



**Kaiser Foundation Health Plan  
of Washington**

**Clinical Review Criteria**

**Treatments for Stress Urinary Incontinence**

- Biofeedback for the Treatment of Urinary Incontinence
- Collagen Injections for Stress Urinary Incontinence
- Extracorporeal Magnetic Innervation for Urinary Incontinence
- Implanted Electrical Stimulator, Sacral Nerve for Fecal and Urinary Incontinence
- Intravaginal Electrical Stimulation
- Radiofrequency Bladder Neck Suspension for the Treatment of Genuine
- SPARC® Sling for Treatment of Urinary Incontinence
- Stress Urinary Incontinence; Transurethral Radiofrequency Energy Tissue Remodeling for Treatment of Stress Urinary Incontinence (TRETTSUI)
- Urgent PC Neuromodulation System for Overactive Bladder; Percutaneous Tibial Nerve Stimulation (PTNS)

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**Criteria**

**For Medicare Members**

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	<a href="#">Non-Implantable Pelvic Floor Electrical Stimulator (230.8)</a> <a href="#">Incontinence Control Devices (230.10)</a> <a href="#">Biofeedback Therapy for the Treatment of Urinary Incontinence (30.1.1)</a> <a href="#">Sacral Nerve Stimulation for Treatment of Urinary Incontinence (230.18)</a> <a href="#">Assessing Patient's Suitability for Electrical Nerve Stimulation Therapy (160.7.1)</a> <a href="#">Bladder Stimulators (Pacemakers) (230.16)</a>
Local Coverage Determinations (LCD)	3/14/2007 Noridian retired <a href="#">LCD Biofeedback Therapy Policy (L14443)</a> . These services still need to meet medical necessity as outlined in the LCD and will require review. LCDs are retired due to lack of evidence of current problems, or in some cases because the material is addressed by a National Coverage Decision (NCD), a coverage provision in a CMS interpretative manual or an article. Most LCDs are not retired because they are incorrect. Therefore, continue to use LCD L14443 for determining medical necessity.
Local Coverage Article	11/01/2023 Noridian retired <a href="#">Posterior Tibial Nerve Stimulation Coverage (A52965)</a> . These services still need to meet medical necessity as outlined in the LCA and will require review. LCAs are retired due to lack of evidence of current problems, or in some cases because the material is addressed by a National Coverage Decision (NCD), a coverage provision in a CMS interpretative manual or an article. Most LCAs are not retired because they are incorrect. Therefore, continue to use LCA 52965 for determining medical necessity.

**For Non-Medicare Members**

Treatments for Urinary Incontinence	Criteria Used
Percutaneous Tibial Nerve Stimulation (PTNS) - Urgent® PC Neuromodulation System for Overactive Bladder	<p>Percutaneous tibial nerve stimulation (PTNS) which consists of a regimen of 30-minute weekly sessions for 12 weeks is medically necessary when <b>ALL</b> of the following are present:</p> <ol style="list-style-type: none"> <li>a. Overactive bladder syndrome</li> <li>b. Symptoms not due to spinal cord injury</li> <li>c. They must meet <b>ONE</b> of the following                             <ul style="list-style-type: none"> <li>o They must EITHER fail at least two medications with adequate trial (for example, two anticholinergics or an anticholinergic and a beta-agonist) OR</li> <li>o Have a contraindication to pharmacotherapy.</li> </ul> </li> <li>d. Behavioral therapy (eg, bladder training, pelvic floor muscle training) that is of a sufficient duration to fully assess its efficacy.</li> </ol> <p>PTNS for any other urinary indication because it is considered experimental, investigational or unproven.</p> <p>More than 12 PTNS treatments are not medically necessary when there is no improvement of OAB symptoms.</p>
Implanted Electrical Stimulator, Sacral Nerve for Fecal and Urinary Incontinence	<p>Kaiser Permanente has elected to use the MCG* Implanted Electrical Stimulator, Sacral Nerve (A-0645) for medical necessity determinations. For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.</p> <p><b>If requesting these services, please send the following documentation to support medical necessity:</b></p> <ul style="list-style-type: none"> <li>• Last 6 months of clinical notes from requesting provider &amp;/or specialist.</li> </ul>
Biofeedback Extracorporeal Magnetic Innervation Radiofrequency Bladder Neck Suspension Transurethral Radiofrequency Energy Tissue Remodeling for Treatment of Stress Urinary Incontinence (TRETTSUI) Intravaginal Electrical Stimulation	<p>There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.</p>
Collagen Injections for Stress Urinary Incontinence SPARC® Sling for Treatment of Urinary Incontinence	<p>Medical necessity review is not required for this service.</p>

\*The MCG\* are proprietary and cannot be published and/or distributed. However, on an individual member basis, Kaiser Permanente can share a copy of the specific criteria document used to make a utilization management decision. If one of your patients is being reviewed using

these criteria, you may request a copy of the criteria by calling the Kaiser Permanente Clinical Review staff at 1-800-289-1363 or access the MCG Guideline Index using the link provided above.

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

## Background

Stress urinary incontinence (SUI) is defined as leakage of urine during activities that cause increased abdominal pressure such as exercise or coughing in the absence of a detrusor contraction. It is the most common form of urinary incontinence in women and is estimated to affect about 6.5 million women in the United States. Current understanding is that urinary continence during stress events requires both intact supportive structures (i.e. endopelvic fascia) and functioning neurological control of the muscles of the pelvic floor and urethra (Agarwala & Liu, 2002).

Treatments for stress urinary incontinence include conservative therapies such as strengthening the pelvic floor muscles with Kegel exercises and devices such as electrical stimulation devices and pessaries. There are also medications such as estrogen and various surgical treatments.

## Evidence and Source Documents

[Biofeedback for the Treatment of Urinary Incontinence](#)

[Collagen Injections for Stress Urinary Incontinence](#)

[Extracorporeal Magnetic Innervation for Urinary Incontinence](#)

[Intravaginal Electrical Stimulation for Urinary Incontinence](#)

[Radiofrequency Bladder Neck Suspension / Transurethral Radiofrequency Energy Tissue Remodeling for Treatment of Stress Urinary Incontinence \(TRETTSUI\)](#)

[SPARC® Sling for Treatment of Urinary Incontinence](#)

[Urgent PC Neuromodulation System for Overactive Bladder; Percutaneous Tibial Nerve Stimulation \(PTNS\)](#)

[Bladder Pacemaker / Sacral Nerve Stimulation for Treatment of Urinary Incontinence](#)

[Sacral Nerve Stimulator for Fecal Incontinence](#)

## Medical Technology Assessment Committee (MTAC)

### *Biofeedback for the Treatment of Urinary Incontinence*

#### **BACKGROUND**

Urinary incontinence (UI), defined as the involuntary loss of urine, is a common problem affecting many women of all ages, but is more prevalent in the elderly. It is estimated that UI affects 30-60% of middle aged and older women in the community, and up to 80% of nursing home residents (Herderschee 2011, Markland 2011, Goode 2010). The main types of UI are stress incontinence (SUI), urge (or urgency) incontinence (UUI), and mixed stress and urgency incontinence (MUI). Stress urinary incontinence is the most common type and occurs in about half of incontinent women. The next most common is the mixed urinary incontinence (around 30%) followed by the urge or urgency urinary incontinence. Mixed and urge incontinence predominate in older women, while stress incontinence mainly occurs in young and middle-age women (Lipp 2011). SUI is the involuntary leakage of urine with activities that increase intra-abdominal pressure such as coughing, sneezing, lifting, or sport activities. SUI occurs as a result of a combination of intrinsic urethral sphincter muscle weakness and an anatomic defect in the urethral support, leading to insufficient closure pressure in the urethra during physical effort. The etiology of SUI is multifactorial and includes pregnancy, vaginal delivery, pelvic surgery, neurologic causes, active lifestyle, and various comorbidities. UUI is the involuntary leakage of urine accompanied by or immediately preceded by a sensation of urgency, or the sudden compelling desire to pass urine which is difficult to defer. This can be caused by an involuntary bladder contraction that overcomes the sphincter mechanism; or poor bladder compliance due to loss of the viscoelastic features of the bladder. UUI is part of the spectrum of overactive bladder. MUI is the symptom complex of involuntary leakage associate with both urgency and effort and exertion (Lipp 2011, Deng 2011, Markland 2011). Urinary incontinence is not a life-threatening condition but has a profound negative impact on the quality of life. Symptoms of UI interfere with the performance of everyday household and social activities, and may lead to anxiety, frustration, social isolation, and depression. It is reported that UI is associated with a 30% increase in functional decline, a 2-fold increase in the risk of falls, and nursing home placement (Goode 2010, Markland 2011, Mladenovic 2011). Treatment options for urinary incontinence can be divided into conservative measures, pharmacotherapy, and surgical interventions. Conservative treatment is usually the first-line therapy for many patients and is useful for both stress and urge incontinence. Behavioral treatments have been well studied and proved to be effective in reducing leakage by 50-80%, with 10-30% of the patients

