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Urinary Incontinence

Number: 0223

(Replaces CPBs 283, 324, and 470)

Policy

**Please see amendment for Pennsylvania Medicaid at the end of this CPB.*

- 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 dynamometry for quantification of pelvic floor muscle strength in female urinary incontinence experimental and investigational because its clinical value has not been established.
- III. Aetna considers genetic testing for stress urinary incontinence experimental and investigational because its clinical value for this indication has not been established.

Policy History

Last Review

04/16/2021

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Next

Review: 02/10/2022

Review History

Definitions

Additional Information

Clinical Policy Bulletin

Notes

IV. 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., Bulkamid [polyacrylamide hydrogel], Coaptite [calcium hydroxylapatite], Contigen [glutaraldehyde cross-linked collagen], Durasphere [carbon-coated spheres/beads], Macroplastique [polydimethylsiloxane], 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 an anti-cholinergic and a beta-3 adrenergic receptor agonist (mirabregon)) 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. (**Note:** Sequential test stimulation of the right and left sides, where leads are placed bilaterally and each side is tested sequentially during a single visit, is considered acceptable. No more than 6 total test stimulations are considered medically necessary).

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, 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 women 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 women 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 *adjustable* retropubic suburethral sling in the treatment of stress urinary incontinence experimental and investigational because its effectiveness has not been established.

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](#) ([../100_199/0132.html](#)).

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. If the member improves after 12 PTNS treatments, continued monthly treatments are considered medically necessary as long as the member's symptoms remain improved.

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.

N. Intravaginal Electrical Stimulation

Intravaginal electrical stimulation of the pelvic floor is considered medically necessary for women with stress, urgency or mixed urinary incontinence.

V. 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 SURx System (paraurethral or transvaginal) for the treatment of UI experimental and investigational because its effectiveness has not been established.

C. Laser Therapy: The Genityte Procedure and FemiLift

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

Aetna considers FemiLift (CO2 laser) for the

treatment of urinary incontinence experimental and investigational because its effectiveness has not been established.

D. 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.

E. 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.

F. 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.

G. 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.

H. Stem Cell Therapy

Aetna considers stem cell therapy (including mesenchymal stem/stromal cells) experimental and investigational for the treatment of UI because its effectiveness for this indication has not been established.

I. Magnetically Controlled Endourethral Artificial

Urinary Sphincter

Aetna considers magnetically controlled endourethral artificial urinary sphincter experimental and investigational because its effectiveness has not been established.

J. Transcutaneous Electrical Nerve Stimulation (TENS) in the Treatment of Overactive Bladder

Aetna considers transcutaneous electrical nerve stimulation in the treatment of overactive bladder experimental and investigational because its effectiveness has not been established.

K. Transperineal Implantation of Permanent Adjustable Balloon Continence Device

Aetna considers transperineal implantation of a permanent adjustable balloon continence device (e.g., ACT, ProACT Therapy System, Uromedica, Inc.) for the treatment of urinary incontinence experimental and investigational because its effectiveness has not been established.

L. Vibratory Perineal Stimulation

Aetna considers vibratory perineal stimulation for the treatment of urinary incontinence experimental and investigational because its effectiveness has not been established.

M. Bariatric Surgery

Aetna considers bariatric surgery experimental and investigational as a treatment of urinary incontinence in persons who would otherwise not meet medical necessity criteria for obesity surgery in [CPB 157 - Obesity Surgery \(../100_199/0157.html\)](#).

N. The Adjustable Transobturator Male System

Aetna considers the Adjustable Transobturator Male System for the treatment of stress urinary incontinence (SUI) experimental and investigational because its effectiveness has not been established.

O. Magnetic Stimulation for the Treatment of Women with SUI

Aetna considers magnetic stimulation for the treatment of women with SUI experimental and investigational because the effectiveness of this approach has not been established.

P. Moxibustion

Aetna considers moxibustion experimental and investigational for the treatment of post-stroke UI because the effectiveness of this approach has not been established.

VI. Other Urinary Incontinence Interventions:**Pelvic Muscle Trainers**

Note: Aetna does not cover the Athena pelvic muscle trainer, Gyneflex, Kegelmaster, Leva Pelvic Floor Trainer, 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 videourodynamics 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 videourodynamics 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, musculotropic 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. Examples of electrical stimulation devices include the Innova and Minnova systems (Empi, Inc., St. Paul, MN). An assessment of nonsurgical treatments for urinary incontinence prepared for the Agency for Healthcare Research and Quality (AHRQ) (Shamliyan, et al., 2012) found that intravaginal electrical stimulation increased continence rates and improved stress urinary incontinence more often than sham stimulation. The AHRQ assessment stated that a high level of evidence suggests increased continence rates and improvement in UI with electrical stimulation. This conclusion was based upon nine studies that examined intravaginal electrical stimulation. The studies included women with predominant urgency UI, clinical or urodynamic stress UI, or urodynamic mixed UI. Electrical stimulation was described with different levels of detail and had variable stimulation parameters, depending on the UI type being treated, including the use of 4 Hz, 10 Hz, 20 Hz, or 50 Hz frequency for 4 weeks, 7 to 8 weeks, 12 weeks, or 15 weeks.

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 (polydimethylsiloxane), 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 relief. 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.

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 H₂O 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 (Karlner, 2008) on RF micro-remodeling for the treatment of female SUI stated that while RF micro-remodeling (Renesss) 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 (odds ratio [OR] 0.85; 95 % confidence interval [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 compare dit 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. Two 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 urethroscopic 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 H₂O (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.

According to the Interstim product labeling, the safety and effectiveness of bilateral sacral nerve stimulation has not been established (Medtronic, 2008).

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.

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 × 10⁶) or high-doses (32, 64 or 128 × 10⁶) 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 (2014) 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.

Test Stimulation of the InterStim

The InterStim product labeling states that, in clinical studies, subjects underwent anywhere from 1 to 6 test stimulation procedures before implantation of InterStim.

The Medtronic InterStim test stimulation lead kit manual stated that “Of the 260 patients (45.0 %) who qualified for implantation, 169 (65.0 %) had a successful result (minimum of 50 % improvement in dysfunctional voiding symptoms) during their first test stimulation procedure. Of the remaining 91 patients, 56 (21.5 %) obtained a successful result during a second test stimulation, and 35 (13.5 %) obtained a successful result during three or more test stimulations. Reasons for repeat test stimulation procedures included inadequate responses to test stimulation or technical problems The safety and effectiveness of this therapy has not been established for pediatric use (patients under the age of 16), patients with neurological disease origins, such as multiple sclerosis or diabetes, and bilateral stimulation”.

Polyacrylamide Hydrogel (Bulkamid)

Kasi et al (2016) performed a systematic review on the effectiveness of polyacrylamide hydrogel (PAHG, Bulkamid) in the treatment of female patients with SUI with regard to reproducibility, feasibility, safety and clinical outcome. These investigators searched MEDLINE (1966 to 2015), Scopus (2004 to 2015), POPLINE (1974 to 2015) and ClinicalTrials.gov (2008 to 2015) along with reference lists of electronically retrieved studies. Observational studies, prospective, retrospective and RCTs were included. Two reviewers independently selected studies, assessed the risk of bias and tabulated data to structured forms. These researchers included 8 studies, which enrolled a total of 767 patients who received treatment with PAHG. They found that 186 of 767 women (24.3 %, range of 12 to 35 %) required re-injection in order to achieve adequate effectiveness. The most frequent adverse effects were pain at the site of injection (4 to 14 %) and urinary tract infections (3 to 7 %). Both the number of incontinence episodes/24 hours and the number of ml/24 hours were significantly reduced 1 year following treatment and the quality of life of patients was significantly improved. The authors concluded that PAHG is a safe intervention for

treating women with SUI, but repeat injections are often required. They stated that further research is needed to compare its effectiveness with other bulking agents.

In a prospective, observational study, Altman and colleagues (2017) examined the effects of transurethral polyacrylamide hydrogel injection in patients considered ineligible for mid-urethral sling surgery. A total of 81 patients received treatment with transurethral polyacrylamide hydrogel injection. Subjects were considered ineligible for placement of a mid-urethral sling based on significant co-morbidity (48 %), 1 or more previously failed invasive treatments (16 %), mixed UI (27 %), continuous incontinence (5 %), or previous pelvic radiation therapy (4 %). Longitudinal assessment of subjective treatment outcomes was performed using the validated UDI and the PFIQ at baseline, 2, and 6 months. To deal with repeated measurements, mixed linear models were used to examine changes in the outcomes over time. There was a significant improvement in the overall UDI score from baseline to month 2 follow-up (FU) ($p < 0.001$). No major differences between the month 2 and 6 FUs were observed. The largest difference in effect was observed for the irritative and stress subscales; 25 patients (33 %) requested a 2nd injection at the month-2 FU visit. At month-6 FU, the UDI scores for patients having had only 1 injection were largely unchanged, whereas all UDI domains worsened further for patients having had a 2nd injection at the month-2 visit. After the injection, there were 3 minor AEs (3.7 %) and no serious AEs. The authors concluded that in patients considered ineligible for mid-urethral sling surgery, transurethral injection with polyacrylamide hydrogel may alleviate UI symptoms. Repeat injections did not improve outcomes in this complicated group of patients.

