Amerigroup

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;
- Endovaginal cryogen-cooled, monopolar radiofrequency remodeling.

Note: This document does not address either of the following types of devices:

- Urinary incontinence devices approved for use without a prescription (for example, the Flyte system)
- Pessaries (removable prosthetic devices inserted into the vagina)

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

- CG-MED-97 Biofeedback and Neurofeedback
- CG-SURG-95 Sacral Nerve Stimulation for Urinary Retention, Urinary Incontinence, and Fecal Incontinence
- CG-SURG-126 Tibial Nerve Stimulation

Position Statement

Medically Necessary:

Injection of periurethral bulking agents is considered **medically necessary** when the individual has stress urinary incontinence (SUI) meeting one the following two criteria (A or B):

A. The incontinence is due to trauma or injury; **or**
B. Both of the following are true (1 and 2):
   1. The incontinence persists despite conservative treatment for at least a sufficient duration to fully assess treatment effect*; **and**
   2. One of the following is true:
      a. The incontinence is caused by intrinsic sphincter deficiency (ISD), **or**
      b. The incontinence is due to urethral hypermobility in individuals with abdominal leak point less than 100 cm H_2O.

Repeat injection of periurethral bulking agents is considered **medically necessary** for individuals who meet the medical necessity criteria for initial injection and have persistent incontinence after the initial injection.

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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 persist despite conservative treatment for at least a sufficient duration to fully assess treatment effect.*

Removal of an artificial urinary sphincter device is considered **medically necessary** for individuals who meet **one** of the following criteria:

A. The individual is no longer obtaining continued benefit derived from use of the device; **or**
B. There is a need to repair or replace the device; **or**
C. The individual has a medical indication for device removal.

Repair of an artificial urinary sphincter device is considered **medically necessary** for individuals who meet **both** of the following criteria:

A. The device experienced mechanical failure; **and**
B. The individual is likely to obtain continued benefit from use of the device.

Implantation of a *replacement* artificial urinary sphincter device is considered **medically necessary** for individuals who meet the following criteria:

A. An artificial urinary sphincter device was removed; **and**
B. The individual continues to meet criteria for implantation of an artificial urinary sphincter device.

***Note**: The time frame for prior conservative treatment measures (for example, exercises, medication, behavioral therapy) to demonstrate a refractory response is at least 2 months duration, subject to individual variability.

Not Medically Necessary:

Injection of periurethral bulking agents is considered **not medically necessary** for individuals who do not meet the medically necessary criteria.

Implantation, reimplantation, removal, or repair of an artificial urinary sphincter device are considered **not medically necessary** for individuals who do not meet the medically necessary criteria.

Investigational and Not Medically Necessary:

The following services are considered **investigational and not medically necessary** as treatments for urinary incontinence:

A. Endovaginal cryogen-cooled, monopolar radiofrequency remodeling.
B. inFlow™ intraurethral valve-pump implantation;
C. ProACT™ adjustable continence therapy;
D. Vaginal weight training with specially designed weights (cones);
E. Transvaginal radiofrequency bladder neck suspension;
F. Transurethral radiofrequency energy collagen micro-remodeling;

Rationale

Periurethral Bulking Agents

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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®, Axonics, 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.

A 2017 Cochrane systematic review by Kirchin and colleagues was limited to RCTs evaluating bulking agents to treat urinary incontinence in women who 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. 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 evaluating bulking agents have included both controlled and uncontrolled observational studies (Capobianco, 2020; Hoe, 2021; Pivazyan, 2021; Siddiui, 2017). 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%).

Pivazyan and colleagues (2021) focused on studies comparing bulking agents with surgical procedures in women with SUI. They identified six eligible studies, three RCTs and three controlled non-randomized studies. A pooled analysis of data from the six studies found significantly greater subjective improvement in symptoms in the surgery group compared with the bulking agents group (p=0.01). A pooled analysis of three studies did not find a statistically significant difference in complications after surgery or after injection of bulking agents (p=0.73).Other systematic reviews listed above (Hoe, 2021; Siddiui, 2017) did not pool study findings.

