



CIGNA HEALTHCARE COVERAGE POSITION

Subject Surgical Interventions for Urinary Incontinence

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Table of Contents

Coverage Position.....	1
General Background	1
Coding/Billing Information	9
References.....	10

Hyperlink to Related Coverage Positions

Biofeedback
 Electrical Stimulators
 Extracorporeal Electromagnetic Stimulation for Urinary Incontinence
 Injectable Bulking Agents for Urinary Conditions
 Physical Therapy
 Sacral Nerve Stimulation for Urinary Voiding Dysfunction

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Coverage Position

CIGNA HealthCare covers ANY of the following surgical interventions as medically necessary for the treatment of stress, urge or mixed urinary incontinence, when there is failure, contraindication or intolerance to conservative medical management:

- suburethral plication
- anterior colporrhaphy
- retropubic urethropexy (RPU)
- pubovaginal slings (e.g., bulbourethral sling, tension-free vaginal tape [TVT], transobturator tape [TOT])

CIGNA HealthCare does not cover transvaginal radiofrequency/microwave surgery for the treatment of urinary incontinence because it is considered experimental, investigational or unproven.

General Background

Urinary incontinence (UI) is defined by the International Continence Society (ICS) as the complaint of any involuntary leakage of urine. This definition encompasses both the symptomatology that may be reported

by the patient and objective, physician-observed demonstrations of urine loss. Urinary incontinence is a widespread problem, affecting men and women of all ages.

Urinary voiding disorders are generally divided into five types of incontinence depending on the pathophysiology involved: urge, overflow, stress, mixed, and functional. In urge incontinence, urine leakage results from the inability to inhibit the voiding reflex consciously. A subtype of this condition, urgency-frequency syndrome, is characterized by uncontrollable urgency without urine loss and the need to void more than seven times per day. Overflow incontinence, or urinary retention, is a condition in which the bladder overfills without causing the sensation of the need to urinate. Stress incontinence is characterized by the leakage of urine during physical activities that increases pressure on the bladder. Mixed incontinence refers to a combination of urge and stress incontinence. Functional incontinence refers to the inability of a person to reach the bathroom due to chronic impairment of physical or mental functioning.

Diagnostic evaluation for UI may include a complete history and physical, urinalysis, and cystometrogram with urodynamic tests, including Q-tip test, postvoid residual volume (PVR) measurement, voiding diary and pad test. If urge incontinence is diagnosed, then the initial management may include the use of estrogen therapy (if deficient), bladder training, pharmacotherapy, and/or physiotherapy with biofeedback. First-line therapy for stress urinary incontinence (SUI) includes estrogen therapy (if deficient), pelvic floor muscle exercises, pharmacotherapy, and physiotherapy with biofeedback and sacral nerve stimulators. When mixed incontinence is diagnosed, the first-line treatment focuses on the main or predominant complaint of urge or stress incontinence (Ogundele, 2006).

If established medical treatments fail to improve the condition, surgical intervention may be necessary. Three types of procedures have been established as safe and effective for the surgical correction or improvement of urinary incontinence: a suburethral plication, a shelf or repositioning type of procedure, or a pubovaginal sling. The selection of the anti-incontinence procedure is determined by many factors, including the need for other concomitant abdominal or vaginal procedures to correct pelvic organ prolapse; history of previous SUI surgery; urethral hypermobility; and the physical health of the individual (Ogundele, 2006; Rackley, 2006; Fenner, 2003).

For patients with stress incontinence due to urethral hypermobility, a colposuspension type of procedure may be done. The hypermobility is managed with a “urethral hammock” support, such as a Marshall-Marchetti-Krantz (MMK), a Burch or a paravaginal repair. The surgical goal for these patients is to elevate and stabilize the urethra-vesical junction (UVJ). If intrinsic sphincter deficiency (ISD) is the cause of the incontinence, then a pubovaginal sling procedure may be done to restore compression and coaptation of the damaged urethral sphincteric mechanism (Rackley, 2006; Fenner, 2003).