Mohr and associates (2017) noted that mixed UI (MUI), defined as mixed symptoms of SUI and OAB, is a difficult entity if conservative treatment has failed. Cure rates are low compared with SUI, particularly the OAB component, may deteriorate after sling insertion. Bulking agents pose an

appealing alternative for the treatment of MUI. They have shown beneficial effect in small case studies, but larger series are lacking. In a prospective study, these investigators examined the safety and efficacy profile of Bulkamid in female patients with MUI. A total of 154 women with MUI symptoms (components of SUI/OAB within the limits of 60 to 40 % either way) received bulking therapy with Bulkamid. Patients were followed-up 3 months post-operatively. Primary outcome was the domain Incontinence impact on the KHQ; secondary outcomes were the other KHQ domains, visual analog scale (VAS), and International Continence Society (ICS) standardized pad weight test as objective measurement of incontinence. Statistically significant improvements were found for all KHQ domains, pad weight test, and the VAS before and after bulking; overall complication rate was 13 %. The authors concluded that the findings of this study showed improvement in MUI after bulking therapy according to both subjective and objective outcomes. These investigators could advocate bulking therapy for treating MUI, as it is simple and safe and showed both objective and subjective improvement and relief. They stated that long-term results (up to 1 year) are awaited.

Hussain and Bray (2019) noted that urethral bulking agents (UBAs) to treat SUI was first described in the 1930s, when paraffin was used to increase urethral resistance. Since then, several agents have been introduced to the market, with varying degrees of safety, efficacy, and durability. The agents currently available include calcium hydroxyl apatite (Coaptite), carbon coated zirconium (Durasphere; polydimethylsiloxane elastomer (Macroplastique); and polyacrylamide hydrogel (Bulkamid). The latest product, PDMS-U (Urolastic) is a silicone gel that polymerizes when injected. The short-term efficacy of UBAs are generally encouraging; however, longer follow-up results show the success rates are reduced and many women will require a repeat treatment.

In a controlled clinical trial, Itkonen Freitas and co-workers (2020) examined if polyacrylamide hydrogel is non-inferior to tension-free vaginal tape in the treatment of women with primary SUI. Subjects were randomized to tension-free vaginal tape or polyacrylamide hydrogel treatment. The primary outcome was patient satisfaction and secondary outcomes were effectiveness in reducing urinary leakage and complications at 1-year follow-up. For statistical power, significance was considered at 5 %, power was set at 80 % and the non-inferiority limit was 20 % with a 10 % expected drop-out rate. A total of 224 women with primary SUI entered the study between September 28, 2015 and March 1, 2017.

Of the women 111 were randomized to tension-free vaginal tape and 113 were randomized to polyacrylamide hydrogel. At 1 year a satisfaction score of 80 or greater on a VAS of 0 to 100 was reached in 95.0 % and 59.8 % of patients treated with tension-free vaginal tape and polyacrylamide hydrogel, respectively. Therefore, polyacrylamide hydrogel did not meet the non-inferiority criteria set in this study. As secondary outcomes, the cough stress test was negative in 95.0 % of tension-free vaginal tape cases versus 66.4 % of polyacrylamide hydrogel cases (difference 28.6 %, 95 % CI: 18.4 to 38.5). However, most peri-operative complications, including those in 19 tension-free vaginal tape cases versus 3 polyacrylamide hydrogel cases (difference 16.0 %, 95 % CI: 7.8 to 24.9), and all 6 re-operations due to complications (difference 5.9 %, 95 % CI: 1.2 to 12.4) were associated with tension-free vaginal tape. The authors concluded that mid-urethral tension-free vaginal tape slings were associated with better satisfaction and cure rates than polyacrylamide hydrogel in women with primary SUI. However, complications were mainly associated with tension-free vaginal tape. Therefore, tension-free vaginal tape should be offered as 1st-line treatment in women who expect to be completely cured by the initial treatment and are willing to accept the complication risks. Since polyacrylamide hydrogel treatment also provides

high satisfaction and cure rates, women with primary SUI can be offered polyacrylamide hydrogel as an alternative treatment.

Furthermore, an UpToDate review on “Stress urinary incontinence in women: Persistent/recurrent symptoms after surgical treatment” (Morgan, 2020) states that “Several materials are available for periurethral injection therapy. Products that are now commonly used include: Polyacrylamide hydrogel (Bulkamid): a homogeneous, stable hydrophilic polymer gel composed of 2.5 % cross-linked dextranomer polyacrylamide and 97.5 % water, available in Europe”.

On January 28, 2020, the Bulkamid Urethral Bulking System was approved by the FDA. It is indicated for urethral injection for the treatment of SUI due to ISD in adult women who have SUI or stress predominant mixed incontinence.

Adjustable Retropubic Suburethral Sling for Stress Urinary Incontinence

In a single-center, prospective study, Leizour and associates (2016) evaluated the safety and effectiveness of the adjustable suburethral sling Remeex in the treatment of male SUI. Participants were patients treated for SUI after radical prostatectomy (RP) or transurethral resection of prostate. The severity of incontinence was evaluated by the number of pads used per day. Success rate, complications and number of adjustments were studied. From February 2011 to May 2015, Remeex was implanted in 25 patients. The average pre-operative number of pads used per day was 3.8 (\pm 1.8). Sling tension has been adjusted the day after surgery in all patients. Mean follow-up was 31 months (\pm 15). During follow-up, 6 patients did not need any re-adjustment (24 %) and 15 patients (60 %) had to be re-adjusted. One Remeex system had to be completely removed because of a sub-occlusive syndrome; 3 patients had early infection requiring partial system removal (Varitensor). At the end of follow-up, 9

patients were cured (36 %), 9 patients (36 %) were significantly improved and 7 patients (28 %) were not improved; 5 patients were waiting for a new re-adjustment. The authors concluded that in this short series of patients who had prostatic surgery, at mid-term follow-up, the placement of an adjustable suburethral sling was associated with an improvement or cure of UI symptoms in 2/3 of cases.

Magnetically Controlled Endourethral Artificial Urinary Sphincter

Mazzocchi and colleagues (2016) stated that UI is a widespread dysfunction that affects more than 300 million people worldwide. At present, no technological solutions are able to restore continence in a minimally invasive and effective way. These researchers described the design, fabrication, and testing of a novel artificial endourethral urinary sphincter that attempts to fully restore continence. The device can be inserted/retracted in a minimally invasive fashion without hospital admission, does not alter the body scheme and can be applied to both women and men. The device core is a uni-directional polymeric valve and a magnetically activated system, which is able to modulate its opening pressure.

Bench tests and ex-vivo tests on a human cadaver demonstrated that the device was able to fully restore continence and allowed urination when desired. The authors concluded that the proposed system showed a high potential as a technological solution that may restore a normal daily life in patients affected by UI. These preliminary findings need to be validated by well-designed studies.

Transcutaneous Electrical Nerve Stimulation (TENS) in the Treatment of Overactive Bladder

Sharma and colleagues (2016) stated that OAB accounts for 40 to 70 % cases of incontinence. The etiology is unknown though detrusor instability is found in urodynamic evaluation of almost all cases. Detrusor instability or hyper-reflexia can be

inhibited by direct inhibition of impulses in the pre-ganglionic afferent neuron or by inhibition of bladder pre-ganglionic neurons of the efferent limb of micturition reflex.

Transcutaneous electrical nerve stimulation (TENS) is based on the gate control theory of abolishing the local micturition reflex arc. In a prospective experimental study, these researchers evaluated the safety and effectiveness of TENS in idiopathic OAB. They evaluated the effectiveness of TENS versus placebo in reducing OAB symptoms (n1 = 20, n2 = 20); 10 treatment sessions (5 sessions/week) of 30 minutes were conducted. There was a significant improvement in Overactive Bladder Symptom Scores (OABSS) in TENS group and 2 patients were completely dry following TENS therapy. The authors concluded that in elderly women, patients with OAB where other co-medications had their own anti-cholinergic side effects and impairment of cognition is a concern, TENS can be a useful intervention. The author also noted that future advancements will likely emphasis on the exact placement site of electrodes with less collateral stimulation. The main drawbacks of this study were; (i) small sample size (n = 20) for the TENS-treated group), and (ii) all patients were uniformly treated with alternate high- and low-frequency TENS with burst therapy intermittently, to prevent the development of tolerance. High-intensity was used to achieve maximum effect, and (iii) the ideal stimulation protocol needs to be worked out.

In a randomized, double-blind, placebo-controlled study, Borch and associates (2017) evaluated the immediate effect on natural fill urodynamic parameters and bladder function during TENS in children with OAB and daytime UI (DUI). A total of 24 children with severe OAB and DUI (mean age of 8.5 ± 1.2 years) underwent 48-hour natural fill urodynamics. After 24 hours of baseline investigation, the children were randomized to either active continuous TENS (n = 12) or placebo TENS (n = 12) over the sacral S2-S3 outflow. The urodynamic recordings were analyzed manually for 3 different bladder contraction patterns resulting in a void. The number of bladder

contractions not leading to a void was also calculated.

