Clinical Policy Bulletin: Urinary Incontinence

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Policy

I. Aetna considers multi-channel urodynamic studies medically necessary when the member has both symptoms and physical findings of urinary incontinence/voiding dysfunctions (such as stress incontinence, overactive bladder, lower urinary tract symptoms) and there is consideration by the provider to perform invasive, potentially morbid or irreversible treatments after conservative management has been tried and failed.

II. Aetna considers the following urinary incontinence interventions medically necessary when criteria are met:

A. Artificial Urinary Sphincter:

Aetna considers the implantation of an artificial urinary sphincter (AUS) medically necessary for the treatment of urinary incontinence (UI) due to intrinsic urethral sphincter deficiency (IUSD) for members with any of the following indications:

1. Children with intractable UI due to IUSD who are refractory to behavioral or pharmacological therapies and are unsuitable candidates for other types of surgical procedures for correction of UI; or
2. Members who are 6 or more months post-prostatectomy who have had no improvement in the severity of UI despite trials of behavioral and pharmacological therapies; or
3. Members with epispadias-exstrophy in whom bladder neck reconstruction has failed; or
4. Women with intractable UI who have failed behavioral, pharmacological, and other surgical treatments.

Aetna considers the artificial urinary sphincter experimental and investigational for all other indications because its effectiveness for
indications other than the ones listed above has not been established.

B. Periurethral Injections of Bulking Agents:

Aetna considers periurethral injections of bulking agents that are cleared by the Food and Drug Administration (FDA) for UI (e.g., Coaptite [calcium hydroxylapatite], Contigen [glutaraldehyde cross-linked collagen], Durasphere [carbon-coated spheres/beads], Macroplastique [polymethylsiloxane], Uryx [ethylene vinyl alcohol copolymer]) medically necessary for the management of members with UI resulting from intrinsic sphincter deficiency that is refractory to conservative management (e.g., Kegel exercises, biofeedback, electrical stimulation, and/or pharmacotherapies).

Members whose incontinence does not improve after 3 treatments with bulking agents are considered treatment failures and are not likely to respond to this therapy. In such cases, further treatment with bulking agents is not considered medically necessary.

Aetna considers injection of periurethral bulking agents for UI experimental and investigational for neurogenic bladder and all other indications.

Periurethral injections of bulking agents have no proven value in any of the following circumstances:

1. Members undergoing or planning to undergo desensitization injections to meat products; or
2. Members with an acute condition involving cystitis, urethritis, or infection; or
3. Members with severe allergies manifested by a history of anaphylaxis, or history or presence of multiple severe allergies; or
4. Previous pelvic radiation therapy; or
5. Unstable or noncompliant bladder.

C. InterStim Continence Control Therapy/Sacral Nerve Stimulation:

Aetna considers implantation of the InterStim (Medtronic Inc., Minneapolis, MN), a device for unilateral stimulation of the sacral nerve, medically necessary for the treatment of urge UI or symptoms of urge-frequency when all of the following criteria are met:

1. The member has experienced urge UI or symptoms of urge-frequency for at least 12 months and the condition has resulted in significant disability (the frequency and/or severity of symptoms are limiting the member's ability to participate in daily activities); and
2. Pharmacotherapies (i.e., at least 2 different anti-cholinergic drugs or a combination of an anti-cholinergic and a tricyclic anti-depressant) as well as behavioral treatments (e.g., pelvic
floor exercise, biofeedback, timed voids, and fluid management) have failed; and
3. Test stimulation provides at least 50% decrease in symptoms.

A test stimulation of the device is considered medically necessary for members who meet selection criteria 1 and 2 above.

Aetna also considers implantation of the InterStim medically necessary for the treatment of non-obstructive urinary retention when all of the following criteria are met:

1. The member has experienced urinary retention for at least 12 months and the condition has resulted in significant disability (the frequency and/or severity of symptoms are limiting the member's ability to participate in daily activities); and
2. Pharmacotherapies (e.g., alpha blockers and cholinergics, and antibiotics for urinary tract infections) as well as intermittent catheterization have failed or are not well-tolerated; and
3. A test stimulation of the device has provided at least 50% decrease in residual urine volume.

A test stimulation of the device is considered medically necessary for members who meet selection criteria 1 and 2 above.

Aetna considers removal of an Interstim medically necessary even where the initial implantation of the Interstim was not indicated.

Aetna considers the Interstim Continence Control System experimental and investigational for all other indications because its effectiveness for indications other than the ones listed above has not been established. (Note: bilateral sacral nerve stimulation is considered experimental and investigational for the treatment of UI because the effectiveness of this approach has not been established).

According to the product labeling, InterStim therapy is contraindicated and has no proven value for individuals who have not demonstrated an appropriate response to test stimulation or are unable to operate the neurostimulator.

Exclusions: InterStim therapy has no proven value for individuals with mechanical obstruction such as benign prostatic hypertrophy, cancer, or urethral stricture; persons with stress incontinence; and individuals with neurologic disease origins, such as multiple sclerosis or diabetes with peripheral nerve involvement. InterStim has not been shown to be effective for urinary retention due to these causes.

D. Vaginal Cones:
Aetna considers weighted vaginal cones (vaginal weights) medically necessary DME when they are used in combination with a structured pelvic floor muscle exercise (Kegel's exercise) program for the treatment of simple (pure) stress UI.

Aetna considers vaginal cones experimental and investigational for other indications because their effectiveness for indications other than the ones listed above has not been established.

E. Pessary (Bladder Neck Support Prosthesis):

Aetna considers a pessary, a plastic device that fits into the vagina to help support the uterus and bladder, medically necessary DME for the treatment of women with stress or mixed UI, and for the treatment of pelvic organ (uterine) prolapse.

Aetna considers a pessary experimental and investigational for other indications because its effectiveness for indications other than the ones listed above has not been established.

F. Tension-Free Vaginal Tape Procedure:

Aetna considers the tension-free vaginal tape (TVT) procedure medically necessary for the treatment of stress UI when members with intractable UI have failed behavioral and pharmacological treatments.

Aetna considers the TVT procedure experimental and investigational for other indications because its effectiveness for indications other than the one listed above has not been established.

G. Transobturator Tape Procedure:

Aetna considers the transobturator tape (TOT) procedure medically necessary for the treatment of stress UI when members with intractable stress UI have failed behavioral and pharmacological treatments.

Aetna considers the TOT procedure experimental and investigational for urge urinary incontinence and other indications because its effectiveness for indications other than the one listed above has not been established.

H. Colposuspension and Sling Procedures:

Aetna considers colposuspension and conventional suburethral sling procedures (e.g., the Solyx single-incision sling) medically necessary for persons with stress UI that is refractory to conservative management (e.g., pelvic floor muscle training, electrical stimulation, and biofeedback).

Aetna considers the colposuspension and suburethral sling procedures experimental and investigational for other indications
because their effectiveness for indications other than the one listed above has not been established.

I. **Biofeedback:**

For biofeedback for UI, see CPB 0132 - Biofeedback.

J. **Percutaneous Tibial Nerve Stimulation:**

Aetna considers percutaneous tibial nerve stimulation (PTNS) (Urgent PC Neuromodulation System, Uroplasty, Inc., Minneapolis, MN) medically necessary for the treatment of members with urge UI or urge-frequency when they meet the first two criteria listed for the InterStim Continence Control Therapy (policy section I. C1 and C2 for the treatment of urge urinary incontinence or symptoms of urge-frequency). In general, 12 treatments (once-weekly) with PTNS are needed for symptom relief. If the member fails to improve after 12 PTNS treatments, continued treatment is considered not medically necessary.

Aetna considers percutaneous tibial nerve stimulation experimental and investigational when criteria are not met.

K. **Transurethral Radiofrequency Therapy (Renessa Procedure):**

Aetna considers transurethral radiofrequency therapy (Renessa procedure) medically necessary for the treatment of stress UI in non-pregnant women who are either not able or not willing to undergo surgery for their condition.

L. **Urethral Inserts:**

Aetna considers urethral inserts medically necessary for the treatment of female stress UI.

Aetna considers urethral inserts experimental and investigational for other indications because their effectiveness for indications other than the one listed above has not been established.

M. **Cunningham Clamp:**

Aetna considers the Cunningham clamp medically necessary for the treatment of post-prostatectomy urinary incontinence in men with stress incontinence and good bladder storage function.

III. The following UI interventions are considered experimental and investigational:

A. **The Neocontrol™ System:**

Aetna considers the Neocontrol system, which uses extracorporeal magnetic innervation (ExMI), experimental and investigational for treatment of UI because its effectiveness has not been established.

B. **Radiofrequency Micro-Remodeling with the SURx System:**
Aetna considers radiofrequency micro-remodeling with the SURs System (paraurethral or transvaginal) for the treatment of UI experimental and investigational because its effectiveness has not been established.

C. **Extraurethral (Non-circumferential) Retropubic Adjustable Compression Devices (ProACT Therapy System):**

Aetna considers extraurethral (non-circumferential retropubic adjustable compression devices (ProACT Therapy System, Uromedica, Inc.) experimental and investigational because their effectiveness has not been established.

D. **The Genityte Procedure (Laser Therapy):**

Aetna considers the Genityte procedure (laser therapy) experimental and investigational for the treatment of UI because its effectiveness has not been established.

E. **Pudendal Nerve Stimulation:**

Aetna considers pudendal nerve stimulation experimental and investigational for the treatment of UI because its effectiveness for this indication has not been established.

F. **Autologous Myoblast Transplantation:**

Aetna considers autologous myoblast transplantation experimental and investigational for the treatment of UI because its effectiveness for this indication has not been established.

G. **Autologous Muscle-Derived Cell Therapy**

Aetna considers autologous muscle-derived cell therapy experimental and investigational for the treatment of UI because its effectiveness for this indication has not been established.

H. **Collagen Porcine Dermis Mesh**

Aetna considers collagen porcine dermis mesh experimental and investigational for the treatment of UI because its effectiveness for this indication has not been established.

I. **Stem Cell Therapy**

Aetna considers stem cell therapy experimental and investigational for the treatment of UI because its effectiveness for this indication has not been established.

J. **Pelvic Floor Stimulation**

Aetna considers pelvic floor electrical stimulation experimental and
investigational for UI because there is inadequate evidence in the peer-reviewed clinical literature regarding its effectiveness.

IV. Other urinary incontinence interventions:

**Pelvic Muscle Trainers:**

*Note:* Aetna does not cover the Athena pelvic muscle trainer, Kegelmaster, Gyneflex or similar devices for the treatment of UI because these devices are considered exercise machines, and they do not meet Aetna's definition of covered durable medical equipment (DME). Most Aetna plans exclude coverage of exercise devices. Please check benefit plan descriptions for details. In addition, such exercise devices do not meet Aetna's definition of covered DME because they are not primarily medical in nature and/or are normally of use to persons who do not have an illness or injury.

**Background**

Urinary incontinence (UI) is the inability to voluntarily control voiding of urine from the bladder. It affects people of all ages especially elderly women. Urinary incontinence is not part of the normal aging process; however, age-related changes in the functioning of the lower urinary tract make the elderly more susceptible to this malady. There are 4 prevalent types of UI in adults: (i) stress incontinence, (ii) urge incontinence, (iii) overflow incontinence, and (iv) mixed stress and urge incontinence. Stress incontinence is more common but less difficult to control than urge incontinence. Mixed incontinence is more prevalent than urge incontinence in women while the latter is more commonly seen in men.

In women, stress incontinence (SI) is generally caused by an incompetent urethral mechanism which arises from damage to the urethral sphincter or weakening of the bladder neck support that typically occurred during childbirth. Some women develop SI as a consequence of multiple anti-incontinence procedures resulting in a condition known as intrinsic urethral sphincter deficiency. In men, SI is usually a consequence of operations for benign prostatic hypertrophy or prostatic carcinoma. The mechanisms of post-prostatectomy UI may involve bladder dysfunction, sphincter incompetence, and mixed.

Urge incontinence occurs when one senses the urge to void, but is unable to prevent leakage of urine before reaching the bathroom. It is usually associated with an overactivity of the detrusor muscle. Overflow incontinence is the result of the bladder's inability to empty normally. It may be due to an underactive detrusor muscle or obstruction of the urethra resulting in the overdistension of the bladder and therefore overflow of urine.