Suburethral Plication/Anterior Colporrhaphy

Suburethral plication, or Kelly-Kennedy plication, is accomplished through an anterior vaginal incision: a series of plicating mattress sutures of either permanent or delayed-absorbable material is surgically placed beneath the UVJ, and any subsequent pubocervical fascial defect that may exist below the urethra and bladder is included. This surgical approach has been reported to have more than a 90% patient-reported success rate, with literature reports of success ranging from 31–69% with a one- to five-year follow-up (Fenner, 2003).

An anterior vaginal repair remains indicated in the treatment of a cystocele caused by central fascial defect. Complications from this surgery may include hemorrhage, vaginal foreshortening, and suture misplacement in the bladder, urethra or ureter (Fenner, 2003).

Colposuspension has been compared with anterior colporrhaphy and with needle suspension procedures. After one year, results favor colposuspension; the results reveal an even stronger difference at three years (88% vs. 57% for anterior colporrhaphy) and 14 years (74% vs. 42%, respectively). It was not noted whether these outcome measures were obtained using subjective or objective measures (Rakel, 2005).

Retropubic Urethropexy (RPU)

RPU procedures for the treatment of SUI have been used since 1949, when the first MMK procedure was done. This surgery involves the placement of several nonabsorbable sutures close to the urethra and

through the pubocervical fascia. The sutures are then anchored to the fibrocartilage of the symphysis pubis, thus elevating the bladder neck. Success rates for MMK have been reported as high as 96%, with reports of detrusor hyperactivity, voiding dysfunction and osteitis pubis reported as complications (Fenner, 2003; Royal College of Obstetrics and Gynecology [RCOG], 2003). Another commonly used RPU is the Burch procedure, which differs from the MMK by the placement of permanent sutures in a figure-eight pattern bilaterally at the UVJ and midurethra. Instead of the sutures being anchored in the fibrocartilage of the symphysis pubis, they are anchored to Cooper's ligament. The Burch procedure has the best long-term continence results (85–90% at one year and 70% at five years) and therefore has become the standard treatment for SUI caused by hypermobility (Ward, 2002; RCOG, 2003; Valpas, 2004).

The Burch procedure can also be accomplished laparoscopically, with similar success rates to the open procedure reported when the suturing techniques were not altered. Continence rates of 85% at six months and 100% at 18 months were reported by RCOG in a meta-analysis that compared the open Burch to the laparoscopic Burch procedure. There were no significant differences between the two groups for postoperative detrusor overactivity or voiding difficulty (RCOG, 2003).

Suburethral plication, anterior colporrhaphy, and retropubic urethropexy are recognized within published textbooks and evidence-based peer-reviewed literature as accepted standards of care for the treatment of urinary incontinence.

Sling Procedures

Pubovaginal Slings: Pubovaginal sling procedures mobilize the bladder neck, often by a vaginal or vaginal/abdominal approach, and allow the interposition of a strip of material (e.g., autologous fascia, cadaveric fascia, xenografts or synthetic [e.g., marlex or mersilene mesh]) under the urethra surrounding the bladder neck. The sling is then attached to an abdominal site at the level of the anterior rectus fascia. The sling is then sutured to maintain its position under the urethra and trigone. Once sutured, the sling is adjusted to gently elevate the urethra. Failures are attributable to inaccurate placement at the bladder neck, inadequate sling tension, poor tissue graft, or inadequate fascial attachment. Postsurgical voiding failure occurs in approximately 20% of all patients. If spontaneous voiding cannot be accomplished by six weeks after surgery, sling revision may be required. Sling procedures are currently being used in patients with intrinsic urethral deficiency and/or genuine stress urinary incontinence, with reported success rates of 85–90% (Fenner, 2003; Sutherland, 2004; Rakel, 2005).

Bulbourethral Slings: Bulbourethral slings may be used to treat SUI in men with urinary incontinence due to sphincter deficiency following prostate surgery for cancer or benign prostatic hypertrophy. These slings may also be used to treat intrinsic sphincter deficiency (ISD) that can result from neurological injuries. Sling techniques may involve the use of perineal mesh with bone anchors or suprapubic suspension of the bulbous urethra to obtain continence.

