



Cigna Medical Coverage Policy

Subject Invasive Treatments for Urinary Incontinence

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Coverage Policy

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

- anterior colporrhaphy with bladder neck (Kelly-Kennedy) plication
- retropubic suspension (e.g., retropubic urethropexy, Burch procedure)
- sling procedure (e.g., pubovaginal/suburethral sling; midurethral sling [transvaginal tapes (TVT), transobturator slings (TOT)]; bulbourethral sling)
- artificial urinary sphincter implantation due to reduced outlet resistance (intrinsic sphincter deficiency) following prostate surgery

Cigna covers the removal of a urinary incontinence repair device as medically necessary for intolerance to or failure of the device.

Cigna does not cover ANY of the following for the treatment of urinary incontinence because each is considered experimental, investigational or unproven:

- transvaginal radiofrequency/microwave surgery (e.g., SURx Transvaginal System)
- transurethral radiofrequency tissue micro-remodeling (e.g., Renessa® System)

- adjustable continence therapy (e.g., ACT[®], ProACT[™])
 - percutaneous tibial nerve stimulation (PTNS) (Urgent[®] PC Neuromodulation System)
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General Background

Urinary incontinence is the involuntary loss of urine. It is not a disease but rather a symptom that can be caused by a wide range of conditions. There are several types of incontinence:

- Stress incontinence is the most common type of leakage. This occurs when urine is lost during activities such as walking, aerobics or even sneezing and coughing. The primary causes are urethral sphincter weakness "intrinsic sphincter deficiency" or a hypermobile urethra. "Urethral hypermobility" occurs when there is weakness of pelvic floor and poor support of the vesicourethral sphincter unit. The proximal urethra can be displaced outside the abdominal pressure zone during straining.
- Urge incontinence, often referred to as "overactive bladder," is another form of leakage. This can happen when a person has an uncontrollable urge to urinate but cannot reach the bathroom in time.
- Overflow incontinence occurs when the bladder is full, is unable to empty and leaks. Frequent small urinations and constant dribbling are symptoms. This is rare in women and more common in men with a history of surgery or prostate problems.
- Functional incontinence is the inability to access a proper facility or urinal container because of physical or mental disability.
- Mixed incontinence refers to a combination of types of incontinence; most commonly stress and urge incontinence.

If conservative medical treatments such as bladder training, pelvic floor muscle exercises, biofeedback, medication or injectable bulking agents fail to improve the condition, additional intervention may be necessary. Several procedures have been developed to treat stress incontinence. Sling procedures are the most common invasive treatment for stress incontinence.

Anterior Colporrhaphy with bladder Neck (Kelly-Kennedy) Plication / Retropubic Suspension (e.g., retropubic urethropexy, Burch procedure)

Anterior colporrhaphy or vaginal wall repair is surgery that tightens the front anterior wall of the vagina. It is done to help with the sinking of the bladder into the vagina (cystocele), or the sinking of the urethra into the vagina (urethrocele or urethral hypermobility). Most descriptions of the technique involve not only plication sutures in the pubocervical fascia underneath the cystocele but also sutures into the attenuated fascia at the level of the bladder neck and urethra to buttress the hypermobile urethra from below. On its own, it is not recommended as a surgical procedure for stress incontinence. Its importance now is that it is has been incorporated into other transvaginal repairs that are done for incontinence to address an anterior midline support defect. Retropubic suspension uses sutures to support the bladder neck. The most common retropubic suspension procedure is called the Burch procedure. In this operation, the surgeon makes an incision in the abdomen a few inches below the navel and then secures the sutures to strong ligaments within the pelvis to support the urethral sphincter. This common procedure is often done at the time of an abdominal procedure such as a hysterectomy.

Literature Review: Anterior colporrhaphy with bladder neck (Kelly-Kennedy) plication has been reported to have more than a 90% patient-reported success rate when followed for five to ten years in patients showing an almost complete loss of posterior urethrovesical (PUV) angle; only 50% of patients with lesser PUV angle loss remained continent over that period. However, after the introduction of retropubic suspension (e.g., retropubic urethropexy, Burch procedure) operations, the 5-year cure rate for these latter patients surpassed 90% in most series. The initial suspension procedure was the Marshall-Marchetti-Krantz (MMK) with success rates reported as high as 96%, with reports of detrusor hyperactivity, voiding dysfunction and osteitis pubis reported as complications. 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 (Katz, 2007; Valpas, et al., 2004; Ward and Hilton, 2002). Continence rates of 85% at six months and 100% at 18 months were reported by Royal College of Obstetricians and Gynecologists (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). Anterior colporrhaphy with bladder neck (Kelly-Kennedy) plication and retropubic suspension (e.g., retropubic urethropexy, Burch

procedure) are recognized within published textbooks and evidence-based peer-reviewed literature as accepted standards of care for the treatment of urinary incontinence. Although more than 100 surgical procedures have been described for the treatment of stress incontinence, gold-standard procedures include the Burch colposuspension and the fascial sling.

Sling Procedures (e.g., pubovaginal/suburethral sling; midurethral sling [transvaginal tapes (TVT), transobturator slings (TOT)]; bulbourethral sling)

Pubovaginal (suburethral) sling procedures are performed through a vaginal incision and use a strip of tissue/fascia or mesh to support the bladder neck. Although slings have traditionally been used in patients who fail primary incontinence surgery, they are becoming more common than primary procedures. Midurethral slings are newer procedures that use synthetic mesh materials that the surgeon places midway along the urethra. The two general types of midurethral slings are retropubic slings, such as the transvaginal tapes (TVT), and transobturator slings (TOT). The TVT procedure involves placing a loosely knitted synthetic polypropylene mesh sling at the midurethra. 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 polypropylene mesh that is held in place by friction and not sutured to the anterior rectus fascia. As an alternative to the TVT procedure, the TOT procedure was developed. 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. The proposed advantage of this procedure over the TVT procedure is the avoidance of a transpelvic introduction. The bulbourethral sling surgery for men requires an incision to be made between the scrotum and rectum. In this procedure, a sling is placed beneath the urethra to support it and is attached to either muscle tissue or the pubic bone. The sling compresses and elevates the urethra, giving the urethra greater resistance to pressure from the abdomen. Men often need to use a catheter to empty their bladders for a short time after this surgery. The bulbourethral sling is usually for men who have lost their urethral sphincter function because of prostate treatment, other surgery, or trauma.

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 slings have also received 510(k) approval based on their equivalence to the Gynecare™ TVT predicate device. Some have intended use for just women while others have intended use for both men and women. Examples of FDA-approved sling devices include: 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 and the MiniArc 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), Male REMEEEX System (Specialities Remeex International, Spain), Coloplast VIRTUE Male Sling System (Coloplast Corporation, Denmark) (this list is not all-inclusive). Some sling devices are intended for both males and females. For example, I-STOP® sling from CL Medical (Sainte Foy Les Lyon, France) is a surgical mesh intended to be used as a sub-urethral sling implant for the treatment of male stress urinary incontinence post-prostatectomy. And for females: for the treatment of urinary stress incontinence due to intrinsic sphincter deficiency and/or intrinsic sphincter deficiency. In October 2008, the FDA released a warning position statement concerning the use of mesh materials in stress incontinence surgery and pelvic organ prolapse surgery, noting more than 1,000 reported complications of vaginal and urinary erosion as well as bowel and vascular injuries.

