Medical Policy

Subject:	Treatments for Urinary Incontinence		
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Description/Scope

This document addresses the following treatments for urinary incontinence:

- Vaginal weight training;
- Injection of periurethral bulking agents;
- Transvaginal radiofrequency bladder neck suspension;
- Transurethral radiofrequency energy collagen micro-remodeling;
- Artificial urinary sphincter devices;
- Intraurethral valve-pump implantation;
- Adjustable balloon system implantation.

Note: Please see the following related document(s) for additional information:

- MED.00125 Biofeedback and Neurofeedback
- CG-SURG-08 Sacral Nerve Stimulation as a Treatment of Neurogenic Bladder Secondary to Spinal Cord Injury
- CG-SURG-95 Sacral Nerve Stimulation and Percutaneous Tibial Nerve Stimulation for Urinary and Fecal Incontinence; Urinary Retention

Position Statement

Medically Necessary:

Injection of periurethral bulking agents is considered **medically necessary** when one or more of the following are met:

- The individual has stress urinary incontinence (SUI) caused by intrinsic sphincter deficiency (ISD) which persists despite at least 12 consecutive months of conventional therapy (for example, exercise, medication); **or**
- Post-traumatic or post-surgical injury; **or**
- Urethral hypermobility in individuals with abdominal leak point less than 100 cm H_2O which persists despite at least 12 consecutive months of conventional therapy (for example, exercise, medication).

Implantation of an artificial urinary sphincter device is considered **medically necessary** in adults following prostate surgery to treat urinary incontinence due to reduced outlet resistance (Intrinsic Sphincter Deficiency [ISD]) when the symptoms of incontinence have been refractory to at least 6 months of conservative medical treatment.*****

***Note:** Artificial urinary sphincter implantation is **not considered first-line treatment** of refractory incontinence in adults following prostate surgery. Examples of first-line conservative medical treatment may include one or more of the following: behavioral therapy, pharmacologic treatments, and intermittent self-catheterization.

Not Medically Necessary:

Implantation of an artificial urinary sphincter device is considered **not medically necessary** for individuals who do not meet the medically necessary criteria and for all other indications.

Investigational and Not Medically Necessary:

The following services are considered **investigational and not medically necessary:**

- The injection of periurethral bulking agents for individuals who do not meet the medically necessary criteria;
- inFlow™ intraurethral valve-pump implantation;
- ProACT™ adjustable continence therapy;
- Vaginal weight training with specially designed weights (cones);
- Transvaginal radiofrequency bladder neck suspension as a treatment of urinary stress incontinence;
- Transurethral radiofrequency energy collagen micro-remodeling as a treatment of stress urinary incontinence.

Rationale

Periurethral Bulking Agents

Periurethral injections of bulking agents, such as cross-linked collagen, carbon-coated beads (for example, Durasphere™ Advanced Uroscience, Inc., St. Paul, MN), calcium hydroxylapatite (for example, Coaptite® BioForm Medical, Inc., San Mateo, CA) and polydimethylsiloxane (for example, Macroplastique® Uroplasty, Inc., Minneapolis, MN) and non-particulate homogenous gel (for example, Bulkamid® Contura, Irvine, CA), have been studied in randomized controlled trials (RCTs). These trials have established the safety and efficacy of agents cleared by the U.S. Food and Drug Administration (FDA) for the treatment of adult women with stress urinary incontinence (SUI) due to intrinsic sphincteric deficiency. Notably, another product, Contigen® Bard Collagen Implant, is no longer available.

A 2017 Cochrane systematic review by Kirchin and colleagues was limited to RCTs evaluating bulking agents to treat urinary incontinence in women that reported at least one objective outcome measure such as pad weight reduction. A total of 14 RCTs met eligibility requirements, with sample sizes ranging from 30 to 355. Comparison interventions included placebo (1 trial), pelvic floor exercises (1 trial) other surgical techniques (2 trials), a different bulking agent (8 trials) and different injection sites using the same agent (2 trials). Due to differences in study design, the investigators did not pool study findings. However, the authors noted that data up to 12 months suggests that injection of bulking agents appears to be less effective but safer than open surgery.