In 2001, Romano introduced a new sling for use in the treatment of urinary incontinence for men. The Argus[®] (Promedon SA, Cordoba, Argentina) system consists of a 4.2 x 2.6 x 0.9 centimeter (cm) thick silicone foam pad that compresses the bulbar urethra. This pad is attached to silicone cone columns that are passed with needles from the perineum to the abdominal wall; silicone rings are then threaded over the columns and tension against the urethra can be regulated. The pads and rings are radio-opaque and can therefore be assessed after placement to document their location. Studies are currently underway regarding the efficacy and durability of this device.

Gynecare[™] Tension-Free Vaginal Tape (TVT) System: The TVT procedure is a modification of the pubovaginal sling, in that the placement of the sling is at the midurethra and not at the UVJ. The sling is made of a prolene mesh that is held in place by friction and not sutured to the anterior rectus fascia. This is a relatively noninvasive procedure that can be done under local or regional anesthesia on an outpatient basis (Fenner, 2003).

In the early 1990s, Petros and Ulmsten proposed the theory that the midurethra should be supported, not elevated or obstructed, in order to cure SUI effectively. They developed the TVT procedure, which involves placing a loosely knitted synthetic polypropylene mesh sling (Gynecare[™] Tension Free Vaginal

Tape System [TVT], Ethicon, Somerville, NJ) at the midurethra. The sling is held in place by friction, not sutures.

A sagittal incision is made in the vaginal wall, one centimeter from the urethral meatus. The mesh, which is wrapped in plastic, is then blindly passed behind the pubic symphysis and up through two suprapubic incisions, where the ends are tied and cut at the skin level. A visual examination of the bladder occurs through the use of a cystoscope to immediately determine the existence of any bladder injury. The patient is asked to cough in order to check for any leakage of fluid from the meatus and also to guide the degree of tension that is placed on the mesh. The patient is then discharged home and can resume regular activities approximately two weeks after the procedure.

Success rates for vaginal taping in patients with hypermobility and a functioning urethra are comparable to established procedures, approaching 90% after a five-year follow-up. There have been reports of perforations of the bladder in as many as 19% of the women who have undergone this procedure after previous incontinence surgeries. Cure rates of 74%, with additional improvement in 12% after a four-year follow-up, have also been reported for a small group of women with ISD (Fenner, 2003).

Mentor™ Trans-Obturator Tape (TOT): As an alternative to the TVT procedure, the trans-obturator tape (TOT) procedure for the treatment of SUI was developed by Delorme in 2001. Using an outside-in needle placement during this procedure, a polypropylene mesh is placed at the midurethra. This mesh may be a monofilament or a polypropylene weave with varying densities (e.g., Monarc™ or the Mentor, ObTape™). The proposed advantage of this procedure over the TVT procedure is the avoidance of a transpelvic introduction. By avoiding this approach, a decrease in significant complications of bladder, bowel and/or vascular injury should occur.

TOT can be performed under local or general anesthesia, on an outpatient basis. The tape is introduced using an “outside-in” approach and has been reported to have similar continence outcomes to the TVT procedure.

The National Institutes of Health (NIH) have several studies currently underway that will compare the efficacy and morbidity following the use of two variations of sling procedures (i.e., the retropubic TVT vs. the trans-obturator [TVT-O] approach). Patient recruitment is underway, and participants will be followed for several years after the surgery to obtain objective surgical outcomes on the management of urodynamic stress urinary incontinence (NIH, 2006).

