Medical Coverage Policy

Effective Date.....09/15/2024
Next Review Date.....09/15/2025
Coverage Policy Number..... 0573

Adjustable Continence Therapy

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Related Coverage Resources

Sacral Nerve and Tibial Nerve Stimulation for Urinary Voiding Dysfunction, Fecal Incontinence and Constipation

INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy

will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

This Coverage Policy addresses the Adjustable Continence Therapy (ACT®) device (for women) and the ProACT™ device (for men) (Uromedica, Inc., Minnetonka, MN, USA).

Coverage Policy

Adjustable Continence Therapy is considered experimental, investigational or unproven for all indications.

Health Equity Considerations

Health equity is the highest level of health for all people; health inequity is the avoidable difference in health status or distribution of health resources due to the social conditions in which people are born, grow, live, work, and age.

Social determinants of health are the conditions in the environment that affect a wide range of health, functioning, and quality of life outcomes and risks. Examples include safe housing, transportation, and neighborhoods; racism, discrimination and violence; education, job opportunities and income; access to nutritious foods and physical activity opportunities; access to clean air and water; and language and literacy skills.

General Background

ACT® is a minimally invasive procedure designed to treat female patients who have stress urinary incontinence (SUI) resulting from intrinsic sphincter deficiency (ISD). ProACT™ is a minimally invasive procedure designed to treat adult men who have stress incontinence arising from intrinsic sphincter deficiency of at least twelve months duration following radical prostatectomy or transurethral resection of the prostate (TURP) and who have failed to respond adequately to conservative therapy. ProACT balloons are designed to be placed using a sheath via two small incisions compared to an invasive open procedure. ProACT can be adjusted postoperatively in an office setting.

U.S. Food and Drug Administration (FDA)
The Adjustable Continence Therapy (ACT®) device (for women) (Uromedica, Inc., Minnetonka, MN, USA) is currently not FDA-approved.

November 2015 the FDA granted premarket approval application (PMA) for the ProACT™ Adjustable Continence Therapy for Men (Uromedica, Inc., Plymouth, MN). This device is indicated for the treatment of adult men who have stress incontinence arising from intrinsic sphincter deficiency of at least twelve months duration following radical prostatectomy or transurethral resection of the prostate (TURP) and who have failed to respond adequately to conservative therapy.

Literature Review—Adjustable Continence Therapy (ACT®) device (for women)

Data supporting the ACT® device for women is lacking. Most studies are small in sample size and lack randomization, a control group or comparator, due to the fact that ACT is proposed to be used when other treatments have failed.

Guerin et al. (2023) conducted a systemic literature review. A total of 13 studies reporting the outcomes of ACT® balloons in female patients with stress urinary incontinence (SUI) due to intrinsic sphincter deficiency (ISD) were included. All were retrospective or prospective case series. Reported results include:

- The success rates ranged from 13.6% to 68% and the improvement rates from 16% to 83%.
- The intraoperative complication rate ranged from 3.5 to 25% and consisted of urethral, bladder, or vaginal perforations.
- The rate of postoperative complications varied from 11 to 56% without major complications. Between 6% and 38% of ACT® balloons were explanted and subsequently reimplanted in 15.2–63% of cases.

The authors concluded that "ACT® balloons can be considered as an option to treat SUI due to ISD in female patients with a relatively modest success rate and quite a high complication rate. Well-designed prospective studies and long-term follow-up data are needed to fully elucidate their role".