Several systematic reviews have included both controlled and uncontrolled observational studies. Siddiui (2017) identified 26 studies examining Bulkamid and Macroplastique for the treatment of SUI. The authors did not pool study findings but reported that objective success rates in individual studies ranged from 25.4% to 73.3%. The most commonly reported adverse events in the 651 individuals treated with Macroplastique were urinary tract infections (9%), implantation site pain and acute urinary retention (9%). This study did not report any comparative outcome data.

A 2020 systematic review by Capobianco and colleagues included 21 studies, 1 of which was an RCT, on bulking agents to treat SUI or mixed urinary incontinence. The pooled improvement rate in studies with at least 1 year of follow-up was 57% (95% confidence interval [CI], 39% to 74%). The pooled cure rate after at least 1 year of follow-up was 21% (95% CI, 16% to 27%). In a pooled analysis of 5 studies that reported objective measures and had at least 1 year of follow-up, the objective treatment success rate was 46% (95% CI, 37% to 55%).

The 2017 joint guideline by the American Urological Association (AUA)/Society of Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction (SUFU) recommended bulking agents as one of several options for patients considering surgery for SUI.

Vaginal Weight Training

Vaginal weight training is a behavioral therapy that employs weights during Kegel or pelvic floor exercises to strengthen pelvic floor muscles. The use of vaginal weights (cones) has not been shown to improve pelvic floor muscle strength more than Kegel exercises alone. A 2013 Cochrane review by Herbison and Dean identified 23 RCTs comparing weighted vaginal cones to a control condition in women with urinary incontinence. The authors noted that all of the studies had small sample sizes, some had high drop-out rates and study quality was difficult to assess in many cases. Most studies used a similar protocol in which individuals held the cones in place twice a day for 15 minutes. Outcome measures varied widely. A comparison of interest is the efficacy of vaginal cones plus pelvic floor muscle training (PFMT) alone. Two trials addressed this comparison and neither found a significant benefit of the addition of vaginal cones. Thirteen trials compared vaginal cones and PFMT. In a pooled analysis of 4 trials, there was not a significant difference between groups in leakage episodes per day (mean difference [MD], 0.00; 95% CI, -0.20 to 0.20). Similarly, a pooled analysis of 5 trials did not find a significant difference between groups in the proportion of individuals with improvement on the pad test (risk ratio [RR], 1.10; 95% CI, 0.82 to 1.49). Four trials reported on subjective improvement of cure and this outcome significantly favored the vaginal cone group (RR, 1.01; 95% CI, 0.75 to 1.36). The ability to conduct pooled analyses was limited by variability in control interventions and outcome measures and thus a relatively small number of studies were included in the meta-analyses. In these meta-analyses, objective measures did not find a significant benefit of vaginal cones compared with PFMT.

In a small prospective study, Haddad and colleagues (2011) evaluated vaginal cone therapy in a passive phase (without voluntary contractions of the pelvic floor) and an active phase (with voluntary contractions). Twenty-four women with SUI were treated and 21 women completed the 3-month study. Outcomes in the pad test favored the active phase as did pelvic floor evaluation and bladder neck mobility. Complete reversal of symptomatology was observed in 12 (57.1%) participants, and satisfaction was expressed by 19 (90.4%). This study lacked a comparison group of women who did pelvic floor exercises without the use of vaginal cones.

Transvaginal Radiofrequency Bladder Neck Suspension (SURx Transvaginal System®)

Several uncontrolled studies have been published. Dmochowski and colleagues (2003) reported on a prospective case series of 120 consecutive women with urinary stress incontinence who underwent transvaginal bladder neck suspension. Enrolled subjects had failed at least a 3-month trial of conservative therapy, including, most commonly, pelvic floor muscle exercises or pelvic floor stimulation. Follow-up examinations at 1, 3, 6 and 12 months consisted of a history, physical examination and urodynamic studies. In addition, each participant completed a voiding diary and quality of life questionnaire. A cure was defined as a negative Valsalva maneuver; improvement was defined as decreased daily episodes or pad use. A total of 73% of the participants were considered cured or improved at 12 months. More than 68% of the participants reported satisfaction with the treatment. The study is limited in that it lacked a comparison group.

Ross and colleagues (2002) conducted a multicenter, prospective single-arm study that included 94 women with stress incontinence. At 1 year, the objective cure rate was 79% based on a negative leak point pressure. Assessment of quality of life was also significantly improved. Larger controlled studies with longer follow-up are needed to further evaluate this procedure.

