



CIGNA MEDICAL COVERAGE POLICY

The following Coverage Policy applies to all plans administered by CIGNA Companies including plans administered by Great-West Healthcare, which is now a part of CIGNA.

Subject Surgical Interventions 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[™])
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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.

Surgical Interventions

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.

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 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.

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.

An artificial urinary sphincter (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).

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 recently 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.

Adjustable Continence Therapy: The Adjustable Continence 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.

U.S. Food and Drug Administration (FDA)

Slings: 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) (this list may not be 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.

Artificial Urinary Sphincter: 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

Radiofrequency Energy: 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).

The Adjustable Continence 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

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-Kranz (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.

Slings: 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). 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). 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. Studies have demonstrated male slings effectively control sphincter incontinence in men after prostate surgery, with an acceptably low complication rate (Bauer, et al., 2010; Davies, et al., 2009; John, et al., 2008; Romano et al 2006).

The National Institute for Health and Clinical Excellence (NICE) published a review of the literature entitled 'Single-incision Sub-urethral Short Tape Insertion for Stress Urinary Incontinence in Women (May, 2008). NICE concluded that current evidence on the safety and efficacy of single-incision sub-urethral short tape insertion for stress urinary incontinence in women is inadequate in quality and quantity. A NICE review of the literature entitled 'Suburethral Synthetic Sling Insertion for Stress Urinary Incontinence in Men (March, 2008) summarized that current evidence on the safety and efficacy of suburethral synthetic sling insertion for stress urinary incontinence in men and concluded that the evidence is sufficient to support the use of this procedure in men.

Artificial Urinary Sphincter (AUS)/Men: 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), transvesical prostatectomy (TVP), transurethral prostatectomy (TURP), and TURP with TVP, in 12, 16, 16, and 1 patient respectively. 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 is 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.

LoE: 1

AUS/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 (Wein, 2007). The AUS is not FDA-approved for use in women and children and therefore is considered experimental, investigational or unproven.

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.

Transurethral Radiofrequency Energy: 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.

Lenihan et al. (2005), Appell et al. (2006) and Appell et al. (2007) report on a randomized, controlled trial 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.

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%).

LoE: 3

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.”

Adjustable Continence Therapy: 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. 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.

Gregoria et al. (2010) retrospectively reported on the results of 79 consecutive patients with post-radical prostatectomy intrinsic sphincter deficiency that underwent transrectal ultrasound–guided implantation of ProACT. The mean follow-up was two years. According to the 24 hour pad test and the mean number of pads per day used, 41 patients were dry (66.1%), 16 patients improved (25.8%), and 5 patients failed treatment (8%). All failures occurred in previously irradiated patients. The mean number of postoperative balloon adjustments required to obtain continence recovery was 3.6. The authors noted a comparison of this technique with the stress urinary incontinence reference treatment (artificial urinary sphincter) is needed.

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.” **LoE: 3**

In a prospective multicenter trial, Leuret 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. All patients in both groups had undergone a radical prostatectomy as their primary operation for prostatic cancer. 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. 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.

Professional Societies/Organizations

American Urological Association (AUA): 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).

Society of Obstetricians and Gynaecologists of Canada

In the guideline entitled 'Midurethral minimally invasive sling procedures for stress urinary incontinence', some recommendations included:

- tension-free vaginal tape can be offered as an alternative of equal efficacy to the Burch procedure for the surgical management of stress urinary incontinence.
- transobturator tape can be offered as an alternative to tension-free vaginal tape that eliminates the risks of intra-abdominal organ injury. It should be offered with the proviso that its long-term effectiveness and safety relative to tension-free vaginal tape remain to be determined.
- midurethral sling procedures performed through a single suburethral incision should be used only in the setting of a clinical trial until their effectiveness and safety are proven. (Schultz, et al., 2008).

National Institute for Health and Clinical Excellence (NICE)

NICE and the National Collaborating Centre for Women's and Children's Health Guideline on urinary incontinence in women (October, 2006) notes the following:

- Anterior colporrhaphy, needle suspensions, paravaginal defect repair and the Marshall–Marchetti–Krantz procedure are not recommended for the treatment of stress UI.
- Laparoscopic colposuspension is not recommended as a routine procedure for the treatment of stress UI in women. The procedure should be performed only by an experienced laparoscopic surgeon working in a multidisciplinary team with expertise in the assessment and treatment of UI.
- Retropubic mid-urethral tape procedures using a 'bottom-up' approach with macroporous (type 1) polypropylene meshes are recommended as treatment options for stress UI if conservative management has failed. Open colposuspension and autologous rectus fascial sling are the recommended alternatives when clinically appropriate.
- Synthetic slings using a retropubic 'top-down' or a transobturator foramen approach are recommended as alternative treatment options for stress UI if conservative management has failed, provided women are made aware of the lack of long-term outcome data.
- Synthetic slings using materials other than polypropylene that are not of a macroporous (type 1) construction are not recommended for the treatment of stress UI.
- In view of the associated morbidity, the use of an artificial urinary sphincter should be considered for the management of stress UI in women only if previous surgery has failed. Life-long follow-up is recommended.

Summary

Evidence in the peer-reviewed literature and textbooks supports the use of certain surgical interventions to treat urinary incontinence when conservative treatments have failed. These include: anterior colporrhaphy with bladder neck (Kelly-Kennedy) placation; 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).

Coding/Billing Information

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

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)
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
57240	Anterior colporrhaphy, repair of cystocele with or without repair of urethrocele
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
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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

Experimental/Investigational/Unproven/Not Covered:

CPT* Codes	Description
53860	Transurethral, radiofrequency micro-remodeling of the female bladder neck and proximal urethra for stress urinary incontinence (code effective 01/01/11)
0193T	Transurethral, radiofrequency micro-remodeling of the female bladder neck and proximal urethra for stress urinary incontinence (code deleted 12/31/10)
53899†	Unlisted procedure, urinary system

†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.

ICD-9-CM Diagnosis Codes	Description
	All codes

*Current Procedural Terminology (CPT®) ©2010 American Medical Association: Chicago, IL.

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Policy History

Pre-Merger Organizations	Last Review Date	Policy Number	Title
CIGNA HealthCare	5/15/2007	0365	Surgical Interventions for Urinary Incontinence
Great-West Healthcare	9/19/2007	05.319.02	Tension-Free Vaginal Tape (TVT) for Stress Urinary Incontinence (SUI)
	9/19/2007	07.353.01	Incontinence, Transurethral Radiofrequency (Renessa System)

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Connecticut General Life Insurance Company has acquired the business of Great-West Healthcare from Great-West Life & Annuity Insurance Company (GWLA). Certain products continue to be provided by GWLA (Life, Accident and Disability, and Excess Loss). GWLA is not licensed to do business in New York. In New York, these products are sold by GWLA's subsidiary, First Great-West Life & Annuity Insurance Company, White Plains, N.Y.