de Guerry et al. (2022) reported on a retrospective cohort study involving five French academic institutions. A total of 281 women were implanted with ACT® balloons to treat SUI. At baseline, 137 women (48.8%) complained of mixed UI and 70 (24.9%) were receiving a concomitant overactive bladder (OAB) therapy. In addition, 182 women (64.6%) had a history of previous SUI surgery, and 88 (31.3%) had a history of vaginal prolapse surgery. The primary endpoint was the effectiveness assessed 1 year after implantation. Success was defined as a maximum 1 pad/24 h associated with a numerical rating scale (NRS) ≥ 8/10. Improvement was defined as a decrease in daily pad use associated with a NRS ≥ 5/10. Failure was defined as an increase or stability in daily pad use or a NRS < 5/10. At 1 year, 70.5% of women achieved success or improvement, while intra- or postoperative surgical complications occurred in 36.1% of them. Intraoperative surgical complications occurred in 13 women (4.6%) while early and late postoperative surgical complications were reported in 35 (12.5%) and 75 (26.7%), respectively. Uni- or bilateral explantation was performed in 26.7% of women—mainly due to surgical complications—almost half of them (46.7%) were reimplanted the same year. Study limitations include retrospective design and short follow-up duration.

Ronzi et al. (2019) conducted a retrospective cohort study in France to assess the effectiveness and complications of treatment for neurogenic stress urinary incontinence (nSUI) by Adjustable Continence Therapy (ACT™ and ProACT™) in 102 patients with neurological pathologies. Patients were followed-up for a mean 2.7 years. After implantation, 5.9% of patients were totally continent, 51.2% had an improvement in symptoms of at least 50% and 48.8% had improvements of < 50%, including 7.3% of treatment failures. Complications occurred in 70 patients (120 balloons): 21 balloon infections, 34 migrations, 18 device failures, 28 urethral erosions and 28 cutaneous erosions. The procedure was ineffective for 35 patients. Twenty patients underwent permanent explantation. The authors note that despite the multicenter study and the learning curves for the surgery, they did not find a place for ACT™/ProACT™ in nSUI therapy and the small number of patients and their heterogeneity did not enable subgroup analyses. The study was limited by the retrospective nature and lack of randomization.

In a prospective study, Aboseif et al. (2010) performed percutaneous placement of the ACT device in female patients with moderate to severe SUI who failed at least one surgical treatment (sling, Burch, suspension, AUS). A total of 89 patients have undergone implantation with 1–3 years of follow-up. Data are available on 77 patients at one year. Of the patients, 47% were dry at one

year and 92% improved after one-year follow-up. Quality of life questionnaire scores improved from 33.9 to 71.6 at one year ($p < 0.001$). The mean number of adjustment visits prior to one year was 2.03. Explanation was required in 21.7% of patients with 50% of those patients re-implanted before one year, while 28% were awaiting re-implantation and 22% had been explanted permanently. The authors stated "our hypothesis is that in some instances, the balloon is placed closer (in some cases, maybe too close) to the urethra or bladder, and so requires less filling to reach continence but also results in a higher incidence of perioperative perforations and postoperative complications leading to explantations."

Literature Review— ProACT™ Adjustable Continence Therapy for Men
The published studies on ProACT consist mainly of retrospective and prospective studies and report high revision rates and explantation rates. Well-designed, comparative trials are needed to demonstrate safety and efficacy of the device as compared to other surgical incontinence treatments such as the artificial urinary sphincter.

Tricard et el. (2023) conducted a meta-analysis to assess the efficacy and safety of proACT in treating male patients with post- post-prostatectomy (RP) stress urinary incontinence (SUI). There were 18 studies involving 1570 patients that were included. Only 8 included more than 100 patients. Retrospective studies were included. The mean follow-up reported was 34.7 months (median 38.5; range 1-128 months). An average of 60.7% patients suffered from mild-to-moderate incontinence, and 40.4% of patients suffered from severe incontinence. The overall dryness rate was 55.1% (definition of 0-1 pads per day). The mean overall complication rate was 31.2% including an explantation rate of 26.5% and a reoperation rate of 22.7%. The authors noted the methodological quality of the 18 studies was very heterogeneous.