Maximum voided volume (MVV) and average voided volume (AVV) were identified for both the baseline and the intervention day. It was found that TENS had no immediate objective effect on bladder capacity. The difference (before minus after treatment) in MVV/EBC in the active TENS group = 0.03 ± 0.23 versus placebo TENS group = -0.01 ± 0.10 ($p = 0.61$).

Furthermore, there was no significant difference in the proportion of different bladder contraction types between the 2 groups; TENS did not significantly influence the number of bladder contractions not leading to a void. Results were presented as mean \pm SD. The authors concluded that there was no immediate objective effect of TENS on bladder activity assessed by natural fill urodynamics in children with OAB and DUI.

Transperineal Implantation of Permanent Adjustable Balloon Contenance Device

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 Interventional 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, Gillling (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.

Dynamometry for Quantification of Pelvic For Muscle Strength

Deegan and colleagues (2018) stated that there remains no gold standard for quantification of voluntary pelvic floor muscle (PFM) strength, despite international guidelines that recommend PFM assessment in females with UI. In this study, methods currently reported for quantification of skeletal muscle strength across disciplines were systematically reviewed and their relevance for clinical and academic use related to the pelvic floor were described. These investigators performed a systematic review via Medline, PubMed, CINAHL, and the Cochrane database using key terms for pelvic floor

anatomy and function were cross-referenced with skeletal muscle strength quantification from 1946 to 2016. Full text peer-reviewed articles in English having female subjects with UI were identified. Each study was analyzed for use of controls, type of methodology as direct or indirect measures, benefits, and limitations of the technique. A total of 1,586 articles were identified of which 50 met the inclusion criteria; 9 methodologies of determining PFM strength were described including: digital palpation, perineometer, dynamometry, electromyography (EMG), vaginal cones, ultrasonography, magnetic resonance imaging (MRI), urine stream interruption test, and the Colpexin pull test; 32 % lacked a control group. The authors concluded that technical refinements in both direct and indirect instrumentation for PFM strength measurement are allowing for sensitivity. However, the most common methods of quantification remain digital palpation and perineometry; techniques that pose limitations and yield subjective or indirect measures of muscular strength. Moreover , they stated that dynamometry has potential as an accurate and sensitive tool, but is limited by inability to assess PFM strength during dynamic movements.

The Leva Pelvic Floor Trainer

The Leva pelvic floor trainer is intended for the purpose of rehabilitation and training of weak pelvic floor muscles for the treatment of stress, mixed and mild moderate urge incontinence in women. This device interacts with the user via smart phone technology. There is lack of evidence that the use of this device provides better outcomes than conventional Kegel exercises.

Oliveira and colleagues (2017) noted that strengthening exercises for PFM (SEPFM) are considered the 1st approach in the treatment of SUI. Nevertheless, there is no evidence about training parameters. These researchers identified the protocol and/or most effective training parameters in the treatment of female SUI. A literature research was conducted

in the PubMed, Cochrane Library, PEDro, Web of Science and Lilacs databases, with publishing dates ranging from January 1992 to March 2014. The articles included consisted of English-speaking experimental studies in which SEPFM were compared with placebo treatment (usual or untreated). The sample had a diagnosis of SUI and their age ranged between 18 and 65 years. The assessment of methodological quality was performed based on the PEDro scale. A total of 7 high methodological quality articles were included in this review. The sample consisted of 331 women, mean age of 44.4 ± 5.51 years, average duration of urinary loss of 64 ± 5.66 months and severity of SUI ranging from mild to severe. SEPFM programs included different training parameters concerning the PFM. Some studies have applied abdominal training and adjuvant techniques. Urine leakage cure rates varied from 28.6 to 80 %, while the strength increase of PFM varied from 15.6 to 161.7 %. The authors concluded that the most effective training protocol consists of SEPFM by digital palpation combined with biofeedback monitoring and vaginal cones, including 12-week training parameters, and 10 repetitions per series in different positions compared with SEPFM alone or a lack of treatment.

Vaginal Laser Therapy

Pergialiotis and co-workers (2017) presented available evidence related to vaginal laser therapy as a treatment option for SUI. These investigators searched the Medline (1966 to 2017), Scopus (2004 to 2017), Clinicaltrials.gov (2008 to 2017) and Cochrane Central Register of Controlled Trials (CENTRAL) (1999 to 2017) databases for relevant studies in this field. They included all observational studies (prospective and retrospective, randomized and non-randomized) that reported outcomes on vaginal laser therapy as a therapeutic option for SUI. A total of 13 studies were included that recruited 818 patients who underwent laser therapy for SUI. The methodological quality of most included studies was low, as they were either individual case-control studies, case series

or poor-quality cohorts (Oxford Level of Evidence 3b and 4). According to the existing evidence, laser therapy may be a useful, minimally invasive approach for treating SUI. However, the methodological limitations of included studies rendered them prone to significant bias, limiting their scientific integrity. The authors concluded that as the demand for minimally invasive approaches for treating SUI increases, it is expected that more patients will seek alternative treatments over current standards (mid-urethral slings). They stated that given the limitations of the existing studies, it appeared that conducting future trials is needed to elucidate this field.

Alsulihem and Corcos (2020) examined the available literature to evaluate the safety, efficacy, and outcomes of lasers in the treatment of female SUI and OAB. PubMed search was performed up to May 2020, including observational and investigational human studies that documented the effects on laser treatment in SUI and OAB. A total of 27 studies, recording subjective or objective measures in SUI or OAB were included. Lasers used included Er:YAG and Fractional CO₂ lasers. The overall quality of studies was poor, and 23/27 studies were case-series studies (Level of evidence [LOE] = 4). Er:YAG laser showed a modest reduction in mild SUI cases, with benefits lasting a maximum of 13 to 16 months. Er:YAG laser for OAB showed conflicting results, with a trend to improve OAB symptoms for up to 12 months.

Fractional CO₂ laser showed an improvement of mild SUI in few studies; however, no long-term data are available. For OAB symptoms, studies showed minimal improvement that was examined in short-term studies. When reported, AEs were insignificant, however, they were not reported systematically. Several drawbacks have been noticed in the current literature of vaginal lasers, including large variation in laser settings and protocols, short-term follow-up, lack of urodynamic evaluation, and appropriate objective measures. The authors concluded that based on the available literature, lasers cannot be recommended as a therapeutic option at this time. These researchers stated that future better-quality

studies are needed to document the exact mechanism of action, longevity, safety and its eventual place into the current treatment algorithms of SUI and OAB.

Vibratory Perineal Stimulation

Rodrigues and associates (2018) noted that PFM play an important part in the urinary continence mechanism. Changes in their structure and functionality may lead to a predisposition to pelvic floor dysfunction such as UI. Some techniques for conservative treatment of UI are already well documented. However, new approaches have been found that require scientific proof of their effectiveness, such as vibratory stimulation (VS). These researchers performed a systematic review of studies that investigated the use of perineal VS (PVS) for the treatment of SUI. This study followed the recommendations of the Cochrane Collaboration for systematic reviews. Studies that used PVS for the treatment of female UI were eligible. A total of 56 studies were found, of which ten were duplicates and were excluded. Analysis of the titles and abstracts led to the exclusion of 30 studies, leaving 16 for detailed analysis. Of these, only 3 were included as they fulfilled all the eligibility criteria previously established for the present study. In spite of the heterogeneity of the protocols, all the studies had the goal of assessing the effects of vibration on the PFM, and the stimulation was found to be effective in reducing urinary leakage, improving muscle strength and consequently the patients' QOL. The authors concluded that because of the heterogeneity and the small number of studies, it is not possible to draw a conclusion as to the effectiveness of PVS for the treatment of SUI, and further studies are needed to provide scientific support for its use.

Stem Cell Therapy

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

Burdzinska and associates (2018) noted that cell therapy constitutes an attractive alternative to treat SUI. Although promising results have been demonstrated in this field, the procedure requires further optimization. The most commonly proposed cell types for intra-urethral injections are muscle derived cells (MDCs) and mesenchymal stem/stromal cell (MSCs). These investigators evaluated the effects of MDC-MSC co-transplantation into the urethra. Autologous transplantation of labeled MDCs, bone marrow MSCs or co-transplantation of MDC-MSC were performed in aged multiparous female goats (n = 6 in each group). The mean number of cells injected per animal was $29.6 \times 10^6 (\pm 4.3 \times 10^6)$; phosphate-buffered saline (PBS)-injected animals constituted the control group (n = 5). Each animal underwent urethral pressure profile (UPP) measurements before and after the injection procedure. The maximal urethral closure pressure (MUCP) and functional area (FA) of UPPs were calculated. The urethras were collected at the 28th or the 84th day after transplantation. The marker fluorochrome (DID) was visualized and quantified using in-vivo imaging system in whole explants. Myogenic differentiation of the graft was immunohistochemically evaluated. The grafted cells were identified in all urethras collected at day 28 regardless of injected cell type. At this time-point the strongest DID-derived

signal (normalized to the number of injected cells) was noted in the co-transplanted group. There was a distinct decline in signal intensity between day 28 and day 84 in all types of transplantation. Both MSCs and MDCs contributed to striated muscle formation if transplanted directly to the external urethral sphincter. In the MSC group those events were rare. If cells were injected into the submucosal region they remained undifferentiated usually packed in clearly distinguishable depots. The mean increase in MUCP after transplantation in comparison to the pre-transplantation state in the MDC, MSC and MDC-MSD groups was 12.3 % (\pm 11.2 %, not significant (ns)), 8.2 % (\pm 9.6 %, ns) and 24.1 % (\pm 3.1 %, $p = 0.02$), respectively. The mean increase in FA after transplantation in the MDC, MSC and MDC-MSD groups amounted to 17.8 % (\pm 15.4 %, ns), 15.2 % (\pm 12.9 %, ns) and 17.8 % (\pm 2.5%, $p = 0.04$), respectively. The authors concluded that the findings of this study suggested that MDC-MSD co-transplantation provided a greater chance of improvement in urethral closure than transplantation of each population alone.