Transurethral Radiofrequency Energy Collagen Micro-Remodeling (Lyrette™, formerly Renessa® System)

A 2015 Cochrane review by Kang and colleagues identified a single RCT evaluating transurethral radiofrequency energy collagen micro-remodeling for treatment of stress urinary incontinence (SUI). This trial, by Appell and colleagues (2006), randomized 173 women with SUI to active (n=110) or sham (n=63) treatment and followed participants for 12 months. Primary outcomes were leak point pressure (LPP) and score on the incontinence quality of life (I-QOL). At 12 months, 136 of 173 participants (79%) were available for the analysis of LPP. Individuals in the active treatment group had an increase in mean LPP of 13.2 cm H2O and those in the sham group had a decrease in mean LPP of 2 cm H2O. The difference in LPP between groups was statistically significant, p=0.002. A total of 142 participants (82%) provided data for the I-QOL outcome at 12 months. The proportion of evaluable participants with at least a 10 point I-QOL improvement (considered clinically meaningful) was 48% in the active treatment arm and 44% in the sham arm. The difference between groups did not differ significantly, p=0.70. The study had mixed findings and was limited by a substantial drop-out rate and the uncertain clinical significance of the LPP measure.

In addition to the RCT, a prospective, single-arm study with 3 years of follow-up evaluated transurethral collagen denaturation (Renessa) in women with SUI caused by bladder outlet hypermobility. Objective measures included voiding diaries and in-office stress pad weight tests. Subjective measures included the I-QOL, Urogenital Distress Inventory (UDI-6), and Global Impression of Improvement (PGI-I) instruments. Of the 136 women who were treated, 75 (55%) were available for 12-month follow-up (Elser 2009). At 12 months, significant reductions existed from baseline in the median number of daily (-0.61) and weekly (-4.0) leaks caused by activity, and 50% of the subjects experienced at least 50% fewer leaks compared with baseline (52% of evaluable participants). At the 18-month follow-up, data were available on 60 women (44%). The study found incontinent episodes decreased whereas quality of life and participant satisfaction with the procedure increased (Elser 2010).

A total of 41 women (30%) completed the 3-year follow-up (Elser 2011). According to diary data available for 39 women, 24 (62%) reported at least a 50% reduction in leaks per day. The investigators also reported an intention-to-treat (ITT) analysis of data from all 136 participants (last observation carried forward), 46.7% reported at least a 50% reduction in leaks from baseline. Based on the ITT analysis with multiple imputations of missing data, 60% of women had at least a 50% reduction in leaks. This study was limited by a large loss to follow-up and a lack of a control or comparison group.

Artificial Urinary Sphincter (AUS) Devices

A number of observational studies have evaluated use of AUS in male adults with refractory urinary incontinence due to ISD following prostate surgery (Boswell, 2019; Dosanjh, 2020; Sacomani, 2017; Tutolo, 2019). No RCTs were identified. A large multicenter retrospective cohort study was published by Tutolo and colleagues in 2019. The study included 892 cases of AUS implantation in men with non-neurogenic SUI after prostate surgery who were followed for at least 1 year. The mean length of follow-up was 32 months (range 12 to 300 months). The primary outcome was the dry rate (DR), defined as not needing to use any pads. Data on pad use prior to surgery

were available for 547 of the 892 individuals in the cohort (61%). All of the 547 individuals used at least 1 pad per day prior to treatment, including 368 (67%) who used at least 5 pads. At follow-up, the DR was 58% for the cohort. Among individuals without previous incontinence surgery, 409 of 724 (57%) were dry at follow-up, and the DR was 48% in individuals with previous incontinence surgery (80 of 168). The overall complication rate was 28% (248 individuals) and consisted of erosion, infection, urethral atrophy and mechanical failure.

A study by Sacomani and colleagues (2017) reported long-term outcomes in 121 consecutive individuals who underwent AUS implantation following prostatectomy. After a mean follow-up of 5.2 years, 106 men (88%) still had their AUS device and 82 of these (68%) reported being completely dry. Investigators have noted high complication rates, (for example, infection, erosion, mechanical failure and device explantation) and need for reoperative procedures in up to 20% of implanted individuals (Imamoglu, 2005; Kim, 2008). For these reasons, AUS is not considered a first-line therapy and is reserved for those who have not responded to conventional treatment options for at least 6 months following prostate surgery.