Multi-channel urodynamics studies are not indicated in the first-line assessment of patients with urinary incontinence/voiding dysfunctions. Guidelines from the American Urological Association (2012), the European Association of Urology (2013) and the National Institute for Health and Care Excellence (2013) are useful in determining when multi-channel urodynamics studies should be performed.
American Urological Association guidelines on adult (Winters et al, 2012) provided the following recommendations:

**Stress Urinary Incontinence (SUI)/Prolapse:**
Clinicians may perform multi-channel urodynamics in patients with both symptoms and physical findings of stress incontinence who are considering invasive, potentially morbid or irreversible treatments. (Option; Evidence Strength: Grade C)
Clinicians should perform stress testing with reduction of the prolapse in women with high grade pelvic organ prolapse (POP) but without the symptom of SUI. Multi-channel urodynamics with prolapse reduction may be used to assess for occult stress incontinence and detrusor dysfunction in these women with associated lower urinary tract symptoms (LUTS). (Option; Evidence Strength: Grade C)

**Overactive Bladder (OAB), Urgency Urinary Incontinence (UUI), Mixed Incontinence:**
Clinicians may perform multi-channel filling cystometry when it is important to determine if altered compliance, detrusor overactivity (DO) or other urodynamic abnormalities are present (or not) in patients with urgency incontinence in whom invasive, potentially morbid or irreversible treatments are considered. (Option; Evidence Strength: Grade C)

**LUTS (Lower Urinary Tract Symptoms):**
Clinicians may perform multi-channel filling cystometry when it is important to determine if DO or other abnormalities of bladder filling/urine storage are present in patients with LUTS, particularly when invasive, potentially morbid or irreversible treatments are considered. (Expert Opinion)

European Association of Urology guidelines on urinary incontinence (EAU, 2013) stated that “urodynamics is generally used as a collective term for all tests of bladder and urethral function. These guidelines will review both non-invasive estimation of urine flow, i.e., uroflowmetry, and invasive tests, including multichannel cystometry, ambulatory monitoring and video-urodynamics, and different tests of urethral function, such as urethral pressure profilometry, Valsalva leak point pressure estimation and retrograde urethral resistance measurement. Multichannel cystometry, ambulatory monitoring and video-urodynamics aim to observe the effects on intra-vesical and intra-abdominal pressures while reproducing a patient's symptoms. Bladder filling may be artificial or physiological and voiding is prompted. Any incontinence observed may be categorized as SUI, detrusor overactivity (DO) incontinence, a mixture of SUI/DO incontinence, or, rarely, urethral relaxation incontinence. A test may fail to reproduce a patient's symptoms because of poor diagnostic accuracy or because the symptoms are not directly attributable to a urodynamically measurable phenomenon. Urodynamic testing is widely used as an adjunct to clinical diagnosis, to direct decisions about treatment and to provide prognostic information. When clinical diagnosis is difficult because of an unclear history or inconclusive examination, urodynamics may provide the only 'diagnosis' available. Although it is unlikely that carrying out a test, in itself, would alter the outcome of treatment, it remains possible that the test...
results would influence treatment decisions to such an extent that better outcomes would be achieved. This has been the rationale for using urodynamics prior to surgery.”

National Institute for Health and Care Excellence guideline Urinary Incontinence: The Management of Urinary Incontinence in Women (NICE, 2013) provided the following recommendations regarding urodynamic testing:

- Do not perform multi-channel cystometry, ambulatory urodynamics, or videourodynamic before starting conservative management. [2006, amended 2013]
- After undertaking a detailed clinical history and examination, perform multi-channel filling and voiding cystometry before surgery in women who have:
  - Symptoms of over-active bladder leading to a clinical suspicion of detrusor over-activity, or
  - Symptoms suggestive of voiding dysfunction or anterior compartment prolapse, or
  - Had previous surgery for stress incontinence [2006, amended 2013]
- Do not perform multi-channel filling and voiding cystometry in the small group of women where pure SUI is diagnosed based on a detailed clinical history and examination. [2006, amended 2013]
- Consider ambulatory urodynamics or videourodynamic if the diagnosis is unclear after conventional urodynamics. [2006, amended 2013]

Treatments for UI include pelvic muscle exercises (Kegel exercise), behavioral therapies such as bladder training and/or biofeedback, pharmacotherapies (e.g., anti-cholinergic agents, musculotropics relaxants, calcium channel blockers, tricyclic anti-depressants, or a combination of anti-cholinergic, anti-spasmodic medications and tricyclic anti-depressants), and a variety of surgical procedures including intra-urethral injection of collagen, and implantation of an artificial urinary sphincter. Specifically, urge incontinence is more effectively managed with peripherally acting receptor agonists or antagonists while stress incontinence is better controlled by pelvic muscle exercises, behavioral therapies, or corrective surgery.

Electrical stimulation has also been employed in the treatment of UI, especially in Europe. The mechanism of action of electrostimulation is still unclear, but it probably serves to provide a kind of muscular training similar to that of pelvic floor exercise. In this regard, Green and Laycock (1990) demonstrated that interferential currents produce increases in muscle activity as indicated by pressure probes at the perivaginal and abdominal areas. It is also conceivable that electrical stimulation may improve re-innervation of partially damaged pelvic floor muscles by enhancing the sprouting of sensory motor axons. Additionally, repeated stimulation of the pelvic floor musculature may also help to strengthen the supporting ligaments. There is a lack of reliable evidence of durable benefit from electrical stimulation of the pelvic floor. Examples of electrical stimulation devices include the Innova and Minnova systems (Empi, Inc., St. Paul, MN).

The artificial urinary sphincter (AUS) has been shown to be effective for UI due to intrinsic urethral sphincter deficiency (IUSD), and is a useful alternative when conservative interventions have failed. Implantation of an AUS is a commonly used surgical option for the management of male urethral deficiency especially,
following prostatectomy. A clinical practice guideline for UI in adults by the Agency for Healthcare Policy and Research (1992) recommends that post-prostatectomy patients wait at least 6 to 12 months before AUS placement, and try behavioral and pharmacologic therapies first. To be considered for AUS implantation, the patient must be motivated and have enough dexterity and ability to operate the device.

The AUS (AS 800, American Medical Systems, Minnetonka, MN) is an externally controlled urethral occlusion device. The transfer of fluid within the device is controlled by a pressure regulating balloon placed extraperitoneally in the patient's pelvis or abdominal cavity and a control pump placed in a subcutaneous pocket in the scrotum or labium. Squeezing of the pump allows the fluid within the closed-loop system to be transferred from the cuff to the balloon. It takes a few minutes before the cuff re-inflates automatically to the preset level, thus allowing the urethra to remain opened for voiding. The AS 800 has the option of primary deactivation. Primary deactivation is performed to limit the cuff compression during the early post-operative healing period, thus minimizing the risk of cuff erosion and infection. In the male, the preferred site of cuff placement is around the bladder neck because erosion is less likely. When implantation of the device at the bladder neck is precluded by previous surgery, the cuff is placed around the bulbous urethra. In the female, the AUS cuff is placed around the bladder neck. The device is implanted abdominally or vaginally.

Aetna’s selection criteria for AUS are consistent with the AHCPR clinical practice guidelines for urinary incontinence in adults. Potential candidates for AUS implantation should be evaluated preoperatively to exclude severe detrusor instability as well as to ensure adequate bladder stability and compliance prior to implantation of the AUS. Appropriate candidates for implantation of an AUS must have adequate motivation and sufficient manual dexterity to operate the device. Post-prostatectomy patients should wait 6 to 12 months and attempt behavioral and pharmacologic therapies first. AUS may also be indicated in: patients with epispadias-exstrophy in whom bladder neck reconstruction has failed; women in whom behavioral or pharmacologic therapies, or other surgical options have failed; and children with intractable UI who are refractory to pharmacologic therapies or unsuitable for other types of operation.

Periurethral injection of bulking agents has been shown to be safe and effective for the treatment of UI resulting from intrinsic sphincter deficiency. One of the first bulking agents available on the market is Contigen (Bard, Canada), which is a sterile, injectable gel composed of highly purified bovine collagen that has been minimally cross-linked with 0.0075 % glutaraldehyde. All patients are required to undergo a pre-treatment skin test. Patients who exhibit local hypersensitivity will not be considered for treatment. Intra-urethral injections of glutaraldehyde crossed-linked (GAX) collagen are performed under local or general anesthesia. In men, the procedure is usually carried out transurethrally. The urethra and bladder are monitored by means of a 21F cystoscope, and the bladder filled with fluid cystoscopically. A percutaneous 10F or 12F suprapubic catheter is inserted into the bladder and its location verified. This catheter drains the bladder during the implantation procedure. Aliquots of GAX collagen are injected in a circumferential manner around the sphincter. In patients in whom no sphincter could be seen or in whom no sphincter existed (after radical prostatectomy), GAX
collagen is injected circumferentially around the bladder neck. Once the lumen is occluded with the water running through the cystoscope, the injections are terminated, and the cystoscope is not inserted past the area of injection again.

In women, intra-urethral injections of GAX collagen are performed transurethrally or periurethrally. In the latter approach, the proximal urethra and bladder neck are visualized under direct cystoscopy. A 22G spinal needle is advanced parallel to the urethra in the periurethral tissue up to the bladder neck, and its position is confirmed by cystoscopy. Aliquots of collagen are then injected cystoscopically into the periurethral tissues to occlude the urethra. If intraluminal extravasation occurs, the injection is stopped, and another injection site is chosen. At the end of the procedure performed under local anesthetics, the patient is asked to cough or strain while in the supine position and then in the upright position. If leakage still occurs, more collagen is injected. If no leakage occurs, and there is no urinary retention, the patient is discharged from the hospital. When the procedure is performed under general anesthesia and the bladder is filled, an 8F feeding tube is inserted to empty the bladder and then removed. All patients receive perioperative antibiotics. If patients remain incontinent after treatment, re-injections of collagen are performed. Satisfactory results are usually obtained within 3 treatment sessions.

Angioli and colleagues (2008) stated that in recent years they used a lot of bulking agents including bovine collagen, Macroplastique (polymethylsiloxane), calcium hydroxylapatite, ethylene vinyl alcohol copolymer, dextranomer in the treatment of urinary incontinence. Urethral injection have success in 40% to 90%. These investigators asserted that Macroplastique is the most effective and safe on the basis of literature data and of their experience. This surgical procedure, in fact, has good percentage of success in accurately selected patients. In the authors' experience, Macroplastique can also be used in oncological patients, in elderly women, in patients with important co-morbidity and with high surgical risk with good objective and subjective results.

In a prospective, randomized, controlled trial, Ter Meulen and associates (2009) evaluated the effectiveness of Macroplastique (MPQ) Implantation System (MIS) in women with urodynamic stress UI (SUI) and urethral hypermobility after an unsuccessful conservative treatment. These subjects had no prior incontinence surgery. A total of 24 women received MPQ; 21 controls underwent a pelvic floor muscle exercises home program. Follow-up was at 3 months and the MPQ group also at 12 months. At 3 months, pad usage decreased significantly more in the MPQ group than in the control group (p = 0.015). According to physician and patient self-assessment, respectively, 71% and 63% women in the MPQ group were considered cured or markedly improved. This was significantly higher compared to controls. There was a significant higher increase of Incontinence Quality-of-Life questionnaire score in the MPQ group compared to controls (p = 0.017). Improvements in MPQ group at 3 months are sustained to 12 months. Adverse events were mild and transient. The authors concluded that the Macroplastique Implantation System is an acceptable option for women with SUI and urethral hypermobility.

Plotti et al (2009) prospectively investigated the effectiveness and complications of Macroplastique transurethral implantation in cervical cancer patients affected by
SUI after radical hysterectomy (RH). Patients affected by de novo SUI post type 3 RH were considered for eligibility in this study. Pre-operative and post-operative assessment included a standardized urogynecological history, urogynecological and neurological physical examination, evaluation of severity of SUI symptoms, a 3-day voiding diary, urine culture and urodynamic assessment. All patients underwent transurethral implantation using the MIS. Patient follow-up was performed 6 and 12 months after surgery. A total of 24 consecutive patients were enrolled. At the 12 month follow-up SUI cure rate was 42 % (10 of 24 patients), the improvement rate was 42 % (10 of 24) and the failure rate was 16 % (4 of 24). The overall success rate was 84 % (10 patients cured and 10 improved). No intra-operative or post-operative early complications were found. The 4 patients in whom treatment was not successful had pre-operative urethral hypermobility. Subjective patient perception of SUI symptom severity showed significant improvement (mean severity of urinary loss perception 6.6 +/- 1.8 versus 2.3 +/- 3.3, p < 0.05). The frequency of incontinence on the 3-day voiding diary was significantly reduced at the follow-up (14.5 +/- 5.8 versus 4.3 +/- 7.9 episodes per 3 days, p < 0.05). The authors concluded that bulking agents urethral injection could be a valid option having no surgical complications. This therapeutic strategy is able to treat SUI and improve well being of cervical cancer patients after radical surgery.