U.S. Food and Drug Administration (FDA): In 2001, the FDA granted 510(k) Class II device approval for the Gynecare™ Tension Free Vaginal Tape (TVT) System manufactured by Gynecare, a division of Ethicon, Inc., Somerville, NJ. This pubourethral sling is indicated for the treatment of stress urinary incontinence (SUI), for female urinary incontinence (UI) resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

Numerous other pubourethral slings have also received 510(k) approval based on their equivalence to the Gynecare™ TVT predicate device. Some of these include: the Biosling™ (Injetx, Inc., San Jose, CA), the SAFYRE® Vaginal Sling and Tape (Promedon SA, Hopkinton, MA), the Advantage® Transvaginal Mid-Urethral Sling System (Boston Scientific, Boston, MA), the T-Sling® (Herniamesh USA, Inc.), the SPARC™ Sling System (American Medical Systems, Minnetonka, MN), the MONARC™ Sling System (American Medical Systems, Inc., Minnetonka, MN), the Mentor™ ObTape Trans-obturator Tape and Introducers (Mentor Corporation, Santa Barbara, CA), and the Minimesh® polypropylene mesh (Mpathy Medical Devices, Ltd., Fairfield, CT) (this list may not be all-inclusive).

Literature Review of Sling Procedures: Bezerra et al. (2006) reported in a Cochrane meta-analysis, their findings on comparing the effects of a traditional suburethral sling on stress incontinence alone or stress with other types of urinary (mixed) incontinence with other management options. Thirteen trials were reviewed that included 760 women, 627 of whom were treated with suburethral slings. The sling procedures were compared to the Burch/Marshall-Marchetti-Krantz; none were compared to anterior repair or artificial sphincters. The authors concluded that there was limited reporting of outcomes (e.g., general health status, return to normal activity, pad testing); the heterogeneity of the populations being studied; the types of comparisons and the size of the trials also varied. Due to this lack of reliable

evidence, a conclusion could not be made concerning the effectiveness of one type of sling procedure versus another or whether a sling procedure was superior to another type of surgical or medical intervention.

Moser et al. (2006) reported on a retrospective cohort study of 63 women who had needle suspension surgery for SUI between 1986 and 1991. The aim of this study was to evaluate the objective and subjective results of needle suspension on the bladder neck after a follow-up of 11 to 16 years. Moser and his colleagues found the objective outcome rates to be higher than the subjective rates (i.e., 56% vs. 41%, respectively). Of the individuals studied, 38% (24/63) considered themselves completely cured, while another 30% (19/63) considered their SUI improved. During this time, seven patients had undergone additional surgery for recurrent SUI, and the researchers counted these individuals as treatment failures. The researchers concluded that determining the success or failure of these procedures requires both the objective and subjective evaluation of the patient, due to varying definitions of SUI, study methodology, variances within patient populations and different modifications of standard procedures. Future studies should include the collection of quality-of-life data prior to the original surgery in order for long-term outcomes to be collected.

In 2006, Romano and colleagues reported the results of a Phase III multicenter trial using a new adjustable male sling (i.e., Argus[®], Promedon, SA, Cordoba, Argentina) for the treatment of urinary incontinence caused by prostate surgery. The Argus was implanted into 48 men with moderate to severe SUI that had persisted for more than one year despite pharmacological therapy, perineal exercises and other conservative medical management. The patients were evaluated at one and three months, and then every three months. Prior to implantation, the patients had mean retrograde leak-point pressure (LPP) levels of 23.5 centimeters of water (cmH₂O), and after surgery these levels were measured as 47.5 cmH₂O. The patients rated their satisfaction with their surgical results via a standardized questionnaire, the International Consultation on Incontinence Questionnaire-Short Form (ICIQ-SF), as 19.2 prior to surgery and four following the procedure. At the time of follow-up (mean=7.5 months), 35 patients were dry, five were improved, and eight were incontinent. Complications included three urethral perforations that occurred at the time of surgery. Five slings had to be removed, three due to erosion and two due to infection. The researchers concluded that additional studies are needed to standardize the exact pressure level that should be applied to obtain continence while decreasing the risk of urethral obstruction; standardization of the procedure needs to occur for ease of duplication, while long-term durability data is needed to determine the efficacy of this device.