Boswell (2019) focused on long-term device survival and reintervention rates. The study included 1154 individuals who underwent AUS placement for SUI following radical prostatectomy or other prostate procedure. Individuals were followed for a mean of 5.4 years. The rate of secondary surgery (removal or revision) was 35% (404 of 1154). According to Kaplan-Meier survival analysis, estimates of rates of device survival were 72% at 5 years, 56% at 10 years, 41% at 15 years and 33% at 20 years.

In a systematic review of studies of men with post-prostatectomy incontinence who were treated with AUS or an adjustable sling (Guachetá Bomba, 2019), the authors identified seven studies with a total of 463 participants, 420 of whom had SUI following prostatectomy. In the studies, 313 received an AUS and 107 received an adjustable sling. There were no RCTs and no head-to-head comparisons of AUS and adjustable slings. The primary outcome of the review was decreased pad use. The analysis for this outcome included three studies on each intervention. Compared with no intervention, pad use decreased with either intervention and there was no statistically significant difference between interventions.

A systematic review (Barakat, 2020) of published literature on AUS for females with SUI identified 15 uncontrolled retrospective and prospective studies with a mean of 68 individuals per study. The authors rated the quality of evidence as very low quality due to high risk of bias in all of the included studies as well as publication bias and "serious imprecision". In a meta-analysis, the authors noted a high degree of heterogeneity in the post-operative continence rate and found a median continence rate of 79%. They also found a revision rate of 15%. Despite the high rate of post-operative continence, the authors concluded that the low quality of evidence and small study population were insufficient to draw firm conclusions about the impact of AUS on the net health outcome in women.

To date, the evidence from well-designed studies is insufficient to form conclusions regarding the safety and efficacy of AUS for other subgroups, such as women and, children with intractable incontinence, and males who have not undergone prostate surgery.

inFlow Intraurethral Valve-Pump and Activator

The inFlow intraurethral valve-pump received clearance through the FDA's de novo approval process in 2014. Chen and colleagues (2005) published a prospective, single-arm crossover study involving 273 subjects with

hypocontractile or acontractile bladder conditions. The first 88 subjects were enrolled directly into the study phase involving an 8-week baseline phase using clean intermittent catheterization (CIC), followed by a 16-week inFlow treatment phase, and a final 4-week treatment withdrawal phase. Subsequent subjects were first enrolled in a 1-week tolerability trial (n=185). Those subjects that satisfactorily passed that phase (n=139) continued to the study phase. A total of 196 of the original 273 (72%) subjects withdrew from the study. These withdrawals were attributed to initial discomfort and leakage of the device. A total of 77 subjects completed the inFlow treatment phase. Post-void residual volume was comparable during baseline CIC phase and inFlow treatment phase (20.3 ml vs. 16.1 ml), with significantly improved quality of life ($p<0.001$). Controlled trials are needed to fully evaluate the inFlow device.

ProACT Adjustable Continence Therapy

The ProACT System (Uromedica, Inc. Plymouth, MN) is an implantable, volume-adjustable balloon device which is connected to bi-lumen tubing that terminates in a subcutaneous injection port. The ProACT was approved by the FDA in November 2015 via a premarket approval (PMA) application for treatment of men with stress incontinence of at least 12 months' duration following prostate surgery who did not respond to conservative therapy.

FDA clearance was based on results of a prospective, multi-center, single-arm, open-label clinical study of 123 subjects in the intent-to-treat cohort. Subjects were followed for a minimum of 18 months following implantation with continued follow-up planned. The primary effectiveness endpoint was the average of two 24-hour pad weight measurements conducted at baseline compared to the average of two 24-hour pad weight measurements conducted at 18 months. Individual success was defined as ≥ 50% reduction in 24-hour pad weight at 18 months, compared to baseline. Overall study success criteria was defined as an exact 95% binomial confidence interval lower boundary of ≥ 50% success at 18 months. The success rate, which was based on the primary endpoint, was 46% (57/124) (95% CI, 37% to 55%), which did not meet the performance goal because the lower bound of the 95% CI was 37%, which is below the target responder rate of 50%. It was concluded that the study's primary effectiveness endpoint was not met.