Ghoniem et al (2009) evaluated the effectiveness and safety of Macroplastique as minimally invasive endoscopic treatment for female SUI primarily due to intrinsic sphincter deficiency. A total of 247 females with intrinsic sphincter deficiency were randomized 1:1 and treated with a transurethral injection of Macroplastique or Contigen (served as the control). Repeat treatment was allowed after the 3-month follow-up. Effectiveness was determined 12 months after the last treatment using Stamey grade, pad weight and Urinary Incontinence Quality of Life Scale scores. Safety assessment was recorded throughout the study. After 12 patients were excluded from study, 122 patients received Macroplastique injection and 125 received Contigen injection. Mean patient age was 61 years and the average history of incontinence was 11.2 years. Of the patients 24 % had undergone prior incontinence surgery. At 12 months after treatment 61.5 % of patients who received Macroplastique and 48 % of controls had improved 1 Stamey grade. In the Macroplastique group the dry/cure rate was 36.9 % compared to 24.8 % in the control group (p < 0.05). In the Macroplastique and control groups the 1-hour pad weight decrease was 25.4 and 22.8 ml from baseline (p = 0.64), and the mean improvement in Urinary Incontinence Quality of Life Scale score was 28.7 and 26.4 (p = 0.49), respectively. The authors concluded that Macroplastique injection was statistically more effective than Contigen for SUI primarily due to intrinsic sphincter deficiency with a 12.1 % cure rate difference.

Available evidence indicates that intra-urethral injection of bulking agents is safe and effective for the treatment of UI, especially in women, resulting from intrinsic sphincter deficiency. Appropriate candidates should have no improvement in incontinence with conservative measures. For collagen-based products, a pre-treatment skin test for collagen should be performed, and show no evidence of local hypersensitivity. Patients whose incontinence does not improve after 3 treatment sessions are considered treatment failures. Periurethral injections of bulking agents should be avoided in the following persons: previous pelvic radiation therapy (less likely to benefit); unstable or non-compliant bladder;
patients with severe allergies manifested by a history of anaphylaxis, or history or presence of multiple severe allergies; patients with an acute condition involving cystitis, urethritis, or infection; patients undergoing or planning to undergo desensitization injections to meat products (for collagen products).

The tension-free vaginal tape (TVT) procedure is an established treatment for intractable stress UI in persons who have failed behavioral and pharmacological treatments. An earlier assessment conducted by the Society of Obstetricians and Gynaecologists of Canada (2003) concluded that "[t]he TVT procedure is promising but currently under evaluation in trials that will establish its efficacy and safety."

Recent randomized trials and studies with long-term follow-up have indicated that TVT procedure is safe and effective for the treatment of stress UI. In a randomized controlled study \( (n = 72) \), Paraiso et al (2004) concluded that the TVT procedure results in greater objective and subjective cure rates for urodynamic SUI than does laparoscopic Burch colposuspension. This is in agreement with the results those by Valpas et al (2004) and Ward et al (2004). In a multi-center randomized controlled trial \( (n = 128) \), Valpas and associates reported that treatment with TVT results in higher objective and subjective cure rates at 1 year than treatment by means of laparoscopic mesh colposuspension. In another multi-center randomized controlled study \( (n = 344) \), Ward and colleagues concluded that the TVT procedure appears to be as effective as colposuspension for the treatment of urodynamic stress UI at 2 years.

Based on the results of a controlled trial with a 2-year follow-up \( (n = 50) \), Meschia and colleagues (2004) stated that TVT can be recommended for patients with prolapse and occult SUI. In a comparison study \( (n = 61) \), deTayrac and co-workers (2004) concluded that transobturator suburethral tape appears to be equally efficient as TVT for surgical treatment of SUI in women, with no reduction of bladder outlet obstruction at 1-year follow-up.

In a prospective observational, multi-center study \( (n = 90) \), Nilsson et al (2004) reported that the TVT procedure for treatment of female SUI is effective over a period of 7 years. This finding extends the observation of that by Abdel-Fattah and associates (2004) who concluded that the Pelvicol pubovaginal sling is a safe procedure in the surgical management of SUI with similar success rate and patient satisfaction rate to TVT up to 3 years of follow-up. An assessment by the National Institute for Clinical Excellence (NICE, 2003) concluded that "[t]he tension-free vaginal tape (TVT) procedure is recommended as one of a range of surgical options for women with uncomplicated urodynamic stress incontinence in whom conservative management has failed." The Ontario Health Technology Advisory Committee (2004) concluded that TVT be offered as one option to treat women who are affected by SUI severely enough to warrant a surgical treatment approach.

There is evidence that percutaneous tibial nerve stimulation (PTNS) (Urgent PC Neuromodulation System, Uroplasty, Inc., Minneapolis, MN) is an effective treatment for chronic non-neurogenic urinary voiding dysfunctions (e.g., overactive bladder/urge incontinence) in persons who have failed conservative treatments. In general, 3 to 12 treatments (once weekly) with PTNS are needed for symptom
If a patient fails to improve after 12 PTNS treatments, further treatments are unlikely to be effective.

Percutaneous tibial nerve stimulation is regarded as an intermediate therapy between pelvic muscle exercise and sacral nerve stimulation (e.g., InterStim). Treatments are usually administered in twelve 30-min sessions. Van der Pal et al (2006a) examined the relationship between quality of life (QoL) and voiding variables in patients with lower urinary tract dysfunction treated with PTNS \( n = 30 \). These investigators concluded that PTNS is useful for treating refractory urge incontinence and should at least be considered as a therapeutic alternative before resorting to aggressive surgery. Patients must have a reduction of greater than or equal to 2 pads/day before their QoL improves, and this might be the best definition of successful therapy for patients with urge UI. De Gennaro and colleagues (2004) assessed pain tolerability and the preliminary results of PTNS in children with unresponsive lower urinary tract symptoms \( n = 23 \). These researchers concluded that PTNS is safe, minimally painful and feasible in children. It seems helpful for treating refractive non-neurogenic lower urinary tract symptoms. This is in agreement with the findings of Hoebeke et al (2002) who reported that PTNS has a significant effect on voiding frequency, the uroflowmetry curve and bladder capacity in children with non-neurogenic bladder sphincter dysfunction. van Balken (2007) stated that PTNS is carried out in 12 weekly sessions of 30 mins each, through a percutaneously placed needle cephalad to the medial malleolus. Success can be obtained in about 2/3 of patients.

Guidelines from the American Urologic Association (Gormley et al, 2012) have concluded: “Clinicians may offer peripheral tibial nerve stimulation (PTNS) as third-line treatment in a carefully selected patient population. Option (evidence strength grade C; balance between benefits and risks/burdens uncertain”).

There is insufficient evidence to support the use of the Neocontrol system, which uses extracorporeal magnetic innervation (ExMI), for treatment of urinary incontinence. The clinical role of this technology as a conservative incontinence therapy has not been defined, and longer follow-up than that reported is required to determine the durability of treatment results. An assessment prepared for the California Technology Assessment Forum (CTAF, 2004) concluded that pelvic floor magnetic stimulation for UI does not meet CTAF’s criteria. The assessment concluded that “There is insufficient evidence from randomized clinical trials to conclude that pelvic floor magnetic stimulation is as beneficial as these alternative therapies.” Since the CTAF assessment was published, an additional randomized controlled clinical trial (Culligan et al, 2005) and an uncontrolled prospective study (Voorham - van der Zalm, 2006) found extracorporeal magnetic stimulation to be ineffective.

There is insufficient evidence to support the use of extra-urethral (non-circumferential retropubic adjustable compression devices (ProACT Therapy System) for treatment of UI. The ProACT Therapy System (Uromedica, Inc.), an adjustable continence therapy, is a minimally invasive urological device designed to treat persons with SUI. A Horizon Scanning Report of the ProACT by the Australian Safety and Efficacy Register of New Intervventional Procedures - Surgical (ASERNIPS, 2006) raised questions about the safety of the device. The report concluded that current available literature on the ProACT system suggested
that the device is safe for implantation. However as the studies presented suggest there are recurring safety issues with the device, namely post-operative complications such as the migration of the device and erosion of the urethra or the bladder. Although these complications were able to be corrected through removal and later re-implantation of the device in most cases, this presents an added risk to the patient as a result of the re-implantation procedure. Intra-operatively, implantation of the device is not reported as overly difficult and successful implantation may increase as surgeons familiarize themselves with the procedure. Further studies investigating the long-term (more than 2 years) effects of the ProACT Therapy System are needed to ascertain any long-term advantage of the ProACT Therapy System over other treatment options. Furthermore, randomized controlled trials or comparative studies are needed to compare differences in rates of complications between the ProACT Therapy System and other treatment options. The National Institute for Health and Clinical Excellence (2006) has concluded that current evidence on the safety and efficacy of insertion of extra-urethral (non-circumferential) retropubic adjustable compression devices for SUI does not appear adequate for this procedure to be used without special arrangements for consent and for audit and research.

Aboseif et al (2009) examined the safety, effectiveness, adjustability and technical feasibility of the adjustable continence therapy device (Uromedica, Plymouth, MN) for the treatment of recurrent female SUI. Female patients with recurrent SUI were enrolled in the study and a defined set of exclusionary criteria were followed. Baseline and regular follow-up tests to determine eligibility, and to measure subjective and objective improvement were performed. A trocar was passed fluoroscopically and with digital vaginal guidance to the urethro-vesical junction through small incisions between the labia majora and minora. The adjustable continence therapy device was delivered and the balloons were filled with isotonic contrast. The injection ports for balloon inflation were placed in a subcutaneous pocket in each labia majora. Device adjustments were performed percutaneously in the clinic post-operatively. An approved investigational device exemption FDA protocol was followed to record all adverse events. A total of 162 subjects underwent implantation with 1 year of data available on 140. Mean Stamey score improved by 1 grade or more in 76.4 % (107 of 140) of subjects. Improvement in the mean incontinence quality of life questionnaire score was noted at 36.5 to 70.7 (p < 0.001). Reductions in mean Urogenital Distress Inventory (60.3 to 33.4) and Incontinence Impact Questionnaire (54.4 to 23.4) scores also occurred (p < 0.001). Mean provocative pad weight decreased from 49.6 to 11.2 gm (p < 0.001). Of the patients 52 % (67 of 130) were dry at 1 year (less than 2 gm on provocative pad weight testing) and 80 % (102 of 126) were improved (greater than 50 % reduction on provocative pad weight testing). Complications occurred in 24.4 % (38 of 156) of patients. Explantation was required in 18.3 % (28 of 153) of the patients during 1 year. In terms of the complications 96.0 % were considered to be mild or moderate. The authors concluded that the Uromedica adjustable continence therapy device is an effective, simple, safe and minimally invasive treatment for recurrent female SUI. It can be easily adjusted percutaneously to enhance efficacy and complications are usually easily manageable. Explantation does not preclude later repeat implantation. Moreover, the authors stated that additional studies are needed to determine the long-term durability of the device.
In an editorial that accompanied the afore-mentioned study, Gilling (2009) stated that the results appear superior to those of bulking agents, although comparison of these heterogenous groups is difficult.

Kocjancic et al (2010) evaluated the implantation procedure and assessed patient outcomes of adjustable continence therapy for severe intrinsic sphincter deficiency and recurrent female SUI. The adjustable continence device consists of 2 silicone balloons on either side of the proximal urethra under the bladder neck, each attached to a titanium port buried in the labia to allow post-operative titration. Urodynamic assessment was done in 57 female patients in whom previous pelvic surgery had failed. Pad use and an incontinence quality of life questionnaire were evaluated before ACT implantation, post-operatively at 1, 3, 6 and 12 months, and annually thereafter. Patients recorded the overall impression and percent of improvement post-operatively based on the Patient Global Impression Index and a visual analog scale. Mean follow-up was 72 months (range of 12 to 84). At 6-year follow-up in 29 patients, mean pad use improved from 5.6 daily at baseline to 0.41 and intrinsic sphincter deficiency improved from 27.2 to 78.6 (p < 0.001). As measured on the visual analog scale, 68% of patients considered themselves dry. On the Patient Global Impression Index questionnaire 64% were very much improved, 23% were much improved and 13% were only minimally improved or unchanged. No patients considered themselves worse after the procedure.

Complications necessitating device removal developed in 21.1% of patients. The authors concluded that relative ease of insertion and the ability to tailor this therapy to individual needs makes this an attractive option for the challenging treatment for recurrent SUI due to intrinsic sphincter deficiency. Furthermore, they noted that these findings are encouraging, especially in terms of patient subjective outcomes, but their study was limited by the number of patients treated, the modification in procedural technique during the study, and the lack of more objective data. More studies are needed to establish the actual ACT mechanism of action in previously failed surgical cases and more closely monitor objective outcomes in the light of procedural and post-operative management.

Radiofrequency (RF) energy has been used for various clinical applications. Characteristics of RF energy allow it to be used for precisely controlled thermal therapy directed at soft tissues so as to induce such changes as collagen deposition and tissue shrinkage. These soft tissue effects are currently being examined for the treatment of genuine SUI in women. Ross et al (2002) evaluated the effectiveness of RF electrothermal energy in the treatment of genuine SUI (n = 94). The authors concluded that RF bipolar electrothermal energy appears to be a safe and efficient means of treating mild to moderate genuine SUI. It resulted in shrinkage and elevation of paravaginal connective tissue, stabilizing the urethra and bladder neck, thereby restoring continence. The authors stated, however, that long-term follow-up is necessary.