A 2022 systematic review by Braga and colleagues included 11 uncontrolled studies on use of bulking agents after the failure of a mid-urethral sling. The pooled cure/improvement rate was 75%, the pooled failure rate was 35% and the pooled reoperation rate was 25%. The authors noted a high degree of statistical heterogeneity among studies but they did not identify publication bias. A limitation of the systematic review is that the authors did not differentiate between the cure rate and the improvement rate. An uncontrolled study (Zivanovic, 2017) reported both a combined cure/improvement rate after urethral bulking after midurethral sling failure, as well as each outcome separately. The cure rate was 56.7% after 1 month, 43.3% after 6 months and 25.4% after 12 months. The improvement rate was 38.3% after 1 month, 46.7% after 6 months and 58.2% after 12 months. The combined cure or improvement rates were 93.3% at 1 month, 88.3% at 6 months and 83.6% after 12 months.

A non-randomized comparative study by Gaddi and colleagues (2014) examined outcomes after either urethral bulking or repeat midurethral sling following primary midurethral sling failure. The study included 165 individuals with midurethral sling failure; 98 received another sling and 67 received urethral bulking. A total of 11 of 98 (11.2%) individuals in the repeat slings group experienced treatment failure compared with 26 of 65 (38.8%)

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individuals in the bulking agents group. The rate of failure was significantly higher in the bulking agent group, p=0.004.

The 2023 update of a 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. The guideline does not address bulking agents after midurethral sling failure (Kobashi, 2023).

A 2024 guideline from the American Urogynecologic Society (AUS, Fleichmann 2024) recommended bulking agents for treatment of "demonstrable SUI". The guideline also included the following recommendation:

> Patients should be counseled on the risks, lack of long-term efficacy data for UBA (urethral bulking agents), potential need for repeat injections, possible need for surgery for recurrent SUI, implications for future procedures, and potential pelvic imaging findings postprocedure.

Regarding the possible need for repeat injections, the guideline stated:

> Due to heterogenous study populations, diverse methodology, and follow-up periods, there is significant variability in the need for repeat injections or "top-ups" between studies. Top-up rates for all UBAs range from 10% to more than 67%, regardless of product type.

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 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) to the efficacy of 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). 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 symptoms 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.

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Transvaginal Radiofrequency Bladder Neck Suspension (SURx Transvaginal System®)

Several uncontrolled studies have evaluated the use of transvaginal radiofrequency bladder neck suspension. Dmochowski and colleagues (2003) reported on a prospective case series of 120 consecutive women with urinary stress incontinence treated with transvaginal bladder neck suspension. Enrolled participants had failed at least a 3-month trial of conservative therapy, most commonly including 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 by the lack of 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 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, now Lyrette) in women with SUI caused by bladder outlet hypermobility (Elser, 2010). 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 participants experienced at least 50% fewer leaks compared with baseline (52% of evaluable participants). At the 18-month follow-up, data were available for 60 participants (44%). The study found incontinent episodes decreased whereas quality of life and participant satisfaction with the procedure increased.

A total of 41 women (30%) completed the 3-year follow-up. 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%

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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.

Additional data from clinical trials with appropriate control groups is needed before conclusions can be made about the effects of transurethral radiofrequency energy collagen micro-remodeling for treatment of SUI.

Artificial Urinary Sphincter (AUS) Devices

A number of observational studies have evaluated use of AUS devices 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) which was 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 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). Reported complications included 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 the 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 men 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 an 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.

Zhang and Xu (2022) published a meta-analysis of studies on the impact of radiation therapy on outcomes of AUS placement. The review included studies with a sample size of at least 25 that compared outcomes of AUS in

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individuals with or without a history of radiation therapy. A total of 18 studies met eligibility criteria; all were cohort studies. In a pooled analysis, individuals without radiation therapy had significantly higher odds of an absence of incontinence after AUS compared with individuals treated with radiation therapy (odds ratio [OR], 1.74; 95% CI, 1.16 to 2.60; p<0.0001). The authors did not report other efficacy outcomes such as improvement in urinary incontinence or pad use. There was not a statistically significant difference in the rate of revision surgery in individuals who had prior radiation therapy compared to those without radiation therapy (pooled OR, 1.24; 95% CI, 0.81 to 1.92; p=0.32). The odds of mechanical failure also did not differ significantly between groups. However, the odds of explantation were significantly higher in the prior radiation group (OR, 3.00; 95% CI, 1.16 to 7.75; p=0.02). There may have been co-morbidities that impacted differences in outcomes.