Literature Review: Randomized controlled trials comparing slings to colposuspension demonstrate no significant difference in cure or complication rates (Jelovsek, et al., 2008; Ward, et al., 2008; Albo, et al., 2007; Sivaslioglu, et al., 2007). The majority of randomized controlled trials comparing tension-free vaginal tape (TVT) and tension-free obturator tape (TVT-O) demonstrate no statistical significant differences concerning the efficacy or complication rates of these techniques (Karateke, et al., 2009; Barber, et al., 2008; Rinne, et al., 2008; Liapis, et al., 2008). Teo et al. (2011) conducted a randomized trial including 127 women. TVT and TVT-O were equally effective based on objective and subjective cure rates. However, more women complained of leg pain after receiving a tension-free vaginal tape-obturator (26.4% vs. 1.7%, p = 0.0001). This finding is statically significant.

In a randomized controlled trial (RCT), Hinoul et al. (2011) compared incision mid urethral tape and an established transobturator procedure. A total of 96 patients received a TVT Secur™ single incision sling and 98 received a TVT™ Obturator System. The primary outcome measure was the stress urinary incontinence (SUI) objective cure rate during 12-month follow-up using repeated measurement analysis. Objective cure was measured by a standing cough stress test with a bladder volume of 300 cc or greater than 70% of maximal bladder capacity according to the patient voiding diary. One-year follow-up was available for 75 single incision sling and 85 obturator system cases. SUI was subjectively reported by 24% of single incision sling and 8% of obturator system patients ($p < 0.05$). Patients with a single incision sling experienced significantly less pain during the first 2 weeks after surgery ($p < 0.05$) and returned significantly earlier to normal daily activity. The major trial limitation was the significant loss to follow-up of patients in the TVT Secur group.

In a Cochrane systematic review, Rehman et al. (2011) compared suburethral slings with other management options, concluding “there is not enough information on which to judge whether traditional sling operations are better or worse than any other treatments. Long term results are awaited. In this review there were few trials, of high quality, comparing slings with other forms of surgery and only one study comparing sling operations with non-surgical treatment.”

Male slings provide an alternative surgical treatment for patients with post-prostatectomy incontinence who are not artificial urinary sphincter (AUS) candidates or who elect not to undergo AUS placement. As with women, there are various types of slings used in males. There are less well-designed studies regard male slings. However, studies have demonstrated male slings effectively control sphincter incontinence in men after prostate surgery, with an acceptably low complication rate (Bauer, et al., 2011; Davies, et al., 2009; John, et al., 2008; Romano et al 2006).

Artificial Urinary Sphincter (AUS)

An AUS is an inflatable cuff that is placed around the urethra and an inflation pump placed in the scrotum or labia. It is primarily used in men following prostate treatment, but also is proposed in women and children with intractable urinary incontinence (e.g., neuropathic bladder, exstrophy/epispadias). All patients must understand the potential complications of the operation and the possibility of future surgical interventions as the long-term reoperation rate is about 20%. The device is proposed to mimic the function of a natural sphincter by keeping tension on the urethra, preventing the flow of urine. A patient squeezes the pump to release the pressure to allow voiding of the bladder. The valve automatically re-tightens itself several minutes later. AUS placement is a successful treatment for up to nine out of ten men who have incontinence after prostate removal. Reported complications with this surgery include the need for additional surgery, or revision. After ten years, about six out of ten men require another surgery. Infection surrounding the prosthesis, erosion of the cuff, and mechanical insufficiency of the device are the main reasons for additional surgery (Staskin and Comiter, 2007; Elliott and Barrett, 1998; Diokno, et al., 1987).

FDA: The AMS Sphincter 800™ Urinary Prosthesis/Control System (American Medical Systems, Inc., Minnetonka, Minnesota) was granted PMA approval June 2001. It is used to treat urinary incontinence due to reduced outlet resistance (intrinsic sphincter deficiency) following prostate surgery. This device is contraindicated in patients:

- whom the physician determines to be poor candidates for surgical procedures and/or anesthesia due to physical or mental conditions
- with urinary incontinence due to or complicated by an irreversibly obstructed lower urinary tract with irresolvable detrusor hyperreflexia or bladder instability

In May 2011, American Medical Systems voluntarily recalled AMS 800® Control Pumps for certain lot numbers.

Literature Review/ Men, following prostate surgery: The AUS is a FDA-approved device intended to treat urinary incontinence due to intrinsic sphincter deficiency following prostate surgery, when other conservative treatments have failed. The majority of studies in peer-reviewed scientific literature suggest that AUS is a safe and effective option for intractable urinary incontinence due to intrinsic sphincter deficiency after prostate surgery (O’Conner, et al., 2008; Kim, et al., 2008; Trigo-Rocha, et al., 2008; Lai, et al., 2007; Imamoglu, et al., 2005). It is utilized when other treatments have failed as it has a long-term reoperation rate of about 20%.

Imamoglu et al. (2005) randomized 45 males with post-prostatectomy incontinence to compare implantation of AUS and macroplastique injection.

The patients had undergone radical retropubic prostatectomy (RRP) (n=12), transvesical prostatectomy (TVP) (n=16), transurethral prostatectomy (TURP) (n=16), and TURP with TVP (n=1). Patients were divided into two groups as minimal (Group I) and total incontinence (Group II) according to the severity of incontinence. Respectively, Group I (n=21) and Group II (n=24) patients were randomized as AUS implantation (n=11, n=11) and macroplastique injection (n=10, n=13). They had urethral pressure profiles (UPP) below 20 cmH₂O and leak point pressures (LPP) below 40 cmH₂O. There was no statistically significant difference between patients with AUS implantation and those with macroplastique injection considering UPP (5–15 cmH₂O) or LPP (0–20 cmH₂O). There was no statistical difference in the mean age between patients who underwent AUS implantation (64 years) and patients who underwent Macroplastique injection (62 years). Follow-up period was 48 months in patients with macroplastique injection and 60 months in AUS implantation. When comparisons between the preoperative and postoperative values of the criteria used to evaluate success such as average pad weight, average number of pads and quality of life scores, both in patients with minimal and total incontinence, there were differences of statistical significance (p<0.05). Total cure rate was 90.9% in Group I and 72.7% in Group II. There was no statistically significant difference in the Group I between two techniques (p<0.2). However, when this comparison was made for Group II there was a significant difference favoring AUS implantation (p<0.01). The authors concluded that in patients with minimal incontinence similar success rates were obtained from the two techniques with a randomized approach; however, in total incontinence AUS implantation had statistically significant success over endourethral injection.

