three-day voiding diaries, were completed at baseline and at 13 weeks. Subject global response assessments were completed at week 13. The 13-week subject global response assessment for overall bladder symptoms demonstrated that 54.5% of percutaneous tibial nerve stimulation patients achieved statistically significant improvement in bladder symptoms compared with baseline results. However, only 20.9% of sham individuals experienced significant improvement in bladder symptom when compared with baseline values. All subset symptom components of the individual global response assessment demonstrated statistically significant improvement from baseline to 13 weeks for percutaneous tibial nerve stimulation compared to sham. No serious device related adverse events or malfunctions were reported. According to the investigators, this multicenter, double-blind, randomized, sham controlled trial provides level I evidence that percutaneous tibial nerve stimulation therapy is safe and effective in treating overactive bladder symptoms. A limitation of this study is the short follow-up period of 12 weeks, which does not allow definitive conclusions regarding the long term durability of PTNS.

A total of 100 adults with urinary frequency were randomized to 12 weeks of treatment with weekly percutaneous tibial nerve stimulation or to 4-mg daily extended-release tolterodine (Peters et al., 2009). The global response assessment demonstrated that subject assessment of overactive bladder symptoms compared to baseline was statistically significant in the percutaneous tibial nerve stimulation arm, with 79.5% reporting cure or improvement, compared to 54.8% of subjects on tolterodine. However, investigator assessments did not reach statistical significance. After 12 weeks of therapy, objective measures improved similarly in both groups for reductions in urinary frequency, urge urinary incontinence episodes, urge severity and nighttime voids, as well as for improvement in voided volume. However, there were no statistically
significant differences between groups for these outcome measures. According to the investigators, this multicenter, randomized trial demonstrates that percutaneous tibial nerve stimulation is safe with statistically significant improvements in patient assessment of OAB symptoms, and with objective effectiveness comparable to that of pharmacotherapy. Percutaneous tibial nerve stimulation may be considered a clinically significant alternative therapy for OAB.

In an extension of the earlier trial by Peters et al. (2009), MacDiarmid et al. (2010) assessed the sustained therapeutic efficacy of percutaneous tibial nerve stimulation in patients with OAB for the period of one year. A total of 33 percutaneous tibial nerve stimulation responders continued therapy with 32 and 25 subjects completing 6 and 12 months of therapy, respectively. The study results indicated that a statistically significant improvement in OAB symptoms was achieved with percutaneous tibial nerve stimulation treatments administered over 12 weeks. Symptomatic improvements were sustained for 12 months.

In another randomized controlled trial, Schreiner et al. (2010) examined the efficacy of transcutaneous electrical tibial nerve stimulation (TTNS) to treat urge urinary incontinence (UUI) in a randomized clinical trial conducted in 51 elderly women (>60 years of age) with UUI. All patients were treated with 12 weeks of bladder retraining and pelvic floor muscle exercises and 25 were randomly selected to receive TTNS in addition to the standard therapy. The cases were evaluated at the baseline and after 12 weeks of therapy by a three-day bladder diary, quality of life (QOL) questionnaires, and subjective responses. Of these patients, 68.0% in TTNS group reported cure or improvement compared with 34.6% in the control group. However, these results were not statistically significant. TTNS showed significant improvement in most areas of QOL and in UUI parameters when compared with the control group. The investigators concluded that TTNS is efficacious to treat UUI in older women.

In a prospective study, Peters et al. (2012) evaluated the safety, sustained effectiveness, and treatment interval for percutaneous tibial nerve stimulation (PTNS) for OAB therapy through 24 months. Following treatment success after 12 weekly PTNS treatments, patients underwent a 14-week tapering protocol, followed by ongoing therapy with a personal treatment plan determined by the investigator in order to sustain symptom improvement. Of 50 patients enrolled, 35 remained in the study at 24 months. During the 24 months following initial treatment success and a 14-week tapering protocol, mean treatments per month was 1.3. Voiding diary and symptom OAB-q data demonstrated sustained improvement through 24 months. Improvements in frequency, urge incontinence episodes, night-time voids and moderate-to-severe urgency episodes from voiding diaries at 6, 12, 18, and 24 months were statistically significant compared to baseline (prior to initial 12 weekly treatments). According to the authors, sustained safety and efficacy of PTNS were demonstrated over 24 months with initial success after 12 weekly treatments, followed by a 14-week prescribed tapering protocol and a personalized treatment plan. The authors concluded PTNS therapy is a safe and durable long-term OAB treatment option to sustain clinically significant OAB symptom control.