achieving continence. These interventions improve incontinence by teaching skills and helping patients change their behavior. Behavioral programs comprise multiple individualized components which may include bladder control strategies, self-monitoring (bladder diary), scheduled or prompted voiding, delayed voiding, urge suppression strategies, moderate weight loss, fluid management, caffeine reduction, pelvic floor muscle training, and /or other lifestyle changes. Behavioral treatment is most useful when the person is motivated, wants to be actively involved in therapy, can follow directions, and when there is a readily identifiable and measurable response (Markland 2011, Lipp 2011). Pelvic floor muscle training (PFMT) and exercise, also known as Kegel exercise, is considered a cornerstone in behavioral treatment. PFMT is a program of repeated voluntary pelvic floor muscle contractions taught and supervised by a health care professional. These work by increasing the strength and tone of the pelvic floor muscles, which in turn increases the urethral closure force and prevents stress incontinence during an abrupt increase in intra-abdominal pressure. It is also useful for urge incontinence as the detrusor contractions can be reflexively or voluntarily inhibited by tightening the pelvic floor. The success of PFMT depends on the patient's ability to perform the exercise correctly and the motivation to actually practice it regularly. In clinical practice, PFMT is often combined by some type of feedback or biofeedback to help the woman learn how to contract the muscle, to improve the effectiveness of the contraction through modulating the performance of the learned contraction, and to encourage further exercising (Herderschee 2011, Goode 2010, Deng 2011). Feedback is defined as the return of part of the output of a system to the input in a way that affects its performance. It thus provides information on what was done, rather than what to do, i.e. the bodily sensation felt by the woman performing the contraction gives inherent feedback about the movement. Augmented feedback is a feedback with supplementary information provided e.g. verbal feedback from a clinician palpating or observing the contraction. Biofeedback (BF) is a form of augmented feedback that uses monitoring devices to display information about the operation of a bodily function that is not normally consciously controlled, to help the patient learn to control the function consciously. When performed in conjunction with Kegel exercises for the treatment of UI, specialized pressure transducers or sensors are inserted in the vagina or rectum, or placed on the perineum, and biofeedback instruments are used to reinforce correct techniques through visual and auditory cues. BF typically gives the user an auditory or visual record of the contraction or both. This can potentially be helpful and motivating women who find it difficult to identify and isolate their pelvic floor muscles. BF devices vary considerably; many of the devices used in the studies consist of air or water filled balloons that are inserted into the rectum or vagina to measure pressure. Other devices measure electrical activity (electromyography) via surface metal electrodes on vaginal or anal probes. Some devices can only be used in clinical setting because they require a health professional to set up and use the equipment, and others are very simple and portable and are designed for home use (Herderschee 2011). A typical program of biofeedback consists of 10 to 20 training sessions; 30 minutes each. Training sessions are typically performed in a quiet environment, and under the supervision of a physiotherapist or specialized nurse. Patients are instructed to use mental techniques to contract the pelvic muscles and feedback is provided for a successful contraction. This feedback may be signals such as lights, verbal praise, or other auditory or visual stimuli. The Food and Drug Administration have cleared a variety of biofeedback devices for marketing. It defines a biofeedback device as "an instrument that provides a visual or auditory signal corresponding to the status of one or more of a patient's physiological parameters) so that the patient can control voluntarily these physiological parameters."

#### **04/14/1999: MTAC REVIEW**

##### **Biofeedback for the Treatment of Urinary Incontinence**

**Evidence Conclusion:** The published scientific evidence on biofeedback consists of small-randomized trials with typically one-month follow-up. These studies reported that adding biofeedback to a trial of pelvic floor muscle exercises did not produce any incremental benefit. It was noted that there were 3 randomized controlled trials that provided good evidence that biofeedback produces no incremental improvement in urinary incontinence compared to pelvic muscle exercise alone. It was also noted that biofeedback was currently a covered service at Kaiser Permanente Northwest and that this policy may undergo re-evaluation as a result of evaluating the evidence.

**Articles:** Berghmans, LCM et al, *Neurology and Urodynamics*, 1996;15:37-52. See [Evidence Table](#). Burns, PA et al, *J. Gerontology*, 1993;48 M167-M174 See [Evidence Table](#). Burton, JR, et al, *J Am Geriatr Soc*. 1988; 36:693-698 See [Evidence Table](#). Burgio, KL, et al. *Am J Obstet Gynecol*, 1986;154:58-64 See [Evidence Table](#).

Biofeedback for the treatment of stress or urge urinary incontinence does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

#### **10/09/2002: MTAC REVIEW**

##### **Biofeedback for the Treatment of Urinary Incontinence**

**Evidence Conclusion:** The new evidence on the benefit of biofeedback compared to pelvic floor muscle exercise alone consists of one RCT and one meta-analysis, both with threatened validity. Even with their methodological

limitations, neither found a significant benefit of adding biofeedback to PFM exercises. There was also an additional RCT that compared PFM exercise with biofeedback to drug treatment (Burgio) and found a greater reduction in incontinent episodes with PFM exercise. Although the Burgio study had reasonably valid methods, it did not include a group receiving PFM exercises without biofeedback, so the additive benefit of using a biofeedback device with an exercise program cannot be determined. The new evidence on biofeedback for the treatment of urinary incontinence is consistent with earlier evidence that biofeedback does not substantially add to the effectiveness of pelvic floor muscle exercise.

**Articles:** The search yielded 73 articles, many of which were review articles or opinion pieces. There was one meta-analysis of RCTs and two RCTs. One of the RCTs was published prior to 1999 but was not included in the previous review. The two RCTs and the meta-analysis were critically appraised: Weatherall M. Biofeedback or pelvic floor muscle exercises for female genuine stress incontinence: A meta-analysis of trials identified in a systematic review. *BJU Internat* 1999; 83: 1015-1016. (Some methodological information taken from: Berghmans LCM, Hendriks HJM, Bo K. Conservative treatment of stress urinary incontinence in women: a systematic review of randomized controlled trials. *Br J Urol* 1998; 82: 181-191. See [Evidence Table](#). Lacock J, Brown J, Cusack C et al. Pelvic floor reeducation for stress incontinence: comparing three methods. *Br. J Commun Nurs* 2001; 6: 230-237. See [Evidence Table](#). Burgio KL, Locher JL, Goode PS. Behavioral vs. drug treatment for urge urinary incontinence in older women. *JAMA* 1998; 280: 1995-2000. See [Evidence Table](#).

The use of biofeedback in the treatment of urinary incontinence does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

### 10/17/2011: MTAC REVIEW

#### **Biofeedback for the Treatment of Urinary Incontinence**

**Evidence Conclusion:** Herderschee and colleagues' (2011) meta-analysis included 24 randomized or quasi randomized trials that compared the use of PFMT program with a form of feedback or biofeedback in women with urinary incontinence. The results of the meta-analysis indicate that women who received biofeedback were significantly more likely to report that their urinary incontinence was improved or cured compared to those who received PFMT alone. The meta-analysis had valid methodology; however, the trials included were small, some were quasi randomized, and all, but one small study, had moderate or high risk of bias. In addition, there were many variations in the regimens of biofeedback added to PFMT and women in the biofeedback or feedback group had more contact with the health providers. The overall results of the meta-analysis show that women in the biofeedback groups had statistically significant higher satisfaction and perception of improvement in symptoms compared to those in the PFMT only groups. However, the number of leak episodes indicates that the addition of biofeedback to PFMT leads to approximately one less leak every eight days. The limitations in the trials included in the analysis make it hard to determine whether the improvement was due to the intervention, bias, more contact with health providers, or other confounding factors.

**Articles:** The search revealed one recent Cochrane review of trials on feedback and biofeedback for augmenting pelvic floor muscle training in women with urinary incontinence. A number of RCTs that were included in the meta-analysis were also identified. Only the Cochrane's meta-analysis was selected for critical appraisal. Herderschee R, Hay-Smith EJ, Herbison GP, et al. Feedback or biofeedback to augment pelvic floor muscle training for urinary incontinence in women. *Cochrane Database Syst Rev*. 2011;(7):CD009252. See [Evidence Table](#).

The use of biofeedback in the treatment of urinary incontinence does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

### **Collagen Injections for Stress Urinary Incontinence**

#### **BACKGROUND**

Stress incontinence is one of the two common types of urinary incontinence. The primary symptom is an involuntary loss of urine during physical exertion associated with increased intra-abdominal pressure, such as with coughing, laughing or sneezing. Treatments for stress incontinence include exercises to strengthen the external urethral sphincter, mechanical devices (pessaries) to support the urinary sphincter muscles, medications such as estrogen and phenylpropanolamine (PPA) and surgery. Injection of periurethral bulking agents for stress incontinence was first described by Murless in 1938 who used a sclerosing agent, sodium morrhuate. Injectable materials are usually used for patients with incontinence due to intrinsic sphincter deficiency (ISD). Currently, the most commonly used bulking agent is collagen. Collagen, however, is biodegradable, and therefore any benefit it may provide is short-lived. According to researchers, the ideal injectable substance has not yet been developed but it would be durable yet nonimmunogenic, noncarcinogenic, nonmigratory and produce minimal inflammatory responses (Lightner; Pannek). Collagen used for treating urinary incontinence is a bovine-derived collagen gel manufactured by the Bard Company and injected sub or periurethral via percutaneous injection. Its mechanism

of action is to increase tissue bulk in the area of the urethra until the urethra becomes closed. Multiple injections of up to 30 ml. may be injected in a single patient and up to 5 subsequent collagen treatments may be required to produce clinical improvement. A collagen implant, which is injected into the submucosal tissue of the urethra and/or the bladder neck and into the adjacent tissues of the urethra, is a prosthetic device used in the treatment of stress urinary incontinence resulting from intrinsic sphincter deficiency (ISD). ISD is a cause of stress urinary incontinence in which the urethral sphincter is unable to contract and generate sufficient resistance in the bladder, especially during stress maneuvers. DuraspHERE is an injectable bulking agent that is composed of pyrolytic carbon-coated beads suspended in a water-based carrier gel. In September 1999 the FDA approved DuraspHERE. A transurethral or periurethral method of injection can be used. A potential advantage of DuraspHERE over collagen is that the particle size is relatively large (251 to 300 $\mu$ ) and particle migration is not believed to occur. DuraspHERE is also believed to not cause allergic reactions. However, recent studies have refuted that assumption.