Literature Review/ Men, other: Chartier Kastler et al. (2011) performed a long-term retrospective study in adult male patients with a neurogenic bladder. The median follow-up was just under seven years (83 months). Of 51 patients, 31% (16/51) had spina bifida and 69% (35/51) had spinal cord injury. The AUS was activated, on average, one month after implantation. At the study end, 15 (29.4%) patients had dropped out, 11 of whom had a working AUS in place. The average follow-up time for the drop-outs was 72 months. At the endpoint 27 (52.9%) patients had an AUS in place and working. For 50%, there was no refitting of the AUS before six years. At 10 years, 74% (37/50) of the patients had a working AUS. Half of the patients had at least one added procedure in the five years following the first AUS implantation. The average AUS lifespan for the patients at the endpoint was 88 months. Post-operative morbidity was observed in 19% (10/50) of the patients (8 urinary tract infection, 1 failure to perform self-intermittent catheterizations [SIC], 1 intracranial hypertension, [a myelomeningocele patient]). A primary study limitation is the retrospective design.

Literature Review/ Women and Children: The AUS has become a standard treatment in women and children with urinary incontinence due to intrinsic sphincter deficiency who have failed conservative and other surgical therapies (e.g., neuropathic bladder dysfunction; congenital, mainly exstrophy; hysterectomy, radiotherapy; pelvic trauma). However, the AUS is not FDA-approved for use in women and children and therefore is considered experimental, investigational or unproven if implanted in women or children. Most studies are small in sample size and lack randomization, a control group or comparator, due to the fact that AUS is used when other treatments have failed in women (Diokno, et al, 1987; Thomas, et al., 2002; Petero, et al., 2005; Chung, et al., 2010) and children (Simeoni, et al., 1996; Kryger, et al., 1999; Hafez, et al., 2002; Herdon, et al., 2003; Ruiz, et al., 2006).

Chung et al. (2010) retrospectively reported on 47 women who received an AUS. The mean follow-up was 13.5 years with no patients lost to follow-up. Comparison of the proportion of AUS device survival over time using Kaplan–Meier analysis showed > 80% of AUS remained functioning after 100 months. Of the women in whom AUS were still in situ, the continence rate with no pads use was 59% with AUS only, which increased to 85% when concurrent clean intermittent self-catheterization (CISC) was performed. A total of 2% of women remained incontinent with AUS despite prescribed anticholinergic or CISC.

Petero et al. (2005) retrospectively reported on results of AUS implantation in men and women. Of 126 consecutive patients who received an AUS for the treatment of stress incontinence, 108 patients (53 men, 55 women), and 168 devices (88 in men, 80 in women) were available for evaluation. Of the 55 women, 49 (89%) had previous pelvic surgeries for incontinence, including 39 (71%) with 2 or more procedures. Three had previous failed AUS (1 implanted elsewhere and 2 with AUS model other than AMS 800™). Mean follow-up was 8.1 years. Of the 108 patients 18 (40%) men and 31 (56%) women had no complications. Of the 168 devices 76 (45%) eventually failed (44 or 50% in men, 32 or 40% in women, p = 0.19). Median device durations were 6.9

and 11.2 years in men and women, respectively ($p = 0.002$). Satisfactory continence was achieved in 82% of patients, in 43 (81%) men and in 46 (84%) women ($p = 0.73$), including 33 (62%) men and 39 (71%) women who required 1 pad or less a day. Satisfactory continence rates between men and women were not significantly different ($p = 0.73$). However, women had a statistically significant better dry rate (0 pad use) compared to men (35 or 64% in women vs. 5 or 9% in men, $p = 0.01$). The erosion rates between men and women were not significantly different ($p = 0.243$). Median duration of the original implanted device in 53 men is 5.0 years and in 55 women is 11.2 years ($p = 0.001$). For all devices median duration in men is 6.9 years and in women is 11.2 years ($p = 0.002$).

Thomas et al. (2002) retrospectively reported on 68 female patients who were followed for a median time of 12 years after AUS insertion. Overall 25 patients (37%) had the original AUS in situ and were dry at a median follow-up of 7 years. The AUS was replaced for loss of function in 12 patients, of whom 11 were dry with the replaced device. The device was removed for erosion or infection in 31 patients, of whom 19 underwent successful replacement or were continent after removal. Overall 55 of 68 patients (81%) were continent. Those with neuropathic bladder dysfunction achieved a continence rate of greater than 90%, although half required sphincter removal initially. When the indication for insertion was stress incontinence, 70% of the patients had the original or a replaced AUS in situ and 82% were continent. All patients with previous pelvic irradiation had the sphincter removed and urinary diversion was done. No statistical values were presented. Ten- to 15-year long-term follow-up of the artificial urinary sphincter in children has been reported. All groups report a continence rate of 80% and a functioning sphincter in 95% of patients. Herndon et al. (2003) retrospectively reported achieving overall continence in 86% of 142 patients with an average follow-up of 10 years. Age at implementation does not appear to affect continence. The AUS is not FDA-approved for use in women and children and therefore is considered experimental, investigational or unproven.

Radiofrequency Energy

Radiofrequency energy (RF) is used for a variety of disorders. It can be used to ablate obstructive or hemorrhagic tissue to the point of necrosis with or without shrinkage with subsequent relief of symptoms or, used at lower temperatures to denature collagen leading to altered tissue compliance without necrosis or gross shrinkage. Researchers have proposed the use of RF technique to shrink and stabilize the endopelvic fascia, thus improving the support for the urethra and bladder neck. Two radiofrequency devices have been specifically designed for the treatment of urinary stress incontinence that can be performed as outpatient procedures under general anesthesia. With the SURx Transvaginal System (SURx, Inc., Livermore, California), an incision is made through the vagina lateral to the urethra, exposing the endopelvic fascia. Radiofrequency energy is then applied over the endopelvic fascia in a slow sweeping manner, resulting in blanching and shrinkage of the tissue. This procedure is similar in concept to thermal capsulorrhaphy as a treatment of shoulder instability. The Renessa[®] procedure (Novasys Medical Inc., Newark, California) induces collagen denaturation in the urethra with a specially designed 4 needle radiofrequency probe. Transurethral treatment changes the collagen at microscopic sites targeted within the bladder neck and areas within the urethral submucosa. The low-level RF energy is believed to strengthen the sphincter without destroying the tissue, by heating only small areas around the probe tip to a specified temperature at which collagen begins the denaturation process.

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. It is no longer marketed in the United States. Novasys Medical, Inc. received 510(k) approval from the FDA for the Novasys Transurethral RF System (Renessa System) in July 2005. It is indicated for the transurethral treatment of stress urinary incontinence due to hypermobility in women who have failed conservative treatment and who are not candidates for surgical therapy (FDA, 2005).

Literature Review/ Transvaginal Radiofrequency Energy: 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.

Two small retrospective studies were published to assess the outcomes of transvaginal radiofrequency for the treatment of women with stress incontinence (Ismail, 2008; Buchsbaum, 2007). Buchsbaum and colleagues reported on 18 women and noted a low cure rate and low patient satisfaction. They reported that two patients were continent, four improved, and ten unimproved and that five patients were extremely satisfied, one patient was satisfied and ten were not satisfied with the results. Seven patients sought additional treatment within one year. The results of the study conducted by Ismail in 2008 concurred. The results of 24 women who had received transvaginal radiofrequency for stress incontinence demonstrated low effectiveness. A rising failure rate was noted at three months postoperative. At 12 months, the cumulative cure rate was 45.8% and the re-operation rate was 37.5%. Both groups of researchers have discontinued this procedure as a treatment option.