In a prospective observational trial, Yoong et al. (2010) described outcome data following a shortened six-week treatment protocol with PTNS in 43 women with OAB syndrome who were unresponsive to bladder retraining and anticholinergic therapy. All 43 women (median age, 55.3 years) completed six treatments with a positive response rate of 69.7%. In the positive responders, the median daytime and nocturnal frequency was reduced by half after 6 weeks of treatment. According to the authors, this early data suggest that the duration of treatment for peripheral neuromodulation can be halved compared with the conventional 12 weeks. The authors state that a randomized controlled trial of 6 weeks vs 12 weeks of PTNS therapy would be useful in determining the optimal duration of treatment.

Finazzi-Agrò et al. (2010) conducted a prospective, double-blind, placebo controlled study to evaluate the efficacy of PTNS. A total of 35 female patients presenting with detrusor overactivity...
incontinence, who were unresponsive to antimuscarinic therapy, were randomly assigned to PTNS (n=18) or sham or placebo treatment (n=17). The sessions lasted for 30 minutes and were performed three times weekly for four weeks. One patient in the PTNS group and 2 patients in the placebo group did not complete the study for reasons not related to the technique. The results of the study indicated that 12/17 (71%) in the PTNS group and of 0/15 (0%) in placebo group were considered responders (defined as the reduction in urge incontinence episodes greater than 50%). Improvement in the number of incontinence episodes, number of voids, voided volume and incontinence QOL scores were statistically significant in the PTNS group, but not in the placebo group.

Finazzi-Argo et al. (2005) compared outcomes of treatment duration. No significant differences in outcomes were observed in 35 patients randomly assigned to PTNS weekly (group 1) versus three times per week (group 2). Thirty-six percent of group 1 incontinent patients and 45% of group 2 incontinent patients were completely cured after treatment.

Capitanucci et al. (2009) evaluated the efficacy of PTNS for different types of pediatric lower urinary tract dysfunction in 14 children with idiopathic OAB, 14 with dysfunctional voiding, 5 with underactive bladder, 4 with underactive valve bladder and 7 with neurogenic bladder resistant to conventional therapy. Follow-up data at 1 and 2 years were compared with those obtained immediately after stimulation. The investigators reported that PTNS is reliable and effective for nonneurogenic, refractory lower urinary tract dysfunction in children. Efficacy seemed better in dysfunctional voiding than in OAB cases.

De Gannaro et al. (2004) evaluated PTNS and pain in 23 children with lower urinary tract symptoms and concluded that PTNS is safe and minimally painful in children. This is in agreement with a study of 32 children that reported that PTNS has a significant effect on voiding frequency, bladder capacity, and uroflowmetry curve in children with bladder sphincter dysfunction (Hoebeke et al., 2002).

Van der Pal et al. (2006) found that 6 weeks after PTNS treatment, 7 of 11 patients with refractory OAB had a 50% or more increase in incontinence episodes and/or voiding frequency. The investigators concluded that continuous therapy is needed in patients with OAB.

A Comparative Effectiveness Review that synthesized published evidence was prepared for the Agency for Healthcare Research and Quality (AHRQ) on Nonsurgical Treatments for Urinary Incontinence in Adult Women. According to the report, PTNS may benefit women with urgency urinary incontinence who have failed conservative treatment. The authors of the report stated that the body of evidence indicated that PTNS improved urinary incontinence. Individual randomized controlled trials demonstrated no difference in adverse effects and treatment discontinuation between PTNS and active or sham stimulation for PTNS (Shamliyan et al., 2012).

The National Institute for Health and Care Excellence (NICE) issued guidance on the use of PTNS for OAB syndrome. The NICE guidance states that current evidence on PTNS for overactive bladder OAB syndrome demonstrates efficacy in reducing symptoms in the short and medium term. There are no major safety concerns. Therefore the procedure may be clinically useful provided that normal arrangements are in place for clinical governance, consent and audit. However, guideline authors commented that long-term efficacy has not been established (NICE, 2010).