## 1999: MTAC REVIEW

### Collagen Injections for Stress Urinary Incontinence

**Evidence Review:** The published scientific evidence on collagen injection consists mostly of small case series with 1-2 year follow up. Several case series with good follow up in a population of women with stress incontinence reported short term benefit in 25-80% of patients which declines to 25-30% over the course of 3 years. Reported complication rates ranged from 10 to 20%. One study report that 9% of women and 25% of men eventually required surgical intervention for their incontinence. The wide range of reported outcomes makes interpretation of the effect of collagen injection difficult. Evidence tables of the relevant published studies are presented below.

**Articles:** Swami, S et al. Collagen for female genuine stress incontinence after a minimum two-year follow-up. 1997, *British Journal of Urology*, 80, 757-761 See [Evidence Table](#). Stothers, L et al. Complications of periurethral collagen for stress urinary incontinence. 1998, *J. Urol.* 159, 806-807 See [Evidence Table](#).

Collagen Injection for urinary incontinence did not pass the *Kaiser Permanente Medical Technology Assessment Criteria*.

## 2002: MTAC REVIEW

### Collagen Injections for Stress Urinary Incontinence

**Evidence Review:** The best evidence was an RCT that compared injections with DuraspHERE to collagen injections among women with stress urinary incontinence due to intrinsic sphincter deficiency (Lightner). The authors did not find a significant difference in effectiveness between the two treatments. In both groups, about 66% of women in the analysis had an improvement of >1 continence grade on the Stamey scale after 12 months of follow-up. There was no placebo comparison and it may be that neither collagen nor DuraspHERE performs better than placebo. MTAC evaluated collagen injections in 1999 and found that there was insufficient evidence of effectiveness. The validity of the Lightner study was also threatened by the high dropout rate. Only 65% of patients completed the 12-month follow-up and there was no intention to treat analysis. The other article reviewed (Pannek) was a small case series that identified two cases of particle migration three months after DuraspHERE injections. Additional research is needed to verify the extent of particle migration and determine any possible harms associated with this migration.

**Articles:** The search yielded 9 articles. There were two empirical articles, one RCT and one case series (n=20). Both articles were reviewed. A case series of this size (n=20) would not normally be reviewed, but this article was included because it dealt with the safety of the technology. *The following articles were critically appraised.* Lightner D, Calvosa C, Andersen R, Klimberg I, Brito CG, Snyder J. et al. A new injectable bulking agent for treatment of stress urinary incontinence: Results of a multicenter, randomized, controlled double-blind study of DuraspHERE. *Urology* 2001; 58:12-15. See [Evidence Table](#). Pannek J, Brands FH, Senge T. Particle migration after transurethral injection of carbon coated beads for stress urinary incontinence. *J Urol* 2001; 166:1350-1353. See [Evidence Table](#).

DuraspHERE Injection for urinary incontinence did not pass the *Kaiser Permanente Medical Technology Assessment Criteria*.

## **Extracorporeal Magnetic Innervation for Urinary Incontinence**

### **BACKGROUND**

Extra-corporeal magnetic innervation therapy (approved by the FDA in June 1998) is a technology designed to treat stress urinary incontinence. Extra-corporeal magnetic innervation therapy is a technology that has been developed to provide conservative therapy for stress urinary incontinence by creating a magnetic field and the induction of electrical activity to de-polarize the nerves and exercise the muscles of the pelvic floor. The technology provides a potential alternative to surgical treatment for incontinence. It provides an additional option

to conservative therapies such as fluid restriction, medical management, timed voiding, Kegel exercises, biofeedback and electrical stimulation. Its promoters state that this technology will prove more attractive to patients than electrical stimulation because patches or probes, skin contact or gel, and undressing for treatment are not necessary. Patients are positioned in a special chair provided with a cushion containing a magnetic field generator which is powered and controlled by an external power unit. The output of the power unit consists of pulses of current at 275 microseconds in duration and which can be adjusted in amplitude by the clinician. Treatment involves approximately ten minutes of intermittent low frequency stimulation (5 Hz) followed by a rest interval of 1-5 minutes and then ten minutes of intermittent high frequency stimulation (50 Hz). Treatments are given twice a week for six weeks. The FDA has approved this as Class II device requiring a physician's prescription and administration.

#### **02/06/2000: MTAC REVIEW**

##### **Extracorporeal Magnetic Innervation for Urinary Incontinence**

**Evidence Conclusion:** Although extracorporeal magnetic innervation therapy has FDA approval, there is insufficient scientific evidence to permit conclusions regarding the effects of this technology on health outcomes. This study is a cohort study without a control group and therefore lacks the validity of a randomized control trial. Validity of the before and after results are threatened by the drop-out or lack of follow-up of 14 patients in the original group. Validity is also threatened by the likelihood of co-interventions such as advice regarding voiding and fluid management. The possibility of a placebo effect is real.

Observation bias is likely in this study (e.g., the investigators received payment from the manufacturer).

**Articles:** Four articles were located using Medline (OVID). Articles were sorted on the basis of study type. One case series of seven male patients was rejected because the population was limited to males with spinal cord injury. A second study was eliminated because the 12 patients underwent saline infusion into the bladder followed by magnetic stimulation of S3. A third study was excluded because it reviewed literature dealing with urethral pressure in anesthetized dogs. Gallaway NT, El-Galley RE, Sand PK et al. Extracorporeal magnetic innervation therapy for stress urinary incontinence. *Urology*. 53 (6): 1108-11, 1999 June. See [Evidence Table](#).

The use of extracorporeal magnetic innervation for the treatment of stress urinary incontinence has been approved by the FDA and therefore meets *Kaiser Permanente Medical Technology Assessment Criteria*.

#### **Intravaginal Electrical Stimulation for Urinary Incontinence**

##### **BACKGROUND**

Urinary incontinence (UI), the accidental release of urine, affects up to 30 million women in the United States. Most symptoms of UI will fall into two different categories. The first, stress incontinence, is characterized by the involuntary loss of urine occurring after exerting some force on the bladder through physical activities such as coughing, sneezing, laughing, exercising or lifting. Urge incontinence, on the other hand, causes urine leakage due to bladder spasms or untimely contractions. Symptoms of both stress and urge incontinence may be experienced at the same time and is most often referred to as mixed incontinence. While some causes of UI can be attributed to medications or urinary tract infection and may improve after treating the cause, in most cases of urinary incontinence, the cause is difficult to target. In any case, urinary incontinence is embarrassing and uncomfortable and can severely disrupt the quality of life. Pelvic floor muscle training (PFMT) is considered first line treatment for UI and is aimed to target the pelvic musculature. It is a noninvasive education and exercise program that involves repeated voluntary contraction of the pelvic floor musculature building strength, endurance and coordination. Biofeedback is often included in PFMT in an effort to promote adherence and efficiency through the contraction and timing of the correct muscles. Biofeedback is also used to assess improvement over time (Berghmans, Hendriks et al. 1998; Domoulin and Hay-Smith 2010). In the same way, intravaginal electrical stimulation (IVES) also targets the pelvic musculature by sending a mild electric current intended to trigger muscle contraction and, consequently, a strengthening effect similar to that of PFMT. It has also been hypothesized that the electrical stimulation encourages growth of nerve cells that cause the muscles to contract (Schreiner, Santos et al. 2013). In any case, the technology is designed to be used at-home for acute and on-going treatment. With a variety of devices on the market, the technology, in its simplest form, consists of a unit with built in surface electrodes that can be temporarily inserted into the vagina. Most of the devices also come with a hand-held controller allowing the regulation of current and duration. Several IVES devices have been approved by the U.S. Food and Drug Administration (FDA) as class II devices under the non-implanted electrical continence device classification.