Dobson et al. (2006) reported the first year results of a prospective, cohort study that they conducted on 52 women who underwent the TOT procedure for SUI between December 2003 and April 2004. During this study, seven women were lost to follow-up, and 34 of the remaining patients returned for their physical exam to document objective physical, postoperative findings. The researchers reported that 15% of the 52 women had erosions of the mesh material; 30% of the 34 women who attended the physical exam follow-up review had some pelvic tenderness with palpation; and 18% reported urge incontinence. Dobson and his colleagues questioned the effect of using a nonknitted, nonwoven mesh with a small pore size (<50 μm) that may restrict the passage of macrophages and fibroblasts. As a result of these physical findings, the researchers are conducting an additional study that will use the TOT approach with a mesh pore size of 75 μm in order to evaluate the potential improvements in erosion outcomes.

A multi-institutional study was conducted by Morey and colleagues (2006) comparing the outcomes of TOT procedures using the Monarc and ObTape slings as compared to the outcomes of using the Transabdominal (TA) slings (e.g., TVT and the SPARC[™]). During this retrospective chart review of 504 women who had been treated for SUI using these procedures (n=154 TO and 350 TA), the researchers focused on and compared the complication rates that were documented within these two groups. The overall complication rate was 16.1%, with post-void residual (PVR) being the most common obstructive finding. The researchers did find that the TO approach was associated with fewer obstructive complications (17 of 154, 11.0%) than the TA approach (64 of 350, 18.3%); concomitant surgery did not increase the incidence of complications, and intraoperative complications were rare. The researchers concluded that, although their study was retrospective and small in nature, the TO sling appears to be a promising new option for the treatment of SUI. Additional prospective studies are needed to define the advantages and disadvantages of this new technique.

Lee et al. (2007) conducted a prospective trial to compare the safety and effectiveness of TVT and transobturator TVT-O for the surgical treatment of SUI. A total of 120 women with SUI were alternately assigned to each group (n= 60—TVT and 60—TVT-O). Patient characteristics were similar in both groups, and each group reported significantly improved quality of life via patient questionnaires at the end of one year post-surgery. No long-term complications were noted; pre-operative urge incontinence resolved in 80% of the TVT patients and 100% in the TVT-O patients. De novo urgency developed in four patients in the TVT-O group. The researchers concluded that both procedures are minimally invasive and similar in operation-related morbidity. The TVT-O procedure appeared to be as effective and safe as TVT for the surgical treatment of SUI.

In a retrospective review that compared two versions of TVT-O tapes, Abdel-Fattah et al. (2006) determined that of 316 women who underwent surgical treatment with vaginal tape, 16 developed tape erosion. Fourteen of these patients underwent surgical intervention with partial tape removal or vaginal refashioning and remained continent at their three month follow-up. Two patients declined additional surgery. None of the patients within this study group developed urethral erosions. The authors concluded that the present study supports the use of mesh in suburethral tapes. In cases of tape erosion and in the absence of clinical signs of infection, excision of the eroded portion of the tape only, under antibiotic cover, as women are more likely to remain continent following partial tape excision.

The Ontario Health Technology Advisory Committee (OHTAC, 2006) published their recommendations concerning the use of midurethral slings for women with SUI. These recommendations were based on the results of seven randomized controlled trials, which all had consistent results; midurethral slings appear to be as effective as open colposuspension and more effective than laparoscopic colposuspension. All slings appear to be, at this time, equal in terms of effectiveness.

In 2005, the National Institute for Health and Clinical Excellence (NICE) published a review of the literature regarding the use of TOT surgery for SUI. Within this review, although the results appeared promising and there was a lack of long-term outcomes results, use of this procedure should include a full disclosure of potential obturator nerve damage as well as other complications. Surgeons were encouraged to closely follow all patients receiving this procedure and to document patient outcomes for data review. In December 2005, NICE withdrew this recommendation and is currently re-evaluating the studies that have occurred to date regarding the use of this procedure.