In a health technology assessment on PTNS, the BlueCross BlueShield Association (2011) concluded that evidence from three randomized controlled trials established a short-term benefit (up to 12 weeks) for PTNS. However, the long term durability of this treatment effect (beyond 12 weeks) is unknown because of insufficient evidence in the published literature. The report indicates that the initial treatment phase consists of 30-minute treatment sessions, conducted 1 to 3 times each week, for a period of 12 weeks. Following the initial treatment phase, maintenance
treatment is continued. The protocol for maintenance treatment is less well defined, with repeat sessions administered at intervals generally dictated by the patient and based on symptom relapse. According to the report, there was insufficient evidence to permit conclusions about whether PTNS improves net health outcomes for the treatment of voiding dysfunction.

Definitive patient selection criteria for PTNS have not been established. The patient selection criteria varied among studies. Included patients were generally diagnosed with OAB, nonobstructive urinary retention, and/or pelvic floor pain. Duration of symptoms of patients varied, and ranged from 1 month to 28 years. Urinary frequency symptoms were defined as more than 8 or more than 10 voids per day, and more than 2 or more than 3 voids per night. Urinary incontinence was documented as more than 1 or more than 3 episodes per 24 hours. Most studies commented that the selected patients were refractory to conservative treatment, defined as medical treatment, Kegel exercise, biofeedback, and/or pelvic floor stimulators. General exclusion criteria were central or peripheral neurological disorders, malignant disease, anatomical insufficiency of pelvic floor, active urinary tract infections, interstitial cystitis, severe cardiopulmonary disease, and stress urinary incontinence (Hayes, 2008).

The clinical evidence was reviewed in November 20015 with no additional information identified that would change the conclusion.

**Transurethral Radiofrequency Therapy:**

In a prospective randomized controlled trial (RCT), 110 women underwent transurethral radiofrequency micro-remodeling and 63 women underwent sham treatment (Appell et al., 2006). At 12 months, 89 of 110 (81%) RF Group patients and 53 of 63 (84%) Sham Group patients were available for evaluation for QOL, and 87 of 110 (79%) and 49 of 63 (78%) were available for evaluation of leak point-pressure (LPP) (approximately 20% dropout rate in both groups). There was no difference in the percentage of patients who achieved a ≥ 10-point improvement in Incontinence Quality of Life (I-QOL) score at 12 months (RF Group, 48% versus Sham Group, 44%). When patients were retrospectively stratified by baseline I-QOL scores, 32 of 43 (74%) radiofrequency (RF) group patients with moderate-to-severe SUI had a ≥ 10-point improvement versus 15 of 30 (50%) sham Group patients. At 12 months, RF group patients had a mean increase in LPP of 13.2 ± 39.2 cm H2O versus a mean decrease of 2.0 ± 33.8 cm H2O among the Sham group patients. The results indicate a positive treatment effect in severe cases of stress urinary incontinence (SUI) that is supported by the leak point pressure (LPP) results. However, the relevance of this finding is weakened by the necessity for the investigators to retrospectively stratify the patient group to obtain a statistically significant difference in quality of life (QOL) score improvements in the face of high placebo response rates. The LPP findings are more robust despite the lack of blinding; however, the clinical significance of the 15-cm H2O difference between the two groups is unknown. This study was supported by the manufacturer, Novasys Medical Inc.

Lenihan (2005) conducted a retrospective study of the data from Appell et al. (2006) to further assess the impact of pre- and postmenopausal status and hormone replacement therapy on QOL after RF energy treatment. Seventy-three patients were retrospectively stratified by menopausal status and use of hormone replacement therapy, with improvement defined as a ≥ 10-point improvement in I-QOL score. However, repeated retrospective subgroup analyses are statistically suspect, and patient numbers following stratification were too low to justify any definitive conclusions. Lenihan also reported a higher overall QOL response to treatment than was found in the original study, the significance of which remains unclear.