Fazeli and colleagues (2019) stated that in recent years, the administration of stem cells has been considered a new therapeutic option for UI. These researchers examined the efficacy of MSC transplantation in the treatment of UI. Combinations of the key words “mesenchymal stem cells”, “MSCs”, “urinary incontinence”, “urethral sphincter” and “involuntary urination” were searched in PubMed and Science Direct databases. Following application of exclusion criteria to the 1,946 papers obtained and review and duplicate articles were removed, 23 articles were considered further. The search was limited to the animal model studies. The data obtained from the evaluation of different studies indicated that the injected MSCs play an important role in the neovascularization and the recovery of muscle cells in UI models through the paracrine process. The authors concluded

that the available evidence suggested that further trials are needed to be focused on clinical phase of MSC therapy on the patients affected by UI.

Artificial Urinary Sphincter (AMS 800)

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.

Peyronnet and associates (2019a) performed a systematic review of studies reporting the outcomes of AMS-800 AUS implantation in women with SUI resulting from intrinsic sphincter deficiency (ISD). A systematic literature search of the Medline and Embase databases was performed in June 2018 in accordance with the PRISMA statement; no time limit was used. Study selection and data extraction were performed by 2 independent reviewers. Of 886 records screened, 17 were included. All were retrospective or prospective non-comparative case series; 1 study reported on vaginal AUS implantation, 11 on open AUS implantation, 2 on laparoscopic AUS implantation, 2 on robot-assisted AUS implantation, and 1 compared open and robot-assisted implantations. The vast majority of patients had undergone at least 1 anti-incontinence surgical procedure prior to AUS implantation (69.1 to 100 %). The intra-operative bladder neck injury rates ranged from 0 % to 43.8 % and the intra-operative

vaginal injury rates ranged from 0 % to 25 %. After mean follow-up periods ranging from 5 to 204 months, the complete continence rates ranged from 61.1 % to 100 %. The rates of explantation, erosion and mechanical failure varied from 0 % to 45.3 %, 0 % to 22.2 % and 0 % to 44.1 %, respectively. The authors concluded that AMS-800 AUS could provide excellent functional outcomes in women with SUI resulting from ISD but at the cost of a relatively high morbidity. These researchers stated that high level of evidence studies are needed to help better define the role of AUS in SUI armamentarium in women.

Reus and colleagues (2020) stated that the use of the AUS for non-neurogenic severe SUI in women due to sphincter deficiency is either not specifically registered and/or reimbursed in some countries worldwide, as opposed to severe SUI in men, in whom it is considered the gold standard. With waning popularity of synthetic mid-urethral slings for the treatment of SUI, evidence-based assessment of AUS performance and safety is mandatory for patient counselling. These investigators carried out a systematic review of studies evaluating short- to long-term AUS performance and safety outcomes in non-neurogenic women with severe SUI. PubMed/Medline, Embase, and the Cochrane Central Register of Controlled Trials were searched, from 1987 to 2018, without language restriction. Included studies had to report outcomes after AUS implantation in at least 5 women with non-neurogenic SUI, after a minimum follow-up of 6 months. A total of 12 articles collecting data from 886 patients were identified, no study being randomized or prospective. The reported zero pad rates ranged from 42 % to 86 %, revision rates from 6 % to 44 %, and mechanical failure rates from 2 % to 41 %. Procedure serious AE rates ranged from 2 % to 54 % and rates of serious adverse device effects such as explantation ranged from 2 % to 27 %. The authors concluded that the level of evidence supporting the use of an AUS for non-neurogenic SUI in women is very low; AUS outcome

assessments necessitate well-designed randomized trials, in accordance with current evidence-based medicine requirements.

Peyronnet and co-workers (2019b) stated that widespread adoption of the AMS-800 AUS in female patients has been hampered by the surgical morbidity of its implantation through an open approach. These researchers described a standardized technique of robotic bladder neck AUS implantation in female patients, and reported the peri-operative and functional outcomes obtained by multiple surgeons with this technique. They retrospectively reviewed the charts of all female patients who underwent robotic AUS implantation for UI due to ISD between March 2012 and March 2017 in 5 institutions. Most of the 10 surgeons involved were not highly experienced in female AUS implantation and/or in robotic surgery. The AUS was implanted at the bladder neck through a trans-peritoneal robotic approach. The finger placed by the assistant surgeon in the vagina is paramount to expose the vesico-vaginal space and guided the robotic surgeon throughout the bladder neck dissection. The primary end-point was the incontinence categorized as complete continence (i.e., no pads used), improved incontinence, or unchanged incontinence. A total of 49 women underwent a robotic AUS implantation. There were 8 intra-operative complications (16.3 %): 5 bladder neck injuries and 3 vaginal injuries; 9 patients experienced post-operative complications (18.3 %), but only 2 were Clavien greater than or equal to 3 (4.1 %). After a median follow-up of 18.5 months, 1 explantation (vaginal erosion, 2.1 %) and 3 revisions (1 mechanical and 2 non-mechanical failure, 6.1 %) were needed. At last follow-up, 40 patients were fully continent (81.6 %), 6 had improved incontinence (12.2 %), and 3 had unchanged incontinence (6.1 %). The authors concluded that in this first multi-center series of robot-assisted AUS implantation, this technique appeared feasible, safe, and reproducible with peri-operative and functional outcomes in the early learning curve not inferior to those reported in large series of open AUS implantation from

tertiary referral centers. These investigators stated that the findings of this study suggested that this technique is feasible and reproducible by surgeons with various levels of surgical expertise; however, further data are needed to confirm the findings of the present report.

The authors stated that this study had several drawbacks. First, it had numerous biases inherent to its retrospective design. The lack of a control group did not allow a proper assessment of the value of robotic female AUS implantation compared with the open or laparoscopic approaches or other therapeutic options (e.g., pubovaginal sling, bulking agents, etc.). The relatively small sample size (n = 49) was another drawback of the present series. Last, opening of the bladder dome performed in challenging cases introduced significant, although isolated, heterogeneity in the technique used, but was part of a “patient's first” policy and had certainly contributed to the safe development of this new surgical technique. Opening of the bladder dome was felt less and less necessary with increasing experience.

Screening for Urinary Incontinence in Women

In a systematic review, Nelson and colleagues (2018) examined if screening for UI in women not previously diagnosed would improve outcomes (symptoms, QOL, and function) and assessed the accuracy of screening methods and potential harms of screening. English-language searches of Ovid Medline, Cochrane Central Register of Controlled Trials, and Cochrane Database of Systematic Reviews (January 1, 1996 to March 30, 2018); ClinicalTrials.gov (April 2018), and reference lists of studies and reviews were carried out. Randomized trials, cohort studies, systematic reviews of studies that enrolled non-pregnant women without previously diagnosed UI and compared clinical outcomes and adverse effects between women who were and were not screened, and diagnostic accuracy studies that reported performance measures of screening tests. No studies evaluated the overall

effectiveness or harms of screening. A total of 17 studies evaluated the diagnostic accuracy of 18 screening questionnaires against a clinical diagnosis or results of diagnostic tests. Of these, 14 poor-quality studies were based in referral clinics, enrolled only symptomatic women, or had other limitations; 1 good-quality and 2 fair-quality studies (evaluating 4 methods) enrolled women not recruited on the basis of symptoms. Areas under the receiver-operating characteristic curve for stress, urge, and any type of incontinence in these studies were 0.79, 0.88, and 0.88 for the Michigan Incontinence Symptom Index; 0.85, 0.83, and 0.87 for the Bladder Control Self-Assessment Questionnaire; and 0.68, 0.82, and 0.75 for the Overactive Bladder Awareness Tool. The Incontinence Screening Questionnaire had a sensitivity of 66 % and specificity of 80 % for any type of incontinence. The authors concluded that available evidence is insufficient on the overall effectiveness and harms of screening for UI in women; and limited evidence in general populations suggested fairly high accuracy for some screening methods. The main drawbacks of this review were studies enrolled few participants, often from symptomatic referral populations; used various reference standards; and infrequently reported CIs.