#### **04/21/2014: MTAC REVIEW**

##### **Intravaginal Electrical Stimulation for Urinary Incontinence**

**Evidence Conclusion:** In 1996, Smith randomized 18 women with genuine stress urinary incontinence to either PFMT or IVES. After at least 16 weeks of treatment, 44% of the patients in the PFMT group showed objective

improvement with one patient reported as cured, three with improvement and the remaining five with no significant improvement. In the IVES group, however, there was 66% improvement with two cured patients, four with improvement and three failures. Smith concludes that the device is safe, however, there was no discussion or reports of either how safety was measured or if data on adverse events were routinely collected. In addition, Smith concludes that IVES is at least as effective as PFMT, however, the total number of patients in the group was small and not statistically significant (Smith 1996). [[Evidence Table 1](#)] In an attempt to assess the effectiveness of physiotherapeutic treatment modalities in women with proven urge urinary incontinence Berghmans and colleagues randomized 68 patients to one of four treatment arms. With one control group of patients receiving no treatment, the remainder of the groups received IVES, PFMT or both. The primary outcome measure, the DAI, is a combined parameter that quantifies bladder over activity using a score between 0 and 1 where '0' represents no activity and '1' represents severe over activity. Ultimately, the investigators concluded that IVES was the only effective treatment for urge urinary incontinence, with a 0.28 difference in DAI score between pre- and post-treatment, but this conclusion is prone to bias as the intended sample size was 80 and only 68 patients were included in the ITT analysis (Berghmans, van Waalwijk van Doorn et al. 2002). [[Evidence Table 2](#)]. IVES treatment was compared to PFMT in a trial including 35 women aged 65 or older. The control group was given verbal instruction on how to perform Kegel exercises while the IVES group received maximal IVES for 30 minutes three times a week. With several objective and subjective outcomes being measured the authors make several conclusions regarding treatment with IVES of one of which claims high physical and emotional cost for the treated individuals. It is unclear how they came to this conclusion as there is no mention of any kind of QoL questionnaires nor was there systematic collection of adverse effects. In terms of the effectiveness of the IVES device, the authors report no significant improvement in objective outcomes and deem it unreasonable to advise elderly women to undertake this treatment (Spruijt, Vierhout et al. 2003). [[Evidence Table 3](#)]. Limitations of the reviewed evidence include small study populations which limit the ability to rule out the role of chance as an explanation of findings and short follow-up times, which limit conclusions regarding the durability of any treatment effects. Data on adverse events and outcomes were not systematically collected in any of the selected studies. Any benefit observed in the urge and stress urinary incontinence studies do not appear to be superior to less invasive treatments such as PMFT. In general, the studies are significantly heterogeneous in their methodology and follow up and suffer from variation in stimulation parameters. Ultimately, there is no clear demonstration that IVES results in improved health outcomes in patients in the long run.

Conclusion: There is insufficient evidence to support the treatment of mixed urinary incontinence with IVES. There is insufficient evidence to support the treatment of stress urinary incontinence with IVES. There is insufficient evidence to support the treatment of urge urinary incontinence with IVES. There is insufficient evidence to support the safety of IVES in females with urinary incontinence.

**Articles:** The search initially revealed over 700 publications related to urinary incontinence. Articles were screened for comparison studies investigating intravaginal electrical stimulation (IVES) treatment for incontinent females after which the literature was narrowed down to 21 randomized controlled trials (RCTs) summarized in tables 1, 2 and 3. The studies varied in the treatment of urinary incontinence ranging from stress urinary incontinence, to urge and mixed urinary incontinence and none were powered to determine equivalence. In addition, IVES treatment was compared to several different treatment options including various nonpharmacologic, pharmacologic and surgical. Studies that compared IVES to PFMT were selected for critical appraisal. The following studies were selected for review: Smith, JJ. Intravaginal stimulation randomized trial. *The Journal of Urology*. 1996;155:127-130 [[Evidence Table 1](#)]. Berghmans B, van Waalwijk van Doorn E, Nieman F, et al. Efficacy of physical therapeutic modalities in women with proven bladder overactivity. *European Urology*. 2002;41:581-587 [[Evidence Table 2](#)]. Spruijt J, Vierhout M, Verstraeten R, et al. Vaginal electrical stimulation of the pelvic floor: a randomized feasibility study in urinary incontinent elderly women. *Acta Obstet Gynecol Scand*. 2003;82:1043-1048 [[Evidence Table 3](#)].

The use of IVES does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

## **Radiofrequency Bladder Neck Suspension / Transurethral Radiofrequency Energy Tissue Remodeling for Treatment of Stress Urinary Incontinence (TRETUSUI)**

### **BACKGROUND**

Urinary incontinence is a common symptom that affects women of all ages. Stress urinary incontinence is one of the most common types of urinary incontinence and is defined as the involuntary leakage of urine on exertion, sneezing, or coughing. Risk factors for stress urinary incontinence include obesity, pregnancy, and childbirth (Deng 2011, Rogers 2008). Treatment options for stress urinary incontinence include conservative measures, pharmacotherapy, and surgical interventions. Conservation treatments such as weight loss, pelvic floor muscles exercise (also known as Kegel exercises), as well as other behavioral and lifestyle modifications are the first-lines of treatment for stress urinary incontinence. Duloxetine, a combined serotonin and norepinephrine reuptake inhibitor, has shown some efficacy for the treatment of stress urinary incontinence; however, it failed to obtain



FDA approval due to concerns for liver toxicity and suicidal events. Currently, there are no FDA approved drug therapies for stress urinary incontinence. Surgical therapy is indicated for patients who have not responded to conservative treatment options. Surgical interventions include retropubic colposuspension (Burch suspension), midurethral or bladder neck slings, injection of urethral bulking agents, and tension-free vaginal tape (Deng 2011, Rogers 2008). Transurethral radiofrequency micro-remodeling has been proposed as a minimally invasive treatment for stress incontinence among women who fail conservative therapies. In this procedure, controlled, low-level radiofrequency energy results in localized collagen denaturation. This leads to reduced regional dynamic tissue compliance without creating stricture or reducing luminal caliber (Appell 2008, Elser 2009).

Another radiofrequency treatment for stress urinary incontinence is transvaginal radiofrequency bladder neck suspension. This approach differs from the transurethral procedure in two ways. First, the transvaginal procedure is a surgical procedure whereas the transurethral procedure is a non-surgical procedure that does not require an incision. Second, higher levels of radiofrequency energy are used in the transvaginal procedure. These higher levels of energy result in higher temperatures which causes tissue necrosis instead of collagen denaturation to reduce involuntary urinary leakage (Appell 2008).

#### **08/13/2003: MTAC REVIEW**

##### **Radiofrequency Bladder Neck Suspension / Transurethral Radiofrequency Energy Tissue Remodeling for Treatment of Stress Urinary Incontinence (TRETTSUI)**

**Evidence Conclusion:** The best available evidence on TRETTSUI is in case series reports, the weakest study design due to the potential for selection and observation bias and lack of a control or comparison group. The case series articles on the SURx laparoscopic and transvaginal systems suggest a substantial decrease in incontinence episodes 12 months after the procedure compared to baseline. In addition to type of study design, these studies are limited by the strong financial links between the authors and the SURx company, which could bias the design, analysis and/or reporting of results.

**Articles:** The Medline search yielded 4 articles. There were no randomized or non-randomized controlled trials. There was one case series on the SURx Transvaginal system that was critically appraised. In addition, there were two publications using the SURx Laparoscopic system that reported on the same series of patients. These two articles were critically appraised in the same evidence table. No published studies on the Novasys product were identified. SURx Transvaginal study: Dmochowski RR, Avon M, Ross J et al. Transvaginal radiofrequency treatment of the endopelvic fascia: A prospective evaluation for the treatment of genuine stress urinary incontinence. *J Urol* 2003; 169: 1028-1032. See [Evidence Table](#). SURx Laparoscopic study: Fulmer BR, Sakamoto K, Turk TM et al. Acute and long-term outcomes of radiofrequency bladder neck suspension. *J Urol* 2002; 167: 141-145. Ross JW, Galen DI, Abbott K. et al. A prospective multisite study of radiofrequency bipolar energy for treatment of genuine stress incontinence. *J Am Assoc Gynecol Laparosc* 2002; 9: 493-499. See [Evidence Table](#).