In a retrospective study, Appell et al. (2007) reported 3-year follow-up results among patients in the treatment arm from the transurethral RF energy therapy study previously described (Appell, 2006). Of 110 RF energy-treated patients, 26 (24%) were available for evaluation. The researchers did not contact patients in the control group. Of the 26 RF energy-treated patients, 5 (19%) had undergone other treatments and were not included in the analysis but were not
counted as failures. Three other patients were not included in the IEF analysis since they reported no episodes of SUI at baseline (although to be included, they must have demonstrated stress leak on clinical examination). Therefore, the analysis of IEF included 18 (16%) patients. Data were obtained by voiding diaries and questionnaires; LPP testing was not repeated at this follow-up. Significant increases in overall I-QOL scores 3 years or more post treatment was the primary end point. Secondary end points were reductions in frequency and severity of incontinence episodes. After 3 years, mean overall I-QOL score improvement was 12.7 (+/-26); 56% of patients achieved 50% or more reduction in frequency. Interpretation of these findings is limited due to the retrospective design of the study, the small numbers of patients available for follow-up, the exclusion of several patients from the data analysis, and the lack of data from the controls. The study was supported by the manufacturer, Novasys Medical Inc.

Two studies reported the 6 month and 12 month results of a prospective, single arm Phase I/II Clinical Trial (Sotomayor and Bernal, 2005; Sotomayor and Bernal, 2003). The trial enrolled 41 women with moderate to severe stress urinary incontinence who underwent radiofrequency energy micro-remodeling. Between 65 to 80% of patients demonstrated an improvement in quality of life (QOL) at 6 months, and 75% to 78% demonstrated improvement at 12 months. These findings require confirmation in a larger well-designed study.

Elser et al. (2009) assessed the efficacy of nonsurgical transurethral collagen denaturation (Renessa) in women with stress urinary incontinence (SUI) caused by bladder outlet hypermobility in a prospective, 36-month, open-label, single-arm clinical trial. Twelve-month results from intent-to-treat (ITT) analysis were reported. A total of 136 women underwent the procedure and comprised the ITT population. By 12 months, 25 patients withdrew consent, 19 patients were lost to follow-up, and 17 reported lack of response, 15 of whom opted for surgery. Consequently, 75 patients were available for evaluation at the 12-month follow-up visit. Voiding diaries and in-office stress pad weight tests yield objective assessments. Subjective measures include the Incontinence Quality of Life (I-QOL), Urogenital Distress Inventory (UDI-6), and Patient Global Impression of Improvement (PGI-I) instruments. Patients experienced significant reductions versus baseline in median number of leaks caused by activity/day and activity/week, with 50% of patients reporting 50% or more reduction. Pad weight tests revealed that 69% of women had 50% or more reduction in leakage; 45% were dry. Significant improvements occurred in median scores on the I-QOL and mean scores on the UDI-6. Furthermore, 71.2% showed I-QOL score improvement, including 50.3% with 10-point or greater improvement, and 49.6% reported on the PGI-I that they were "a little," "much," or "very much" better. The investigators concluded that treatment of SUI with nonsurgical transurethral collagen denaturation resulted in significant improvements in activity-related leaks and quality of life. Limitations of the study include the lack of controls, inadequate follow-up time, and high attrition rate. While the authors had no financial interests in this therapy, the research investigation was supported by the manufacturer, Novasys Medical, Inc.

Elser et al. (2010) reported on the 18-month results from an ongoing 3-year study designed to prospectively assess the efficacy and safety of transurethral collagen denaturation and the durability of these results. Between previously published results at 12 months (Elser, 2009) and current evaluations at 18 months, 12 patients withdrew from the study. Subsequently, 63 patients completed the 18-month follow-up visit, with data available for 60 patients. At 18 months, intent-to-treat analysis revealed that patients experienced significant reductions in the median number of stress leaks daily and weekly versus baseline, with 46.7% reporting a 50% or greater reduction in leakage. Mean I-QOL score improved 10.9 points, with 47.8% having a 10-point or greater improvement and 50.4% reporting improved symptoms versus baseline. Mean UDI-6 improvement was 13.0 points, with a stress incontinence sub-score improvement of 17.0 points. Overall, 47.0% of patients were "somewhat" or "very" satisfied, and 52.9% would recommend the procedure to a friend. The procedure was shown to be safe and effective, with no new treatment-related adverse events reported at 18 months. The investigators concluded that transurethral collagen denaturation resulted in significant improvements in stress leaks and quality of life for at
least 18 months. Continuing evaluation of this study population during a 3-year period will further assess the long-term durability of this treatment. Limitations of the study include the lack of controls, inadequate follow-up time, and high attrition rate. While the authors had no financial interests in this therapy, the research was supported by the manufacturer, Novasys Medical Inc.