Several additional single-arm studies evaluating ProAct in men with SUI following prostate surgery have been published (Nestler, 2018; Noorhoff 2017, Ronzi, 2019). Complication rates and/or need for revision surgery tended to be high. In the Nestler (2018) study, 59 of 112 implants of the ProAct system (53%) had to be revised after a median of 26 months due to rupture or dislocation/migration. Ronzi and colleagues (2019) identified complications in 70 of 102 cases (69%) including 34 migrations, 18 device failures, 28 urethral erosions and 28 cutaneous erosions.

A systematic review of studies on ProAct in men with SUI was published in 2019 by Larson and colleagues. No RCTs were identified. The authors included 19 studies with a total of 1264 individuals. In a pooled analysis of data on ProAct treatment, 60.2% of individuals were 'dry' at follow-up and 81.9% were either 'dry' or 'improved'. No data from any comparison intervention were reported. A pooled analysis of adverse event data from 18 studies found a 5.3% rate of intraoperative bladder or urethra perforation and a 22.2% revision rate over a mean follow-up of 3.6 years.

Background/Overview

Urinary voiding dysfunction includes urinary incontinence (UI) which is the inability to hold urine in the bladder and urinary retention, which is the inability to pass urine out of the bladder. Both men and women can experience urinary voiding dysfunction. Many women experience some UI due to pregnancy and childbirth, menopause, and the structure of the female urinary tract. Urinary retention in women can be caused by bladder muscle failure or obstruction. Many men experience incontinence and retention along with prostate enlargement or after prostate surgery.

There are a variety of therapies used to treat urinary incontinence. The least invasive approaches include behavioral techniques such as fluid management and bladder training, pelvic floor muscle exercises and scheduled toilet trips. Medications used to treat urinary incontinence include anticholinergics and mirabegron. In addition, the following medical devices are potential treatment options:

Periurethral bulking agents refer to a variety of materials (collagen, carbon coated beads, calcium hydroxylapatite or polydimethylsiloxane) that may be injected around the urethra to provide better bladder control.

Vaginal weight training involves the use of small, specially designed weights ("cones") that can be placed in the vagina and held there to strengthen the muscles in the pelvic area. Over time, increasingly heavier weights are used and this is thought to increase muscle strength. The vaginal cones are made from surgical grade stainless steel surrounded by a double welded plastic case. They are smooth with a plastic coated retrieval cord.

The SURx Transvaginal System (SURx, Inc., Livermore, California), which obtained FDA clearance in March 2002, is a radiofrequency device that has been specifically designed as a transvaginal treatment of urinary stress incontinence that can be performed as an outpatient procedure under general anesthesia. An incision is made through the vagina lateral to the urethra, exposing the endopelvic fascia. Radiofrequency energy is then applied over the endopelvic fascia in a slow sweeping manner, resulting in blanching and shrinkage of the tissue. As of 2006, the SURx device is no longer marketed in the U.S.

Transurethral radiofrequency energy collagen micro-remodeling is a non-surgical treatment for women with SUI. Radiofrequency energy is used to apply controlled heat to targeted tissues in the lower urinary tract. The heat denatures submucosal collagen in the tissue at the treatment sites. After healing, the tissue is reported to be firmer and have increased resistance to involuntary leakage at times of increased intra-abdominal pressure, thus reducing or eliminating SUI episodes. The Renessa System, originally marketed by Novasys Medical, Inc. (Newark, CA) obtained FDA clearance as substantially equivalent to prior predicate devices and is indicated, “For the transurethral treatment of female stress urinary incontinence due to hypermobility in women who have failed conservative treatment and who are not candidates for surgical therapy” (FDA, 2005). Verathon Medical Ltd (Bothell, WA) acquired the product and rebranded it as Lyrette™.