Larson et al. (2019) conducted a systematic review and meta-analysis to evaluate the efficacy of adjustable balloon devices or adjustable continence therapy (ProACT) in the treatment for male stress urinary incontinence (SUI) and also to investigate the safety profile and rates of adverse events associated with the implantation of adjustable balloon devices. The review included studies with adult male patients with SUI and the outcomes included pads or pad weight per day and quality of life (QOL) questionnaires, as well as safety outcomes. Nineteen studies were included with a total of 1,264 patients and 4,517 patient-years of follow-up data (mean follow-up time 3.6 years). Ten studies were found to be of good quality, seven of fair quality, and two of poor quality. ProACT implantation resulted in an incontinence QOL improvement of 30.8 points from baseline. At baseline, patients on average were using 4.0 pads per day (PPD), which was reduced to an average of 1.1 PPD after ProACT implantation. The number of patients that were considered "dry" was 60.2% and the number of patients who were found to be either "dry" or improved greater than 50% was 81.9%. The meta-analysis estimate for intraoperative perforation of the bladder or urethra is 5.3%. Estimates for infection and urinary retention were 2.2% and 1.5%, respectively. The estimated overall revision rate for all causes is 22.2% with a mean follow-up of 3.6 years (range 12-118 months). Heterogeneity in the studies was a major issue in areas of the median follow-up ranges, the number of patients per study, surgical technique, and management of complications were greatly variable across studies. The review does not include the type of studies or comparators used in studies.

Angulo et al. (2019) conducted a meta-analysis to determine the safety and efficacy of Adjustable Transobturator Male System (ATOMS) and ProACT for male SUI. Combined data of 41 observational studies with 3059 patients showed higher dryness (68 vs. 55%; $p = .01$) and improvement (91 vs. 80%; $p = .007$) rate for ATOMS than ProACT. Mean pad-count (-4 vs. -2.5 pads/day; $p = .005$) and pad-test decrease (-425.7 vs. -211.4 cc; $p < .0001$) were also significantly lower. Satisfaction was higher for ATOMS (87 vs. 56%; $p = .002$) and explant rate was higher for proACT (5 vs. 24%; $p < .0001$). Complication rate for ProACT was also higher, but not statistically significant (17 vs. 26%; $p = .07$). Mean follow-up was 25.7 months, lower for

ATOMS than ProACT (20.8 vs. 30.6 months; p = .02). The rate of working devices favored ATOMS at 1-year (92 vs. 76; p < .0001), 2-years (85 vs. 61%; p = .0008) and 3-years (81 vs. 58%; p = .0001). The authors concluded that both the ProACT and the ATOMS system appear efficacious and safe procedures to treat male stress incontinence. However, taking into account the statistical summary of effect size ATOMS is a more efficacious alternative compared to ProACT with higher dryness, improvement and patient satisfaction rates, lower explant rate and higher durability.

Munier et al. (2020) reported results of a retrospective study in France that evaluated 27 patients who underwent second-line ProACT balloon implantation for persistent SUI post-radical prostatectomy (RP) after insufficient improvement from a sling. Five patients previously had adjuvant radiotherapy (18%). The mean follow-up was 36 months. All patients presented with persistent SUI after sling implantation. After ProACT with an average 3 mL refilling (±1.2 min 2–max 6), 18 patients (66.7%) were continent. Eight of the remaining patients (29.6%) were improved; their number of pads per day (PPD) decreased from 2.6 to 1. Three patients (14.8%) needed ProACT replacement. The authors concluded that ProACT as a second-line intervention does not seem to bring a high risk of infection. Limitations of this study include the lack of prospective randomized comparison and the small study population.

Noordhoff et al. (2019) retrospectively reported on a case series that evaluated the use of ProACT in the treatment of SUI after transurethral resection of the prostate (TURP). ProACT was implanted in 29 patients with post-TURP SUI between 2007 and 2018 in two facilities. Preoperative UI was mild in 7 (24%), moderate in 12 (41%), and severe in 10 (35%) patients. After a median follow-up of 21 months, two-thirds (22 of 29) of the patients reported to use fewer pads daily, and 13 of the 29 patients were even dry. All but one patient reported improvement on the PGI-I scale. Within 30 days postoperatively, a Clavien-Dindo grade less than or equal to II complication had occurred in 24% of the patients. These findings are limited by lack of comparison group and small sample size. The authors noted that future research is needed to compare different devices and determine outcome predictors.