The use of Transurethral Radiofrequency Energy Tissue Remodeling in the treatment of Stress Urinary Incontinence does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

#### **06/20/2011: MTAC REVIEW**

##### **Radiofrequency Bladder Neck Suspension / Transurethral Radiofrequency Energy Tissue Remodeling for Treatment of Stress Urinary Incontinence (TRETTSUI)**

**Evidence Conclusion:** A randomized controlled trial that included 173 women evaluated the safety and efficacy of transurethral radiofrequency micro-remodeling for the treatment of female stress urinary incontinence compared to sham treatment. There were two primary outcomes for this study – quality of life and leak pressure point (LPP). An improvement in quality of life was defined as a 10 point or greater increase on the Incontinence Quality of Life (I-QOL) score. After 12 months of follow-up, 48% of subjects in the intervention group and 44% in the control group experienced an improvement in quality of life (P=0.07). However, in patients with moderate to severe stress urinary incontinence (I-QOL score of 0 to 60 points), 74% of subjects in the intervention group compared to 50% in the control group experienced an improvement in quality of life (P=0.03). There was no significant difference in the percent of subjects with mild stress urinary incontinence (I-QOL score of 61 to 90 points) who experienced an improvement in quality of life (intervention=22% vs. control=35%, P=0.02). Women in the intervention group experienced an increase in LPP at 12 months (13.2 ± 39.2 cmH<sub>2</sub>O), while women in the control group experienced a decrease in LPP (-2.0 ± 33.8 cmH<sub>2</sub>O) (P=0.02). There was no significant difference in adverse events between the two treatment groups. The most commonly reported adverse events were wet overactive bladder and dysuria (Appell 2006). This trial had several methodological limitations: an intent-to-treat analysis was not performed; it is not clear if the investigators were blinded; power was not assessed; and it is not stated if the subgroup analyses were planned. An interim analysis from a prospective case-series that included 139 women with stress urinary incontinence who had failed conservative treatments and had not undergone surgery or bulking agent treatment also evaluated the safety and long-term efficacy of transurethral

radiofrequency micro-remodeling for the treatment of female stress urinary incontinence. After 18 months, patients experienced significant reductions in the median number of leaks per day (-0.43, range -34.3 to 18.9,  $P=0.006$ ) and per week (-3.0 range -240.0 to 132.0,  $P=0.006$ ) compared to baseline. Additionally, 46.7% of patients had at least 50% fewer leaks ( $P<0.0001$ ) compared to baseline. With regard to quality of life, 65 patients (47.8%) experienced at least a 10-point improvement in I-QOL score. During the first three days post-treatment, the most common adverse events were dysuria ( $N=7$ , 5.2%), urinary retention ( $N=6$ , 4.4%), post-procedure pain ( $N=4$ , 2.9%), and urinary tract infection ( $N=4$ , 2.9%). At 12 months, one patient reported an increase in leakage, which was probably treatment related. Between 12 and 18 months one patient experienced a myocardial infarction, which was determined to be unrelated to the treatment (Elser 2009). Results from this study should be interpreted with caution as this study is a case-series and therefore more prone to bias. Additionally, 73 subjects (53%) discontinued the study for various reasons. **Conclusion:** Transurethral radiofrequency micro-remodeling: Results from a randomized controlled trial with several methodological limitations suggest that transurethral radiofrequency micro-remodeling may be safe and effective for the treatment of female stress urinary incontinence. More studies are needed to address the durability of the effect and whether women who undergo transurethral radiofrequency micro-remodeling can subsequently undergo other procedures such as retropubic colposuspension (Burch suspension) or tension-free vaginal tape without undo complications. Transvaginal radiofrequency bladder neck suspension: There is insufficient information to determine the safety and efficacy of transvaginal radiofrequency bladder neck suspension for the treatment of female stress urinary incontinence. **Articles:** *Assessment objective* to determine the safety and efficacy of transurethral radiofrequency micro-remodeling for the treatment of stress urinary incontinence. To determine the safety and efficacy of transvaginal radiofrequency bladder neck suspension for the treatment of stress urinary incontinence. Only one randomized controlled trial was identified that evaluated the safety and efficacy of transurethral radiofrequency micro-remodeling for the treatment of stress urinary incontinence. It was selected for review. Since the 2003 MTAC review, two retrospective cohort studies were identified that evaluated transvaginal radiofrequency bladder neck suspension for the treatment of stress urinary incontinence. As both of these studies included less than 25 participants, neither of them was selected for review (Buchsbaum 2007, Ismail 2008). The following study was critically appraised: Appell RA, Juma S, Wells WG, et al. Transurethral radiofrequency energy collagen micro-remodeling for the treatment of female stress urinary incontinence. *Neurourol Urodyn* 2006; 25: 331-336. See [Evidence Table](#).

The use of Transurethral Radiofrequency Energy Tissue Remodeling in the treatment of Stress Urinary Incontinence does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

The use of transvaginal radiofrequency bladder neck suspension in the treatment of Stress Urinary Incontinence does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

## **SPARC® Sling for Treatment of Urinary Incontinence**

### **BACKGROUND**

Stress urinary incontinence (SUI) is defined as leakage of urine during activities that cause increased abdominal pressure such as exercise or coughing in the absence of a detrusor contraction. It is the most common form of urinary incontinence in women and is estimated to affect about 6.5 million women in the United States. Current understanding is that urinary continence during stress events requires both intact supportive structures (i.e. endopelvic fascia) and functioning neurological control of the muscles of the pelvic floor and urethra (Agarwala & Liu, 2002). Treatments for stress urinary incontinence include conservative therapies such as strengthening the pelvic floor muscles with Kegel exercises and devices such as electrical stimulation devices and pessaries. There are also medications such as estrogen and various surgical treatments. Surgical procedures for stress incontinence attempt to provide support to the bladder neck and/or urethra to limit the movement of these structures. Sling procedures are a surgical option for treating common stress urinary incontinence secondary to intrinsic sphincteric deficiency and urethral hypermobility. The sling procedure involves using abdominal fasci, cadaveric fasci or polypropylene mesh as sling material. The piece of muscle fiber or synthetic material is attached under the urethra and bladder neck and secured to the abdominal wall and pelvic bone. When the patient's abdominal fasci is used, an abdominal incision is required. Synthetic slings are generally inserted through a vaginal approach. Newer sling procedures include SPARC and tension-free vaginal tape (TVT). Both procedures place the sling under the urethra without tension that is intended to minimize disruption of normal urethral mobility. In addition, both use a sling made of loosely woven polypropylene mesh, require a relatively short operating time and can be performed under local anesthesia with sedation (Staskin & Pizak, 2002). The SPARC system differs from TVT in the way in which the sling is placed under the urethra. TVT passes the sling anchoring trocars from below, using a rigid catheter guide. In contrast, SPARC uses small diameter needles that are passed from above through two small suprapubic incisions". In addition, unlike TVT, the SPARC mesh has a knotted "tensioning suture" that allows adjustment of the sling (Staskin & Pizak, 2002).

## 08/13/2003: MTAC REVIEW

### SPARC® Sling for Treatment of Urinary Incontinence

**Evidence Conclusion:** There is insufficient evidence to determine the effectiveness of the SPARC sling for the treatment of stress urinary incontinence in women. The single published empirical study reports only on 4 patients who experienced vaginal erosion after the SPARC procedure.

**Articles:** The search yielded 27 articles. Most of these were on related procedures such as tension-free vaginal tape. There was one empirical article on SPARC. This was a case series that presented data on 4 patients who experienced vaginal erosion of the mesh after the sling procedure. Due to the small sample size and the lack of data on the patients in the series who did not experience vaginal erosion, this study was not critically appraised.

The use of SPARC Sling in the treatment of urinary incontinence does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

## **Urgent PC Neuromodulation System for Overactive Bladder; Percutaneous Tibial Nerve Stimulation (PTNS)**

### **BACKGROUND**

Overactive bladder (OAB) is defined by the International Continence Society as the presence of urinary urgency with or without urge incontinence that is usually accompanied by frequency and nocturia, in the absence of urinary tract infection or other obvious pathology. Urgency, the hallmark of OAB, is defined as the sudden compelling desire to urinate, a sensation that is difficult to defer. Urinary frequency is defined as voiding 8 or more times in a 24-hour period. Nocturia is defined as the need to wake up one or more times per night to void. The National Overactive Bladder Evaluation (NOBLE) epidemiologic study estimated that 16.9% of adult women in the US had OAB syndrome; 9.3% with incontinence, and 7.6% without incontinence (Abrams 2002, Stewart 2003, Martinson 2013). OAB is not a disease but a symptom complex that is generally not life-threatening but has a significant impact on the quality of life, sleep, work productivity, social relationships, mental health, sexual and physical activity. Treatment options for overactive bladder can be divided into 1. Conservative measures as behavioral interventions and pharmacotherapy, and 2. More invasive procedures. Most treatments may improve patient symptoms but are unlikely to eliminate all symptoms. A successful treatment requires a participant who is motivated and well informed about the variable and chronic course of the condition. The first line treatment of OAB is typically behavioral interventions, which consist of bladder training, bladder control, pelvic floor muscle exercises, fluid management, and weight loss. Behavioral interventions may not eliminate all symptoms but lead to significant reductions of symptoms and improve the quality of life of most patients. Pharmacological therapy may be used in combination with behavioral intervention or as a second line treatment. Antimuscarinic drugs or anticholinergics lead to significant improvement in the patient symptoms but are commonly associated with side effects as dry mouth, blurred vision, urinary retention and infection, dyspepsia, and impaired cognitive function. Patients who fail behavioral and pharmacological therapy, who do not tolerate its side effects, or are not candidates for conservative therapy and still have bothersome symptoms, may be offered alternative invasive measures. These include invasive surgical procedures e.g. bladder denervation, detrusor myomectomy, urinary diversion, bladder augmentation, neobladder construction, and others. Surgical procedures have variable cure rates and adverse events. Other less invasive options include detrusor injection with botulinum toxin (BTX), and pelvic neuromodulation therapy (Ridout 2010, Peters 2009, 2010, 2012, Gormley 2012). Pelvic neuromodulation utilizes electrical stimulation to target specific nerves in the sacral plexus that control the pelvic floor and bladder functions. Neuromodulation is either invasive using implantable sacral nerve stimulation (SNS), or minimally or noninvasive using a removable device such as transvaginal or transanal electrostimulation, magnetic stimulation, or percutaneous tibial nerve stimulation (PTNS). The specific mechanism of action is unknown, but it is thought that neuromodulation may have a direct effect on the bladder or a central effect on the micturition centers in the brain. Neuromodulation of the sacral nerve, also known as pacemaker for the bladder, uses mild electrical pulse to activate or inhibit neural reflexes by continuously stimulating the sacral nerves that innervate the pelvic floor and lower urinary tract. A unilateral lead is implanted in the vicinity of S3 nerve root and attached to a small pacemaker placed within a subdermal pocket in the buttock region. SNS therapy was found to be effective for refractory OAB but is invasive and associated with adverse events related to the implant procedure, the presence of the implant, or due to undesirable stimulation. In addition, SNS requires reoperation to replace the implantable generator due to the limited longevity of the neurostimulator. The SNS technology continues to evolve (Peters 2009, 2010, 2012, Al-Shaiji 2011, Mossdoeff-Steinhauser 2013). PTNS, also known as Stoller afferent nerve stimulation (SANS), developed by Stoller in the late 1990s, is a form of peripheral neuromodulation. It is a minimally invasive, office-based procedure that involves percutaneous insertion of a fine (34-gauge) needle at the level of the posterior tibial nerve, slightly above the medial malleolus of the ankle (the insertion point for the needle corresponds with an acupuncture point used for a variety of urinary disorders). The needle is connected to a low voltage (6V) stimulator device with 0-10mA at a fixed frequency of 20Hz. The amplitude is increased until the toes are seen to fan or the big toe to flex. The current is set at the highest tolerated level and the stimulation is