Literature Review/ Transurethral Radiofrequency Energy: The California Technology Assessment Forum evaluated Radiofrequency Micro-remodeling for the Treatment of Female Stress Urinary Incontinence (October, 2008). The CTAF stated “while RF micro-remodeling (Renessa) for SUI does not show as high success rates as the gold standard approaches (Burch and TVT), it does demonstrate a good safety profile and moderate improvement in objective urinary leakage and quality of life, particularly for women with moderate to severe SUI. Some questions remain, including whether there is drop-off in improvement over time and how much, and whether women who undergo RF micro-remodeling (Renessa) can subsequently undergo other SUI procedures such as the Burch and TVT without undo complication, and confirmation in larger studies that RF micro-remodeling (Renessa) can be comfortably undergone as a simple office procedure with local anesthesia and oral analgesia/sedation. It is recommended that radiofrequency micro-remodeling with the Renessa system meets CTAF criteria 1-5 for safety, effectiveness and improvement in health outcomes for the treatment of moderate to severe female stress urinary incontinence in non-pregnant women who are either not able or not willing to undergo surgery for their SUI treatment.”

Elser et al. (2010) conducted a prospective study including 136 women with stress urinary incontinence caused by bladder outlet hypermobility who had failed non-surgical treatment and were not considered good surgical candidates or wished to avoid or postpone surgery. A transurethral collagen denaturation procedure was performed in a physician's office or ambulatory treatment center. Patients kept voiding diaries and completed surveys. At 18 months, 63 women attended the 18-month follow-up visit, with data available for 60 patients. Intent-to-treat (ITT) analysis was completed on 136 women. At 18 months, 46.7% of patients in the ITT population and 61.7% of patients evaluated reported a reduction of at least 50% from baseline in leaks due to activity. This study is limited by the large loss to follow-up (total attrition rate by 18 months in this trial was 48%).

Lenihan et al. (2005), Appell et al. (2006), and Appell et al. (2007) reported on a randomized controlled trial (RCT) that included the same 173 patients. Appell et al. (2006) conducted a randomized controlled trial to demonstrate the safety and efficacy of non-surgical, transurethral radiofrequency (RF) micro-remodeling in the treatment of female stress urinary incontinence (SUI). A total of 173 women with SUI were enrolled and randomized to receive RF micro-remodeling (n=110) or sham treatment (brief bladder catheterization) (n=63). Efficacy was measured using I-QOL and leak point pressure (LPP) testing at 12 months. No serious adverse events were reported. At 12 months, the evaluable population for the quality of life outcome analysis included 142 women (82% of enrolled), 89 in the treatment (80.1%) and 53 in the sham treatment (84.1%) arm. Ignoring baseline SUI severity, 48% of all treatment arm and 44% of all sham treatment arm subjects demonstrated ≥ 10 point I-QOL score improvement at 12 months ($p=0.7$). Seventy-four percent of women suffering from moderate to severe SUI experienced ≥ 10 point I-QOL score improvement at 12 months following RF micro-remodeling versus 50% of women who underwent sham treatment ($p=0.03$). This was statistically significant. Twenty two percent of women with mild SUI experienced a ≥ 10 point I-QOL score improvement at 12 months following micro-remodeling treatment versus 35% of women who underwent sham treatment ($p=0.2$). Statistical significance was not achieved for the entire treatment versus sham treatment population due to the high sham treatment arm “placebo effect” which was particularly pronounced (relative to treatment arm results) in women with mild baseline SUI. At 12 months, the evaluable population for the leak point pressure (LPP) analysis included 136 women (78.6% of enrolled), 87 in the treatment (79.1%) and 49 in the sham treatment (77.8%) arm. Women who underwent RF micro-remodeling demonstrated an increase in mean LPP at 12 months (13.2 ± 39.2 cm H₂O), while women who underwent sham treatment demonstrated a reduction in mean LPP at 12 months (-2.0 ± 33.8 cm H₂O), and the difference in mean LPP change between the two arms was statistically significant ($p=0.02$). A limitation of this trial is loss to follow-up of 18%. In 2007, a retrospective three-year evaluation of the

2006 trial patients was conducted by Appell and colleagues. Of the original 110 women in the treatment group of the original study, 18 were evaluable (completed three day diaries). Of the 18, 50% of these patients had achieved a 50% or greater reduction in incontinence episode frequency. There were no new reports of serious adverse events.

Sotomayor and Bernal (2003) conducted an initial human study to determine the safety and quality of life impact of transurethral RF micro-remodeling of the proximal urethral and bladder outlet in women suffering from stress urinary incontinence. The data from 37 patients were analyzed and reported. The 37 patients were divided into four different groups dependent on the number of RF lesions administered (Group I, n=8, 24 lesions; Group II, n=9, 36 lesions; Group III, n=11, 48 lesions; Group IV, n=9, 60 lesions). All subjects completed a urinary incontinence quality of life questionnaire (I-QOL) at baseline, one month, three months, and six months. No serious adverse events were noted at any time. At six months, 75–80% of patients in all four groups had demonstrated improvement in quality of life with statistically significant elevations in mean I-QOL score compared to baseline in two groups (Group II $p = 0.004$; Group IV $p = 0.02$). The authors also noted that 22–75% of patients in all groups reported being dry (i.e., no incontinence episodes and no pad use in the three months prior to the six month follow-up visit) at six months with a statistically significant decrease in mean incontinence frequency for Group II ($p < 0.05$) and Group IV ($p < 0.005$) and a statistically significant decrease in mean pad use for group IV ($p < 0.04$). In 2005, Sotomayor and Bernal reported on the 12 month follow-up results of the 2003 study. I-QOL scores at 12 months ranged from 75–80% and statistically significant incontinence episode frequency was demonstrated in three of the four treatment groups. There were no serious adverse events reported. The limitations of these studies, including the small sample size, lack of control, long term data, and the lack of urodynamic testing at baseline or follow-up, does not allow for a determination to be made regarding the safety and efficacy of this approach in the treatment of stress incontinence.

Adjustable Continenence Therapy

The Adjustable Continenence Therapy (ACT[®]) device (for women) and the ProACT[™] device (for men) (Uromedica, Inc., Minnetonka, MN, USA) consists of two silicone balloons placed at either side of the bladder neck. Each balloon is attached to a titanium port, aiming to achieve continence through static extrinsic compression and support of the urethra. The balloons is purported to help protect against accidental leaking of urine by increasing the amount of pressure required to urinate. When the patient needs to urinate, a normal amount of effort is still required to push the urine out. It is proposed the pressure from the balloons will help guard against unintentional urine loss, such as during a sneeze or cough.

FDA: The Adjustable Continenence Therapy (ACT[®]) device (for women) and the ProACT[™] device (for men) (Uromedica, Inc., Minnetonka, MN, USA) are currently in clinical trials and not FDA-approved.