Mamane and colleagues (2022) published a study with a relatively large sample size. The study included 1277 men who had an AUS and over 1 year of follow-up; 437 (37%) of these had a history of radiotherapy. Mean length of follow-up was 36.8 months. Rates of social continence at follow-up were 78.8% in the group with prior radiotherapy and 78.2% in the group without radiotherapy (p=0.84). The primary study outcome, explantation-free survival, was significantly lower in the radiotherapy group than the non-radiotherapy group (p=0.001). Revision-free survival, however, was significantly higher in the radiotherapy group (p=0.02). Non-mechanical failure-free survival was somewhat higher in the radiotherapy group, but the difference between groups was not statistically significant (p=0.07). In multivariate analysis, radiation therapy, age, Charlson score (a measure of co-morbidities) and previous pelvic surgery were independently associated with revision.

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 due to a 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.

A 2021 uncontrolled retrospective study reported results for 45 women over 75 years of age with SUI due to ISD who had AUS implantation (Denormandie, 2021). During surgery, bladder dome injuries occurred in 9 women (20%) and vaginal injuries occurred in 3 (6.7%) women. There were 26 early postoperative complications in 18 individuals (40%); all except 1 were minor complications. Median follow-up was 36 months. Five individuals died for reasons unrelated to the surgery and did not complete follow-up. Late postoperative complications occurred in 7 women (15.5%). At the final follow-up, 32 of the 45 individuals (71%) had their original AUS, 2 had explanted AUS, 9 had AUS revisions and 2 had AUS deactivations. In an ITT analysis, 31 of the 45 women (69%) had total continence at last follow-up.

In 2024, Roth and colleagues published a retrospective review of 136 individuals who had AUS implantation for SUI post-prostatectomy. There were 108 primary implantations and 28 revision implantations. In the primary implantation group at follow-up (median 80 months), 49.1% reported complete dryness and 85.2% were socially continent. In the group that received revision, the rate of complete dryness was 32.1% and the rate of social continence was 46.4%. The rates of incontinence improvement were lower after revision surgery, but the difference between groups was not statistically significant. In the group that received revision, the 3-year and 5-year device survival rates were 62% and 57%, respectively.

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A clinical guideline from the AUA, SUFA and the Society of Genitourinary Reconstructive Surgeons (GURS, Breyer, 2024) addressing incontinence after prostate treatment included the following statements on AUS:

- Clinicians should discuss the option of artificial urinary sphincter with patients who are experiencing mild to severe stress urinary incontinence after prostate treatment. (Strong Recommendation; Evidence Level: Grade B)
- Prior to implantation of artificial urinary sphincter, clinicians should ensure that patients have adequate physical and cognitive abilities to operate the device. (Clinical Principle)
- In patients with stress urinary incontinence after primary, adjuvant, or salvage radiotherapy who are seeking surgical management, clinicians should offer artificial urinary sphincter over male slings or adjustable balloons. (Moderate Recommendation; Evidence Level: Grade C)

There were no treatment recommendations on AUS determined to be evidence level Grade A ("well-conducted and highly-generalizable RCTs or exceptionally strong observational studies with consistent findings").

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 or children with intractable incontinence, or for 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 participants with hypocontractile or acontractile bladder conditions. The first 88 participants were enrolled directly into an 8-week baseline "study" phase using clean intermittent catheterization (CIC), followed by a 16-week inFlow treatment phase, and a final 4-week treatment withdrawal phase. Subsequent participants were first enrolled in a 1-week tolerability trial (n=185). Those participants that satisfactorily passed that phase (n=139) continued to the study phase. Out of the original 273, 196 (72%) participants withdrew from the study. These withdrawals were attributed to initial discomfort and leakage of the device. A total of 77 participants 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 ($p<0.001$). Significant attrition limits the applicability of this study's findings. Controlled trials are needed to enable conclusions to be drawn about the effectiveness of the inFlow intraurethral pump compared to more established treatments.