continued for 30 minutes. Neuromodulation to the pelvic floor is delivered through the S2-S4 junction of the sacral nerve plexus through the posterior tibial nerve. During the initial therapy, treatment is delivered for 30 minutes and repeated weekly for 12 weeks. OAB is a chronic disease and patients who respond to PTNS may need to receive long-term therapy in order to sustain the benefit of PTNS therapy (Peters 2009, Shaiji 2011, Burton 2012, Martinson 2013, Mossdordff-Steinhauser 2013).

PTNS was approved by the FDA in 2000 as an office-based therapy for OAB.

#### **10/01/2007: MTAC REVIEW**

##### **Urgent PC Neuromodulation System for Overactive Bladder; Percutaneous Tibial Nerve Stimulation (PTNS)**

**Evidence Conclusion:** There is insufficient evidence to determine the safety and efficacy of percutaneous tibial nerve stimulation (PTNS) for treating urinary urgency, urinary frequency and urge incontinence. No published randomized or non-randomized controlled trials were identified. This is particularly problematic because there is known to be a high placebo effect in studies evaluating treatments for urinary incontinence. Only case series were available. A team based in the Netherlands published several case series that used either the Urgent PC Neuromodulation System (Uroplasty) or a precursor of this device. The studies were conducted before FDA approval. Results of the case series on the Urgent PC were similar. Vandoninck et al. (2003), for example, reported a substantial reduction in incontinence episodes and voiding frequency at the end of treatment among patients for whom data were available. Two other case series were evaluated. Both of these utilized the PerQ Sans (UroSurge), a device similar to the Urgent PC. It is not known whether the PerQ Sans is currently commercially available in the U.S. The Ruiz (2004) and Govier (2001) case series found significant improvement in urinary incontinence symptoms. One study was conducted in the United States; two of the five authors in the U.S. study reported financial relationships with the device manufacturer. Other limitations of the case series include missing data and lack of long-term follow-up.

**Articles:** The ideal study is a randomized controlled trial comparing PTNS to a placebo and/or alternative established intervention. No randomized controlled trials or non-randomized comparison studies were identified. The search yielded only case series. Sample sizes ranged from 11 to 132, most were in the range of 35 to 55 patients. Seven out of the 10 case series identified were conducted by the same research group in the Netherlands. The articles differed on the indications for treatment (urge incontinence, overactive bladder syndrome, etc.) and the outcomes reported. The largest case series from the Netherlands team, and two other case series (one conducted in Spain, the other in the U.S.) were critically appraised. The remaining case series was excluded because they did not report clinical outcomes. A news release from Uroplasty in July 2006 stated that the company is initiating a randomized controlled trial comparing Urgent PC to anticholinergic medication for patients with symptoms of urge incontinence and urgency and frequency. The announcement did not report the expected date of study completion. *The studies critically appraised in evidence tables are:*

Vandoninck V, van Balken MR, Agro EF et al. Percutaneous tibial nerve stimulation in the treatment of overactive bladder: Urodynamic data. *Neurol Urodynam* 2003; 22: 227-232. See [Evidence Table](#). Ruiz BC, Outeirino P, Martinez PC et al. Peripheral afferent nerve stimulation for treatment of urinary tract irritative symptoms. *Eur Urol* 2004; 45: 65-67. See [Evidence Table](#). Govier FE, Litwiller S, Nitti V et al. Percutaneous afferent neuromodulation for the refractory overactive bladder: Results of a multicenter study. *J Urol* 2001; 165: 1193-1198. See [Evidence Table](#).

The use of Percutaneous Tibial Nerve Stimulation in the treatment of overactive bladder does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

#### **04/15/2013: MTAC REVIEW**

##### **Urgent PC Neuromodulation System for Overactive Bladder; Percutaneous Tibial Nerve Stimulation (PTNS)**

**Evidence Conclusion:** The larger published randomized controlled trials on the use of PTNS for overactive bladder syndrome were mainly supported by the manufacturer of the PTNS system and conducted by the same group of researchers who had financial interest and/or other relationships with the manufacture. PTNS was compared either to sham therapy or to antimuscarinic drugs. No comparisons were made versus behavioral therapy or other methods of neuromodulation as sacral nerve stimulation. There were variations between published studies in the inclusion criteria, gender, severity and duration of symptoms, previous treatments, treatment protocol, number of sessions per week during therapy, and treatment intervals during maintenance therapy. Outcome measures were mainly subjective and based on reported patient diaries. No well-conducted trials with long term follow-up and objective urodynamic outcomes were identified. Definition of response or treatment success varied between studies. Burton et al (2012), meta-analysis of randomized and prospective trials showed that the success rate varied from 37-82%. Two of the published RCTs (ORBIT and SUMiT) were

followed by reports on mid-term follow-up (12 months for ORBIT and up to 36 months for SUmIT), but only the responders to PTNS (60-70% of those receiving the PTNS therapy) were included in the follow-up studies. Studies showed that OAB symptoms worsen after discontinuation of treatment, and that maintenance therapy, is needed to avoid recurrence of symptoms.

#### Comparison of PTNS vs. Sham therapy

Peters and colleagues (2010) compared the efficacy of PTNS to sham therapy in 220 adult men and women with OAB (SUmIT trial, evidence table 1). The results showed a statistically significant improvement in bladder symptoms in the PTNS group compared to sham therapy group, with some non-serious adverse events. However, only just over half the patients (54.5%) who received the PTNS therapy showed moderate or marked response to the therapy, almost two third of the patients still had urinary urge incontinence after 12 weeks of PTNS, and more than half still complained of urinary urgency and frequency.

In another sham-controlled, but small and single-blinded trial, Finazzi-Agro and colleagues (2010) randomized 35 women with OAB who did not respond to antimuscarinic therapy to receive PTNS or a sham therapy for 12 sessions. The sessions were performed for 30 minutes three times weekly. Patients with a 50% or greater reduction in urge incontinence episodes were considered responders. The primary outcome was the percent of responders in the two groups. The results of the trial showed that 12/17 (71%) of the patients randomized to PTNS reported a 50% or greater reduction in incontinence episodes compared to none of those in the sham therapy. Improvement in the number of incontinence episodes, number of voids, voided volume, and incontinence quality of life score were statistically significant in the PTNS group but not in the sham therapy group.

#### Comparison of PTNS vs. active therapy with extended-release tolterodine

In the OrBIT trial (evidence table 2), Peters and colleagues compared the effectiveness of PTNS to extended-release tolterodine (Detrol LA) in reducing OAB symptoms. The trial included 100 adults with OAB symptoms, at least 8 voids/24 hours, and with or without a history of anticholinergic drug use. The primary outcome of the trial was the reduction in frequency of urinary voids /24 hours. The study was randomized and controlled, but it was not blinded, and the outcomes were subjective, which does not allow ruling out the placebo effect of PTNS. The patients in the two arms were observed differently during follow-up (visits were made in person for the PTNS group and by phone for the Detrol La group). The duration of follow- was only 12 weeks, the dropout rate was >15%, and analysis was not based on ITT. The study was supported by the manufacturer, and the authors had financial interest with the industry. The results of the OrBIT trial showed a significantly higher improvement in the Global Response Assessment rate with PTNS compared to Detrol LA when self-reported, but not when assessed by the investigator. There was no significant difference in the OAB symptom improvement between the two treatment groups.