Literature Review: Data supporting the ACT[®] device for women and the ProACT[™] device for men are lacking. Most studies are small in sample size and lack randomization, a control group or comparator, due to the fact that ACT is used when other treatments have failed. A number of case series (n= 37-128) of patients with neurogenic (Mehnert, et al., 2012) or post-prostatectomy (Roupret, et al., 2011; Gregoria, et al., 2010) stress incontinence have reported improvement rates of 54%- 68% in a follow-up period of 48-60 months. Adverse events have included erosion/migration, infection and device failure.

In a prospective study, Aboseif et al. (2010) performed percutaneous placement of the ACT device in female patients with moderate to severe SUI who failed at least one surgical treatment (sling, Burch, suspension, AUS). A total of 89 patients have undergone implantation with 1–3 years of follow-up. Data are available on 77 patients at one year. Of the patients, 47% were dry at one year and 92% improved after one-year follow-up. Quality of life questionnaire scores improved from 33.9 to 71.6 at one year ($p < 0.001$). The mean number of adjustment visits prior to one year was 2.03. Explantation was required in 21.7% of patients with 50% of those patients re-implanted before one year, while 28% were awaiting re-implantation and 22% had been explanted permanently. The authors stated “our hypothesis is that in some instances, the balloon is placed closer (in some cases, maybe too close) to the urethra or bladder, and so requires less filling to reach continence but also results in a higher incidence of perioperative perforations and postoperative complications leading to explantations.”

In a prospective multicenter trial, Lebret et al. (2008) assessed the safety and efficacy of the ProACT system in the treatment of stress urinary incontinence (SUI) after prostate surgery. All 62 patients had failed previous rehabilitation (including pelvic floor training and electrostimulation). Daily pad usage decreased from a mean of 4.6 per day (range, 1 to 10) before surgery to 1.8 per day at 6 months (range, 0 to 10) and 1.06 per day (range 0

to 6) at 1 year after surgery. After 6 months (adjustments completed) 71% of the patients were wearing no pads or 1 pad per day (including security pads). Among the 44 patients who had RP without adjuvant radiotherapy, 89% improved, including 30% of patients becoming pad free. Conversely, for the 12 patients with adjuvant radiotherapy before ProACT implantation the failure rate was 83%. A total of 19 patients required explantation due to device-related problems (2), infection or erosion (5), migration (1), iatrogenic traumatism (2), or nonresponse (9). Of these patients, 4 were reimplanted with ProACT balloons, and 2 went on to have artificial urinary sphincters implanted.

In a prospective longitudinal trial, 80 consecutive men who had undergone either ProACT (n = 44) or bone anchored male sling (n = 36) for post prostatectomy incontinence were followed (Crivellaro, et al., 2008). The two procedures were carried out in two different centers by two different surgeons. All men had significant stress urinary incontinence for at least one year after radical prostatectomy and the incontinence had persisted despite conservative measures (pharmacotherapy or kegel exercises). All patients with urge incontinence or pre-existing voiding dysfunction were excluded from the study. At a mean follow-up of 19 and 33 months respectively, 30/44 (68%) patients treated with ProACT were dry in comparison with 23/36 (64%) patients treated with a sling ($p > 0.05$). Stratifying the results, ProACT had 33/39 (85%) dry patients in severe (more than three pads/day) preoperative incontinence, in comparison with 21/26 (81%) for the sling ($p > 0.05$). The authors noted their results indicate a significant improvement in urinary incontinence and quality of life improvement in patients undergoing these procedures based on pre-operative degree of incontinence. ProACT results seem to be better for moderate to severe incontinence and a bone anchor sling for mild incontinence. The complication rate was higher for ProACT (13% vs. 5%, $p > 0.05$), primarily reflecting the development and refinement of the new surgical technique and its instrumentation.

Hübner et al. (2007) retrospectively reported on the use of ProACT in 100 men. The authors compared the results of the first 50 men they operated on with the results of the latest group of 50 men they have operated on, noting their "learning curve" and the evolution of the use of the device. All patients in both groups had undergone a radical prostatectomy as their primary operation for prostatic cancer. Observed were changes in pad use and incontinence quality of life (I-QOL) with a mean follow-up of 23 months in group 1 and 20 months in group 2. Complications requiring revision surgery occurred in 29 of 50 patients (58%; total 49 revision surgeries) of group 1 and in 12 patients (24%; total 16 revision surgeries) of group 2. There was a high rate of primary non-response in the first 50 patients (20 of 50, 40%) as the operation and implants evolved. All of these patients proceeded to using an AUS. In group 2 there were four cases (8%) of primary non-response requiring explantation, with two of these proceeding to bulbar urethral slings and two proceeding to implantation with the AUS. Overall, group 2 patients had more consistent outcomes in pad use reduction compared to group 1 (80% vs. 60% dry or >50% improved) and the number of non-responding patients was also dramatically reduced in group 2 compared to group 1 (16% vs. 40%). The authors note that although the "reference standard" for the treatment of severe incontinence remains the AUS, a place exists for a minimally invasive alternative, especially for men who may not have sufficient fine-motor control or the motivation to operate the implanted pump used with the AUS.

Well-designed comparative trials are needed to demonstrate safety and efficacy of the device as compared to other surgical incontinence treatments such as the artificial urinary sphincter.

Percutaneous Tibial Nerve Stimulation (PTNS)

The Urgent[®] PC Neuromodulation System (Uroplasty, Inc., Minneapolis, MN) is a minimally invasive neuromodulation system designed to deliver retrograde access to the sacral nerve through percutaneous electrical stimulation of the tibial nerve. It is performed in a physician office. The method of treatment is referred to as percutaneous tibial nerve stimulation (PTNS). The mechanism of action in neuromodulation of the bladder is not precisely understood, but neuromodulation likely interrupts abnormal reflex neurologic arcs, thus improving coordination of the detrusor and sphincter muscles. The majority of research in percutaneous tibial nerve stimulation (PTNS) has been for the treatment of overactive bladder (OAB) and/or urges incontinence. OAB is the current term used to describe urgency symptoms and/or urge incontinence. PTNS was developed as a less-invasive alternative to sacral nerve stimulation. A needle electrode is inserted at a depth of 3 to 4 cm near the tibial nerve at the medial malleolus. The needle is connected to a low-voltage, adjustable, hand-held stimulator, which sends an electrical impulse through the tibial nerve (Blue Cross and Blue Shield, 2011).

FDA: Urgent[®] PC Neuromodulation System (Uroplasty, Inc., Minneapolis, MN) was FDA-approved October 2005. The Urgent PC Neuromodulation System delivers PTNS, and is intended to treat patients with overactive bladder and associated symptoms of urinary urgency, urinary frequency, and urge incontinence.