Elser et al. (2011) reported on the 3-year results from the ongoing study designed to prospectively assess the efficacy and safety of transurethral collagen denaturation and the durability of these. This study included 139 women with stress urinary incontinence due to bladder outlet hypermobility. Radiofrequency collagen denaturation was performed using local anesthesia in an office setting. Assessments included incontinence quality of life (I-QOL) and urogenital distress inventory (UDI-6) instruments. In total, 139 women were enrolled and 136 women were treated (mean age, 47 years). At 36 months, intent-to-treat analysis (n=139) revealed significant improvements in quality of life. Mean I-QOL score improved 17 points from baseline, while mean UDI-6 score improved (decreased) 19 points. The authors concluded that transurethral collagen denaturation is a low-risk, office-based procedure that results in durable quality-of-life improvements in a significant proportion of women for as long as 3 years. Limitations of the study include the high dropout rate and lack of randomization into treatment and control groups.

In a small, multicenter, prospective uncontrolled trial, Wells and Lenihan (2007) evaluated the efficacy and safety of transurethral RF energy therapy for SUI performed with local anesthesia and oral sedation in 33 patients with SUI. Patients had a mean baseline I-QOL score of 56 ± 18 points (range 22 to 86). The mean score at 1 month post-RF energy therapy was 69 ± 27 points (range 16 to 99). This 76% improvement from baseline was statistically significant, and 64% of the patients achieved ≥ 10-point improvement. Recovery was relatively short for this in-office procedure with most patients voiding normally shortly after its completion. Limitations of this study include its small size and lack of controls. The study was supported by the manufacturer, Novasys Medical Inc.

In a systematic review, Vianello et al. (2007) reviewed the literature on the mini-invasive surgical technique for the treatment of female SUI. Thirty-eight prospective studies including 27 studies on midurethral slings; 8 studies on urethral injections; and 3 studies on RF treatments were included in the review. Fifteen studies were RCTs. According to the authors, RF showed worse results than mid-urethral slings but is a valuable choice in women who refuse more invasive procedures.

The California Technology Assessment Forum (CTA) reviewed the body of evidence for the use of RF micro-remodeling for the treatment of female SUI. They found that while RF micro-remodeling (Renessa) for SUI does not show as high success rates as the gold standard approaches (Burch and trans-vaginal tape), it does demonstrate a good safety profile and moderate improvement in objective urinary leakage and quality of life (QOL), particularly for women with moderate-to-severe SUI. However, Renessa met all the CTAF criteria for safety, effectiveness, and improvement in health outcomes (Karliner, 2008).

Although the evidence suggests that there are potential benefits of transurethral RF energy therapy for SUI, the strength of the existing data is somewhat weakened by flaws in study design and execution, particularly the loss of patients to followup, and the lack of controls in some studies. Additional independent studies are required to establish the long-term safety and efficacy of this technology since the existing studies are sponsored by the manufacturer. Additional studies are also needed to evaluate the feasibility, efficacy, and safety of repeat RF energy therapy, and of other therapies should RF energy therapy fail (Hayes, 2010).

The clinical evidence was reviewed in November 20015 with no additional information identified that would change the conclusion.
Transvaginal Radiofrequency Therapy:
Dmochowski et al. (2003) conducted a multicenter study of 120 women with stress incontinence who underwent transvaginal radiofrequency treatment of the endopelvic fascia. Cure was defined as a negative Valsalva maneuver, and improvement was defined as decreased daily episodes of pad use. A total of 73% of patients were considered cured or improved at 12 months. More than 68% of patients reported satisfaction with the treatment. The authors concluded that the results were encouraging but long-term evaluation is needed to assess the durability of the procedure.

Ross et al. (2002) assessed the efficacy of radiofrequency in the treatment of stress incontinence (n=94). At 1 year the objective cure rate was 79% by urodynamic testing. The investigators indicated that longer term follow-up is necessary.

Ismail (2008) assessed the efficacy and safety of transvaginal radiofrequency remodelling of the endopelvic fascia as a primary procedure for urodynamic stress incontinence due to urethral hypermobility in 24 women. Outcome measures included the pad test, urodynamic assessment, continence diary, and pain scores during hospital admission and at 3, 6 and 12 months follow-up. A rising failure rate was noted as early as 3 months, leading to a cumulative cure rate of 45.8% at 12 months follow-up. This low effectiveness could be attributed to inherent weakness of the endopelvic fascia.