Valpas et al. (2004) conducted a multicenter, randomized, two-arm study in Finland to compare objective and subjective outcomes of TVT versus laparoscopic mesh colposuspension (Burch) as a primary treatment for female SUI. Cure measurements were based on outcomes of a stress test and the 48-hour pad test. One hundred and twenty-eight women with urodynamically confirmed stress incontinence were randomized into two treatment groups. Seventy were treated with the TVT procedure and 51 with laparoscopic Burch (mesh colposuspension). Exclusion criteria included:

- age > 70 years
- previous incontinence surgery
- more than three episodes of urinary tract infection within the last two years
- coincident other gynecological surgery
- body mass index > 32 kilograms per meter (kg/m²)
- urethral closure pressure < 20 cm H₂O
- preoperative urodynamic residual volume > 100 ml

Although open colposuspension (Burch procedure) is regarded as the gold standard for operative treatment of SUI in women, a laparoscopic approach was used in this study (Valpas, 2004). Patients were randomized via a computer dial-in system, and the severity of their incontinence was quantified via a visual analog scale, the Urinary Incontinence Severity Score and a version of the King's College Health Questionnaire. Surgical outcomes were:

- a negative stress test in 60 (85.7%) of the TVT group and 29 (56.9%) of the laparoscopic mesh group
- a negative pad test in 51 (72.9%) of the TVT patients and 30 (58.8%) of the mesh group patients

After one year of follow-up, Valpas and colleagues reported results were comparable for these two procedures. This study was not designed to determine the efficacy of TVT compared to that of the Burch procedure.

Nilsson et al. (2004) conducted a prospective, observational, three-center study of 90 women who had undergone the TVT procedure for SUI. The study goal was to determine the surgical effectiveness of this procedure using subjective and objective outcome measures. The researchers were able to locate 80 women. Sixteen were interviewed by telephone only, while the remaining 64 were both interviewed and physically examined. Fifty-four women (84.4%) had negative pad tests; seven (10.9%) had a positive result (range: 10–132 g per 24 hours); and three women refused to perform the pad test. The objective cure rate was reported as 81.3%. Eighty-eight percent of the women felt their quality of life was unchanged over the previous five years; only 5% felt improved; and 8% felt their condition had become worse. The seven-year results were reported as comparable to those of the open Burch procedure (81.3% versus 70–80%, respectively).

Stanton (2004) conducted a literature review of all midurethral tape procedures and the studies conducted on each. The clinical studies were small in size and had short-term follow-up; thus, they could not provide a statistically significant clinical comparison. Only one randomized clinical study has compared TVT with colposuspension.

In 2002, Rardin et al. conducted a 27-month retrospective, multicenter study of 245 consecutive women who were treated with TVT for genuine SUI. Cure rates among patients with recurrent versus primary SUI were similar (85% vs. 87%, respectively); complication rates were similar (4.5% vs. 7.6%); and postoperative voiding dysfunction occurred in both groups. Success and failure rates were both measured by patient-reported questionnaire and took into account the absence of urine leakage, the return of urinary incontinence and the need for additional surgery. Bladder perforation was the most commonly reported intraoperative complication. Other complications included surgical site and pelvic hematomas, abscesses, and vaginal graft erosion. This study was retrospective, had a small sample size, lacked a control group, and based the outcomes of success on patient-response questionnaires.

Ward et al. (2002) conducted a prospective, multicenter, randomized trial comparing the surgical outcomes of TVT to those of colposuspension as primary treatment for SUI in the United Kingdom and Ireland. Three hundred and forty-four women with urodynamically documented SUI who had completed their families participated. One hundred and seventy-five patients had the TVT procedure (according to Ulmsten's method), while 169 patients were randomized to undergo a colposuspension. Exclusion criteria included:

- detrusor overactivity
- vaginal prolapse requiring additional treatment
- previous prolapse or incontinence surgery
- major degree of voiding dysfunction (defined by cystometry as voiding pressure > 50 cm H₂O, maximum flow < 15 ml/s, and residual urine volume > 100 ml)
- neurological disease
- allergy to local anesthesia

All patients were followed for 15 months. Success was measured by patient questionnaire, clinical examination, one-hour pad test and urodynamic studies. Secondary success measures included subjective cure of incontinence versus the development of voiding problems, urge symptoms and vaginal prolapse. Objective cure outcomes showed negative pad test and negative cystometry in 115 (66%) of the TVT group and 97 (57%) of the colposuspension group. Subjective findings showed no significant difference in the patient-perceived success of the surgeries at six months: 63 (36%) in the TVT group versus 48 (28%) in the culposuspension group. Intraoperative complications occurred more frequently in the TVT group and consisted of bladder injuries, vaginal perforations and tape erosion, while in the colposuspension group, the only postoperative complication reported was urinary retention. After six months of follow-up, this study showed outcome results of TVT versus colposuspension (the gold

standard) to be comparable. The researchers have indicated that follow-up is planned at the end of five years.