Literature Review: PTNS has been evaluated primarily for overactive bladder syndrome in RCTs and systematic reviews/meta-analysis. An RCT by Peters et al. (2013) reported safety and efficacy results of PTNS for overactive bladder after three years of therapy. Patients (n=50) in the randomized, double-blind SUmIT (Sham Effectiveness in Treatment of Overactive Bladder Symptoms) Trial who met the primary effectiveness end point after 12 weekly percutaneous tibial nerve stimulation treatments were enrolled in this prospective study to assess long-term outcomes. Subjects in this STEP (Sustained Therapeutic Effects of Percutaneous Tibial Nerve Stimulation) Study were prescribed a fixed schedule 14-week tapering protocol followed by an individual treatment plan aimed at sustaining overactive bladder symptom improvement. A total of 29 patients completed the 36-month protocol. Statistical analysis estimated that 77% of patients maintained moderate or marked improvement in overactive bladder symptoms at three-year follow-up. Compared to baseline, the frequency of median voids per day, urge incontinence episodes, and nighttime voids, decreased significantly (all $p < 0.0001$). All quality of life parameters remained markedly improved from baseline through three years ($p < 0.0001$). Limitations of this study include the small patient population and loss to follow-up.

The Agency for Healthcare Research and Quality (AHRQ) published a 2012 comparative effectiveness review of nonsurgical treatments for urinary incontinence in adult women. The clinical effects of PTNS were examined in four RCTs. These study result indicated that PTNS improved urinary incontinence compared to sham treatment. No RCTs compared continence after PTNS versus sham stimulation in adults with UI. Evidence from one study was insufficient to conclude better effectiveness of PTNS compared to medication (AHRQ, 2012).

A systematic review and meta-analysis (n=16 studies/940 subjects) by Burton et al. (2012) evaluated the effectiveness of posterior PTNS in treating overactive bladder symptoms. Studies included RCTs (n=6), and prospective, non-comparative studies (n=10). PTNS was compared to sham in four RCTs showing a significant difference favoring PTNS [RR 7.02 95% confidence interval (CI) 1.69-29.17]. PTNS was compared to anticholinergic medication in two RCTs with no significant difference in the change in bladder diary parameters between the treatments. The pooled subjective success rate was 61.4% (95% CI 57.5-71.8) and objective success rate was 60.6% (95% CI 49.2-74.7). Although there was evidence of significant improvement in overactive bladder symptoms comparable to the effect of anticholinergic medication, the studies included in the review only considered short-term outcomes after initial treatment. The review summarized that in order to recommend PTNS as a practical treatment option, long-term data and health economic analysis are needed.

Monga et al. (2012) performed a systematic review of the evidence for a range of electrical stimulation therapies in the treatment of lower urinary tract symptoms. Of the 72 studies reviewed, a total of 16 evaluated PTNS. These included prospective case series (n=13) and randomized comparative studies (n=3). Findings indicated that median mean reductions in incontinence episodes and voiding frequency were similar for implanted SNS and PTNS, with median mean values of 72 and 66% for incontinence episodes and median mean values of 40 and 32.5% for voiding frequency for SNS and PTNS, respectively. However it was determined that additional long-term follow-up studies are needed to validate the ability of this therapy to produce sustained benefit (Monga, et al., 2012).

Peters et al. (2010) conducted a RCT comparing the efficacy of PTNS to sham through 12 weeks of therapy. The eligibility criteria included a score of at least four on the overactive bladder questionnaire (OAB-q) short form for urgency, self-reported bladder symptoms lasting at least three months, and failure of conservative management. A total of 220 patients were randomized, 110 to the PTNS group and 110 to the sham group. Females accounted for 86 (78.2%) of the PTNS subjects and 88 (80.0%) of the sham subjects. The sham group underwent stimulation through a TENS unit with no needle insertion. Both groups received 12 weekly 30-minute intervention sessions. The 12-week course of treatment was completed by 103 of 110 (94%) in the PTNS group and 105 of 110 (95%) in the sham group. Global response assessment (GRA) at 13 weeks compared to baseline for overall bladder symptoms improvement demonstrated 60/103 (58.3%) for PTNS and 23/105 (21.9%) for sham (< 0.001). This is statistically significant. In total, six PTNS subjects reported nine mild or moderate treatment related adverse events consisting of ankle bruising (1 of 110, 0.9%), discomfort at the needle site (2 of 110, 1.8%), bleeding at the needle site (3 of 110, 2.7%) and tingling in the leg (1 of 110, 0.9%). No local treatment related adverse events were reported in the sham group. In addition, no systemic adverse events were experienced in either group. The authors concluded that PTNS therapy is safe and effective in

treating OAB symptoms. Limitations of the SUMiT trial include the primary outcome measured used was a single response, patient-reported global response assessment (GRA); there is short follow-up of three months.

Finazzi-Agro et al. (2010) also performed a RCT comparing PTNS with a sham. A total of 35 female patients presenting with detrusor overactivity incontinence that did not respond to anti-muscarinic therapy were randomly assigned to percutaneous tibial nerve stimulation or to a control group. The percutaneous tibial nerve stimulation group (18 patients) was treated with 12 percutaneous tibial nerve stimulation sessions. The control group (17 patients) received an original placebo treatment using a 34 gauge needle placed in the medial part of the gastrocnemius muscle. Patients showing a reduction in urge incontinence episodes greater than 50% were considered responders. PTNS was performed 3 times per week for 4 weeks. The primary outcome for this study was the percent responders, defined as a greater than 50% reduction in incontinent episodes. This endpoint was reached by 71% (12/17) of patients in the PTNS group, compared with 0% (0/15) in the placebo group ($p < 0.001$). No serious side effects were reported in either group but patients in both groups reported occasional transient pain at the stimulation site. Study limitations include small patient population and short follow-up.

In an RCT, Peters et al. (2009) compared the effectiveness of a series of 12 weekly, 30-minute office based PTNS treatments and 12 weeks of 4 mg daily extended-release tolterodine tartrate (Detrol[®] LA). Included were ambulatory adults with overactive bladder (OAB) symptoms, with or without a history of previous anticholinergic drug use, with at least eight voids per 24 hours documented by history and physical and voiding diary. Females made up 90% of the participants. Of the patients who completed 12 weeks of therapy, 41 of 44 receiving PTNS and 43 of 43 on tolterodine completed the voiding diary. Using the Global Response Assessment (GRA), subject assessment of OAB symptom improvement compared to baseline was dramatically greater in the PTNS arm with 79.5% reporting cure or improvement compared to 54.8% of subjects on tolterodine ($p = 0.01$). This global assessment of improvement may have been greater because subjects in the PTNS arm may have had less significant side effects or more perceived improvement in subjective changes such as urgency, or because of the novel nature of the treatment. Limitations of this study include: industry-sponsored; no sham/placebo control group; potential for observation bias (PTNS group assessed in-person, tolterodine group assessed by phone). After 12 weeks, subjects randomized to weekly PTNS were offered an additional nine months of treatment with assessments at six and 12 months from baseline (MacDiarmid, et al., 2010). A total of 33 PTNS responders continued therapy with 32 and 25 subjects completing six and 12 months of therapy, respectively. Subjects received a mean of 12.1 treatments during an average of 263 days, with a median of 17 days between treatments. At 6 months 94% of subjects classified OAB symptoms as improved from baseline and 96% reported improvement at 12 months. Overactive bladder questionnaire symptom severity was significantly improved from 12 weeks to 12 months ($p < 0.01$) as well as from 6 to 12 months ($p < 0.01$). No serious adverse events occurred. Limitations include: no control group; the definition of response used was not standardized and based entirely on a GRA; there was not a standardized treatment protocol as patients returned for maintenance therapy at irregular intervals as dictated by patient preference.