Nash et al. (2019) reported on four-year follow-up results for patients enrolled in a pivotal study conducted to support an FDA premarket approval application (PMAA). The study evaluated the safety and efficacy of the ProACT Adjustable Continence Therapy for the treatment of post-prostatectomy stress urinary incontinence (SUI). One hundred twenty-three patients underwent ProACT implantation with baseline and outcomes for 68 patients who completed 4-year follow-up visits reported. Endpoints included 24-h pad weight, Incontinence Quality of Life Questionnaire (I-QOL), UCLA Prostate Cancer Index-Urinary Function (PCI-UF), residual volume, and incidence and severity of device or procedure-related adverse events. Statistically significant improvements during follow-up were observed in 24-h pad weight, for which the mean pre-implant urine loss was 293 g, which was reduced at 4 years to 73 g (P < 0.001). Reductions in pad weight were observed across all levels of pre-implant SUI severity. Significant improvements were also seen in quality of life as measured by the I-QOL (P < 0.001) as well as measures of urinary function and pad use. Out of the 68 patients included in this analysis, 19 patients had one explant and re-implant and three patients had two explants and re-implants. Overall, 77.3% of the 22 explanted and re-implanted patients experienced a reduction of greater than 50% from baseline to four years. The time to first explant for this cohort was 16.4 months +/−12.0 SD, a median of 12.7 months, and range of 0.4-45.6 months. There was a total of twelve procedure-related adverse events (AEs) recorded, with the most common being urethral or bladder perforation during implant. There was a total of 39 device-related adverse events recorded, balloon migration being the most common. The majority of device-related adverse events were resolved by explant.

Nestler et al. (2019) conducted a retrospective study to evaluate the success and revision rates of ProACT over long-term follow-up and if repeat ProACT implantation after failure is a reasonable strategy. The study obtained a recent follow-up of all patients, who underwent an implantation of

a ProACT system between 2003 and 2013 by a single surgeon. One hundred thirty four patients were implanted a ProACT system. Median age was 71 years; median follow-up was 118 months. Initially, 112 implantations were successful (82.6%) and the number of pads used decreased significantly ($p < 0.005$); 63 patients were revised and 49 were successful (77.8%). No differences in success rate, pads used, or filling volume were seen (all $p > 0.8$). Ten of 59 successfully revised patients (20.4%) underwent a second revision after a median of 39 months (IQR 22–65) due to rupture ($n = 6$) or dislocation ($n = 4$) of at least one of the balloons. Eight of ten patients were successfully reimplanted (80%). In the second revision, no differences in success rate or pads used were noted (all $p > 0.7$). The study is limited by the retrospective design, and lack of randomization.

Nash et al. (2018) reported on eight-month follow-up results for patients enrolled in a pivotal study conducted to support an FDA premarket approval application (PMAA) of the ProACT Adjustable Continence Therapy for the treatment of post-prostatectomy stress urinary incontinence (SUI). One hundred twenty-three patients underwent ProACT implantation, of whom 98 completed 18-month follow-up. The endpoints included 24-h pad weight, Incontinence Quality of Life Questionnaire (I-QOL), UCLA Prostate Cancer Index-Urinary Function (PCI-UF), residual volume, and device or procedure-related adverse events (AEs). Statistically significant improvements during follow-up were observed in 24-h pad weight, for which the cohort mean pre-implant urine loss was 399 g, which was reduced at 18 months to 160 g ($P < 0.001$). Reductions in pad weight were observed across all levels of pre-implant SUI severity. Improvements were also seen in quality of life as measured by the I-QOL ($P < 0.001$) as well as measures of urinary function and pad count. A total of 30 subjects (24.2%) underwent device explant at some point during the 18-month follow-up, of which 22 were ultimately re-implanted and continued in the study. The most common reason for explant was device migration. Thirty-one procedure-related adverse events (AEs) were recorded, with the most common being urethral or bladder perforation during implant.