The AUS 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 individual's pelvis or abdominal cavity and a control pump placed in a subcutaneous pocket in the scrotum. Squeezing of the pump allows 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, allowing the urethra to remain open for voiding. The valve then automatically re-tightens several minutes later which closes the urethra, thereby enabling control of urine flow and continence to be achieved. In 2001, the AMS Sphincter 800™ Urinary Control System, (American Medical Systems, Minnetonka, MN) obtained clearance from the FDA to treat urinary incontinence due to reduced outlet resistance following prostate surgery. The AUS is contraindicated in individuals with repetitive urinary infections; urethral diverticula at

the expected implant site; in complex, unstable, or recurrent urethral stricture disease; in small capacity and/or non-compliant bladder prior to definitive treatment; in irreversibly obstructed urinary tracts; in irresolvable detrusor hyperreflexia or bladder instability; or in those who lack the physical and/or mental dexterity to manipulate the pump.

The inFlow intraurethral valve-pump and activator is a urinary device for women with incomplete bladder emptying, due to impaired detrusor contractility (IDC). The inFlow is promoted as an alternative to urinary catheters. The device consists of a small catheter with an internal, magnetically-activated pump-valve mechanism which is placed in the female urethra for up to 29 days or less. Upon activation by a battery-powered wand held low over the pubic area, the valve opens and the pump induces urine flow. The device blocks urine flow when continence is desired, and an internal pump draws urine out of the bladder when activated by the user. Proper device sizing and initial insertion is done by a physician. Subsequent device replacements are self-inserted, or inserted by a caregiver, approximately every 29 days. This device obtained FDA clearance through the de novo approval process in 2014 and is indicated for, "Use in female individuals 18 years of age or older who have incomplete bladder emptying, due to impaired detrusor contractility of neurologic origin, and who are capable of operating it in accordance with instructions or who have trained caregivers" (FDA, 2014).

The ProACT system consists of two postoperatively adjustable silicone balloons placed under fluoroscopic guidance at the prostatic apex (in post-TURP individuals), or at the vesico-urethral anastomosis (in post prostatectomy subjects) in males. Balloon titration is via tubing connected to a titanium port in the scrotum to enable post-implantation adjustments. The balloons are filled with isotonic solution following implantation; 1 ml can be titrated monthly until optimum continence is achieved.

Definitions

Bulking agent: Refers to a substance, such as collagen, which is injected near the urinary opening to help increase pressure at the opening and prevent involuntary loss of urine.

Detrusor instability: A bladder that contracts and empties out urine even though it is not full, or when the person does not intend to urinate.

Intrinsic sphincter deficiency (ISD): A poor or non-functioning urethral outlet muscle.

Mixed incontinence: A combination of urge and stress incontinence.

Overflow incontinence: The bladder overfills without causing a sensation to urinate.

Periurethral: Around the urethra.

Stress urinary incontinence (SUI): The leakage of urine during physical activities that increase pressure on the bladder.

Urethra: The natural channel or tube through which urine passes from the bladder to outside of the body.

Urethral hypermobility: A condition of the urethra in which the bladder and urethra move downwards when abdominal pressure rises and a cause of SUI. Urethral hypermobility is linked to childbirth, especially vaginal deliveries, and risk of the condition increases with multiple births, larger babies and longer labor.

Urinary urge incontinence: Leakage of urine when there is a strong urge to void.

Urinary urgency-frequency: An uncontrollable urge to urinate resulting in very frequent, small volumes.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Injection of Periurethral Bulking Agents
When services may be Medically Necessary when criteria are met:

CPT	
51715	Endoscopic injection of implant material into the submucosal tissues of the urethra and/or bladder neck
ICD-10 Procedure	
0TUC8JZ	Supplement bladder neck with synthetic substitute, via natural or artificial opening endoscopic
0TUD8JZ	Supplement urethra with synthetic substitute, via natural or artificial opening endoscopic
3E0K3GC	Introduction of other therapeutic substance into genitourinary tract, percutaneous approach [when specified as injection of bulking agent]
3E0K8GC	Introduction of other therapeutic substance into genitourinary tract, via natural or artificial opening endoscopic [when specified as injection of bulking agent]
ICD-10 Diagnosis	
N36.41-N36.44	Urethral functional and muscular disorders (hypermobility of urethra, ISD)
N39.3	Stress incontinence (female) (male)
N39.46	Mixed incontinence (urge and stress incontinence)
N99.89	Other postprocedural complications and disorders of genitourinary system
S37.20XA-S37.29XS	Injury of bladder
S37.30XA-S37.39XS	Injury of urethra

When services are Investigational and Not Medically Necessary:
For the procedure codes listed above when criteria are not met or for all other diagnoses, or when the code describes a procedure indicated in the Position Statement section as investigational and not medically necessary.