In 2001, the Australian Safety and Efficacy Register of New Interventional Procedures-Surgical (ASERNIP/S) published a systematic review of tension-free urethropexy for stress urinary incontinence, comparing an intravaginal slingplasty or the TVT procedure to the gold standard procedures for treating stress incontinence (i.e., the Burch colposuspension and pubovaginal sling). The review concluded that the safety and efficacy of the TVT procedure cannot be determined, due to the incompleteness and poor quality of evidence-based studies. Further research is needed to establish the safety and efficacy of this procedure (Merlin, 2001).

Ulmsten et al. (1999) provided a three-year follow-up report on 50 women who underwent the TVT procedure. Forty-three women (86%) were completely cured, as measured by the absence of reported stress incontinence, a negative pad test and a > 90% quality-of-life improvement per patient-reported questionnaire. Six women improved significantly, and surgery failed in one patient. Postoperative catheterization was required by five women, with one woman requiring an indwelling catheter for 12 days. Although a high success rate was reported in this study, outcomes were based on patient response questionnaires; there was no control group; and outcomes of success did not include a comparison to an existing gold standard surgical procedure.

Summary of Sling Procedures: Pubovaginal slings have been documented as having equivalent efficacy rates when compared to a Burch or colposuspension within the evidence-based, peer-reviewed literature. Modifications of these procedures (e.g., transvaginal and obturator tapes) have also been documented as having equivalent efficacy rates for the treatment of urinary incontinence. The long-term durability of these devices is the focus of ongoing studies.

Transvaginal Radiofrequency/Microwave Surgery

In an attempt to decrease patient morbidity and to provide a minimally invasive procedure for the cure of stress urinary incontinence, radiofrequency energy, as a distinct form of electromagnetic energy, has been applied to strengthen the endopelvic fascia. Recently, this treatment was applied via a laparoscopic approach to the endopelvic fascia to induce fascial shrinkage or contraction with minimal safety concerns in women with genuine stress urinary incontinence. This procedure is now being conducted using a transvaginal delivery system, on an outpatient basis.

During this procedure, a two-to-three centimeter incision is made lateral to the urethra, through the full thickness of the vaginal mucosa at the level of the midurethra. Once the anterior aspect of the endopelvic fascia is exposed, the surgeon then repeats this process exposing the endopelvic fascia contralaterally. Radiofrequency thermal energy, using the SURx Transvaginal System (SURX, Inc. Livermore, California) is then applied evenly over the exposed fascia. The proposed mechanism of effect is shrinkage of the collagenated tissue which composes the endopelvic fascia that supports the bladder neck and proximal urethra, thus stabilizing these structures.

Additional studies and ongoing analysis of the safety and long-term efficacy of this surgical technique have been proposed in the peer-reviewed literature. This procedure may have a role in the treatment of young patients where repeat procedures may be anticipated, or in very frail patients. The efficacy of this procedure in patients with severe SUI has been poor to date (O'Shaughnessy, 2007).

U.S. Food and Drug Administration (FDA): In January, 2002 the FDA approved the SURx Laparoscopic Probe (LP) Radio Frequency (RF) System (manufactured by SURX, Inc., Livermore, CA) as a class II device for the 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. This 510(k) approval was based on its equivalence to other predicate electrosurgical devices.