A retrospective chart review of 18 women treated with the transvaginal radiofrequency bladder neck suspension procedure for stress urinary incontinence was conducted. Prior to treatment, the mean number of leaks per day was 5.7. Postoperatively, two patients were continent, four were improved, and ten were unimproved. The mean number of daily leaks was reduced to 2.7. Five patients reported to be extremely satisfied with the procedure. One patient was satisfied, and ten were not satisfied. Seven patients sought additional treatment within 1 year. Low cure rate, low patient satisfaction, and high rate of additional treatment led the investigators to discontinue transvaginal radiofrequency bladder neck suspension procedure as a treatment option (Buchsbaum et al., 2007).

The clinical evidence was reviewed in November 20015 with no additional information identified that would change the conclusion.

U.S. FOOD AND DRUG ADMINISTRATION (FDA)


Percutaneous Tibial Nerve Stimulation: Percutaneous tibial nerve stimulators are classified in the FDA 510(k) database under the general Product Code “NAM”, which identifies them as non-implanted, peripheral nerve stimulators for pelvic floor dysfunction, or non-implanted, peripheral electrical continence devices. The FDA defines these devices as consisting of an electrode that is connected by an electrical cable to a battery-powered pulse source. The electrode is placed onto or inserted into the body at a peripheral location and is used to stimulate the nerves associated with pelvic floor function to maintain urinary continence. When necessary, the electrode may be removed by the user. Percutaneous tibial nerve stimulators are intended for use by patients
suffering from urinary urgency, frequency and urge incontinence. They deliver retrograde access to the sacral nerve through percutaneous stimulation of the tibial nerve.

FDA Approvals: Enter “NAM” in the Product Code field or the 510(k) number in the form at this site: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm Accessed November 4, 2014

There are five device approvals for this product classification listed in the FDA database. The first device, manufactured by UroSurge Inc. and called UroSurge Percutaneous SANS Device, was approved on February 9, 2000. The device is currently manufactured under the name Urgent PC® Neuromodulation System at Uroplasty Inc. Four FDA approvals include subsequent versions of the device manufactured by Uroplasty Inc. The Urgent PC Neuromodulation System is intended to treat patients with OAB and associated symptoms of urinary urgency, urinary frequency, and urge incontinence.

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Medicare does not have a National Coverage Determination (NCD) for Percutaneous Tibial Nerve Simulation (PTNS). Local Coverage Determinations (LCDs) exist for Percutaneous Tibial Nerve Stimulation (PTNS) and Percutaneous Tibial Nerve Stimulation for Urinary Control and Surgery: Posterior Tibial Nerve Stimulation (PTNS) for Urinary Control and compliance with these policies is required where applicable.

Medicare does not have a National Coverage Determination (NCD) for Radiofrequency Treatment for Urinary Incontinence. Local Coverage Determinations (LCDs) exist for Radiofrequency Treatment for Urinary Incontinence and compliance with these policies is required where applicable. Accessed November 4, 2014

REFERENCES


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### POLICY HISTORY/REVISION INFORMATION

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| 02/01/2015 | - Reorganized policy content  
- Added benefit considerations language for *Essential Health Benefits for Individual and Small Group plans* to indicate:  
  o For plan years beginning on or after January 1, 2014, the Affordable Care Act of 2010 (ACA) requires fully insured non-grandfathered individual and small group plans (inside and outside of Exchanges) to provide coverage for ten categories of Essential Health Benefits (“EHBs”)  
  o Large group plans (both self-funded and fully insured), and small group ASO plans, are not subject to the requirement to offer coverage for EHBs; however, if such plans choose to provide coverage for benefits which are deemed EHBs (such as maternity benefits), the ACA requires all dollar limits on those benefits to be removed on all Grandfathered and Non-Grandfathered plans  
  o The determination of which benefits constitute EHBs is made on a state by state basis; as such, when using this guideline, it is important to refer to the enrollee specific benefit document to determine benefit coverage  
- Updated coverage rationale:  
  o Reformatted and relocated information pertaining to medical necessity review; added language to indicate if service is “medically necessary” or “not medically necessary” to applicable proven/unproven statement  
- Archived previous policy version 2013T0183P