Artificial Urinary Sphincter
When services may be Medically Necessary when criteria are met:

CPT	
53445	Insertion of inflatable urethral/bladder neck sphincter, including placement of pump, reservoir, and cuff

53446	Removal of inflatable urethral/bladder neck sphincter, including pump, reservoir, and cuff
53447	Removal and replacement of inflatable urethral/bladder neck sphincter including pump, reservoir, and cuff at the same operative session
53448	Removal and replacement of inflatable urethral/bladder neck sphincter including pump, reservoir, and cuff through an infected field at the same operative session including irrigation and debridement of infected tissue
53449	Repair of inflatable urethral/bladder neck sphincter including pump, reservoir, and cuff

HCPCS

C1815	Prosthesis, urinary sphincter (implantable)

ICD-10 Procedure

0THC0LZ-0THC8LZ	Insertion of artificial sphincter into bladder neck [by approach; includes codes 0THC0LZ, 0THC3LZ, 0THC4LZ, 0THC7LZ, 0THC8LZ]
0THD0LZ-0THDXLZ	Insertion of artificial sphincter into urethra [by approach; includes codes 0THD0LZ, 0THD3LZ, 0THD4LZ, 0THD7LZ, 0THD8LZ, 0THDXLZ]

ICD-10 Diagnosis

N36.42	Intrinsic sphincter deficiency (ISD)
N39.3	Stress incontinence
N39.41-N39.498	Other specified urinary incontinence
N99.89	Other postprocedural complications and disorders of genitourinary system
R32	Unspecified urinary incontinence
T83.111A-T83.111S	Breakdown (mechanical) of urinary sphincter implant
T83.121A-T83.121S	Displacement of urinary sphincter implant
T83.191A-T83.191S	Other mechanical complication of urinary sphincter implant

When services are Not Medically Necessary:
For the procedure codes listed above when criteria are not met, for all other diagnoses, or when the code describes a procedure indicated in the Position Statement section as not medically necessary.

Other procedures and devices
When services are Investigational and Not Medically Necessary:

CPT

53860	Transurethral radiofrequency micro-remodeling of the female bladder neck and proximal urethra for stress urinary incontinence
0548T	Transperineal periurethral balloon continence device; bilateral placement, including cystoscopy and fluoroscopy [ProACT system]
0549T	Transperineal periurethral balloon continence device; unilateral placement, including cystoscopy and fluoroscopy [ProACT system]
0550T	Transperineal periurethral balloon continence device; removal, each balloon [ProACT system]
0551T	Transperineal periurethral balloon continence device; adjustment of balloon(s) fluid volume [ProACT system]

0596T	Temporary female intraurethral valve-pump (ie, voiding prosthesis); initial insertion, including urethral measurement [inFlow system]
0597T	Temporary female intraurethral valve-pump (ie, voiding prosthesis); replacement [inFlow system]
	No code for vaginal weight training

HCPCS

A4335	Incontinence supply; miscellaneous [when specified as inFlow intraurethral valve-pump]

ICD-10 Diagnosis

All diagnoses

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AMS Sphincter 800
Artificial Urinary Sphincter, (AUS)
Bulkamid
Coaptite
Durasphere
InFlow intraurethral valve-pump
Lyrette
Macroplastique
Periurethral Injection of Bulking Agents
ProACT System
Renessa
Transurethral Radiofrequency Energy Collagen Micro-Remodeling
Transvaginal Radiofrequency
Vaginal Weight Training

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

Document History

Status	Date	Action
Revised	05/13/2021	Medical Policy & Technology Assessment Committee (MPTAC) review. Removed "male" and "females" from medically necessary statements. Edited 'not medically necessary' statement to 'individuals who do not meet the medically necessary criteria and for all other indications'. Rationale and References sections updated.
Reviewed	05/14/2020	MPTAC review. Rationale and References sections updated. Updated Coding section with 07/01/2020 CPT changes; added 0596T, 0597T.