Sotomayor and Bernal (2003) studied the safety and quality of life impact of transurethral RF energy tissue micro-remodeling of the proximal urethra and bladder outlet in patients with SUI. Forty-one patients with SUI were sequentially enrolled into 4 treatment groups and then underwent rapid outpatient treatment under conscious sedation using an investigational RF energy delivery device. At 6 months, 75 to 80% of patients in all 4 groups have demonstrated an improvement
in quality of life. Two groups demonstrated statistical significance in both mean quality of life improvement and incontinence frequency reduction at 6 months. However, it is unclear if treatment resulted in clinically significant improvements in these parameters. Furthermore, long-term effectiveness of this approach is still unavailable.

Sotomayor and Bernal (2005) published longer follow-up findings of their 2003 study. They reported that significant incontinence episode frequency reduction was demonstrated by 3 of 4 treatment groups. They also noted that RF micro-remodeling demonstrated 12-month safety, quality of life improvement, and incontinence episode frequency reduction. No one treatment group demonstrated clear superiority in efficacy outcomes. Moreover, the authors stated that this pilot study had a number of limitations and weakness, namely, the trial was uncontrolled, and there were few subjects in any one treatment group. Also, diagnosis and follow-up evaluation lacked urodynamic testing.

Lenihan and colleagues (2005) examined the feasibility, safety, and patient comfort associated with RF tissue micro-remodeling in women with SUI given oral and local anesthesia. A total of 16 women with SUI and hypermobility (based on history and physical examination) with no history of previous definitive incontinence therapy were enrolled in this study. The women had a mean age of 49.7 years (range of 30 to 76 years) and a mean duration of incontinence of 7.6 years (range of 1 to 30 years). The non-surgical RF micro-remodeling treatment, which was previously shown to be of significant benefit when administered under intravenous (IV) sedation in an out-patient surgical center setting, was successfully completed in all 16 women. Either the treating physician or the patient had the option to convert to IV sedation during the procedure if there was too much discomfort; however, this did not occur in any of the 16 patients. Thus, neither the treating physician nor any patient determined that conversion to IV conscious sedation was needed for treatment completion. The first 6 patients received an oral sedative and oral analgesic as well as a local peri-urethral anesthetic block with 10-ml of 2% lidocaine. The final 10 patients (63%) received only 1 oral sedative or analgesic and a total of 10-ml lidocaine local anesthetic. Two women who received the maximum oral regimen (both oral sedation and analgesics) experienced nausea and emesis when drinking immediately after treatment, and 1 of these women also experienced urinary retention, which resolved after 24 hours of catheterization. Immediately before discharge, subjects classified their pain on a scale from 0 (“no pain”) to 10 (“terrible pain”). Mean score was 1.8, and 38% of subjects selected “0”. The authors concluded that this pilot trial demonstrated the feasibility, safety, and patient comfort associated with performing a novel new successful technique of non-surgical RF of the urethra for the treatment of SUI in an office-based setting using oral plus local anesthesia. It should be noted that this study was not designed to evaluate the effectiveness of RF micro-remodeling in the treatment of SUI.

Lenihan (2005) examined the effect of menopause and hormone replacement therapy (HRT) on incontinence quality of life (I-QOL) score improvement in women with moderate-to-severe SUI after transurethral RF tissue micro-remodeling. A total of 173 women with genuine SUI with bladder outlet hypermobility were enrolled. Subjects were randomly assigned to undergo either RF micro-remodeling (n = 110) or sham treatment (n = 63). Participants were analyzed by
menopausal status and HRT use for 10-point or greater I-QOL score improvement (an increase associated with subjective and objective SUI improvement).

Radiofrequency micro-remodeling resulted in 81% of subjects achieving 10-point or greater I-QOL score improvement versus 49% of sham subjects at 12 months (p = 0.04). Outcomes did not differ statistically when pre-menopausal (85%), post-menopausal using HRT (70%), and post-menopausal not using HRT (71%) groups were compared. The authors concluded that menopausal status and HRT demonstrated no impact on the quality of life improvement experienced by women with moderate-to-severe SUI who underwent RF tissue micro-remodeling. They also stated that further studies in pre-menopausal and post-menopausal women with SUI that measure additional effectiveness outcomes after RF micro-remodeling may provide further information concerning the clinical impact of menopause and HRT on this collagen-based treatment modality.

Appell and co-workers (2006) performed a prospective, randomized, controlled trial to demonstrate the 12 months safety and effectiveness of transurethral RF collagen micro-remodeling in women with SUI. Women with SUI, bladder outlet hypermobility, and leak point pressure (LPP) greater than or equal to 60 cm H(2)O were randomized to RF micro-remodeling or "sham treatment". Adverse events (AEs) were recorded. Incidence of greater than or equal to 10-point I-QOL score improvement, a magnitude of improvement with a demonstrated responsiveness to patient satisfaction with treatment and to greater than or equal to 25% reduction in both incontinence episode frequency and stress pad weight, served as a subjective outcome measurement. Change in mean LPP served as an objective outcome measurement. The 12-month RF micro-remodeling safety profile was statistically no different than that of sham treatment (a brief bladder catheterization). Seventy-four % of women with moderate-to-severe baseline SUI experienced greater than or equal to 10-point I-QOL score improvement at 12 months (p = 0.04). Women who underwent RF micro-remodeling demonstrated LPP elevation at 12 months, while sham-treated women demonstrated LPP reduction (p = 0.02). The authors concluded that transurethral RF micro-remodeling is a safe treatment for women with SUI. In women with moderate-to-severe SUI, this novel therapy resulted in statistically significant improvement in QOL of a magnitude associated with patient satisfaction with the treatment. Women who underwent RF micro-remodeling demonstrated a statistically significant elevation in mean LPP at 12 months. While this study found statistically significant improvement in frequency and severity of incontinence episodes, the criterion of greater than or equal to 25% reduction in both incontinence episode frequency and stress pad weight seems to be a "low bar" to clear. While RF micro-remodeling demonstrated a statistically significant elevation in mean LPP at 12 months; its clinical relevance is unclear. It is also interesting that the authors concluded that "transurethral RF micro-remodeling is a safe treatment for women with SUI" (effectiveness was not addressed). Furthermore, this study appeared to have the same group of subjects as reported by Lenihan (2005) -- 110 women underwent RF micro-remodeling and 63 underwent virtually identical "sham treatment".

In a retrospective study, Appell and associates (2007) evaluated long-term safety and effectiveness of RF collagen denaturation for SUI in 21 patients from a 12-month, randomized controlled trial utilizing 3-day diaries and the I-QOL survey. Significant increases in overall I-QOL scores 3 years or more post-treatment was
the primary end point. Secondary end points were reductions in frequency and severity of incontinence episodes. After 3 years, mean overall I-QOL score improvement was 12.7 (+/- 26); 56 % of patients achieved 50 % or more reduction in frequency. No new AEs occurred. These results indicated that RF collagen denaturation is safe and provides durable effectiveness. This was a longer follow-up (3 years) study of the previous studies reported (Lenihan, 2005; Appell et al, 2006). The authors also noted that additional studies of RF collagen denaturation are ongoing, including a study to expand the indication of RF collagen denaturation in patients who experienced suboptimal responses to a surgical intervention.

Vianello et al (2007) reviewed recent literature on mini-invasive surgical technique for the treatment of female SUI. Surgical aspects, intra-operative and peri-operative complications and objective and subjective outcomes were analyzed and compared. Studies had to investigate at least 40 women with a minimum follow-up of 12 months. A total of 38 prospective studies were found: 27 of them were on mid-urethral slings; 8 assessed urethral injections; and 3 RF treatment. Fifteen studies were randomized. Follow-ups ranged from 12 to 60 months, except for sexual function which had a 6-month follow-up. Ten out of 38 studies assessed patients who did not refer pelvic organ prolapse or detrusor over-activity and had not undergone any previous anti-incontinence procedure. The authors concluded that mid-urethral slings showed good outcomes and are safe and brief to perform and have a relatively short learning curve. Urethral injections showed discouraging results, as they have poor outcomes and repetitive treatments are frequently necessary. Injections can be used in women with contra-indications to major surgical procedures, with intrinsic sphincter deficiency as the main cause of incontinence. Radiofrequency showed worse results than mid-urethral slings, but is a valuable choice in women who refuse more invasive procedures.

Appell (2008) stated that patients who received transurethral collagen denaturation by means of non-ablative RF energy applied through a transurethral probe have shown improvements in quality of life and in Valsalva leak point pressure. This procedure presents a beneficial non-surgical treatment option for women with SUI.

An assessment by the California Technology Assessment Forum (Karliner, 2008) on RF micro-remodeling for the treatment of female SUI stated that 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. It stated that RF micro-remodeling with the Renessa System meets its criteria for safety, effectiveness and improvement in health outcomes for the treatment of moderate-to-severe female SUI in non-pregnant women who are either not able or not willing to undergo surgery for their condition.

In a continuing, prospective, 36-month, open-label, single-arm clinical trial, Elser et al (2009) evaluated the effectiveness of non-surgical transurethral collagen denaturation (Renessa) in women with SUI caused by bladder outlet hypermobility. Twelve-month results from intent-to-treat (ITT) analysis were reported. Women with SUI secondary to bladder outlet hypermobility for 12 months or longer who failed earlier conservative treatment and had not received
earlier surgical or bulking agent therapy were included in the study. Subjects were treated as out-patients and received an oral antibiotic and local periurethral anesthesia before undergoing Renessa therapy. Voiding diaries and in-office stress pad weight tests yield objective assessments. Subjective measures include the Incontinence Quality of Life (I-QOL), Urogenital Distress Inventory (UDI-6), and Patient Global Impression of Improvement (PGI-I) instruments. A total of 136 women received treatment (ITT population). Patients experienced significant reductions versus baseline in median number of leaks caused by activity/day and activity/week (p < 0.0026 for both), with 50 % of patients reporting 50 % or more reduction. Pad weight tests revealed that 69 % of women had 50 % or more reduction in leakage (median reduction 15.2 g; p < 0.0001); 45 % were dry (29 % no leaks; 16 % less than 1-g leakage). Significant improvements occurred in median scores on the I-QOL (+9.5 [range of -66.0 to 91.0]; p < 0.0001) and mean scores on the UDI-6 (-14.1 +/- 24.7; p < 0.0001). Furthermore, 71.2 % showed I-QOL score improvement, including 50.3 % with 10-point or greater improvement, and 49.6 % reported on the PGI-I that they were "a little," "much," or "very much" better. The authors concluded that at 12 months, treatment of SUI with non-surgical transurethral collagen denaturation resulted in significant improvements in activity-related leaks and quality of life.

It is also interesting to note that transvaginal RF bladder neck suspension procedure for SUI has not been shown to provide satisfactory results. Buchsbaum and colleagues (2007) evaluated the outcome and patient acceptance of the transvaginal RF bladder neck suspension procedure. A retrospective chart review of 18 women treated with the transvaginal RF bladder neck suspension procedure for SUI was conducted. Data on demographics, urodynamics, daily leakage episodes, complications, patient satisfaction, and further intervention were collected. The mean number of leaks per day was 5.7. There were no complications. Post-operatively, 2 patients were continent, 4 were improved, and 10 were unimproved. The mean number of daily leaks was reduced to 2.7. Five patients reported to be extremely satisfied with the procedure; 1 patient was satisfied, and 10 were not satisfied. Seven patients sought additional treatment within 1 year. Low cure rate, low patient satisfaction, and high rate of additional treatment led these researchers to abandon transvaginal RF bladder neck suspension procedure as a treatment option.