In a prospective multicenter trial, Lebret et al. (2008) assessed the safety and efficacy of the ProACT system in the treatment of stress urinary incontinence (SUI) after prostate surgery. All 62 patients had failed previous rehabilitation (including pelvic floor training and electrostimulation). Daily pad usage decreased from a mean of 4.6 per day (range, 1 to 10) before surgery to 1.8 per day at 6 months (range, 0 to 10) and 1.06 per day (range 0 to 6) at 1 year after surgery. After 6 months (adjustments completed) 71% of the patients were wearing no pads or 1 pad per day (including security pads). Among the 44 patients who had RP without adjuvant radiotherapy, 89% improved, including 30% of patients becoming pad free. Conversely, for the 12 patients with adjuvant radiotherapy before ProACT implantation the failure rate was 83%. A total of 19 patients required explantation due to device-related problems (2), infection or erosion (5), migration (1), iatrogenique traumatism (2), or nonresponse (9). Of these patients, four were reimplanted with ProACT balloons, and two went on to have artificial urinary sphincters implanted.

In a prospective longitudinal trial, 80 consecutive men who had undergone either ProACT ($n = 44$) or bone anchored male sling ($n = 36$) for post-prostatectomy incontinence were followed (Crivellaro, et al., 2008). The two procedures were carried out in two different centers by two different surgeons. All men had significant stress urinary incontinence for at least one year after radical prostatectomy and the incontinence had persisted despite conservative measures (pharmacotherapy or Kegel exercises). All patients with urge incontinence or pre-existing voiding dysfunction were excluded from the study. At a mean follow-up of 19 and 33 months respectively, 30/44 (68%) patients treated with ProACT were dry in comparison with 23/36 (64%) patients treated with a sling ($p > 0.05$). Stratifying the results, ProACT had 33/39 (85%) dry patients in severe (more than three pads/day) preoperative incontinence, in comparison with 21/26 (81%) for the sling ($p > 0.05$). The authors noted their results indicate a significant improvement in urinary incontinence and quality of life improvement in patients undergoing these procedures

based on pre-operative degree of incontinence. ProACT results seem to be better for moderate to severe incontinence and a bone anchor sling for mild incontinence. The complication rate was higher for ProACT (13% vs. 5%, $p > 0.05$), primarily reflecting the development and refinement of the new surgical technique and its instrumentation.

Hübner et al. (2007) retrospectively reported on the use of ProACT in 100 men. The authors compared the results of the first 50 men they operated on with the results of the latest group of 50 men they have operated on, noting their ''learning curve'' and the evolution of the use of the device. All patients in both groups had undergone a radical prostatectomy as their primary operation for prostatic cancer. Observed were changes in pad use and incontinence quality of life (I-QOL) with a mean follow-up of 23 months in group 1 and 20 months in group 2. Complications requiring revision surgery occurred in 29 of 50 patients (58%; total 49 revision surgeries) of group 1 and in 12 patients (24%; total 16 revision surgeries) of group 2. There was a high rate of primary non-response in the first 50 patients (20 of 50, 40%) as the operation and implants evolved. All of these patients proceeded to using an AUS. In group 2 there were four cases (8%) of primary non-response requiring explantation, with two of these proceeding to bulbar urethral slings and two proceeding to implantation with the AUS. Overall, group 2 patients had more consistent outcomes in pad use reduction compared to group 1 (80% vs. 60% dry or >50% improved) and the number of non-responding patients was also dramatically reduced in group 2 compared to group 1 (16% vs. 40%). The authors note that although the ''reference standard'' for the treatment of severe incontinence remains the AUS, a place exists for a minimally invasive alternative, especially for men who may not have sufficient fine-motor control or the motivation to operate the implanted pump used with the AUS.

Professional Societies/Organizations
American Urological Association (AUA)/Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction (SUFU) Updates to Surgical Treatment of Female Stress Urinary Incontinence (SUI): AUA/SUFU Guideline (Kobashi, et al., 2023) does not address adjustable continence therapy (ACT).