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 connected to a subcutaneous injection port. The ProACT system 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 individuals in the intent-to-treat cohort. Participants 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

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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 18months compared to baseline. Overall study success criteria were defined as an exact 95% binomial confidence interval lower boundary of ≥ 50% success at 18 months. The success rate for the primary endpoint was 46% (57/124) (95% CI, 37% to 55%). However; the study did not meet the performance goal because the lower bound of the 95% CI was 37%, which was below the target responder rate of 50%. The authors concluded that the study's primary effectiveness endpoint was not met.

Nash and colleagues reported 4-year outcomes in 68 of the 123 (55%) individuals who completed follow-up to the study described above. As previously stated, the primary effectiveness outcome was measured at 18 months and efficacy was not established. In the 4-year analysis, 55 of 68 (80.9%) individuals achieved a 50% or greater reduction in 24-hour pad weight. Data were not available for 45% of the original study participants. Of the 68 men included in the analysis, 22 (32%) had at least one explant; most of these occurred due to device migration. The time to first explant was 16.4 months. In this cohort, there were 11 procedure-related adverse events in 12 individuals. This included 8 perforations during implant. Significant attrition and lack of a control group limit the applicability of this follow up study's findings.

Several additional single-arm studies evaluating ProAct in men with SUI following prostate surgery have been published (Bada, 2022; Nestler, 2018; Noorhoff, 2017; Ricard, 2022; Ronzi, 2019). These studies generally reported high rates of complications and the 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. In the Bada (2022) study, 62 individuals underwent ProAct implantation and only 42 of these were included in the analysis; of these 42 individuals, 8 (19%) required revision or explantation. Ricard (2022) included 200 individuals. Of these, 95 (47.5%) required explantation due to failure or local complications. In addition, 46 individuals (23%) had a second implantation and 11 (5.5%) had a third implantation.

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.

A 2023 systematic review of studies on ProAct in men with SUI identified 18 eligible studies involving a total of 1570 individuals (Tricard, 2023). They were all observational studies; no RCTs were available. The mean continence rate at follow-up (0-1 pads used) in the studies was 55.2%. The mean follow-up time was 34 months. The overall complication rate was 32% with a major complication rate of 11%. Device failure was reported in 11% of cases.

The 2024 AUA/SUFA/GURS clinical guideline on incontinence after prostate treatment (Breyer, 2024) addressed adjustable balloon devices in the two recommendations, both of which were determined to have a Grade C evidence level ("RCTs with serious deficiencies of procedure or generalizability or extremely small sample sizes or

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observational studies that are inconsistent, have small sample sizes, or have other problems that potentially confound interpretation of data"):

- Clinicians may offer adjustable balloon devices to non-radiated patients with mild to severe stress urinary incontinence after prostate treatment. (Conditional Recommendation; Evidence Level: Grade C)
- In patients with stress urinary incontinence after primary, adjuvant, or salvage radiotherapy who are seeking surgical management, clinicians should offer artificial urinary sphincter over male slings or adjustable balloons. (Moderate Recommendation; Evidence Level: Grade C)

Endovaginal cryogen-cooled, monopolar radiofrequency remodeling

The Viveve system delivers cryogen-cooled, monopolar radiofrequency remodeling endovaginally and is proposed for treatment of stress urinary incontinence in women.

A feasibility RCT was published in 2020 by Allan and colleagues. The study included 37 adult women with mild to moderate SUI, defined as 1 to 50 g leakage on a 1-hour pad weight test. In addition, participants needed to have normal pelvic exams and not be pregnant or have given birth or discontinued breastfeeding within 6 months of enrollment. Participants were randomized to receive either one or two Viveve cryogen-cooled monopolar radiofrequency treatments. Two participants dropped out of the study. At 12 months, the percentage of participants with at least a 50% reduction in pad weight was similar in the one-treatment (54%) and two-treatment (50%) groups. The cure rate, defined as less than 1g of leakage on the 1-hour pad weight test, was higher in the one-treatment group (75%) than in the two-treatment group (54%). Statistical significance tests and p-values were not reported. This study lacked a comparison group of individuals who did not receive Viveve treatment. An RCT comparing active Viveve treatment to cryogen-only treatment and sham treatment (NCT04206085) is underway.

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.