Literature Review of Transvaginal Radiofrequency/Microwave Surgery: Dmochowski et al. (2003) reported on a prospective, multicenter single-arm, nonrandomized, investigational device exemption study of the safety and efficacy of using transvaginal radiofrequency for the treatment of Type I or II SUI due to hypermobility in 120 women. At the end of one year, following the procedure, the researchers reported a cure/improved rate of 76% as a result of urodynamic evaluation and/or patient surveys. While

reviewing the outcomes, the researchers noted that different techniques of applying the thermal energy had occurred; one was a consistent application of heat while the other incorporated numerous on/off applications. Moisture (i.e., serum or blood) within the surgical field also caused a diffusion of thermal energy which negatively impacted the treatment outcomes. The researchers also questioned the long-term efficacy of the therapy and suggested that additional studies be conducted to measure long-term effectiveness as well as standardize the treatment protocols.

Summary of the Transvaginal Radiofrequency/Microwave Surgery: There is limited evidence within the peer-reviewed literature that supports the use of transvaginal radiofrequency/microwave surgery. Additional studies are needed to determine patient selection criteria and the long-term safety and efficacy of this procedure in the treatment of urinary incontinence.

Professional Societies/Organizations

American Urogynecologic Society (AUS): The AUS published in 2003 a summary of surgical interventions that may be used to treat incontinence. These included bladder suspensions (e.g., BURCH [open or laparoscopic], MMK, cystocele repairs and sling procedures.

American Urological Association (AUA): In 1997, the AUA published their clinical recommendations for the treatment of stress urinary incontinence. Within these guides, the association recognized the use of retropubic suspensions and slings as being efficacious in the treatment of SUI, with anterior repairs having short-term duration effectiveness.

Summary

For the treatment of urinary incontinence, the evidence-based, peer-reviewed literature and textbooks provide support for a number of well-established surgical interventions, including suburethral plication, anterior colporrhaphy, retropubic urethropexy (RPU) and pubovaginal slings. Laparoscopic approaches for some of these procedures have been introduced, with surgical continence outcomes equivalent to those of the gold standard procedures.

There is minimal evidence within the peer-reviewed literature or textbooks that provide support for the use of transvaginal radiofrequency surgery. The efficacy and long-term effectiveness of transvaginal radiofrequency surgery for the treatment of urinary incontinence has not been determined.

Coding/Billing Information

Note: This list of codes may not be all-inclusive.

Covered when medically necessary:

CPT [®] * Codes	Description
51800	Cystoplasty or cystourethroplasty, plastic operation on bladder and/or vesical neck (anterior Y-plasty, vesical fundus resection), any procedure, with or without wedge resection of posterior vesical neck
51820	Cystourethroplasty with unilateral or bilateral ureteroneocystostomy
51840	Anterior vesicourethropexy, or urethropexy (eg, Marshall-Marchetti-Kranz, Burch); simple
51841	Anterior vesicourethropexy, or urethropexy (eg, Marshall-Marchetti-Kranz, Burch); complicated (eg, secondary repair)
51845	Abdomino-vaginal vesical neck suspension, with or without endoscopic control (eg, Stamey, Raz, modified Pereyra)
51990	Laparoscopy, surgical; urethral suspension for stress incontinence
51992	Laparoscopic sling operation for stress incontinence (eg, fascia or synthetic)
57240	Anterior colporrhaphy, repair of cystocele with or without repair of urethrocele
57287	Removal or revision of sling for stress incontinence (eg, fascia or synthetic)
57288	Sling operation for stress incontinence (eg, fascia or synthetic)

HCPSC Codes	Description
	No specific codes

ICD-9-CM Diagnosis Codes	Description
618.01	Cystocele female midline (without uterine prolapse)
618.02	Cystocele female lateral (without uterine prolapse)
618.03	Urethrocele
618.05	Perineocele
625.6	Female stress incontinence
788.30	Unspecified urinary incontinence
788.31	Urge incontinence
788.32	Stress incontinence, male
788.33	Mixed incontinence urge and stress (male)(female)
788.34	Incontinence without sensory awareness
788.35	Post-void dribbling
788.36	Nocturnal enuresis
788.37	Continuous leakage
788.38	Overflow incontinence
788.39	Other urinary incontinence

***Current Procedural Terminology (CPT®) © 2006 American Medical Association: Chicago, IL.**

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