Despite the lack of studies determining the benefits and harms of UI screening, the Women's Preventive Services Initiative (WPSI) recommended that doctors screen women of all ages, including adolescents, for UI yearly by using a questionnaire. The WPSI recommended referring women with UI for further evaluation if it affects their activities and QOL. These recommendations were based on indirect evidence that UI is common, treatment may be effective, and the harms of screening are unlikely to be serious. The recommendations might change if studies directly evaluating the benefits and harms of screening for UI become available. There are no data to support that the correct frequency of screening is yearly (no authors listed, 2018).

Bariatric Surgery for the Treatment of Urinary Incontinence in Obese Women

Shimonov and colleagues (2017) examined the effect of bariatric surgery on female pelvic floor disorders (PFDs). A total of 80 consecutive obese women who underwent a laparoscopic sleeve gastrectomy were prospectively enrolled. Four validated questionnaires (ICIQ-UI, BFLUTS-SF, PFDI-20, PISQ-12) were used to evaluate pelvic floor symptoms before and 6 months after surgery. Outcome results were analyzed according to the presence of pre-operative UI, defined as a positive answer to the question "how often do you leak urine?" on the ICIQ-UI questionnaire. A total of 77 women (aged 41.3 ± 11.5 years; parity 1.9 ± 1.6) completed all pre- and post-operative questionnaires. Mean body mass index (BMI) before and 6 months after surgery was 42 ± 4.7 and 33 ± 4.7 , respectively. Pre-operatively, 29 (37.7 %) women (mean age of 45.6 ± 11 , mean BMI 42.3 ± 5.2) had UI, 17 (59 %) of whom had SUI. Surgically induced weight loss was associated with statistically significant improvement in UI and filling symptoms, pelvic organ prolapse and colorectal-anal scores, and condition-specific sexual function and QOL parameters. Specifically, the total score of the ICIQ-UI questionnaire decreased from 9.28 ± 3.6 pre-operatively to 2.9 ± 3.8 post-operatively ($p < 0.001$), and the urinary score of the PFDI-20 questionnaire decreased from 31.4 ± 17.9 pre-operatively to 9.3 ± 12.3 post-operatively ($p < 0.001$).

Furthermore, 15 (51.7 %) women reported complete resolution of UI following weight loss. The authors concluded that surgically induced weight loss resulted in resolution of UI in up to 52 % of pre-operatively incontinent women and subsequent improvement in other pelvic floor symptoms.

Moreover, they stated that larger studies with longer follow-up are required to examine the possible impacts of bariatric surgery on various aspects of pelvic floor function.

In a meta-analysis, Lian and associates (2017) evaluated the effects of bariatric surgery on PFD in obese women. These researchers carried out a systematic search of PubMed, Cochrane Library, CNKI and CBM databases up to October 2016, and studies reporting pre-operative and post-operative outcomes in obese women undergoing bariatric surgery were included. The Pelvic Floor Distress Inventory (PFDI-20), the Pelvic Floor Incontinence Questionnaire (PFIQ-7), the Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire, Female Sexual Function Index and the International Consultation on Incontinence Questionnaire-Urinary Incontinence short form score were used for evaluating pelvic floor dysfunction after bariatric surgery. A total of 11 cohort studies were finally included. Pooled results revealed that bariatric surgery was associated with a significant improvement in PFD for obese women on the whole [PFDI-20: standard mean difference [SMD] = 0.89, 95 % CI: 0.44 to 1.34), $p < 0.001$; PFIQ-7: SMD = 1.23, 95 % CI: 0.17 to 2.29), $p = 0.023$]. In the subscale analysis, there was significant improvement in UI and pelvic organ prolapse. However, no significant improvement was found in fecal incontinence and sexual function. The authors concluded that bariatric surgery is associated with significant improvement in UI, and has a benefit on pelvic organ prolapse for obese women. However, there is no significant improvement in fecal incontinence and sexual function. These investigators stated that further multi-center, large-scale and longer-term RCTs are needed to confirm these findings.

In a meta-analysis, Zhang and colleagues (2020) examined the effectiveness of bariatric surgery in obese women with UI. Searches of PubMed, the Cochrane Library, and Embase databases were performed using "weight loss surgery/bariatric surgery/gastric bypass surgery" and "incontinentia urinae/uracratia/urinary incontinence/urolepsia" in the title/abstract before January 2018. Then, meta-analysis was analyzed by Review Manager 5.3 (Cochrane Collaboration, Oxford, United Kingdom). The SMD and OR were used to

describe results of continuous variables and dichotomous variables, respectively. Pooled data showed that bariatric surgery reduced the incidence of UI in obese women at the follow-up of 6 months (OR, 3.27; 95 % CI: 2.55 to 4.21; $p < 0.00001$) and 12 months (OR, 4.04; 95 % CI: 2.62 to 6.22; $p < 0.00001$) and significantly reduced the BMI at 6 months (SMD, 1.86; 95 % CI: 1.19 to 2.53; $p < 0.00001$) and 12 months (SMD, 2.04; 95 % CI: 1.44 to 2.64; $p < 0.00001$). In addition, bariatric surgery could also significantly increase the QOL (SMD, 0.53; 95 % CI: 0.27 to 0.80; $p < 0.00001$) and improve the function of pelvic floor disorders (SMD, 0.55; 95 % CI: 0.38 to 0.72; $p < 0.00001$) based on QOL questionnaires and Pelvic Floor Distress Inventory 20, respectively. The authors concluded that this meta-analysis demonstrated that bariatric surgery is an effective choice for obese women with UI; however, more RCTs are needed to confirm these findings.

Furthermore, UpToDate reviews on “Treatment of urinary incontinence in women” (Lukacz, 2018a) and “Treatment of urgency incontinence/overactive bladder in women” (Lukacz, 2018b) do not mention bariatric surgery as a therapeutic option.

FemiLift (CO2 Laser) for the Treatment of Urinary Incontinence in Women

In an observational study, Pitsouni et al (2016) examined the effect of the micro-ablative fractional carbon dioxide (CO2) -laser therapy on vaginal pathophysiology and the symptoms of the genitourinary syndrome of menopause (GSM). Post-menopausal women with moderate-to-severe symptoms of GSM underwent 3 sessions of CO2-laser therapy at monthly intervals. Participants were evaluated at baseline and 4 weeks after the last treatment. The primary outcomes were Vaginal Maturation Value (VMV) and Vaginal Health Index Score (VHIS). Secondary outcomes included symptoms of GSM, Female Sexual Function Index (FSFI), International Consultation on Incontinence Questionnaire of Female Urinary

Tract Symptoms (ICIQ-FLUTS) and Urinary Incontinence Short Form (ICIQ-UI SF), Urogenital Distress Inventory (UDI-6) and King's Health Questionnaire (KHQ). A total of 53 post-menopausal women completed this study; VMV, VHIS and FSFI increased significantly. Dyspareunia, dryness, burning, itching, dysuria, frequency, urgency, urgency incontinence, stress incontinence and scores on the ICIQ-FLUTS, ICIQ-UI SF, UDI-6 and KHQ decreased significantly. Factors predicting for which women the CO₂-laser therapy was more effective were not identified. The authors concluded that the findings of this study suggested that intravaginal CO₂-laser therapy for post-menopausal women with clinical signs and symptoms of GSM may be effective in improving both vaginal pathophysiology and reported symptoms. This was an observational study, with a relatively small (n = 53) sample size and short-term follow-up (4 weeks). These preliminary findings need to be validated in well-designed studies.

Gonzalez et al (2018) examined the long-term effect of thermo-ablative fractional CO₂ laser (TACO2L) as an alternative treatment for early stages of stress urinary incontinence (SUI) in post-menopausal women with genitourinary syndrome of menopause. A total of 161 post-menopausal patients (age of 53.38 ± 5.1 years, range of 45 to 65 years) with a clinical diagnosis of mild SUI were prospectively enrolled in the study. Patients received 1 treatment with TACO2L every 30 to 45 days, each treatment comprising 4 sessions, followed in all patients by a yearly treatment session at 12, 24 and 36 months. SUI was evaluated using the International Continence Society 1-hour pad test and the ICIQ-UI SF before and after TACO2L treatment. TACO2L treatment was associated with a significant improvement in ICIQ-UI SF scores and 1-hour pad weight test at 12 months (both p < 0.001), 24 months (both p < 0.001) and 36 months (both p < 0.001). Improvements were maintained for up to 36 months without the need for any further intervention. The results were confirmed by significant histological changes related to trophic restoration of the

vagina, responsible for extrinsic and intrinsic mechanisms involved in urinary continence. The authors concluded that these findings suggested that TACO2L was a safe and efficient novel treatment strategy in patients with mild SUI. These researchers stated that further investigation to confirm the long-term results presented here is still needed. These researchers stated that this was a prospective, non-randomized study of an observational nature with no control group. Since all patients enrolled were relatively young (45 to 65 years), the results of this particular study could not be translated into older populations.