**Articles:** The literature search for studies published after the 2007 MTAC review of PTNS for the treatment of overactive bladder in adults revealed four randomized controlled trials, two of which were conducted by the same group of authors (SUmIT and OrBIT trials) and two had additional publications with extended follow-up data (2 and 3 years follow-up of SUmIT were published as STEP trial). The search also identified two systematic reviews (one with a meta-analysis) of studies on the effect of PTNS for overactive bladder, and an updated Cochrane review that compared anticholinergic drug vs. non-drug active therapies for OAB in adults. The two larger trials and the meta-analysis on the effectiveness of PTNS for OAB were selected for critical appraisal: Burton C, Sajja A, Latthe PM. Effectiveness of percutaneous posterior tibial nerve stimulation for overactive bladder: a systematic review and meta-analysis. *Neurourol Urodyn*. 2012 ;31 :1206-1216. See [Evidence Table](#). MacDiarmid SA, Peters KM, Shobeiri SA, et al. Long-term durability of percutaneous tibial nerve stimulation for the treatment of overactive bladder. *J Urol*.2010; 183:234-240. See [Evidence Table](#). Peters KM, Carrico DJ, Perez-Marro RA, et al. Randomized trial of percutaneous tibial nerve stimulation versus Sham efficacy in the treatment of overactive bladder syndrome: results from the SUmIT trial. *J Urol*.2010; 183:1438-1443. See [Evidence Table](#). Peters KM, Carrico DJ, MacDiarmid SA, et al Sustained therapeutic effects of percutaneous tibial nerve stimulation: 24-month results of the STEP study. *Neurourol Urodyn* 2013; 32:24-29. See [Evidence Table](#). Peters KM, Carrico DJ, Woolridge LS Percutaneous Tibial Nerve Stimulation (PTNS) for the Long-Term Treatment of Overactive Bladder: Three-Year Results of the STEP Study. *J Urol*. 2012; Dec. See [Evidence Table](#). Peters KM, MacDiarmid SA, Woolridge LS, et al. Randomized trial of percutaneous tibial nerve stimulation versus extended-release tolterodine: results from the overactive bladder innovative therapy trial. *J Urol*.2009; 182:1055-1061. See [Evidence Table](#)

The use of Percutaneous Tibial Nerve Stimulation in the treatment of overactive bladder does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

## **Bladder Pacemaker /Sacral Nerve Stimulation for Treatment of Urinary Incontinence**

### **BACKGROUND**

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Urinary incontinence (UI) refers to an involuntary leak of urine. There are several types of UI. Stress UI, the most common form, is an involuntary leak on effort or exertion and urge UI is an involuntary leak accompanied or immediately preceded by a sense of urgency. Mixed UI is a combination of stress and urge UI. A related condition is urinary retention, the inability to completely empty the bladder. Another diagnosis is overactive bladder syndrome (OAB), an urge that occurs with us without a leak of urine, and usually occurs with increased urinary frequency and nocturia. The condition is often categorized as either OAB dry (without incontinence) or OAB wet (with incontinence). The prevalence of urinary incontinence in women is approximately 50% when defined as any urine loss and is 8-36% when limited to bothersome urine loss. About half of all cases are stress incontinence. Urinary incontinence that is severe enough it cannot be easily concealed can have a major impact on quality of life, especially if it includes urinary urgency. Severe urinary incontinence has been found to increase the risk of urinary tract infections in post-menopausal women, and the risk of falls and hip fractures in elderly women (Gray, 2005). Treatments for urge incontinence include the use of absorbent pads, bladder training/pelvic floor muscle exercises, treatment with medications (anti-cholinergic agents, antispasmodics, tricyclic antidepressants), topical estrogen, pelvic floor electrical stimulation, and surgery. The most common treatment for urinary retention is self-catheterization. Sacral nerve stimulation using an implantable device (bladder pacemaker) is proposed as an additional alternative to surgery for patients with urge incontinence, urgency-frequency symptoms or urinary retention. (It is not proposed for stress incontinence, the most common form of urinary incontinence). The InterStim Therapy for Urinary Control is an FDA-approved device developed by Medtronic. Consistent with the protocol in clinical trials, patients undergo percutaneous test stimulation in an outpatient setting before implantation. This involves insertion of an electrode into a sacral foramen. An external device produces continuous stimulation. The implantable InterStim system uses an implanted lead stimulating the appropriate sacral nerve root, most commonly S3. The proximal part of the lead is tunneled under the skin and connected to the neurostimulator which is placed in a subcutaneous pocket in the lower abdomen. The physician can use a microprocessor-based console programmer to set stimulation settings. There is also a handheld programmer that patients can use to turn the stimulator on and off, and to adjust the voltage output amplitude. The battery operating the device is expected to last 7 to 9 years. It is challenging to evaluate the efficacy of treatments for urinary incontinence because there is no gold standard for outcome assessment. In addition, there is a high placebo effect in randomized incontinence studies; as many as 30-40% of patients in placebo groups report success. The high placebo effect has been attributed to several factors including the strong subjective component in voiding dysfunction, and potentially therapeutic effects of study design components such as keeping a voiding diary and interacting with study personnel (Dmochowski, 2001). Because of the high placebo effect, in order to show that an intervention is effective, it is necessary to show that it has an impact beyond that of a placebo. Sacral nerve stimulation for urinary incontinence was reviewed by MTAC in February 1999 and February 2001. The technology did not meet MTAC evaluation criteria. An evidence update was conducted outside of MTAC in October 2002. The GHP Urology Department has requested an updated review.

#### **01/2001: MTAC REVIEW**

##### **Bladder Pacemaker /Sacral Nerve Stimulation for Treatment of Urinary Incontinence**

**Evidence Conclusion:** The Schmidt et al. study found a significant improvement in urinary incontinence symptoms at 6 months among patients who received an InterStim device compared to patients receiving standard medical treatment. This study has several threats to validity including substantial selective loss to follow-up, self-report data and lack of blinding or intention-to-treat analysis. Moreover, the research team had with financial ties to the manufacturer of the device. Due to the potential biases in this study, the existing data are insufficient to permit conclusions about the effectiveness of this technology.

**Articles:** Eleven articles were identified. Six articles were not directly relevant, did not include clinical outcomes or were review articles; five articles presented empirical data on clinical outcomes. Articles were selected based on study type. There were three randomized controlled trials (RCTs) and two case series. The three RCTs were done by a single group of investigators. Only one of the 3 RCTs were examining urinary incontinence as the outcome. An evidence table was created for this RCT: Schmidt RA, Jonas U, Oelson KA, Janknegt RA, Hassouna MM, Siegel SW, Kerrebroek for the Sacral Nerve Stimulation Study Group. J Urol 1999; 162: 352-57. See [Evidence Table](#).

The use of sacral nerve stimulation for the treatment of urinary incontinence does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

#### **10/2002: MTAC REVIEW**

##### **Bladder Pacemaker /Sacral Nerve Stimulation for Treatment of Urinary Incontinence**

**Evidence Conclusion:** The RCT that generated the three reports was done by the same multinational research team and was funded by Medtronic, the device manufacturer. All of the three first authors had financial relationships with Medtronic. The articles reviewed included the identical intervention for urology patients with

different presenting symptoms (urge incontinence, urgency-frequency and non-obstructive urinary retention) and were limited by the same biases. The RCT compared implantation of the Interstim device to standard medical treatment for 6 months, among patients who demonstrated during a 3-7-day testing period that they responded to the Interstim device. All found that sacral nerve stimulation was superior to standard medical care during the 6 months before patients in the control group were offered implantation. Bias was introduced because 1) only patients who were shown to respond to the device were included (about 45% of otherwise eligible patients); 2) Treatment was not blinded and did not allow for a placebo effect of the Interstim device and; 3) The intervention was compared to standard medical treatment, which the patients had already failed. A more valid comparison would be to implant the device in all eligible patients and randomly assign patients to receive active stimulation or no stimulation (this type of placebo control group was used in studies of biventricular pacing).

**Articles:** The search yielded 17 articles, many of which were review articles, opinion pieces, dealt with technical aspects of the procedures or addressed other, similar treatments. There were three articles on a single randomized controlled trial and five case series. The three RCT articles reported on different patient populations enrolled in the same trial (those with urge incontinence, urgency-frequency and non-obstructive urinary retention) and were all critically appraised. The Schmidt study was included in the February 2001 MTAC review. Evidence tables were created for the following articles: Schmidt RA, Jonas U, Oleson KA et al. Sacral nerve stimulation for treatment of refractory urinary urge incontinence. *J Urol* 1999; 162: 352-357. See [Evidence Table](#). Hassouna MM, Siegel SW, Lycklama AAB et al. Sacral neuromodulation in the treatment of urgency-frequency symptoms: A multicenter study on efficacy and safety. *J Urol* 2000; 163: 1849-1854. See [Evidence Table](#). Jonas U, Fowler J, Chancellor B et al. Efficacy of sacral nerve stimulation for urinary retention: Results 18 months after implantation. *J Urol* 2001 165: 15-19. See [Evidence Table](#).