The AUA/SUFU 2019 guideline on Incontinence after Prostate Treatment was updated in 2024 (Breyer, et al., 2024). It recommends:

- Clinicians should discuss the option of artificial urinary sphincter (AUS) with patients who are experiencing mild to severe stress urinary incontinence after prostate treatment. (Strong Recommendation; Evidence Level: Grade B*)
- 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, Low Certainty).
- In patients with stress urinary incontinence after primary, adjuvant, or salvage radiotherapy who are seeking surgical management, clinicians should offer AUS over male slings or adjustable balloons. (Moderate Recommendation; Evidence Level: Grade C)

The guideline notes, "While adjustable balloon devices demonstrate efficacy for incontinence, providers should be aware of the unique intraoperative complications and device management. Serial additions of contrast solution to the balloons in the outpatient clinic will optimize efficacy. Adjustable balloons have an advantage in procedure length, less invasive placement, and elimination of the need for patient manipulation. Device removal is more common than AUS. Efficacy, complication rates, and complication types have been proven to be directly linked to case numbers. Thus, obtaining specialty training from an experienced implanter would be beneficial before device implantation" (Breyer, et al., 2024).

	*Evidence Strength A (High Certainty)	Evidence Strength B (Moderate Certainty)	Evidence Strength C (Low Certainty)
Strong Recommen-dation (Net benefit or harm substantial)	Benefits > Risks/Burdens (or vice versa) Net benefit (or net harm) is substantial. Applies to most patients in most circum-stances and future re-search is unlikely to change confidence.	Benefits > Risks/Burdens (or vice versa) Net benefit (or net harm) is substantial. Applies to most patients in most circumstances but better evidence could change confidence.	Benefits > Risks/Burdens (or vice versa) Net benefit (or net harm) appears substantial. Applies to most patients in most circumstances but better evidence is likely to change confidence. (Rarely used to support a Strong Recommendation.)
Moderate Recom-mendation (Net benefit or harm moderate)	Benefits > Risks/Burdens (or vice versa) Net benefit (or net harm) is moderate. Applies to most patients in most circum-stances and future re-search is unlikely to change confidence.	Benefits > Risks/Burdens (or vice versa) Net benefit (or net harm) is moderate. Applies to most patients in most circumstances but better evidence could change confidence.	Benefits > Risks/Burdens (or vice versa) Net benefit (or net harm) appears moderate. Applies to most patients in most circumstances but better evidence is likely to change confidence.
Conditional Recom-mendation (No apparent net benefit or harm)	Benefits = Risks/Burdens Best action depends on individual patient circumstances. Future research unlikely to change confidence.	Benefits = Risks/Burdens Best action appears to depend on individual patient circumstances. Better evidence could change confidence.	Balance between Benefits & Risks/Burdens unclear Alternative strategies may be equally reasonable. Better evidence likely to change confidence.
Clinical Principle: A statement about a component of clinical care that is widely agreed upon by urologists or other clinicians for which there may or may not be evidence in the medical literature.			
Expert Opinion: A statement, achieved by consensus of the Panel, that is based on members clinical training, experience, knowledge, and judgment for which there is no evidence (Sandhu, et al., 2019).			

Medicare Coverage Determinations

	Contractor	Determination Name/Number	Revision Effective Date
NCD	National	No Determination found	
LCD		No Determination found	

Note: Please review the current Medicare Policy for the most up-to-date information.
(NCD = National Coverage Determination; LCD = Local Coverage Determination)

Coding Information

Notes:

1. This list of codes may not be all-inclusive since the American Medical Association (AMA) and Centers for Medicare & Medicaid Services (CMS) code updates may occur more frequently than policy updates.
2. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Urology Services Considered Experimental/Investigational/Unproven:

CPT®* Codes	Description
53451	Periurethral transperineal adjustable balloon continence device; bilateral insertion, including cystourethroscopy and imaging guidance
53452	Periurethral transperineal adjustable balloon continence device; unilateral insertion, including cystourethroscopy and imaging guidance

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Revision Details

Type of Revision	Summary of Changes	Date
Annual review	• No clinical policy statement changes.	9/15/2024