Lin and associates (2018) noted that female pelvic floor disorders, including female SUI or sexual dysfunction are notorious for affecting the quality of life (QOL) in women. It has been reported that laser therapy might result in collagen remodeling and improvement in tissue firmness. These investigators evaluated the short-term outcome of female pelvic floor disorders treated by laser therapy. Women with self-reported symptoms of female pelvic floor disorders (limited to SUI and sexual dysfunction) were included in the study. Participants were treated with the Er:YAG laser or the fractional micro-ablative CO₂ laser. The therapeutic effect was focused on SUI symptoms and sexual dysfunction. There were 31 women who underwent laser treatment, including 21 patients treated with Erbium:YAG laser and 10 treated with CO₂ laser. In the Erbium:YAG laser group, ICIQ-SF scores were dropped from 8.25 ± 5.66 to 5.00 ± 3.99 ($p = 0.007$); and in the CO₂ laser group, scores were dropped from 11.11 ± 6.85 to 6.44 ± 4.25 ($p = 0.035$), contributing to the drop of ICIQ-SF scores from 9.14 ± 6.08 to 5.45 ± 4.05 for all enrolled patients ($p = 0.001$). However, objective measure using pad test did not show a statistically significant difference between before and after treatment (from 3.20 ± 5.84 g to 1.54 ± 3.18 g, $p = 0.224$). Sexual dysfunction was improved in 13 patients (44.83 %), but Female Sexual Function Index (FSFI) scores were not different before and after laser treatment (44.22 ± 23.36 versus 44.09 ± 24.51 , $p = 0.389$). The authors

concluded that laser therapy either by Erbium:YAG laser or CO2 laser appeared to be useful for female pelvic floor disorders, especially on improvement of SUI symptoms; however, the effectiveness needs further confirmation in large prospective and randomized studies. This was a small (n = 10 in the CO2 laser group), non-randomization study with short-term follow-up (2 months).

Furthermore, an UpToDate review on "Treatment of urinary incontinence in women" (Lukacz, 2019) states that "There is insufficient evidence to support the use of vaginal laser (CO2 or erbium) for the treatment of urinary incontinence in the setting of genitourinary syndrome of menopause".

Gene Testing for Stress Urinary Incontinence

In a systematic review, Isali and colleagues (2020) provided insight into the genetic pathogenesis of SUI by gathering and synthesizing the available data from studies evaluating differential gene expression in SUI patients and identified possible novel therapeutic targets and leads. A systematic literature search was conducted through September 2017 for the concepts of genetics and SUI. Gene net-working connections and gene-set functional analyses of the identified genes as differentially expressed in SUI were performed using GeneMANIA software. Of 3,019 studies, 4 were included in the final analysis. A total of 13 genes were identified as being differentially expressed in SUI patients; 11 genes were over-expressed: skin-derived antileukoproteinase (SKALP/elafin), collagen type XVII alpha 1 chain (COL17A1), plakophilin 1 (PKP1), keratin 16 (KRT16), decorin (DCN), biglycan (BGN), protein bicaudal D homolog 2 (BICD2), growth factor receptor-bound protein 2 (GRB2), signal transducer and activator of transcription 3 (STAT3), apolipoprotein E (APOE), and Golgi SNAP receptor complex member 1 (GOSR1), while 2 genes were under-expressed: fibromodulin (FMOD) and glucocerebrosidase (GBA). GeneMANIA revealed that these genes are involved in intermediate filament cytoskeleton and

extra-cellular matrix organization. The authors concluded that many genes are involved in the pathogenesis of SUI. Furthermore, whole-genome studies are needed to identify these genetic connections. These researchers stated that this study laid the groundwork for future research and the development of novel therapies and SUI biomarkers in clinical practice.

An UpToDate review on “Evaluation of women with urinary incontinence” (Lukacz, 2019) states that “The risk of urinary incontinence, particularly urgency incontinence, may be higher in patients with a family history. One study found that the risk of incontinence was increased for both daughters (relative risk [RR] 1.3, 95 % CI 1.2-1.4) and sisters (RR 1.6, 95 % CI 1.3-1.9) of women with incontinence. Twin studies attribute a 35 to 55 % genetic contribution to urgency incontinence/overactive bladder but only 1.5 % for stress incontinence”.

Furthermore, an UpToDate review on “Urinary incontinence in men” (Clemans, 2019) does not mention genetic testing as a management option.

The Adjustable Transobturator Male System for the Treatment of Stress Urinary Incontinence

In a systematic review and meta-analysis, Esquinas and Angulo (2019) examined the effectiveness of the Adjustable Transobturator Male System (ATOMS) device to treat male SUI. Two independent reviewers identified studies eligible for a systematic review and meta-analysis of various sources written in English, German and Spanish, using the databases PubMed, Embase and Web of Science. They excluded studies on female incontinence. These researchers employed the DerSimonian and Laird method for defining heterogeneity, calculating the grouped SMD. The primary objective of this review was the evaluation of clinical efficacy based on the achievement of dryness following device adjustment, defined

as use of no pad or 1 safety pad per day (PPD). The secondary objective was focused on analyzing improvement of incontinence with the device. Magnitude of effect was calculated by analyzing decrease in PPD and/or in 24-hour pad test. Number and severity of complications according to Clavien-Dindo classification were also reviewed. The pooled data of 1,393 patients from 20 studies (13 retrospective and 7 prospective) showed that treatment with ATOMS resulted in a mean 67 % dryness rate and 90 % improvement after adjustment. Mean total number of system fillings per patient was 2.4. Mean pad count and 24-hour pad test decrease were -4.14 PPD and -443 cc, respectively. There was significant heterogeneity of the sample analyzed, mainly based on variable baseline severity of incontinence, proportion of patients treated with irradiation and different generation devices. Proportion of irradiated patients affected dryness rate ($p = 0.0014$), together with baseline severity of incontinence ($p = 0.0035$) and different generation device used ($p < 0.0001$). Standardized mean follow-up was 20.9 months, with complications occurring in 16.4 % (major complications 3.0%) and explantation in 5.75 %. No randomized study has been developed so far to compare ATOMS to other devices for treating male SUI. The authors concluded that despite the evidence being exclusively based on descriptive studies and limited follow-up, ATOMS has proven to be a safe alternative to treat different degrees of male SUI following prostate surgery; better results were observed for patients with less than 6 PPD before implantation, non-irradiated patients and use of 3rd-generation device with silicone-covered pre-attached scrotal port. These researchers stated that ATOMS appeared to be a safe and effective procedure, with pooled data showing high objective effectiveness and low rate of complications in the short- and medium-term. They noted that it would be of great interest to develop comparative prospective studies in the future among ATOMS and other devices, not only regarding effectiveness but also including patient-reported outcomes.

The authors stated that the main drawbacks of this systematic review and meta-analysis lied in the scant level of evidence provided by the design and nature of the non-controlled, and mainly retrospective, studies available, and in their relatively short follow-up. The variable nature and severity of SUI and the different proportion of patients receiving radiation likely explained the high heterogeneity observed. Combining the results of individual studies increased the total number of participants and more participants imply more statistical power. However, combining studies with differences among participants could also reduce statistical power and make real effects more difficult to identify.

In a systematic review and meta-analysis, Angulo and colleagues (2019) examined the safety and efficacy of ATOMS compared to ProACT for male SUI according to literature findings; studies on female or neurogenic incontinence were excluded. Differences between ATOMS and ProACT in primary objective: dryness status (no-pad or 1 safety pad/day) after initial device adjustment, and in secondary objectives: improvement, satisfaction, complications and device durability, were estimated using random-effect model. Statistical heterogeneity among studies included in the meta-analysis was assessed using tau², Higgins's I² statistics and Cochran's Q test. Combined data of 41 observational studies with 3,059 patients showed higher dryness (68 % versus 55 %; p = 0.01) and improvement (91 % versus 80 %; p = 0.007) rate for ATOMS than ProACT. Mean pad-count (-4 versus -2.5 pads/day; p = 0.005) and pad-test decrease (-425.7 versus -211.4 cc; p < 0.0001) were also significantly lower. Satisfaction was higher for ATOMS (87 % versus 56 %; p = 0.002) and explant rate was higher for ProACT (5 % versus 24 %; p < 0.0001). Complication rate for ProACT was also higher, but not statistically significant (17 % versus 26 %; p = 0.07). Mean follow-up was 25.7 months, lower for ATOMS than ProACT (20.8 months versus 30.6 months; p = 0.02). The rate of working devices favored ATOMS at 1-year (92 % versus 76 %; p < 0.0001), 2-years (85 versus 61 %; p =

0.0008) and 3-years (81 % versus 58 %; $p = 0.0001$).

Significant heterogeneity was evidenced, due to variable incontinence severity baseline, difficulties for a common reporting of complications, different number of adjustments and time of follow-up and absence of randomized studies. The authors concluded that despite the limitations that studies available were exclusively descriptive and the follow-up was limited, literature findings confirmed ATOMS was more effective, with higher patient satisfaction and better durability than ProACT to treat male SUI.