The use of sacral nerve stimulation for the treatment of urinary incontinence does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

## 10/01/2007: MTAC REVIEW

### **Bladder Pacemaker /Sacral Nerve Stimulation for Treatment of Urinary Incontinence**

**Evidence Conclusion:** The RCT that generated the three reports was done by the same multinational research team and was funded by Medtronic, the device manufacturer. All of the three first authors had financial relationships with Medtronic. The articles reviewed included the identical intervention for urology patients with different presenting symptoms (urge incontinence, urgency-frequency and non-obstructive urinary retention) and were limited by the same biases. The RCT compared implantation of the InterStim device to standard medical treatment for 6 months, among patients who demonstrated in a 3-7-day testing period that they responded to the device. All found that sacral nerve stimulation was superior to standard medical care during the 6 months before patients in the control group were offered implantation. Bias was introduced because 1) only patients who were shown to respond to the device were included (about 45% of otherwise eligible patients); 2) treatment was not blinded and did not allow for a placebo effect of the InterStim device and; 3) the intervention was compared to standard medical treatment, which the patients had already failed. A more valid comparison would be to implant the device in all eligible patients and randomly assign patients to receive active stimulation or no stimulation (this type of placebo control group was used in studies of biventricular pacing). An alternative study design to evaluate the effectiveness of InterStim among patients who respond to a test trial would be to compare InterStim to a different treatment that patients had not already failed. Especially in a non-blinded study with some subjective outcomes, bias can be introduced if one group perceives that they are receiving a new and innovative treatment and the other group is receiving the same treatment they have already received. There are no new RCTs to supplement the above data.

**Articles:** The ideal study would be a randomized controlled trial comparing InterStim therapy to a placebo and/or established alternative intervention. At the time of the 2002 evidence review, conducted outside of the MTAC meeting, there were several RCTs by the same group of investigators. The RCTs compared InterStim to standard medical therapy. No new RCTs evaluating the efficacy and/or safety of the InterStim device were identified. There was one additional publication on the original RCT, evaluating psychosocial outcomes in a subset of the study population (Das et al., 2004; *Urol*). One new RCT was identified on a related topic, comparing two methods for predicting which patients would proceed to device implantation (Borawski et al., 2007). The study did not compare the effectiveness of InterStim treatment compared to placebo or an alternative treatment and was thus not reviewed further. In addition, there were several new case series with sample sizes of approximately 30 patients. Since higher grade evidence has been published, the small case series were not reviewed. *The RCTs on InterStim that have been critically appraised are* Schmidt RA, Jonas U, Oleson KA et al. for the Sacral Nerve Stimulation Study Group. *J Urol* 1999; 162: 352-57. See [Evidence Table](#). Hassouna MM, Siegel SW, Lycklama AAB et al. Sacral neuromodulation in the treatment of urgency-frequency symptoms: A multicenter study on efficacy and safety. *J Urol* 2000; 163: 1849-1854. See [Evidence Table](#). Jonas U, Fowler J, Chancellor B et al.

Efficacy of sacral nerve stimulation for urinary retention: Results 18 months after implantation. J Urol 2001 165: 15-19. See [Evidence Table](#).

The use of sacral nerve stimulation for the treatment of urinary incontinence does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

**Sacral Nerve Stimulator**

**2/11/2013: MTAC REVIEW**

**Evidence Conclusion:** Based on evidence from one randomized controlled trial and several observational studies, the Kaiser Medical Technology Assessment Team found that the evidence on the safety and efficacy of sacral nerve stimulation for treating severe fecal incontinence is of insufficient quality and quantity to determine whether sacral nerve stimulation is medically appropriate for the treatment of fecal incontinence. The best evidence comes from the randomized controlled trial conducted by Tjandra and colleagues (see below) (Kaiser 2011).

Results from a RCT that included 120 patients with severe fecal incontinence suggest that compared to optimal medical therapy patients who were treated with sacral nerve stimulation had significantly fewer incontinence episodes per week, days with incontinence, days with straining, and significantly better quality of life at 12 months. Adverse events included pain at implant site, seroma, and excessive tingling in the vaginal region. All patients in the sacral nerve stimulation group needed the program readjusted. The mean number of readjustments per person was three. Adjustments included changes in the electrode used for stimulation as well as changes in amplitude and rate. This study had several limitations: power was not assessed, results are only applicable to patients with severe incontinence, and patients included in the study were refractory to medical therapy and pelvic floor exercises, which was the control group treatment (Tjandra 2008).

Conclusion: There is limited evidence on the safety and efficacy of sacral nerve stimulation for the treatment of fecal incontinence.

**Articles:** In February 2011, Kaiser Permanente's Medical Technology Assessment Team reviewed implantable sacral nerve stimulators for fecal incontinence. The randomized controlled trial that was included in the Kaiser technology assessment was also selected for review as this was the highest quality study assessing the effects of sacral nerve stimulation for the treatment of fecal incontinence. Since the Kaiser Technology Assessment, several observational studies were identified that evaluated the effects of sacral nerve stimulation. None of these studies were selected for review as they did not compare sacral nerve stimulation to other treatments.

The following study and technology assessment were selected for review: Kaiser Permanente. Implantable sacral nerve stimulators for severe fecal incontinence. February 2011;

[http://pkc.kp.org/national/cpg/intc/topics/03\\_19\\_125.html](http://pkc.kp.org/national/cpg/intc/topics/03_19_125.html)

Accessed November 6, 2012.

The use of Sacral Nerve Stimulation for Fecal Incontinence meets the *Kaiser Permanente Medical Technology Assessment Criteria*.

**Applicable Codes**

**Considered Medically Necessary when criteria in the applicable policy statements listed above are met:**

CPT® or HCPC Codes	Description
53860	Transurethral radiofrequency micro-remodeling of the female bladder neck and proximal urethra for stress urinary incontinence
64561	Percutaneous implantation of neurostimulator electrode array; sacral nerve (transforaminal placement) including image guidance, if performed
64566	Posterior tibial neurostimulation, percutaneous needle electrode, single treatment, includes programming
64581	Incision for implantation of neurostimulator electrode array; sacral nerve (transforaminal placement)
0587T	Percutaneous implantation or replacement of integrated single device neurostimulation system including electrode array and receiver or pulse generator, including analysis, programming, and imaging guidance when performed, posterior tibial nerve
0588T	Revision or removal of integrated single device neurostimulation system including electrode array and receiver or pulse generator, including analysis, programming, and imaging guidance when performed, posterior tibial nerve



<b>E0740</b>	Nonimplanted pelvic floor electrical stimulator, complete system
<b>E0746</b>	Electromyography (EMG), biofeedback device
<b>L8603</b>	Injectable bulking agent, collagen implant, urinary tract, 2.5 ml syringe, includes shipping and necessary supplies
<b>L8604</b>	Injectable bulking agent, dextranomer/hyaluronic acid copolymer implant, urinary tract, 1 ml, includes shipping and necessary supplies
<b>L8606</b>	Injectable bulking agent, synthetic implant, urinary tract, 1 ml syringe, includes shipping and necessary supplies

**Biofeedback:**

**Non-Medicare—Considered Not Medically Necessary:**

**Medicare—Considered Medically Necessary when criteria in the applicable policy statements listed above are met**

<b>CPT® or HCPC Codes</b>	<b>Description</b>
<b>90901</b>	Biofeedback training by any modality
<b>90912</b>	Biofeedback training, perineal muscles, anorectal or urethral sphincter, including EMG and/or manometry, when performed; initial 15 minutes of one-on-one physician or other qualified health care professional contact with the patient
<b>90913</b>	Biofeedback training, perineal muscles, anorectal or urethral sphincter, including EMG and/or manometry, when performed; each additional 15 minutes of one-on-one physician or other qualified health care professional contact with the patient (List separately in addition to code for primary procedure)

**\*Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

\*\*To verify authorization requirements for a specific code by plan type, please use the [Pre-authorization Code Check](#).

CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

<b>Date Created</b>	<b>Date Reviewed</b>	<b>Date Last Revised</b>
11/1998	08/03/2010 <sup>MDCRPC</sup> , 04/05/2011 <sup>MDCRPC</sup> , 05/03/2011 <sup>MDCRPC</sup> , 12/06/2011 <sup>MDCRPC</sup> , 10/02/2012 <sup>MDCRPC</sup> , 06/04/2013 <sup>MDCRPC</sup> , 08/06/2013 <sup>MPC</sup> , 11/05/2013 <sup>MPC</sup> , 09/02/2014 <sup>MPC</sup> , 07/07/2015 <sup>MPC</sup> , 05/03/2016 <sup>MPC</sup> , 03/07/2017 <sup>MPC</sup> , 01/09/2018 <sup>MPC</sup> , 12/04/2018 <sup>MPC</sup> , 12/03/2019 <sup>MPC</sup> , 12/01/2020 <sup>MPC</sup> , 12/07/2021 <sup>MPC</sup> , 12/06/2022 <sup>MPC</sup>	11/13/2023

<sup>MDCRPC</sup> Medical Director Clinical Review and Policy Committee

<sup>MPC</sup> Medical Policy Committee

<b>Revision History</b>	<b>Description</b>
09/08/2015	Revised LCD L35008 and 34886
06/28/2015	Added coverage article A52965
03/07/2017	MPC approved criteria for PTNS
12/02/2022	Added Retired LCD 14443
11/13/2023	Updated Medicare coverage article link A52965, which has been retired as of 11/1/23.