Blue Cross Blue Shield Association Technology Evaluation Center (TEC) Assessment Percutaneous Tibial Nerve Stimulation for the Treatment of Voiding Dysfunction (March 2011) reported that the scientific evidence is not sufficient to permit conclusions on the long-term efficacy of PTNS treatment. The evidence is not sufficient to permit conclusions; therefore, the evidence is not sufficient to determine the effect on the net health outcome and/or whether it is as beneficial as alternatives. Whether PTNS for the treatment of voiding dysfunction improves the net health outcome has not been demonstrated in the investigational setting. PTNS as treatment for voiding dysfunction does not meet the TEC criteria.

There is insufficient evidence in the peer-reviewed scientific literature to support the long-term safety and clinical utility PTNS.

Professional Societies/Organizations

American Urological Association (AUA): The 2012 AUA guideline on the treatment and diagnosis of non-neurogenic overactive bladder addressed PTNS as a treatment option. The guideline stated that clinicians may offer PTNS as third-line treatment in a carefully selected patient population, characterized by moderately severe baseline incontinence and frequency and willingness to comply with the PTNS protocol. This determination was based on evidence the AUA categorized as Grade C because of the primarily observational designs, varying patient inclusion criteria and short follow-up in most studies.

An update of 1997 AUA guideline on the surgical management of female stress urinary incontinence (Dmochowski, et al., 2010) notes the following:

Retropubic Suspensions

Data from retropubic open suspensions regardless of type (including Burch suspensions), open Burch suspensions alone and laparoscopic suspensions were analyzed. At 24 months and beyond, the cured/dry rates were similar among all procedures, ranging from 73% to 76%. Common complications for Burch suspension were fever (11%), UTI (15%), bladder injury (6%) and voiding dysfunction (10%). Laparoscopic suspensions appeared to have a lower overall risk of febrile complications (0%) and UTI (2%).

Slings

Autologous Fascial Slings: include autologous slings without bone anchors and autologous vaginal wall slings with or without bone anchors). The estimated cured/ dry rates with no prolapse treatment ranged between 90% at 12 to 23 months and 82% at 48 months or longer. Complication estimates for autologous fascial slings without bone anchors were generally infrequent and included UTI (11%), bladder injury (4%) and wound complications (8%).

Cadaveric Slings: due to the decline in the use of cadaveric slings, limited data were available for analysis.

Synthetic Slings: efficacy data were available for slings placed at the bladder neck and slings placed at the midurethra. For slings at the bladder neck, most of the data were on slings without bone anchors and the estimated cured/dry rate without prolapse treatment was 73% at 24 to 47 months. Longer term data were not available. For slings at the bladder neck with concurrent prolapse treatment, the estimated cured/dry rates were similar. For slings at the midurethra without prolapse treatment (transvaginal/retropubic technique), the estimated cured/dry rates ranged from 81% to 84%.

Complications occurring with synthetic slings at the bladder neck without bone anchors included UTI (10%) and erosion/extrusion (5% urethral/bladder, 8% vaginal and 17% unknown). While these data may overestimate the risk of complications, they do suggest increased rates of urinary tract erosion following synthetic slings placed at the bladder neck. Complication rates for synthetic slings placed at the midurethra included bladder injury (6%), UTI (11%) and extrusions (7% vaginal and 1% unknown). Overall reported complication rates were generally higher than recently reported data. Wound complications were also reported in the literature.

Mesh in Pelvic Floor Surgery

Based upon review of the Oct 2008 FDA warning statement and meta-analysis, the Panel has reached the following conclusions:

- 1) In this meta-analysis, the midurethral slings had an efficacy comparable to autologous slings in the surgical treatment of SUI.
- 2) Several "versions" of the midurethral sling procedures do not have similar long-term efficacy data.
- 3) There are complications that may occur that are unique to specific mesh materials; however, these complications appear to be rare. Intraoperative use of cystoscopy can be performed to minimize the risk of urinary tract injury or erosion.
- 4) The midurethral sling is an alternative in the management of SUI. The incidence and implications of these complications along with the more rapid recovery and more efficient return to normal voiding after surgery should be discussed with patients before surgery.

Transobturator Tape Procedures

Modifications to the pubovaginal sling for the surgical treatment of SUI include the tension-free vaginal tape procedure introduced in 1996 and the transobturator technique introduced in 2001. Since the cutoff date for the literature review for this guideline was June 2005, limited data were available in the peer-reviewed literature to analyze these procedures, although subsequently numerous studies have been published. The Panel is aware of the importance of the transobturator technique in the treatment of SUI.

Artificial Urinary Sphincters

Data on the use of the artificial urinary sphincter in the index patient were limited, precluding analysis. The AUS is occasionally used in the patient with severe intrinsic sphincteric deficiency after other

surgical procedures have failed or in those with diabetes or back injury and significant SUI and poor bladder contractility. Erosion, infection and device malfunction are potential complications. Based on the only recent study of complications the erosion/extrusion rate was 28%. With respect to the index patient the AUS might be useful in the woman using the Valsalva maneuver to void who must abdominally strain to empty the bladder. When the cuff is opened for voiding, the AUS is not likely to be obstructive to the bladder in contrast to slings when straining may cause obstruction to the urinary flow. The Panel believes the role of the AUS in the treatment of SUI is limited.

International Consultation on Incontinence: In a systematic review by the International Consultation on Incontinence on Surgical Treatment of Stress Incontinence in Men (Herschorn, et al., 2010), the following conclusions were drawn:

Male sling

In the intermediate term, the male sling performs reasonably well. The National Institute for Health and Clinical Excellence (NICE) in the UK has stated that current evidence on the safety and efficacy of slings appears adequate to support their clinical use. The best candidates may be those with lower and moderate degrees of incontinence, who have not had previous radiation. While reported revision rates due to recurrent incontinence are quite low, longer follow-up is needed before definitive comparisons to the AUS can be made. Nevertheless, in men with adequate detrusor contractility and mild to moderate degrees of SUI, or for patients demanding a less invasive procedure or non-mechanical device, a sling procedure is a reasonable alternative to AUS, although longer term outcome is unknown.

Adjustable balloons (Adjustable Continence Therapy)

The ProACT balloon technique appears to be a feasible procedure in the short to medium term, with better results occurring with more operator experience. Appropriate candidates are those with mild to moderate leakage and no previous radiation. The benefit of an adjustable system should be weighed against the need for multiple sessions of refilling the balloon, and the reported rate of peri- and post-operative complications. Longer follow-up is needed before definitive comparison to male sling or AUS can be made. No recommendation is possible due to variable data on complication rates (12–58%).

Artificial urinary sphincter

The AUS remains the gold standard for the treatment of severe incontinence post-prostatectomy, even in those who have had external beam radiation. It has the largest body of literature reporting long-term success. The success and high patient satisfaction rates seem to outweigh the need for periodic revision. Intermediate-term data with the male sling demonstrate that it is an alternative to the AUS in patients with mild-moderate SUI and normal bladder contractility. Previously failed AUS surgery and radiation are adverse factors.