The authors stated that the main drawbacks of this meta-analysis included the short-term follow-up (mean of 25.7 months), especially in the ATOMS-arm, and in the very high heterogeneity observed between studies; probably reflecting a variable severity of sphincteric damage included and the absence of RCTs. Furthermore, the criteria to report complications appeared variable between the studies analyzed. The drawbacks highlighted were in consonance with the publication bias identified according to Egger's linear regression. It should also be noted that the ATOMS studies had shorter follow-up than the ProACT studies (20.8 months versus 30.6 months).

Furthermore, an UpToDate review on "Urinary incontinence in men" (Clemens, 2019) does not mention Adjustable Transobturator Male System as a therapeutic option.

Magnetic Stimulation for Women with Stress Urinary Incontinence

In a meta-analysis of studies with short-term follow-up, Peng and colleagues (2019) examined the efficacy of magnetic stimulation (MS) in female patients with SUI by investigating peer-reviewed RCTs. PubMed, Embase, and Cochrane library were retrieved for any peer-reviewed original articles in English. Databases were searched up to July 2018. Included studies examined effects of MS on SUI. The data were

analyzed by review manager 5.3 software (Cochrane Collaboration, Oxford, UK). A total of 4 studies involving 232 patients were identified and included in present meta-analysis. Compared with the sham stimulation, the MS group had statistically significantly fewer leaks/3 days (MD=-1.42; 95 % CI: -2.42 to -0.59; p=0.007), less urine loss on pad test (g/24 hours) (MD=-4.99; 95 % CI: -8.46 to -1.53; p=0.005), higher QoL scores (MD=0.42; 95 % CI: 0.02 to 0.82; p=0.009), and lower ICIQ scores (MD=-4.60; 95 % CI: -5.02 to -4.19; p<0.001). MS presented higher cure or improvement rate, with a statistically significant improvement in UDI and IIQ-SF scores compared to sham stimulation. No MS-related AEs were reported in study. The authors concluded that MS led to an improvement in SUI without any reported safety concerns and an improvement in patient QoL; however, the long-term outcome of this technique remains unclear and is the subject of ongoing research.

The authors stated that the drawbacks of this present study were: First, its small sample size and insufficient statistical power. Second, the stimulation parameters and duration of the studies were not consistent, which made these investigators doubted whether meta-analysis could be performed. However, the results based on RCTs were excellent despite inconsistent variables. Third, when analyzing the data of Pad test, a hug heterogeneity that most likely caused by incomplete experimental design was recorded if these researchers added the study by Manganotti et al (2007) to the analysis. Therefore, this study data were finally excluded by performing sensitivity analysis. These researchers stated that further well-designed RCTs with a long-term follow-up with a large sample size are needed.

The Neocontrol™System

In a systematic review and meta-analysis, Ho and colleagues (2020) examined the effectiveness of extracorporeal magnetic stimulation for treatment of SUI. Data sources included 4

electronic databases from inception to May 18, 2019. Two authors independently carried out the search, evaluated the methodological quality, and extracted data. The final studies included in the analysis were selected after reaching consensus with the 3rd author. A total of 20 studies were included in the systematic review and 12 of these in the meta-analysis. Quality assessment indicated that only 8 of 17 RCTs had low risk in overall risk of bias, whereas all controlled trials had serious risk of bias. The weighted mean effect size of magnetic stimulation on QoL, number of leakages, pad test outcomes, and number of incontinence events was 1.045 (95 % CI: 0.409 to 1.681), -0.411 (95 % CI: 0.178 to 0.643), -0.290 (95 % CI: 0.025 to 0.556), and -0.747 (95 % CI: -1.122 to -0.372), respectively. Subgroup analysis revealed a significant difference in the type of QoL measurement used. Sensitivity analyses revealed that a high degree of heterogeneity persisted even after omitting studies individually. The authors concluded that extracorporeal magnetic stimulation may be effective in treating UI and improving QoL without major safety concerns; however, because of a high degree of heterogeneity among studies, inferences from the results must be made with caution. These investigators encouraged researchers to conduct further qualitative and quantitative studies to develop consistent content and dosage for the intervention.

Moxibustion for the Treatment of Post-Stroke Urinary Incontinence

Li and colleagues (2020) noted that UI is a frequently identified complication among stroke survivors. Moxibustion is commonly used to treat post-stroke UI in Asian countries. In a systematic review and meta-analysis, these researchers examined the evidence of using moxibustion for post-stroke UI management. A total of 12 databases were searched to identify RCTs using moxibustion to improve post-stroke UI management; 4 Chinese journals were also manually screened for potentially eligible articles. A total of 10 studies with 719 subjects and 1 completed trial without published

results were included. Compared with "routine methods of treatment and/or care", the meta-analyses revealed that moxibustion had superior effects in improving UI symptoms and alleviating the severity of UI. The authors concluded that this systematic review identified preliminary research evidence that moxibustion may be effective in managing the symptoms of post-stroke UI; these investigators stated that more rigorously designed, large-scale RCTs are needed to provide more robust evidence in this area.

CPT Codes / HCPCS Codes / ICD-10 Codes

Information in the [brackets] below has been added for clarification purposes. Codes requiring a 7th character are represented by "+":

Code	Code Description
<i>Multi-channel Urodynamic Studies:</i>	
CPT codes covered if selection criteria are met:	
51726	Complex cystometrogram (ie, calibrated electronic equipment)
51727	with urethral pressure profile studies (ie, urethral closure pressure profile), any technique
51728	with voiding pressure studies (ie, bladder voiding pressure), any technique
51729	with voiding pressure studies (ie, bladder voiding pressure) and urethral pressure profile studies (ie, urethral closure pressure profile), any technique
51741	Complex uroflowmetry (eg, calibrated electronic equipment)

Code	Code Description
51784	Electromyography studies (EMG) of anal or urethral sphincter, other than needle, any technique
51785	Needle electromyography studies (EMG) of anal or urethral sphincter, any technique
51792	Stimulus evoked response (eg, measurement of bulbocavernosus reflex latency time)
51797	Voiding pressure studies, intra-abdominal (ie, rectal, gastric, intraperitoneal) (List separately in addition to code for primary procedure)
51798	Measurement of post-voiding residual urine and/or bladder capacity by ultrasound, non-imaging
ICD-10 codes covered if selection criteria are met:	
N32.0 - N32.9	Other disorders of bladder
N39.3 - N39.9	Urinary incontinence
R32	Unspecified urinary incontinence
R39.81 - R39.89	Other symptoms and signs involving the genitourinary system
Genetic Testing:	
CPT codes not covered for indications listed in this CPB:	
Genetic testing for stress urinary incontinence - no specific code:	
ICD-10 codes not covered for indications listed in the CPB:	
N39.3	Stress incontinence (female) (male)
N39.46	Mixed incontinence

Code	Code Description
Artificial Urinary Sphincter [Not covered for magnetically controlled endourethral 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-10 codes covered if selection criteria are met:	
N36.42	Intrinsic sphincter deficiency (ISD)
N39.3 - N39.9, R32	Urinary incontinence
Q64.0	Epispadias
Q64.10 - Q64.19	Exstrophy of urinary bladder
Q62.5, Q64.5 - Q64.9	Other specified anomalies of bladder and urethra

Code	Code Description
Z85.46	Personal history of malignant neoplasm of prostate
<i>Periurethral Injections of Bulking Agents:</i>	
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
Other HCPCS codes related to the CPB:	
C9743	Injection/implantation of bulking or spacer material (any type) with or without image guidance (not to be used if a more specific code applies)

Code	Code Description
ICD-10 codes covered if selection criteria are met:	
N36.42 - N36.43	Intrinsic (urethral) sphincter deficiency (ISD)
N39.3 - N39.9, R32	Urinary incontinence
ICD-10 codes not covered for indications listed in the CPB:	
N30.00 - N30.91	Cystitis
N31.9	Neuromuscular dysfunction of bladder, unspecified [Neurogenic bladder]
N34.0 - N34.2	Urethritis
N35.010 - N35.92	Urethral stricture
N39.0	Urinary tract infection, site not specified
Z92.3	Personal history of irradiation
<i>Transperineal implantation of permanent adjustable balloon continence device:</i>	
HCPSC codes not covered for indications listed in this CPB:	
C9746	Transperineal implantation of permanent adjustable balloon continence device, with cystourethroscopy when performed and/or fluoroscopy, when performed [for the treatment of urinary incontinence]
<i>InterStim Continence Control Therapy/Sacral Nerve Stimulation [not covered for bilateral sacral nerve stimulation for urinary incontinence]:</i>	
CPT codes covered if selection criteria are met:	

Code	Code Description
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 wave form, 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 (ie, peripheral nerve, sacral nerve, neuromuscular) (except cranial nerve) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming
HCPCS codes covered if selection criteria are met:	

Code	Code Description
A4290	Sacral nerve stimulation test lead, each
C1767	Generator, neurostimulator (implantable), non-rechargeable
C1778	Lead, neurostimulator (implantable)
C1816	Receiver and/or transmitter, neurostimulator (implantable)
C1820	Generator, neurostimulator (implantable), with rechargeable battery and charging system
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