Ismail (2008) evaluated the safety and effectiveness of transvaginal RF remodelling of the endopelvic fascia as a primary procedure for SUI due to urethral hypermobility in women. It included 24 patients who had the procedure at 2 district general hospitals. Outcome measures included the pad test, urodynamic assessment, continence diary, pain scores, as well as operative and post-operative complications and assessment was made on recruitment during hospital admission and at 3, 6 and 12 months follow-up. A rising failure rate was noted as early as 3 months, leading to a cumulative cure rate of 45.8 % at 12 months follow-up. This low effectiveness could be attributed to inherent weakness of the endopelvic fascia. No major complications were encountered and pain scores were mild. In this regard, a draft assessment by the California Technology Assessment Forum (2008) on RF micro-remodeling for the treatment of female SUI stated that RF micro-remodeling with the SURx System (paraurethral or transvaginal) does not meet its criteria for safety, effectiveness and improvement in health outcomes for the treatment of female SUI.
Polypropylene meshed tape may be placed at the mid urethra or bladder neck using retropubic or transobturator approaches. Various types of sub-urethral tapes inserted via the transobturator route (TVT obturator route [TVTO] and transobturator tape [TOT]) have been used for the treatment of SUI. In a systematic review, Latthe and co-workers (2007) evaluated the effectiveness and complications of TOTs as treatment of SUI. Randomized controlled trials (RCTs) that compared the effectiveness of TVTO or TOT with synthetic TVT by retropubic route for the treatment of SUI in all languages were included. Two reviewers extracted data on participants’ characteristics, study quality, population, intervention, cure and adverse effects independently. There were 5 RCTs that compared TVTO with TVT and 6 RCTs that compared TOT with TVT. When compared by subjective cure, TVTO and TOT at 2 to 12 months were no better than TVT (OR 0.85; 95% CI: 0.60 to 1.21). Adverse events such as bladder injuries (OR 0.12; 95% CI: 0.05 to 0.33) and voiding difficulties (OR 0.55; 95% CI: 0.31 to 0.98) were less common, whereas groin/thigh pain (OR 8.28; 95% CI: 2.7 to 25.4), vaginal injuries or erosion of mesh (OR 1.96; 95% CI: 0.87 to 4.39) were more common after tape insertion by the transobturator route. The authors concluded that the evidence for short-term superiority of effectiveness of TOTs is currently limited. Bladder injuries and voiding difficulties are lower, but the risk of vaginal erosions and groin pain is higher with TVTO/TOT. Methodologically sound and sufficiently powered RCTs with long-term follow-up are needed, and the results of continuing trials are awaited.

In a prospective, single-blinded, multi-center RCT, Barry et al (2008) compared the safety and effectiveness of the transobturator tape (Monarc) with the retropubic tape (tension-free vaginal tape, TVT) for the treatment of SUI. A total of 187 women with SUI were randomly allocated to undergo surgery with either the Monarc sling (n = 80) or TVT (n = 107). Outcome measures were intra-operative complications (especially bladder injury), peri-operative complications, symptomatology, quality of life as well as urodynamic outcomes. At 3 months, data were available on 140 women, 82 (59%) TVT and 58 (42%) Monarc. The TVT group was significantly more likely to be complicated by bladder injury (7 TVT, 0 Monarc, p < 0.05). Blood loss and operative time were significantly less in the Monarc group, which was 49 mls (31) versus that of the TVT group, which was 64 mls (41) p < 0.05; 18.5 mins (6.5) TVT versus 14.6 mins (6) Monarc (p < 0.001). The subjective and objective SUI cure rates were 86.6% (71) versus 72.4% (42) p = 0.77 and 79.3 versus 84.5%, p = 0.51 for the TVT and Monarc groups, respectively. Both groups reported similar improvement in incontinence impact and satisfaction with their operation, although return to activity was significantly quicker with the transobturator route (p = 0.029). The authors concluded that the transobturator tape appears to be as effective as the retro-pubic tape in the short-term, with a reduction in the risk of intra-operative bladder injury, shorter operating time, decreased blood loss, and quicker return to usual activities.

Barber et al (2008) compared the safety and effectiveness of the transobturator tape to TVT in the treatment of SUI in patients with and without concurrent pelvic organ prolapse. A total of 170 women were randomized to receive TVT or transobturator tape. Subjects with detrusor over-activity or previous sling surgery were excluded. The primary outcome was the presence or absence of abnormal bladder function, a composite outcome defined as the presence of any the
following: incontinence symptoms of any type, a positive cough stress test, or re-treatment for SUI or post-operative urinary retention assessed 1 year following surgery. This study was a non-inferiority study design. Of 180 women who enrolled in the study, 170 underwent surgery and 168 returned for follow-up, with a mean follow-up of 18.2 +/- 6 months. Mean operating time, length of stay, and post-operative pain scores were similar between the 2 groups. Bladder perforations occurred more frequently in the TVT group (7% compared with 0%, p = 0.02); otherwise, the incidence of peri-operative complications was similar. Abnormal bladder function occurred in 46.6% of TVT patients and 42.7% of transobturator tape patients, with a mean absolute difference of 3.9% favoring transobturator tape (95% CI: -11.0% to 18.6%). The "p" value for the 1-sided non-inferiority test was 0.006, indicating that transobturator tape was not inferior to TVT. The authors concluded that the transobturator tape is not inferior to TVT for the treatment of SUI and results in fewer bladder perforations. Moreover, they also noted that larger studies are needed to assess the relative risk of the less common but potentially severe complications that have been seen with both procedures. Furthermore, studies with longer follow-up are necessary to ascertain if the effectiveness of transobturator tape is durable.

Koch and Zimmern (2008) evaluated the evidence base for surgical management of SUI in women. Pubovaginal sling has a higher success rate than the Burch at the expense of a higher morbidity. A prophylactic Burch procedure at the time of an abdominal sacrocolpopexy can reduce secondary SUI and urge incontinence. Suburethral tapes have a higher cure rate for patients with predominant SUI and can safely be placed at the time of concomitant pelvic surgery. The TVT has a higher rate of lower urinary tract injury and voiding dysfunction when compared with transobturator tape. The authors concluded that the Burch and pubovaginal sling have a high success rate for treating SUI; prospective RCTs are needed to evaluate the long-term results of suburethral slings. This is in agreement with the observation of Rogers (2008) who stated that the use of the transobturator tape (one of the many newer techniques) entails the placement of polypropylene mesh through the obturator foramen rather than through the retropubic space, but large, randomized trials with adequate follow-up comparing these newer anti-incontinence procedures are limited.

A systematic evidence review by Sung et al (2007) found that the transobturator approach was associated with a lower risk of complications than the retropubic approach to midurethral slings for the treatment of stress incontinence, but there was insufficient evidence to compare the effect of surgical approaches on objective and subjective outcomes.

Guidelines on choice of surgery for SUI from the Society of Obstetricians and Gynaecologists of Canada (Robert et al, 2005) concluded that there is insufficient evidence to support the use of the TOT procedure for stress urinary incontinence. Guidelines on UI from the National Collaborating Centre for Women's and Children's Health concluded that the TOT procedure is recommended as alternative treatment option for SUI if conservative management has failed, "provided women are made aware of the lack of long-term outcome data." This was a "D" recommendation, based on consensus or low quality evidence. Earlier guidance on the TOT procedure from the National Institute for Health and Clinical Excellence (NICE, 2005) was withdrawn when NICE was made aware that one of
the main studies that was considered in the overview of evidence on the safety and efficacy of this procedure had been withdrawn by the journal that published it.

Tahseen and Reid (2009) estimated changes in overactive bladder (OAB) symptoms and urge UI in patients undergoing the TOT procedure for SUI and mixed UI. Telephone interviews were conducted using the International Consultation on Incontinence-Female Lower Urinary Tract Symptoms questionnaire, the International Consultation on Incontinence-Overactive Bladder (ICIQ-OAB) questionnaire, and the Verbal Analogue Satisfaction (VeAS) scale. Pre-operative OAB scores were compared with post-operative scores in women with SUI only (group 1), mixed UI with predominant stress leakage (group 2), and mixed UI with predominant urge (group 3). Case notes were reviewed for pre-operative assessment and complications. At median follow-up of 13 months, significant improvement was noted in ICIQ-OAB scores, from a median of 10 (1 to 15) pre-operatively to a median of 3 (0 to 11) post-operatively ($p < 0.001$). Overall, urge UI was cured in 19 of 44 (43%) patients, improved in a further 16 (36%), and was persistent in only 9 (21%). In group 2 (SUI predominant), urge UI was cured in 10 of 23 (43.5%) patients, improved in 10 (43.5%), and persistent in 3 (13%). In group 3 (urge UI predominant), urge UI was cured in 9 of 21 (43%) patients, improved in 6 (28.5%), and persistent in 6 (28.5%). Post-operative lower urinary tract symptom scores were low in all 3 groups (median 4/48 [0 to 18]). Stress incontinence was cured in 77%, improved in a further 19%, and unchanged in 4%. Median VeAS score was 9 (2 to 10); 21% (11/52) of participants had low satisfaction scores (less than 8) owing to persistent urge and slow voiding. The authors concluded that marked resolution or improvement (79%) in urge UI after the TOT procedure was noted, and no case of de novo urge UI was identified. Moreover, the authors noted that it is unclear how to predict who will benefit and remain free of urge following the surgery. Furthermore, they stated that larger outcome studies of TOT with longer follow-up are needed, ideally using standardized, validated assessment tools, focusing on the common problem of mixed UI, with clear reporting criteria, and assessment at baseline and after surgery.

On behalf of the Agency for Healthcare Research and Quality, the Vanderbilt Evidence-based Practice Center systematically reviewed evidence on treatment of OAB, urge UI, and related symptoms. These investigators focused on prevalence and incidence, treatment outcomes, comparisons of treatments, modifiers of outcomes, and costs. They included studies published in English from January 1966 to October 2008; and excluded studies with fewer than 50 subjects, fewer than 75% women, or lack of relevance to OAB. Of 232 included publications, 20 were good quality, 145 were fair, and 67 poor. These researchers calculated weighted averages of outcome effects and conducted a mixed-effects meta-analysis to examine outcomes of pharmacotherapies across studies.

Overactive bladder affects more than 10 to 15% of adult women, with 5 to 10% experiencing urge UI monthly or more often. Six available medications are effective in short-term studies: estimates from meta-analysis models suggest extended release forms (taken once-daily) reduce urge UI by 1.78 (95% CI: 1.61, 1.94) episodes per day, and voids by 2.24 (95% CI: 2.03, 2.46) per day. Immediate release forms (taken twice-daily or more) reduce urge UI by 1.46 (95% CI: 1.28, 1.64), and voids by 2.17 (95% CI: 1.81, 2.54). As context,
placebo reduces urge UI episodes by 1.08 (95% CI: 0.86, 1.30), and voids by 1.48 (95% CI: 1.19, 1.71) per day. No one drug was definitively superior to others, including comparison of newer more selective agents to older anti-muscarinics. Procedural and surgical treatments, such as sacral nerve stimulation (neuromodulation), and bladder instillation of oxybutynin or injections of botulinum toxin, were found to treat symptoms in select groups of women though more information is needed to understand safety and effectiveness. Acupuncture was the sole complementary and alternative medicine treatment, among reflexology and hypnosis, with early evidence of benefit. The strength of the evidence is insufficient to fully inform choice of these treatments. Select behavioral interventions were associated with symptom improvements comparable to medications. Limited evidence suggests no clear benefit from adding behavioral interventions at the time of initiation of pharmacotherapy. The authors concluded that OAB and associated symptoms are common; treatment effects are modest. Quality of life and treatment satisfaction measures suggest such improvements can be important to women. The amount of high quality literature available is meager for helping guide women’s choices. Gaps include weak or absent data about long-term follow-up, poorly characterized and potentially concerning harms, information about best choices to minimize side effects, and study of how combinations of approaches may best be used. This is problematic since the condition is chronic and a single treatment modality is unlikely to fully resolve symptoms for most women.

Sirls et al (2002) reported the long-term results of the FemSoft urethral insert for the management of female SUI. This 5-year controlled multi-center study enrolled 150 women. Outcome measures included pad weight tests (PWT), voiding diary (VD), quality of life (QoL) and satisfaction questionnaires. Outcome measures during the baseline period were compared to evaluations during follow-up. Concurrent evaluations with and without device use were also performed. Safety evaluations included urinalysis and culture, LPP and cystoscopy. Adverse events were recorded throughout the study. One to 2 years of follow-up were collected on all study participants (mean of 15 months). Statistically significant reductions in overall daily incontinence episodes (p < 0.001) and PWT urine loss (p < 0.001) were observed with the device at all follow-up intervals, and 93% of women had a negative PWT at 12 months. Women were satisfied with ease of use of the device, comfort and dryness, and significant improvements in QoL were observed (p < 0.001). Sub-group analysis revealed that the insert was effective, despite the presence of urgency, low LPP, failed surgery and advanced age. Adverse events included symptomatic urinary tract infection in 31.3%, mild trauma with insertion in 6.7%, hematuria in 3.3%, and migration in 1.3% of women. The results of PWT and VD demonstrated device efficacy. Women were satisfied and significant improvements in QoL were observed; AE were transient and required minimal or no treatment. The authors concluded that the urethral insert should be considered as an option for the management of SUI.