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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 Lyrette system (formerly, 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-transurethral resection of the prostate [TURP] procedures), or at the vesico-

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urethral anastomosis (in post prostatectomy procedures) 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.

The Viveve treatment of stress urinary incontinence involves placement of a probe into the vagina that emits cryogen-cooled radiofrequency energy. The intention is for the cryogen cooling to protect the tissue from damage while the radiofrequency energy delivers energy into the tissue to prompt production of collagen and improve the structural integrity of the vagina, including support of the urethra. The Viveve device has received FDA clearance "for use in general surgical procedures for electrocoagulation and hemostasis" (FDA, 2020). It is not currently cleared specifically for treatment of urinary incontinence.

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. ISD can be distinguished from other causes of incontinence with urodynamic studies.

Mixed incontinence: A combination of urge and stress incontinence.

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

Periurethral: Around the urethra.

Pessary: A device worn in the vagina to support the pelvic floor as a treatment for pelvic organ prolapse, stress urinary incontinence, or both.

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

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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 Not Medically Necessary:
For the procedure codes listed above when criteria are not met or for all other diagnoses.

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

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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.

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

CPT

53451	Periurethral transperineal adjustable balloon continence device; bilateral insertion, including cystourethroscopy and imaging guidance [ProACT System]
53452	Periurethral transperineal adjustable balloon continence device; unilateral insertion, including cystourethroscopy and imaging guidance [ProACT System]
53453	Periurethral transperineal adjustable balloon continence device; removal, each balloon [ProACT System]
53454	Periurethral transperineal adjustable balloon continence device; percutaneous adjustment of balloon(s) fluid volume [ProACT System]
53860	Transurethral radiofrequency micro-remodeling of the female bladder neck and proximal urethra for stress urinary incontinence
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]
0672T	Endovaginal cryogen-cooled, monopolar radiofrequency remodeling of the tissues surrounding the female bladder neck and proximal urethra for urinary incontinence No code for vaginal weight training

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A4341	Indwelling intraurethral drainage device with valve, patient inserted, replacement only, each [inFlow system]
A4342	Accessories for patient inserted indwelling intraurethral drainage device with valve, replacement only, each [inFlow system]

ICD-10 Diagnosis

All diagnoses

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Websites for Additional Information

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AMS Sphincter 800
Artificial Urinary Sphincter, (AUS)
Bulkamid
Coaptite
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InFlow intraurethral valve-pump
Lyrette
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ProACT System
Renessa
Transurethral Radiofrequency Energy Collagen Micro-Remodeling
Transvaginal Radiofrequency
Vaginal Weight Training
Viveve

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	05/08/2025	MPTAC review. Added MN statement on repeat injection of bulking agents. Added MN statements on removal of an artificial sphincter, repair of an artificial sphincter and implantation of a replacement artificial sphincter. Revised NMN statement on artificial sphincter. Revised formatting of INV/NMN statement. Revised Rationale, Definitions and References sections.
Reviewed	11/14/2024	MPTAC review. Revised Description/Scope, Rationale, and References sections.
Revised	11/09/2023	Medical Policy & Technology Assessment Committee (MPTAC) review. Revised MN statements and changed to alphanumeric. Revised Note. Added NMN statement on periurethral bulking agents and revised existing NMN statement. Removed line on periurethral bulking agents from INV/NMN statement and changed to alphanumeric. Updated Rationale, Coding and References sections.
	03/29/2023	Updated Coding section with 04/01/2023 HCPCS changes; added A4341, A4342 replacing A4335 NOC code no longer applicable.

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Revised	11/10/2022	MPTAC review. Removed intermittent self-catheterization from note in medically necessary statement. Rationale and References sections updated.
Revised	11/11/2021	MPTAC review. Added bullet point to Investigational and Not Medically Necessary statement on endovaginal cryogen-cooled, monopolar radiofrequency remodeling. Added "as treatments for urinary incontinence" to Investigational and Not Medically Necessary Statement and removed wording on urinary incontinence from individual bullet points. Description, Rationale, References and Index sections updated. Updated Coding section with 01/01/2022 CPT changes; added 0672T, added 53451, 53452, 53453, 53454 replacing 0548T, 0549T, 0550T, 0551T deleted 12/31/2021.
Revised	05/13/2021	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.

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	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

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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

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