

Healthcare Operations Utilization Management Protocol

Radiofrequency Therapy and Tibial Nerve Stimulation for Urinary Incontinence

HEALTH PLAN OF NEVADA, INC. SM SIERRA HEALTH AND LIFE INSURANCE COMPANY, INC. [®]

Number
OTH013

For Sierra Health-Care Options products, please review plan documents prior to issuing a determination.

Description	After evaluating relevant benefit document language (exclusions or limitations), refer to Coverage sections of this document to determine coverage.
This policy describes the use of radiofrequency energy and percutaneous tibial nerve stimulation for the treatment of urinary incontinence.	

Coverage	All reviewers must first identify member eligibility, any federal or state regulatory requirements and the plan benefit coverage prior to use of this policy.
<p style="text-align: center;">Commercial, Medicare and Medicaid Coverage Rationale</p> <ul style="list-style-type: none">• Radiofrequency Energy Therapy Transurethral radiofrequency energy therapy (Renessa(R) System) and transvaginal radiofrequency energy therapy are not medically necessary for the treatment of urinary incontinence. The evidence for transurethral radiofrequency treatment of urinary incontinence is limited. 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. More data is needed to establish the clinical benefits, safety, and long-term effectiveness of transvaginal radiofrequency therapy.• Percutaneous Tibial Nerve Stimulation Percutaneous tibial nerve stimulation is not medically necessary for the treatment of urinary incontinence. There are no randomized controlled trials comparing the efficacy of PTNS to placebo or other urinary incontinence treatments. Most of the published studies are uncontrolled case series with no long-term data. A wide variety of mixed patient groups and outcome measures are included in these studies making it difficult to determine the effectiveness of PTNS for the treatment of urinary incontinence. <p>For Medicare and Medicaid Service Determinations Related to States Outside of Nevada: Please review Local Coverage Determinations that apply to other states outside of Nevada. http://www.cms.hhs.gov/mcd/search</p>	

Regulatory Requirements

U. S. Food and Drug Administration (FDA):

Radiofrequency Energy Therapy: On January 8, 2002, the FDA approved the SURx Laparoscopic (LP) System for Radio Frequency Bladder Neck Suspension followed by the approval of the Transvaginal (TV) System for Radio Frequency Bladder Neck Suspension in March 2002. The SURx Probe (LP, TV) Radio Frequency (RF) System is indicated for shrinkage and stabilization of female pelvic tissue for treatment of type II stress urinary incontinence due to hypermobility in women not eligible for major corrective surgery. Novasys Medical Inc. received FDA approval of a transurethral radiofrequency system (Renessa) for stress incontinence due to hypermobility in July 2005. The FDA approved the Renessa system for treatment of women with stress urinary incontinence due to urethral hypermobility who have failed conservative therapy and who are not candidates for surgical therapy. See the following Web site for more information: <http://www.fda.gov/cdrh/pdf4/k042132.pdf>. Accessed April 2009.

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. There are three device approvals for this product classification listed in the FDA database.

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 April 2009)
(K061333: Urgent PC Neuromodulation System [second generation device]
K052025: Urgent PC Neuromodulation System [first generation device]
K992069: UroSurge Percutaneous SANS TR)

Research Evidence

Background

Urinary voiding dysfunction or urinary incontinence is categorized into several types depending on the pathophysiology involved. These include urge, overflow, stress, mixed, and functional incontinence. Stress urinary incontinence (SUI) is usually related to urethral hypermobility and/or intrinsic sphincter deficiency. The most common cause is urethral hypermobility, wherein weak pelvic muscles allow the bladder neck and urethra to drop momentarily in response to increased intra-abdominal pressure, allowing urine leakage. It is characterized by involuntary leakage on effort or exertion, or on coughing or sneezing. SUI may coexist with urge and/or urgency incontinence and this is termed mixed incontinence.

Treatment options for urinary voiding disorders include behavioral strategies, pharmacological interventions, electrical stimulation, and reconstructive surgery. Usually, the less invasive first tier behavioral and pharmacological interventions are advised before reconstructive surgery is considered. Urinary incontinence therapy that is addressed in this policy includes percutaneous tibial nerve stimulation and radiofrequency therapy.

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 tissue stiffening but low enough to avoid gross destruction of tissue. 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. Another approach is through the urethra using the Renessa System which uses a transurethral probe to emit low levels of RF energy along small circumferential sites from the bladder neck to the proximal urethral submucosa.

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., overactive bladder/urge incontinence) in persons who have failed conservative treatments.

Research

Transvaginal Radiofrequency Therapy: Dmochowski et al. 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. (Dmochowski et al., 2003)

Ross et al. 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. (Ross et al., 2002)

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)

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) Women who underwent radiofrequency treatment demonstrated a statistically significant elevation in mean leak point pressure 12 months after surgery, while sham treated women demonstrated leak point pressure reduction. Radiofrequency also led to a greater incontinence quality of life score improvement versus the sham treated women.