Robinson et al (2003) evaluated the safety and efficacy of an urethral device (NEAT) and compared it with the Reliance Insert. The ease of use of both devices was then evaluated. A total of 24 women with mixed or SUI were enrolled in the study. Study subjects were blinded and randomly assigned to a device group. Device efficacy was assessed by pad weighing at 0 and 4 months. Success was defined as a 50% or greater reduction in urine loss using the formula 100 [(pad
weight without device - pad weight with device)/pad weight with device]. Safety was evaluated using urinalysis and urine cultures. Ease of use assessment scales were also completed. Eleven patients were randomized to the Reliance Insert and 13 to the NEAT device. There were no significant differences between the 2 groups in age, height, weight, duration of incontinence, pad weight, leakage score, parity or QoL score. Based on the pad weight success formula, there was no significant difference in device success between the 2 groups at 4 months. Women who were post-menopausal had a trend towards a higher level of success in reduction of their pad weight. Previous treatment, diagnosis and hormone replacement therapy all had no relationship to device success. Leakage score data showed that subjects had a significant decrease in urine leakage when using either device. There was no statistically significant difference in ease of use between the 2 devices. Adverse symptoms most commonly noted were awareness of the device (62.5 %), urgency (29.2 %), and urethral discomfort or pain (20.8 %). One urinary tract infection (UTI) was observed. The most common finding on urinalysis was trace hematuria (15.8 %). The authors concluded that the NEAT device appears to be at least as effective and safe as the Reliance Insert. Both devices are effective at decreasing urine leakage in patients with SUI or mixed UI. The risk of UTI is low, but these devices may cause trace hematuria.

The Genityte procedure is a novel approach for the treatment of SUI. It entails the use of laser that works in a similar fashion to skin tightening treatments. The treatment stimulates the skin’s natural production of collagen making it more supple and elastic. Genityte works to regain bladder control by tightening the tissue around the urethra. The number of treatments needed to restore the function of a woman’s urethra supposedly depends largely on how much collagen is still present in her skin. The clinical value of the Genityte procedure needs to be validated by well-designed studies.

In a pilot study, Groen and colleagues (2005) evaluated the results of chronic pudendal nerve neuromodulation (CPNN) on women with idiopathic refractory detrusor over-activity incontinence. A percutaneous screening test (PST) was performed in patients with urodynamically demonstrated detrusor over-activity incontinence. Such a test includes the performance of a cystometrogram without and with percutaneous pudendal nerve stimulation and is considered positive if stimulation results in a more than 50 % increase in the bladder volume at the first involuntary detrusor contraction or the maximum cystometric capacity. Patients with a positive PST qualified for the implantation of a mini-neurostimulator with an integrated electrode, a so-called Bion(R), adjacent to the pudendal nerve at Alcock’s Canal. Five-day voiding-incontinence diaries were the main tool for the evaluation of therapy. A PST was performed in 14 women; 6 patients responded positively and received a Bion(R). The degree of incontinence decreased significantly in this group, which also included patients in whom sacral neuromodulation had failed. There were no severe adverse events. The authors concluded that CPNN may reduce the degree of detrusor over-activity incontinence, even in patients in whom sacral neuromodulation fails.

Spinelli et al (2005) stated that pudendal nerve stimulation has beneficial effects on numerous pelvic floor function impairments such as urinary and/or fecal incontinence, retention, and constipation. In preceding literature the implant technique required a fairly complex and invasive surgery, although recent
advances with percutaneous placement of the lead through an introducer have made the procedure much less invasive. These researchers performed staged procedure similar to that of sacral neuromodulation (SNM) to place tined lead near the pudendal nerve, using neurophysiological guidance that allowed accurate pudendal nerve stimulation through either perineal or posterior approach. They have named this approach CPNN. A total of 15 neurogenic patients (8 males, 7 females) with symptoms of urge UI due to neurogenic over-active bladder underwent CPNN. All patients had complete neurophysiological and urodynamic evaluation at baseline and follow-up and were asked to complete voiding and bowel diary for 7 days. During screening, average number of incontinent episodes per day decreased from 7 +/- 3.3 to 2.6 +/- 3.3 (p < 0.02, paired t-test). Eight patients became continent, 2 improved by more than 88 % (from 9 to 1 daily incontinence episode) and 2 patients reduced the number of incontinence episodes by 50 %. The implantable pulse generator (IPG) was subsequently implanted in those 12 patients. Three patients without improvement did not continue to second stage. In implanted patients with 6 months follow-up, urodynamic evaluation showed an objective improvement in the maximum cystometric capacity which increased from 153.3 +/- 49.9 to 331.4 +/- 110.7 ml (p < 0.01, paired t-test). The maximum pressure decreased from 66 +/- 24.3 to 36.8 +/- 35.9 cm H2O (p = 0.059, paired t-test). Eight patients reported significant improvement in bowel function. The authors concluded that CPNN is feasible. Neurophysiological guidance is mandatory to place the lead near the pudendal nerve either using perineal or posterior approach. They stated that further studies must be carried out to identify the best stimulation parameters and to verify the long-term results.

Seif and associates (2005) noted that sacral neuromodulation is known to be an alternative therapeutic option for patients with anti-cholinergic resistant overactive bladder (OAB). For the same indication, a microstimulation system called BION is available since last year. The BION-stimulator, which only measures 2.8 x 0.3 cm, is designed for pudendal nerve stimulation. Its implantation technique as well as the first clinical results were presented and discussed. During an out-patient PST, a pudendal nerve stimulation is performed with a needle electrode in local anesthesia. A 50 % increase in the urodynamic parameters (bladder capacity, first desire to void, compliance, etc.) is an indication for a chronic implantation of the BION stimulator, which also can be placed in local anesthesia. Two patients have been treated with a BION-stimulator in the authors' clinic so far. Patient 1 suffered from an OAB with frequent UI and patient 2 had a sensory OAB with high voiding frequency. After the BION(R)-implantation, patient 1 showed a reduction in incontinence episodes by 31.5 % a day and patient 2 had lowered voiding frequencies from 12.6 to 7 a day. The post-operative urodynamic investigations confirmed these clinical results. The authors concluded that the BION-system and CPNN seem to be alternatives to sacral neuromodulation, however, patient selection is difficult as subchronic stimulation for a longer period of time is not possible so far.

Madjar et al (2001) reviewed the evolution of appliances and devices used for treating post-prostatectomy UI. These investigators used the MEDLINE to search the literature from 1966 to March 2000 and then manually searched bibliographies to identify studies that their initial search may have missed. The evolution of treatment for post-prostatectomy UI may be traced back to the 18th century.
main schools of thoughts simultaneously evolved. The first fixed urethral compression devices were constructed to enable urethral obstruction by fixed resistance. This outlet resistance allows voiding after intra-abdominal and intra-vesical pressure is elevated but it is sufficient to prevent leakage between urinations. The other school of thought preferred creation of dynamic urethral compression in which outlet resistance is not fixed but may be decreased when voiding is desired or elevated between urinations. Therapeutic fixed and dynamic urethral compression interventions may be further divided into external or internal compressive devices or procedures. External fixed compression devices may be traced back to antiquity. A penile clamp, similar to the later Cunningham clamp, and a truss designed to compress the urethra by external perineal compression were presented in the Heister textbook of surgery, Institutiones Chirurgicae, as early as 1750. Dynamic compressive devices applied externally were developed much later, such as the first artificial urinary sphincter, described by Foley, in 1947 and the Vincent apparatus, described in 1960. The modern era of fixed urethral compression began in 1961 with Berry. Acrylic prostheses impregnated with bismuth to allow radiographic visualization were produced in various shapes and sizes, and used to compress the urethra against the urogenital diaphragm. In 1968 the UCLA group under the direction of Kaufman began to use cavernous crural cross-over to compress the bulbous urethra (Kaufman I). Later, 2 other modifications were described, including approximation of the crura in the midline using a polytetrafluoroethylene mesh tape (Kaufman II) and an implantable silicone gel prosthesis (Kaufman III). With the advent of the artificial urinary sphincter pioneered by Scott in 1973 interest in passive urethral compression disappeared in favor of the implantation of an inflatable circumferential prosthetic sphincter. Recently, there has been a trend back to passive urethral compression. The authors concluded that much creativity has been dedicated to solve the complex and challenging problem of post-prostatectomy UI. Devices used for treating this condition may be grouped according to the mechanism of action and how they are applied. Passive urethral compression, long abandoned in favor of dynamic implantable sphincters, has re-emerged.

Moore et al (2004) evaluated the safety, effectiveness, comfort, and patient satisfaction with 3 penile compression devices: the Cunningham clamp, C3, and U-Tex. The devices were tested in random order in a multiple-period, cross-over study design using a Latin squares configuration. The subjects had undergone radical prostatectomy 6 months or more before the study, had no neurologic or cognitive impairment, and had not undergone radiotherapy. Baseline penile Doppler ultrasonography was followed by ultrasound scanning with each device. In random order, subjects completed a 4-hour pad test, with and without each device, and the questionnaire. A total of 12 men completed the study. The mean Mini-Mental State Examination score was 29.6 (SD 1.2, range of 27 to 30). The mean urine loss at baseline was 122.8 g (SD 130.8). The mean urine loss with each device was 53.3 g (SD 65.7) with the U-Tex, 32.3 g (SD 24.3) with C3, and 17.1 g (SD 21.3) with the Cunningham clamp (p < 0.05). No device had an impact on the resistive index; the C3 and U-Tex allowed good cavernosal artery flow, and the Cunningham clamp significantly lowered the distal blood flow velocity (from 12.5 to 7.3 cm/s [left systolic velocity] to 9.5 cm/s [right systolic velocity]) even at the loosest setting. The Cunningham clamp was ranked positively by 10 of 12 men; 2 of 12 men rated the C3 positively; none rated the U-Tex positively. The
authors concluded that the Cunningham device was the most effective and most acceptable to users, but also contributed to reduced systolic velocity in all men. None of the devices completely eliminated urine loss when applied at a comfortable pressure. Individualized instruction to cognitively capable men is necessary to ensure appropriate application, comfort, and fit.

An UpToDate review on "Urinary incontinence in men" (Clemens, 2012) states that "[a]djunctive measures include incontinence pads, indwelling catheters, external urinary catheters, and penile incontinence clamps. The treatment of urinary incontinence with an indwelling catheter is usually a poor management choice, as it is associated with urethral trauma, infection, and nephrolithiasis. Incontinence pads and indwelling catheterization are discussed elsewhere. In men, external urinary catheters (condom catheters) can be useful in managing urinary incontinence, with less associated morbidity compared to indwelling catheterization. Successful use of an external catheter requires adherence of the condom sheath to the penis. Use of external catheters may not be possible in some patients who are not able to keep catheters in place (e.g., due to skin infections) or not physically able to place catheters (e.g., obesity, neurologic impairment). In patients with neurogenic bladder dysfunction, the use of an external catheter may be associated with progressive renal damage unless it is confirmed with urodynamics that bladder storage pressures remain low .... Another option is the use of a penile incontinence clamp. A clamp is most suitable in ambulatory men with stress incontinence and good bladder storage function. Clamps are meant to be used on an intermittent basis. Their use in men with sensory abnormalities should be avoided, as tissue damage from the clamp can occur with prolonged use".

The Athena pelvic muscle trainer is an electronic device designed to strengthen pelvic muscle in women. This would appear to be similar to Kegelmaster. Per CPB 223, Aetna does not cover the Kegelmaster, Gyneflex or similar devices for the treatment of UI because these devices are considered exercise machines, and they do not meet Aetna's definition of covered durable medical equipment (DME). Furthermore, there is a clinical trial on the effectiveness of the Athena pelvic muscle trainer device in the treatment of stress, urge or mixed incontinence in women. http://clinicaltrials.gov/ct2/show/NCT01073878.

Elmi et al (2011) evaluated the effectiveness of endourethral autologous myoblast transplantation in the treatment of UI in children with bladder exstrophy-epispadias complex. Subjects were evaluated at 4 years of follow-up regarding the safety, efficacy and durability of the procedure, and health related quality of life. A total of 7 boys underwent autologous myoblast transplantation between May and December 2006. All patients had persistent UI after bladder neck reconstruction and bulking agent injection. Patients were followed for 4 years after autologous myoblast transplantation regarding clinical outcomes and cystometric, urodynamic, uroflowmetric and urethrocytoscopic evaluations. Health related quality of life was also measured before treatment and at final follow-up. No evidence of urinary obstruction was observed. Five children (71 %) were completely continent and 2 (29 %) were socially dry with complete daytime dryness at final follow-up. Health related quality of life was improved significantly. Urodynamic studies revealed a progressive increase in bladder capacity (p < 0.001). Mean detrusor leak point pressure showed a 27 cm H(2)O (158 %) increase during 4-year follow-up.
Uroflowmetry parameters of voided volume and average maximum flow rate were improved significantly (p < 0.001). The authors concluded that the 4-year outcomes demonstrate that autologous myoblast transplantation for UI in children with bladder exstrophy-epispadias complex is relatively reliable, reproducible, safe and effective with minimal morbidity. This novel treatment represents a promising therapeutic approach in patients with UI. They stated that further randomized trials with larger numbers of patients and longer follow-up are needed.