Code	Code Description
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-10 codes covered if selection criteria are met:	
N31.2	Flaccid neuropathic bladder, not elsewhere classified
N39.41	Urge incontinence
R32	Unspecified urinary incontinence
R33.0 - R33.9	Retention of urine
R35.0	Frequency of micturition
R39.14	Feeling of incomplete bladder emptying
R39.15	Urgency of urination
ICD-10 codes not covered for indications listed in the CPB (not all-inclusive):	

Code	Code Description
E75.21 - E75.29 E75.4, E75.6	Disorders of sphingolipid metabolism and other lipid storage disorders
G10 - G32.89	Systemic atrophies primarily affecting the central nervous system
G35 - G47.9	Demyelinating diseases of CNS and episodic and paroxysmal disorders
G50.0 - G59	Disorders of the peripheral nervous system
G90.01 - G91.9	Disorders of autonomic nervous system
N13.9	Urinary obstruction
N31.0 - N31.1, N31.9	Neurogenic bladder
N32.0	Bladder neck obstruction
N35.010 - N35.92	Urethral stricture
N39.3	Stress incontinence, (female) (male)
N39.46	Mixed incontinence (female) (male)
N40.0	Enlarged prostate without lower urinary tract symptoms
<i>Vaginal Cones (no specific codes):</i>	
Other HCPCS codes related to the CPB:	
A4335	Incontinence supply; miscellaneous
<i>Pessary (Bladder Neck Support Prosthesis):</i>	
CPT codes covered if selection criteria are met:	

Code	Code Description
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-10 codes covered if selection criteria are met:	
N39.3 - N39.9	Urinary incontinence
N39.46	Mixed incontinence (female) (male)
N81.0 - N81.9	Female genital prolapse
<i>Tension-Free Vaginal Tape Procedures (no specific codes):</i>	
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-10 codes covered if selection criteria are met:	
N39.3 - N39.9	Urinary incontinence
N39.46	Mixed incontinence (female) (male)
<i>Colposuspension and Sling Procedures [Not covered for adjustable retropubic suburethral sling]:</i>	

Code	Code Description
CPT codes covered if selection criteria are met:	
51990	Laparoscopy, surgical; urethral suspension for stress incontinence
51992	slings 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-10 codes covered if selection criteria are met:	
N39.3 - N39.9	Urinary incontinence
N39.46	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:	

Code	Code Description
E0746	Electromyography (EMG), biofeedback device
ICD-10 codes covered if selection criteria are met:	
N39.3 - N39.9	Urinary incontinence
N39.41 - N39.498, R32	Urinary incontinence
<i>Percutaneous Tibial Nerve Stimulation:</i>	
CPT codes covered if selection criteria are met:	
0587T	Percutaneous implantation or replacement of integrated single device neurostimulation system including electrode array and receiver or pulse generator, including analysis, programming, and imaging guidance when performed, posterior tibial nerve
0588T	Revision or removal of integrated single device neurostimulation system including electrode array and receiver or pulse generator, including analysis, programming, and imaging guidance when performed, posterior tibial nerve
0589T	Electronic analysis with simple programming of implanted integrated neurostimulation system (eg, electrode array and receiver), including contact group(s), amplitude, pulse width, frequency (Hz), on/off cycling, burst, dose lockout, patient-selectable parameters, responsive neurostimulation, detection algorithms, closed-loop parameters, and passive parameters, when performed by physician or other qualified health care professional, posterior tibial nerve, 1-3 parameters

Code	Code Description
0590T	4 or more parameters
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

Code	Code Description
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-10 codes covered if selection criteria are met [non-neurogenic]:	
N39.3 - N39.9, R32	Urinary incontinence
R35.0	Frequency of micturition
R39.14	Feeling of incomplete bladder emptying
R39.15	Urgency of urination
ICD-10 codes not covered for indications listed in the CPB:	
G83.4	Cauda equina syndrome
N31.0 - N31.1, N31.9	Neurogenic bladder, not elsewhere classified
N31.2	Flaccid neuropathic bladder, not elsewhere classified
<i>Transurethral Radiofrequency Therapy (Renessa Procedure):</i>	
CPT codes covered if selection criteria are met:	

Code	Code Description
53860	Transurethral, radiofrequency micro-remodeling of the female bladder neck and proximal urethra for stress urinary incontinence
ICD-10 codes covered if selection criteria are met:	
N39.3 - N39.9	Urinary incontinence
Urethral inserts:	
HCPCS codes covered if selection criteria are met:	
A4336	Incontinence supply, urethral insert, any type, each
ICD-10 codes covered if selection criteria are met:	
N39.3 - N39.9	Urinary incontinence
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-10 codes covered if selection criteria are met:	
N39.3 - N39.9, R32	Urinary incontinence [post-prostatectomy urinary incontinence]
Macroplastique (polydimethylsiloxane):	
No specific code	
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:	

Code	Code Description
No specific codes	
<i>Radiofrequency Micro-Remodeling with the SURs System (paraurethral or transvaginal) :</i>	
No specific codes	
ICD-10 codes not covered for indications listed in the CPB:	
N39.3 - N39.9. R32	Urinary incontinence
<i>Extraurethral (Non-circumferential) Retropubic Adjustable Compression Devices (ProACT Therapy System):</i>	
CPT codes not covered for indications listed in the CPB:	
0548T	Transperineal periurethral balloon continence device; bilateral placement, including cystoscopy and fluoroscopy
0549T	unilateral placement, including cystoscopy and fluoroscopy
0550T	removal, each balloon
0551T	adjustment of balloon(s) fluid volume
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
C9746	Transperineal implantation of permanent adjustable balloon continence device, with cystourethroscopy, when performed and/or fluoroscopy, when performed
<i>Laser Therapy :</i>	
CPT codes not covered for indications listed in the CPB:	

Code	Code Description
Genityte Procedure and FemiLift - no specific code:	
ICD-10 codes not covered for indications listed in the CPB:	
N39.3 - N39.9, R32	Urinary incontinence
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-10 codes not covered for indications listed in the CPB:	
N39.3 - N39.9, R32	Urinary incontinence
Autologous Myoblast Transplantation:	
No specific code	
Autologous muscle-derived cell therapy:	
No specific code	
ICD-10 codes not covered for indications listed in the CPB:	
N39.3 - N39.9, R32	Urinary incontinence
Collagen Porcine Dermis mesh:	
No specific code	
ICD-10 codes not covered for indications listed in the CPB:	

Code	Code Description
N39.3 - N39.9, R32	Urinary incontinence
<i>Stem Cell Therapy:</i>	
CPT codes not covered for indications listed in the CPB:	
38241	Hematopoietic progenitor cell (HPC); autologous transplantation
ICD-10 codes not covered for indications listed in the CPB:	
N39.3 - N39.9, R32	Urinary incontinence
<i>Transobturator Tape:</i>	
No specific code	
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 (eg, 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-10 codes covered if selection criteria are met:	
N39.3 - N39.9	Urinary incontinence [intractable and has failed behavioral and pharmacologic treatments]
ICD-10 codes not covered for indications listed in the CPB:	

Code	Code Description
N39.46	Urge incontinence
<i>Pelvic Floor Stimulation:</i>	
CPT codes covered if selection criteria are met:	
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 covered if selection criteria are met:	
E0740	Incontinence treatment system, pelvic floor stimulator, monitor, sensor and/or trainer
G0238	Electrical stimulation (unattended), to one or more areas for indication(s) other than wound care, as part of a therapy plan of care
ICD-10 codes covered if selection criteria are met:	
N39.3 - N39.9, R32	Urinary incontinence (female) (male)
<i>Bariatric Surgery:</i>	
CPT codes not covered for indications listed in the CPB:	
46344 - 43645, 43770 - 43775, 43842 - 43848, 43886 - 43888	Bariatric surgery
ICD-10 codes not covered for indications listed in the CPB:	

Code	Code Description
N39.3 - N39.9, R32	Urinary incontinence
Adjustable Transobturator Male System:	
CPT codes not covered for indications listed in the CPB:	
<i>Adjustable Transobturator Male System - no specific code</i>	
<i>Magnetic Stimulation:</i>	
CPT codes not covered for indications listed in the CPB:	
<i>Magnetic Stimulation - no specific code</i>	
<i>Moxibustion:</i>	
CPT codes not covered for indications listed in the CPB:	
<i>Moxibustion - no specific code</i>	
ICD-10 codes not covered for indications listed in the CPB:	
N39.498	Other specified urinary incontinence [post-stroke urinary incontinence]
<i>Pelvic Muscle Trainers:</i>	
No specific code	
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
<i>Transcutaneous electrical nerve stimulation:</i>	
CPT codes not covered for indications listed in the CPB:	
64550	Application of surface (transcutaneous) neurostimulator

Code	Code Description
HCPSC codes not covered for indications listed in the CPB:	
E0720	Transcutaneous electrical nerve stimulation (TENS) device, 2 lead, localized stimulation
E0730	Transcutaneous electrical nerve stimulation (TENS) device, 4 or more leads, for multiple nerve stimulation
ICD-10 codes not covered for indications listed in the CPB:	
N32.81	Overactive bladder

The above policy is based on the following references:

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**Amendment to
Aetna Clinical Policy Bulletin Number: 0223 Urinary
Incontinence**

There are no amendments for Medicaid.