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. Seventy-five to eighty percent of patients demonstrated an improvement in quality of life at 6 months, and 75% to 78% demonstrated improvement at 12 months.

Elser et al. (2009) assessed the efficacy of nonsurgical transurethral collagen denaturation (Renessa) in 136 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. 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 ($p < .0026$ for both), with 50% of patients reporting 50% or more reduction. Pad weight tests revealed that 69% of women had 50% or more reduction in leakage (median reduction 15.2 g; $p < .0001$); 45% were dry (29% no leaks; 16% < 1 -g leakage). Significant improvements occurred in median scores on the I-QOL (+9.5 [range -66.0 to 91.0]; $p < .0001$) and mean scores on the UDI-6 (-14.1 +/- 24.7; $p < .0001$). 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.

A retrospective study evaluated long-term safety and efficacy of transurethral radiofrequency in 21 patients from a 12-month, randomized controlled trial utilizing 3-day diaries and the Incontinence Quality of Life (I-QOL) survey. 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. (Appell et al, 2007)

Lenihan (2005) assessed the effect of menopause and hormone replacement therapy (HRT) on incontinence quality of life (I-QOL) score improvement in 73 women with moderate-to-severe stress urinary incontinence (SUI) after nonsurgical, transurethral radiofrequency energy (RF) tissue micro-remodeling in a retrospective review of prospective, randomized, controlled clinical trial. RF micro-remodeling resulted in 81% of subjects achieving 10-point or greater I-QOL score improvement versus 49% of sham subjects at 12 months (P = .04). Outcomes did not differ statistically when premenopausal (85%), postmenopausal using HRT (70%), and postmenopausal not using HRT (71%) groups were compared. The investigators concluded that menopausal status and HRT demonstrated no impact on the quality of life improvement experienced by women with moderate-to-severe SUI who underwent RF tissue micro-remodeling.

The California Technology Assessment Forum (CTA) reviewed the evidence for the use of RF micro-remodeling for the treatment of female SUI and 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, particularly for women with moderate-to-severe SUI. Renessa met all the CTAF criteria for safety, effectiveness, and improvement in health outcomes (Karliner, 2008).

Percutaneous Tibial Nerve Stimulation (PTNS): The literature surrounding PTNS is complicated by reports of outcomes for mixed patient groups, such as those who have overactive bladder syndrome, which may or may not include incontinence. It was also noted that there is significant overlap of investigators and, very likely, of patient groups evaluated in these clinical trials. Studies that are included in this policy are limited to clinical trials published in the last 5 years.

Finazzi et al. found little difference in outcomes in 35 patients randomly assigned to PTNS weekly (group 1) versus 3 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. (Finazzi et al., 2005) In another randomized controlled trial, 43 patients with symptoms of detrusor overactivity were randomized to receive PTNS alone (group 1) or to receive PTNS with an anticholinergic (group 2). The treatment response rate was 61.6% in group 1 and 83.2% in group 2. (Karademir et al., 2005)

Vondoninck et al. evaluated 90 patients with overactive bladder (OAB) and found that PTNS delayed onset of detrusor instability (DI) but could not abolish DI. (Vondoninck et al., 2003a) Additional studies conducted by Vondoninck et al. assessed patients (n=35 to 39) treated with PTNS and concluded that PTNS is an effective, minimally invasive procedure to treat urge incontinence and idiopathic voiding dysfunction. (Vondoninck et al., 2003b, 2003c, 2004)

van der Pal et al. evaluated 30 patients who were treated with PTNS and concluded that PTNS is useful for treating refractory urge incontinence. (van der Pal et al., 2006a) In another study, van der Pal et al. 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. (van der Pal et al., 2006b) A prospective observational study of 35 patients with OAB found that 19 of these patients (54%) experienced complete recovery after PTNS treatment. Complete recovery was maintained in 8 of the 19 patients at one year. (Nuhoglu et al., 2006)

De Gannaro et al. evaluated PTNS and pain in 23 children with lower urinary tract symptoms and concluded that PTNS is safe and minimally painful in children. (De Gannaro et al., 2004) 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)

Additional Search Terms

Collagen denaturation

References and Resources

Resources

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History/Update Approval

04/16/2009	Medical Technology Assessment Committee
07/24/2009	Corporate Medical Affairs Committee

Coding

The Current Procedural Terminology (CPT) codes and 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 benefit document.

CPT Codes:	
0913T	Transurethral, radiofrequency micro-remodeling of the female bladder neck and proximal urethra for stress urinary incontinence
64999	Unlisted procedure, nervous system
ICD9 Diagnosis Codes:	
625.6	Female stress incontinence
788.32	Stress incontinence, male

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