In a pilot study, Marcelissen et al (2011) examined if bilateral sacral nerve stimulation can be effective to restore treatment efficacy in patients in whom unilateral sacral neuromodulation fails. Patients in whom unilateral sacral neuromodulation failed were included in analysis. The percutaneous nerve evaluation test was used to evaluate the effect of contralateral and bilateral stimulation. The stimulation electrode was placed in the contralateral S3 foramen and symptoms were self-recorded using a 3-day voiding diary. Clinical success was defined as more than 50 % improvement in at least 1 relevant voiding diary parameter versus baseline. The 15 study patients underwent test stimulation with percutaneous nerve evaluation. In 3 patients lead migration was suspected and, thus, they were not included in analysis. Four of the remaining 12 patients had a successful response to percutaneous nerve evaluation, of whom 3 were eventually implanted with a contralateral lead. After 12 months of treatment 2 of the 3 patients had a successful outcome. The authors concluded that only a select group of patients appeared to benefit from bilateral stimulation after unilateral therapy failure. They stated that further investigation is needed to determine the predictive factors and cost-effectiveness of this treatment.

Guidelines from the American Urologic Association (Gormley et al, 2012) have concluded: “Clinicians may offer sacral neuromodulation (SNS) as third-line treatment in a carefully selected patient population characterized by severe refractory OAB symptoms or patients who are not candidates for second-line therapy and are willing to undergo a surgical procedure. Recommendation (evidence strength grade C; benefits outweigh risk/burdens)”.  

Woodruff et al (2008) stated that little is known about the host response to the various biologic and synthetic graft materials used as substitutes for autologous fascia. These researchers investigated the host response to sling graft materials in humans. A total of 24 women undergoing sling revision had a portion of the graft material removed for comparative analysis. At exploration, the degree of graft preservation (integrity), encapsulation, infection, and fibrosis was quantified. A histopathologic analysis was performed by systematically examining each specimen for the inflammatory response, neovascularity, and host fibroblast infiltration. A total of 24 grafts were explanted at 2 to 34 months after implantation. The indications for removal were a lack of sling efficacy in 2, urinary retention in 9, and sling obstruction in 13. The types of graft material were polypropylene mesh (PPM) in 10, autologous fascia in 5, porcine dermis in 4, cadaveric dermis in 3, and cadaveric fascia in 2. No graft degradation had occurred in PPM material. Autologous and cadaveric fascia had the most demonstrable graft degradation. No encapsulation had occurred with autologous fascia or PPM. The porcine dermis was the most encapsulated. No host infiltration had occurred with the encapsulated porcine grafts, and only peripheral infiltration of fibroblasts had occurred in the cadaveric grafts. The PPM grafts had
the greatest number of fibroblasts throughout the entire graft. Neovascularity was the most prevalent in mesh and was also present in the autologous fascia. Giant cells were seen in 2 mesh and 2 porcine grafts. The authors concluded that the results of this study have shown that porcine dermis has the potential to encapsulate. The degree of host tissue infiltration was greatest with PPM, and no degradation of the mesh material had occurred with time.

An UpToDate review on “Treatment of urinary incontinence” (DuBeau, 2012) does not mention the use of collagen porcine dermis mesh as a therapeutic option. Furthermore, an UpToDate review on “Overview of transvaginal placement of reconstructive materials (surgical mesh or biografts) for treatment of pelvic organ prolapse or stress urinary incontinence” (Trabuco and Gebhart, 2012) states that “Midurethral slings, using macroporous polypropylene mesh, are the most common procedures for treatment of SUI [11]. A sling made of microporous material (ObTape) for midurethral slings was associated with high complication rates and was removed from the market”. It does not mention the use of collagen porcine dermis.

Goldman et al (2012) reviewed the current state of research in the use of stem cells (SCs) for SUI and assessed the likelihood of this becoming a relevant treatment option. The peer-reviewed literature consisting of relevant clinical and animal studies on the topic of SUI was surveyed and reviewed. Animal studies have demonstrated the potential utility of SCs in promoting functional recovery of the urethra after simulated childbirth injury. Research in animals suggests similar urethral recovery after injection of bone marrow derived mesenchymal SC secretions as after injection of the SCs themselves. Therefore, whether the improvements result from the injection of the SCs themselves or from their secretion of specific proteins is unclear. Early clinical trials have demonstrated the feasibility and short-term safety of injecting muscle-derived SCs into the urethra to treat SUI. The authors concluded that larger and longer-term clinical trials are needed.

In an open, prospective, single-center study, Cornu et al (2011) evaluated the safety of intra-sphincteric injections of autologous muscular cells in patients with post-prostatectomy incontinence (PPI; n = 12). Patients underwent intra-sphincteric injections of autologous muscular cells isolated from a biopsy of deltoid muscle. The primary endpoint was the Q(max) variation at the 3-month visit in order to assess potential bladder outlet obstruction. Secondary endpoints assessed side effects and efficacy parameters based on symptoms, quality of life score, voiding diary, pad-test, and urethral pressure profile at 1, 2, 3, 6 and 12 months after injection. No immediate complication occurred and no significant variation was noted on Q(max). The only side effects possibly product-related were 3 cases of urinary tract infection treated by antibiotics. An acceptable safety and tolerability of the procedure whatever the injected dose of muscular cells was demonstrated. Results on efficacy after 1 year were heterogeneous, with 4/12 patients describing reduced urine leakage episodes, 1/12 patient presenting increased maximal closure pressure, and 8/12 patients showing improvement on pad-test. The authors concluded that cell therapy consisting of intra-sphincteric injections of autologous muscular cells in patients with PPI was a feasible and safe procedure. They stated that these findings pointed out that some subjects may positively respond to this procedure, but clinical efficacy remains to be confirmed.
In a prospective, dose ranging, feasibility study, Carr et al (2013) evaluated the 12-month safety and potential efficacy of autologous muscle derived cells (Cook MyoSite Incorporated, Pittsburgh, PA) as therapy for SUI. A total of 38 women in whom SUI had not improved with conservative therapy for 12 or more months underwent intra-sphincter injection of low-doses (1, 2, 4, 8 or 16 \( \times 10^6 \)) or high-doses (32, 64 or 128 \( \times 10^6 \)) of autologous muscle derived cells, which were derived from biopsies of their quadriceps femoris. All patients could elect a second treatment of the same dose after 3-month follow-up. Assessments were made at 1, 3, 6 and 12 months after the last treatment. The primary end point was the incidence and severity of adverse events. In addition, changes in SUI severity were evaluated by pad test, diary of incontinence episodes and quality of life surveys. Of the 38 patients, 33 completed the study. Treatment-related complications were limited to minor events such as pain/bruising at the biopsy and injection sites. Of patients who received 2 treatments of autologous muscle derived cells who were eligible for analysis, a higher percentage of those in the high-dose versus the low-dose group experienced a 50 % or greater reduction in pad weight (88.9 %, 8 of 9 versus 61.5 %, 8 of 13), had a 50 % or greater reduction in diary reported stress leaks (77.8 %, 7 of 9 versus 53.3 %, 8 of 15) and had 0 to 1 leaks during 3 days (88.9 %, 8 of 9 versus 33.3 %, 5 of 15) at final follow-up. The authors concluded that injection of autologous muscle derived cells in a wide range of doses appears safe with no major treatment-related adverse events reported. They stated that treatment with autologous muscle derived cells shows promise for relieving SUI symptoms and improving quality of life. Moreover, they noted that the most effective dose of cells has yet to be determined, and a placebo-controlled study powered to determine treatment efficacy is necessary. Two ongoing studies have been designed to address these issues.

Phe and colleagues (2013) described the minimally invasive adjustable continence therapy (ACT) balloon placement surgical technique and analyzed the results of ACT balloon in the treatment for female SUI. A review of the literature was performed by searching the PubMed database using the following search terms: ACT balloons, female urinary incontinence, and female continence. A total of 8 studies were published between 2007 and 2013. The mean follow-up of these studies was 1 to 6 years. The mean age of the patients ranged between 62 and 73 years; 40 to 100 % of patients had already been treated surgically for their SUI. A significant reduction in the number of pads used per day was observed after ACT balloon placement, with improvement of short pad tests from 49.6 to 77.3 g pre-operatively to 11.2 to 25.7 g after ACT balloon placement; 15 to 44 % of patients considered that their SUI had been cured and 66 to 78.4 % were satisfied with the result. The explantation rate ranged between 18.7 and 30.8 %. Quality of life was significantly improved, and no major complication was reported. The authors concluded that ACT balloons constitute a reasonable, minimally invasive alternative for the treatment for female SUI due to intrinsic sphincter disorder, especially in patients who have already experienced failure of standard surgical treatment and in clinical settings incompatible with invasive surgical placement of an artificial urinary sphincter (especially women over the age of 80 years). Moreover, they stated that long-term results are essential to evaluate the effectiveness of this treatment.
CPT Codes / HCPCS Codes / ICD-9 Codes

**Artificial Urinary Sphincter:**

CPT codes covered if selection criteria are met:

- 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
- 53449 Repair of inflatable urethral/bladder neck sphincter, including pump, reservoir, and cuff

HCPCS codes covered if selection criteria are met:

- C1815 Prosthesis, urinary sphincter (implantable)

ICD-9 codes covered if selection criteria are met:

- 599.82 Intrinsic (urethral) sphincter deficiency [ISD]
- 752.62 Epispadias
- 753.5 Exstrophy of urinary bladder
- 753.8 Other specified anomalies of bladder and urethra
- 788.30 Urinary incontinence
- 788.39 Urinary incontinence
- V10.46 Personal history of malignant neoplasm of prostate

Other ICD-9 codes related to the CPB:

- 596.55 Detrusor sphincter dyssynergia
- 596.59 Other functional disorder of bladder

**Periurethral Injections of Bulking Agents:**

CPT codes covered if selection criteria are met:

- 11950 Subcutaneous injection of filling material (e.g., collagen); 1 cc or less
- 11951 1.1 to 5.0 cc
11952  5.1 to 10.0 cc
11954  over 10.0 cc
51715  Endoscopic injection of implant material into the submucosal tissues of the urethra and/or bladder neck

**HCPCS codes covered if selection criteria are met:**

L8603  Injectable bulking agent, collagen implant, urinary tract, 2.5 ml syringe, includes shipping and necessary supplies
L8604  Injectable bulking agent, dextranomer/hyaluronic acid copolymer implant, urinary tract, 1 ml, includes shipping and necessary supplies
L8606  Injectable bulking agent, synthetic implant, urinary tract, 1 ml syringe, includes shipping and necessary supplies
Q3031  Collagen skin test

**ICD-9 codes covered if selection criteria are met:**

599.82  Intrinsic (urethral) sphincter deficiency (ISD)
625.6  Stress incontinence, female
788.30 - 788.39  Urinary incontinence

**ICD-9 codes not covered for indications listed in the CPB:**

595.0 - 595.9  Cystitis
596.54  Neurogenic bladder NOS
597.0 - 597.89  Urethritis
598.00 - 598.9  Urethral stricture
599.0  Urinary tract infection, site not specified
V15.3  Personal history of irradiation

*InterStim Continence Control Therapy/Sacral Nerve Stimulation [not covered for bilateral sacral nerve stimulation for urinary incontinence]:

**CPT codes covered if selection criteria are met:**

64561  Percutaneous implantation of neurostimulator electrode array; sacral nerve (transforaminal placement) including image guidance, if performed
64581 Incision for implantation of neurostimulator electrode array; sacral nerve (transforaminal placement)

64590 Insertion or replacement of peripheral or gastric neurostimulator pulse generator or receiver, direct or inductive coupling

64595 Revision or removal of peripheral or gastric neurostimulator pulse generator or receiver

95970 Electronic analysis of implanted neurostimulator pulse generator system (e.g., rate, pulse amplitude and duration, configuration of waveform, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); simple or complex brain, spinal cord, or peripheral (i.e., cranial nerve, peripheral nerve, sacral nerve, neuromuscular) neurostimulator pulse generator/transmitter, without reprogramming

95971 Simple spinal cord, or peripheral (i.e., peripheral nerve, sacral nerve, neuromuscular) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming

95972 Complex spinal cord, or peripheral (i.e., peripheral nerve, sacral nerve, neuromuscular) (except cranial nerve) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming, first hour

+ 95973 Complex spinal cord, or peripheral (i.e., peripheral nerve, sacral nerve, neuromuscular) (except cranial nerve) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming, each additional 30 minutes after first hour (List separately in addition to code for primary procedures)

**HCPCS codes covered if selection criteria are met:**

- **A4290** Sacral nerve stimulation test lead, each
- **C1767** Generator, neurostimulator (implantable), non-rechargeable
- **C1778** Lead, neurostimulator (implantable)
- **C1816** Receiver and/or transmitter, neurostimulator (implantable)
- **C1883** Adaptor/extension, pacing lead or neurostimulator lead (implantable)
- **C1897** Lead, neurostimulator test kit (implantable)
- **E0745** Neuromuscular stimulator, electronic shock unit
L8680  Implantable neurostimulator electrode, each