Overall summary

Although the literature is replete with well-done cohort studies, there is a need for prospective randomized clinical trials. Recommendations for trials include standardized workup and outcome measures and complete reporting of adverse events and long-term results. Further research is also needed to elucidate the mechanism of post-prostatectomy incontinence.

American College of Obstetricians and Gynecologists (ACOG)

The ACOG guideline entitled 'Urinary incontinence in women' lists the following "Major Recommendations":

Level B evidence:

- Long-term data suggest that Burch colposuspension and sling procedures have similar objective cure rates; therefore, selection of treatment should be based on patient characteristics and the surgeon's experience.
- The combination of a hysterectomy and a Burch colposuspension does not result in higher continence rates than a Burch procedure alone.
- Tension-free vaginal tape and open Burch colposuspension have similar success rates.
- Anterior colporrhaphy, needle urethropexy, and paravaginal defect repair have lower cure rates for stress incontinence than Burch colposuspension.

Levels of Recommendations

Level A — Recommendations are based on good and consistent scientific evidence.

Level B — Recommendations are based on limited or inconsistent scientific evidence.

Level C — Recommendations are based primarily on consensus and expert opinion (ACOG, 2005).

Use Outside of the US

The Australia and New Zealand Horizon Scanning Network's (ANZHSN) scanning program is a collaborative Commonwealth and State initiative guided by the Health Policy Advisory Committee on Technology (HealthPACT). HealthPACT provides jurisdictions with evidence-based advice on emerging technologies. This information is used to inform jurisdiction financing decisions and to assist in the managed introduction of new technologies. A Horizon Scanning report prepared by the Australian Safety and Efficacy Register of New Interventional Procedures – Surgical (ASERNIP-S) on behalf of HealthPACT provided recommendations on ProAcCT device for male stress urinary incontinence. The ProACT Therapy system has already being approved for clinical use in the European market and is distributed throughout Europe, Canada, Brazil, Malaysia and Australasia. The ProACT Therapy system is registered in the Australian Register of Therapeutic Goods (ARTG). Stage of development of the technology was determined to be “established” in Australia, with limited use in Europe. According to the HealthPACT recommendation, “higher quality studies, preferably randomized controlled trials are required to better evaluate the safety and efficacy of this implant for male stress urinary incontinence” (HealthPACT, 2006). A 2008 update to the report stated that “long-term comparative evidence is still required for ProACT therapy, but the potential of the device warrants monitoring for a further 12 months” (HealthPACT, 2008).

A 2006 Horizon Scanning Technology Summary on Renessa® radiofrequency micro-remodelling treatment for female stress urinary incontinence stated that the Renessa system was not currently listed in the Australian Register of Therapeutic Goods and had not yet emerged in Australia. The report further stated that the Renessa RF micro-remodelling system received the Conformité Européene (CE) Mark in April 2003 allowing Novasys Medical Inc. to market the system in European Union countries (HealthPACT, 2006).

A 2004 Horizon Scanning Technology Prioritizing Summary found “limited evidence assessing the safety and effectiveness of the Gynecare TVT Obturator System, but predicted that there would be a rapid uptake of this technology in the Australian public health system. Stage of development of the technology was determined to be investigational in Australia, with no Therapeutic Goods Administration approval in place (HealthPACT, 2004).

According to NICE guidance on the use of PTNS for overactive bladder syndrome, the current evidence shows that PTNS is efficacious in reducing symptoms in the short and medium term. There are no major safety concerns. Therefore the procedure may be used provided that normal arrangements are in place for clinical governance, consent and audit. It was noted that long-term efficacy has not been established (NICE, 2010).

Summary

Evidence in the peer-reviewed literature and textbooks supports the use of certain invasive interventions to treat urinary incontinence when conservative treatments have failed. These include: anterior colporrhaphy with bladder neck (Kelly-Kennedy) placcation; retropubic suspension (e.g., retropubic urethropexy, Burch procedure); sling procedures (e.g., pubovaginal slings, midurethral slings, bulbourethral sling); and artificial urinary sphincter implantation following prostate surgery. Laparoscopic approaches for some of these procedures have been introduced, with surgical continence outcomes equivalent to those of the gold standard procedures. The AUS is not FDA-approved for use in women and children and therefore is considered experimental, investigational or unproven if implanted in women or children.

There is insufficient evidence within the peer-reviewed literature to support the use of transvaginal radiofrequency surgery or transurethral radiofrequency tissue micro-remodeling. The efficacy of these modalities for the treatment of urinary incontinence and their impact on long-term health outcomes has not been adequately demonstrated. Additionally, optimal patient selection criteria and comparative effectiveness of these radiofrequency-based procedures against other well-established non-invasive and invasive incontinence procedures has not been demonstrated through well-designed, large population trials.

There is limited evidence in the published peer-reviewed literature evaluating the safety and efficacy of adjustable continence therapy (ACT® device for women and the ProACT™ device for men). Also, there is insufficient evidence in the peer-reviewed scientific literature to support the long-term safety and clinical utility percutaneous tibial nerve stimulation (PTNS).

Coding/Billing Information

Note: 1) This list of codes may not be all-inclusive.

2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

Covered when medically necessary:

CPT®* Codes	Description
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)
53440	Sling operation for correction of male urinary incontinence (eg, fascia or synthetic)
53442	Removal or revision of sling for male urinary incontinence (eg, fascia or synthetic)
53444	Insertion of tandem cuff (dual cuff)
53445	Insertion of inflatable urethral/bladder neck sphincter, including placement of pump, reservoir, and cuff
53446	Removal of inflatable urethral/bladder neck sphincter, including pump, reservoir, and cuff
53447	Removal and replacement of inflatable urethral/bladder neck sphincter including pump, reservoir, and cuff at the same operative session
53448	Removal and replacement of inflatable urethral/bladder neck sphincter including pump, reservoir, and cuff through an infected field at the same operative session including irrigation and debridement of infected tissue
53449	Repair of inflatable urethral bladder neck sphincter, including pump, reservoir, and cuff
57220	Plastic operation on urethral sphincter, vaginal approach (e.g., Kelly urethral placcation)
57240	Anterior colporrhaphy, repair of cystocele with or without repair of urethrocele
57287	Removal or revision of sling for stress incontinence (e.g. fascia or synthetic)
57288	Sling operation for stress incontinence (eg, fascia or synthetic)

HCPCS Codes	Description
C1771	Repair device, urinary incontinence, with sling graft
C1815	Prosthesis, urinary sphincter (implantable)
C2631	Repair device, urinary, incontinence, without sling graft

Experimental/Investigational/Unproven/Not Covered:

CPT* Codes	Description
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53860	Transurethral, radiofrequency micro-remodeling of the female bladder neck and proximal urethra for stress urinary incontinence
53899†	Unlisted procedure, urinary system
64566	Posterior tibial neurostimulation, percutaneous needle electrode, single treatment, includes programming

†**Note: Experimental, investigational or unproven and not covered when used to report adjustable continence therapy or any other procedure listed as not covered in this policy.**

***Current Procedural Terminology (CPT®) © 2012 American Medical Association: Chicago, IL.**

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