Reviewed	06/06/2019	MPTAC review. Rationale and References sections updated. Updated Coding section with 07/01/2019 CPT and HCPCS changes; added 0548T-0551T, removed C9746 deleted 06/30/19.
Revised	07/26/2018	MPTAC review. The document header wording updated from "Current Effective Date" to "Publish Date". Administrative changes made to investigational and not medically necessary statement. Rationale, Background/Overview and References sections updated.
Revised	08/03/2017	MPTAC review. Added the ProACT system to the investigational and not medically necessary listing. The Rationale, Background, Coding and References sections were updated.
Revised	02/02/2017	MPTAC review. Added inFlow intraurethral valve-pump to the investigational and not medically necessary section. Updated Rationale, Background, Coding and References sections.
Reviewed	02/04/2016	MPTAC review. References were updated. Removed ICD-9 codes from Coding section.
Revised	02/05/2015	MPTAC review. Artificial urinary sphincter devices were added to the scope and position statements with medically necessary criteria and not medically necessary indications. The Rationale, Background, Coding, and References were updated.
Reviewed	08/14/2014	MPTAC review. References were updated.
Reviewed	08/08/2013	MPTAC review. Rationale and References updated.
Reviewed	08/09/2012	MPTAC review. Rationale and References updated.
Revised	08/18/2011	MPTAC review. Document revised to only address vaginal weight training, injection of periurethral bulking agents, transvaginal radiofrequency bladder neck suspension, and transurethral radiofrequency energy collagen micro-remodeling with no change to position statements. Revised title, updated Rationale, Background, Definition, Coding, and References sections. Sacral nerve stimulation and posterior tibial nerve stimulation addressed separately in SURG.00117.
Reviewed	02/17/2011	MPTAC review. Rationale and References updated.
	01/01/2011	Updated Coding section with 01/01/2011 CPT changes; removed 0193T deleted 12/31/2010.
Revised	02/25/2010	MPTAC review. Position statements revised: • to include children in the investigational and not medically necessary biofeedback statement; • to remove electrical stimulation, alone or in combination with other treatments. Rationale, background, references, coding updated.
Revised	02/26/2009	MPTAC review. Removed Tegress® from document as it was discontinued by the manufacturer. Removed device brand names from position statement. Clarified position statement. Rationale, coding, background and references updated.
	01/01/2009	Updated coding section with 01/01/2009 CPT changes; removed 0029T deleted 12/31/2008.
Revised	02/21/2008	MPTAC review. Added language addressing repeat collagen injections. Clarified PTNS statement. Rationale, coding and references updated. The phrase "investigational/not medically necessary" was clarified to read "investigational

		and not medically necessary." This change was approved at the November 29, 2007 MPTAC meeting.
Revised	03/08/2007	MPTAC review. Coaptite and Macroplastique added as medically necessary with criteria.
Revised	12/07/2006	MPTAC review. Clarified peripheral nerve evaluation test and temporary sacral nerve stimulator. Added GYNECARE TVT SECUR System to Index. Noted name change of URYX® to Tegress™.
Revised	09/14/2006	MPTAC review. Added transurethral radiofrequency energy collagen micro-remodeling as INV/NMN. Coding updated; removed HCPCS E0752, E0754, E0756, E0757, E0758 deleted 12/31/2005.
Revised	06/08/2006	MPTAC review.
	01/01/2006	Updated coding section with 01/01/2006 CPT/HCPCS changes
	11/21/2005	Added reference for Centers for Medicare and Medicaid Services (CMS) – National Coverage Determination (NCD).
Revised	07/14/2005	MPTAC review. Revision based on Pre-merger Anthem and Pre-merger WellPoint Harmonization.

Pre-Merger Organizations	**Last Review Date**	**Document Number**	**Title**
Anthem, Inc.	01/25/2004	SURG.00010	Urinary Incontinence Therapy, Adult (Including Sacral Nerve Stimulation)
WellPoint Health Networks, Inc.	06/24/2004	2.08.03	Biofeedback for the Treatment of Urinary Incontinence
	06/24/2004	2.08.07	Pelvic Floor Stimulation as a Treatment of Incontinence
	04/28/2005	2.08.08	Urethral Bulking Agents and Artificial Urinary Sphincters for the Treatment of Incontinence
	06/24/2004	2.08.09	Sacral Nerve Neuromodulation as a Treatment of Pelvic Floor Dysfunction
	09/23/2004	3.08.03	Radiofrequency Therapy as a Treatment of Urinary Incontinence