L8681  Patient programmer (external) for use with implantable programmable neurostimulator pulse generator, replacement only

L8682  Implantable neurostimulator radiofrequency receiver

L8683  Radiofrequency transmitter (external) for use with implantable neurostimulator radiofrequency receiver

L8684  Radiofrequency transmitter (external) for use with implantable sacral root neurostimulator receiver for bowel and bladder management, replacement

L8685  Implantable neurostimulator pulse generator, single array, rechargeable, includes extension

L8686  Implantable neurostimulator pulse generator, single array, non-rechargeable, includes extension

L8687  Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension

L8688  Implantable neurostimulator pulse generator, dual array, non-rechargeable, includes extension

L8689  External recharging system for battery (internal) for use with implantable neurostimulator, replacement only

L8695  External recharging system for battery (external) for use with implantable neurostimulator, replacement only

**ICD-9 codes covered if selection criteria are met:**

596.4  Atony of bladder

788.20  Retention of urine, unspecified

788.21  Incomplete bladder emptying

788.29  Other specified retention of urine

788.30 - 788.39  Urinary incontinence

788.41  Urinary frequency

788.63  Urgency of urination

**ICD-9 codes not covered for indications listed in the CPB (not all-inclusive):**

185  Malignant neoplasm of prostate
198.82  Secondary malignant neoplasm of genital organs
233.4   Carcinoma in situ of prostate
330.0 - 337.9  Hereditary and degenerative diseases of the central nervous system
340 - 349.9  Other disorders of the central nervous system
350.0 - 359.9  Disorders of the peripheral nervous system
596.0   Bladder neck obstruction
596.54  Neurogenic bladder
598.00 - 598.9  Urethral stricture
599.60 - 599.69  Urinary obstruction
600.00 - 600.01  Hypertrophy (benign) of prostate
600.20 - 600.21  Benign localized hyperplasia of prostate
600.90 - 600.91  Hyperplasia of prostate, unspecified
625.6  Stress incontinence, female
788.32  Stress incontinence, male
788.33  Mixed incontinence (female) (male)

Vaginal Cones (no specific codes):

Other HCPCS codes related to the CPB:
A4335  Incontinence supply; miscellaneous

Pessary (Bladder Neck Support Prosthesis):

CPT codes covered if selection criteria are met:
57160  Fitting and insertion of pessary or other intravaginal support device

HCPCS codes covered if selection criteria are met:
A4561  Pessary, rubber, any type
A4562  Pessary, non-rubber, any type

ICD-9 codes covered if selection criteria are met:
618.00 - Genital prolapse [female genital tract]
618.9

625.6 Stress incontinence, female

788.32 Stress incontinence, male

788.33 Mixed incontinence (female) (male)

**Tension-Free Vaginal Tape Procedures (no specific codes):**

**Other CPT codes related to the CPB:**

51992 Laparoscopy, surgical; sling operation for stress incontinence (e.g., fascia or synthetic)

57288 Sling operation for stress incontinence (e.g., fascia or synthetic)

**Other HCPCS codes related to the CPB:**

C1771 Repair device, urinary, incontinence, with sling graft

C2631 Repair device, urinary, incontinence, without sling graft

**ICD-9 codes covered if selection criteria are met:**

625.6 Stress incontinence, female

788.33 Mixed incontinence (female) (male)

**Colposuspension and Sling Procedures:**

**CPT codes covered if selection criteria are met:**

51990 Laparoscopy, surgical; urethral suspension for stress incontinence

51992 Sling operation for stress incontinence (e.g., fascia or synthetic)

53440 Sling operation for correction of male urinary incontinence (e.g., fascia or synthetic)

53442 Removal or revision of sling for male urinary incontinence (e.g., fascia or synthetic)

57287 Removal or revision of sling for stress incontinence (e.g., fascia or synthetic)

57288 Sling operation for stress incontinence (e.g., fascia or synthetic)

**HCPCS codes covered if selection criteria are met:**

C1771 Repair device, urinary, incontinence, with sling graft
C2631 Repair device, urinary, incontinence, without sling graft

ICD-9 codes covered if selection criteria are met:

625.6 Stress incontinence, female
788.32 Stress incontinence, male
788.33 Mixed incontinence (female) (male)

Biofeedback:

CPT codes covered if selection criteria are met:

90911 Biofeedback training, perineal muscles, anorectal or urethral sphincter, including EMG and/or manometry

HCPCS codes covered if selection criteria are met:

E0746 Electromyography (EMG), biofeedback device

ICD-9 codes covered if selection criteria are met:

625.6 Stress incontinence, female
788.30 - 788.39 Urinary incontinence

Percutaneous Tibial Nerve Stimulation:

CPT codes covered if selection criteria are met:

64566 Posterior tibial neurostimulation, percutaneous needle electrode, single treatment, includes programming

HCPCS codes covered if selection criteria are met:

C1767 Generator, neurostimulator (implantable), non-rechargeable
C1778 Lead, neurostimulator (implantable)
C1816 Receiver and/or transmitter, neurostimulator (implantable)
C1883 Adaptor/ extension, pacing lead or neurostimulator lead (implantable)
C1897 Lead, neurostimulator test kit (implantable)
E0745 Neuromuscular stimulator, electronic shock unit
L8680 Implantable neurostimulator electrode, each
L8681 Patient programmer (external) for use with implantable programmable neurostimulator pulse generator, replacement only
L8682  Implantable neurostimulator radiofrequency receiver
L8683  Radiofrequency transmitter (external) for use with implantable neurostimulator radiofrequency receiver
L8685  Implantable neurostimulator pulse generator, single array, rechargeable, includes extension
L8686  Implantable neurostimulator pulse generator, single array, non-rechargeable, includes extension
L8687  Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension
L8688  Implantable neurostimulator pulse generator, dual array, non-rechargeable, includes extension
L8689  External recharging system for battery (internal) for use with implantable neurostimulator, replacement only
L8695  External recharging system for battery (external) for use with implantable neurostimulator, replacement only

ICD-9 codes covered if selection criteria are met [non-neurogenic]:

788.21  Retention of urine [incomplete bladder emptying]
788.30 - 788.39  Urinary incontinence
788.41  Urinary frequency
788.63  Urgency of urination

ICD-9 codes not covered for indications listed in the CPB:

344.61  Cauda equina syndrome with neurogenic bladder
596.53  Paralysis of bladder
596.54  Neurogenic bladder NOS

Transurethral Radiofrequency Therapy (Renessa Procedure):

CPT codes covered if selection criteria are met:

53860  Transurethral, radiofrequency micro-remodeling of the female bladder neck and proximal urethra for stress urinary incontinence

ICD-9 codes covered if selection criteria are met:

625.6  Stress incontinence, female

Urethral inserts:
HCPCS codes covered if selection criteria are met:
A4336  Incontinence supply, urethral insert, any type, each

ICD-9 codes covered if selection criteria are met:
625.6  Stress incontinence, female

**Cunningham Clamp:**

HCPCS codes covered if selection criteria are met:
A4356  External urethral clamp or compression device (not to be used for catheter clamp), each [Cunningham Clamp]

ICD-9 codes covered if selection criteria are met:
788.30 - 788.39  Urinary incontinence [post-prostatectomy urinary incontinence]

**Macroplastique (polydimethysiolxane) (no specific codes):**

HCPCS codes covered if selection criteria are met:
L8606  Injectable bulking agent, synthetic implant, urinary tract, 1 ml syringe, includes shipping and necessary supplies

**Neocontrol System (no specific codes):**

**Radiofrequency Micro-Remodeling with the SURs System (paraurethral or transvaginal) (no specific codes):**

ICD-9 codes not covered for indications listed in the CPB:
625.6  Stress incontinence, female
788.30 - 788.39  Urinary incontinence

**Extraurethral (Non-circumferential) Retropubic Adjustable Compression Devices (ProACT Therapy System):**

HCPCS codes not covered for indications listed in the CPB:
A4356  External urethral clamp or compression device (not to be used for catheter clamp), each
A4360  Disposable external urethral clamp or compression device, with pad and/or pouch, each

**Genityte procedure (laser therapy) (no specific codes):**

ICD-9 codes not covered for indications listed in the CPB:
625.6  Stress incontinence, female
788.30 - Urinary incontinence
788.39

**Pudendal nerve stimulation:**

**CPT codes not covered for indications listed in the CPB:**

97014  Application of a modality to 1 or more areas; electrical stimulation (unattended)
97032  Application of a modality to 1 or more areas; electrical stimulation (manual), each 15 minutes

**HCPCS codes not covered for indications listed in the CPB:**

E0740  Incontinence treatment system, pelvic floor stimulator, monitor, sensor and/or trainer

**ICD-9 codes not covered for indications listed in the CPB:**

625.6  Stress incontinence, female
788.30 - Urinary incontinence
788.39

**Autologous Myoblast Transplantation (no specific code):**

**ICD-9 codes not covered for indications listed in the CPB:**

788.30 - Urinary incontinence
788.39

**Autologous muscle-derived cell therapy (no specific code):**

**ICD-9 codes not covered for indications listed in the CPB:**

788.30 - Urinary incontinence
788.39

**Collagen Porcine Dermis mesh (no specific code):**

**ICD-9 codes not covered for indications listed in the CPB:**

788.30 - Urinary incontinence
788.39

**Stem Cell Therapy:**

**CPT codes not covered for indications listed in the CPB:**

38241  Hematopoietic progenitor cell (HPC); autologous transplantation

**ICD-9 codes not covered for indications listed in the CPB:**
788.30 - Urinary incontinence
788.39

**Transobturator Tape (no specific codes):**

Other CPT codes related to the CPB:

51992 Laparoscopy, surgical; sling operation for stress incontinence (e.g., fascia or synthetic)

53440 Sling operation for correction of male urinary incontinence (e.g., fascia or synthetic)

57288 Sling operation for stress incontinence (e.g., fascia or synthetic)

Other HCPCS codes related to the CPB:

C1771 Repair device, urinary, incontinence, with sling graft

C2631 Repair device, urinary, incontinence, without sling graft

**ICD-9 codes covered if selection criteria are met:**

625.6 Stress incontinence, female [intractable and has failed behavioral and pharmacologic treatments]

788.32 Stress incontinence, male

788.33 Mixed incontinence (female) (male) [intractable and has failed behavioral and pharmacologic treatments]

**ICD-9 codes not covered for indications listed in the CPB:**

788.31 Urge incontinence

**Pelvic Floor Stimulation:**

**HCPCS codes not covered in the CPB:**

E0740 Incontinence treatment system, pelvic floor stimulator, monitor, sensor and/or trainer

**ICD-9 not codes covered for indications listed in the CPB:**

625.6 Stress incontinence, female

788.30 - Urinary incontinence

788.39

**Pelvic Muscle Trainers (no specific codes):**

**HCPCS codes covered for indications listed in the CPB:**
E0740  Incontinence treatment system, pelvic floor stimulator, monitor, sensor and/or trainer [not covered for Athena pelvic muscle trainer]

Other HCPCS codes related to the CPB:

A4335  Incontinence supply; miscellaneous

The above policy is based on the following references:

General References:


Multichannel Urodynamic Studies:


Colposuspension and Sling Procedures:


**Artificial Urinary Sphincter:**


**Periurethral Injections of Bulking Agents:**


InterStim Continence Control Therapy/Sacral Nerve Stimulation:

Electrical Muscle Stimulation:


The Neocontrol™ System:


Vaginal Cones:


**Pessaries:**


**Tension-Free Vaginal Tape Procedure:**


Radiofrequency Electrothermal Energy:


Percutaneous Tibial Nerve Stimulation:


**Extraurethral (Non-circumferential) Retropubic Adjustable Compression Devices (The ProACT Therapy System):**


**Transobturator Tape Procedure:**


Urethral Inserts:


Pudendal Nerve Stimulation:

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http://qawww.aetna.com/cpb/medical/data/200_299/0223_draft.html

01/28/2015


Cunningham Clamp:


Autologous Myoblast Transplantation:


Pelvic Floor Electrical Stimulati on:


4. Richardson DA; Miller KL; Siegel SW; Karram MM; Blackwood NB; Stadkin DR. Pelvic floor electrical stimulation: a comparison of daily and every-other-day therapy for genuine stress incontinence. Urology, 48(1): 110-8 1996.


6. Siegel SW; Richardson DA; Miller KL; Karram MM; Blackwood NB; Sand PK; Staskin DR; Tuttle JP. Pelvic floor electrical stimulation for the treatment of urge and mixed urinary incontinence in women. Urology, 50 (6):934-40 1997.


Other Experimental and Investigational Interventions for Urinary Incontinence:


4. Trabuco EC, Gebhart JB. Overview of transvaginal placement of reconstructive materials (surgical mesh or biografts) for treatment of pelvic organ prolapse or stress urinary incontinence. Last reviewed October 2012. UpToDate Inc. Waltham, MA.


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