Periurethral Transperineal Adjustable Balloon Continence Device

Effective: January 1, 2024

Next Review: November 2024
Last Review: November 2023

IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

Use of a transperineally implanted periurethral volume-adjustable balloon device is proposed as a treatment for urinary incontinence.

MEDICAL POLICY CRITERIA

Use of a transperineally implanted periureteral adjustable balloon continence device (e.g., ACT, ProACT™) is considered **investigational** for all indications.

NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.

CROSS REFERENCES

1. Pelvic Floor Stimulation as a Treatment of Urinary and Fecal Incontinence, Allied Health, Policy No. 04
2. Sacral Nerve Modulation/Stimulation for Pelvic Floor Dysfunction, Surgery, Policy No. 134

BACKGROUND

Urinary voiding dysfunction is a broader term that 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. Males and females can experience urinary voiding dysfunction. Physical stress on the urinary system can cause urine to be released unintentionally, which is referred to as stress urinary incontinence (SUI).

A common cause of SUI in males results from a procedure to remove a benign or a cancerous prostate that has enlarged, resulting in difficulties urinating. The two most frequently performed prostate surgeries leading to stress incontinence are transurethral resection of the prostate (TURP) and radical prostatectomy. SUI also can occur in those who have had pelvic trauma or a neurologic disorder (eg, traumatic spinal cord injury, spina bifida).

There are a variety of therapies used to treat urinary incontinence. Minimally invasive approaches include behavioral interventions such as fluid management and bladder training, pelvic floor muscle exercises and scheduled voiding. There are some medications that are used to treat urinary incontinence, including anticholinergics and mirabegron. Medical or surgical interventions suggested for SUI include transurethral bulking agents, perineal slings, and artificial urinary sphincters.

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 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 controlled via tubing connected to a titanium port in the scrotum. The balloons are filled with isotonic solution following implantation; 1 ml can be titrated monthly until optimum continence is achieved.

REGULATORY STATUS

Uromedica received premarket approval (PMA) for the ProACT™ Adjustable Continence Therapy for Men from the US Food and Drug Administration (FDA) in November 2015.[1] The ProACT™ system is “indicated for the treatment of adult men who have stress urinary 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.” Product code EZY.

Uromedica also is investigating Adjustable Continence Therapy for the treatment of female stress urinary incontinence, however approval for this indication has not yet been granted in the United States.[2]

EVIDENCE SUMMARY

Premarket approval (PMA) from the FDA for the ProACT™ Adjustable Continence Therapy for Men was based in part on results of a prospective, multi-center, single-arm, open-label clinical study of 123 subjects.[1] There were 11 investigational sites (eight in the U.S., two in Canada, and one in New Zealand). Six of the sites enrolled fewer than 10 subjects. One U.S. site did not implant any subjects. 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 the same measure at 18 months. All comparisons were made against baseline, pre-implant data, thus using each patient as his own control. Individual success was defined as ≥ 50% reduction

in 24-hour pad weight at 18 months, compared to baseline. Overall study success was defined as an exact 95% binomial confidence interval lower boundary of ≥ 50% success at 18 months. Additional safety data were reported through 24 months of follow-up. 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%. Through 24 months of follow-up, there were 574 total adverse events reported in 114 of 123 implanted subjects. Ninety-eight patients experienced adverse events that were non-serious and that were related, or possibly related, to the device or procedure. Adverse events included worsening of incontinence in 28.5% of patients, device migration in 18.7% of patients, and perforation of bladder or urethra in 15.4% of patients. The FDA also concluded that the study did not follow subjects for a sufficiently long period to enable an assessment of the probability of possible late-developing adverse events such as urethral stricture and device erosion.

Systematic Reviews

Guérin (2023) conducted a systematic review of the outcomes of adjustable continence therapy (ACT) balloons in female patients with stress urinary incontinence due to intrinsic sphincter deficiency.[3] The review included 13 retrospective studies and case series. 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 to 63% of cases. The review authors described the overall success rate as modest and concluded that the procedure has a high complication rate. The authors concluded that well-designed prospective studies and long-term follow-up data are necessary to assess the efficacy and safety of ACT balloon therapy for treating incontinence.

Choinière (2021) published a systematic review with meta-analysis of data on implantable continence devices used to treat postprostatectomy urinary incontinence (PPI).[4] Observational studies addressing PPI surgical interventions were include in the review if they involved cohorts of at least 50 participants. A total of 85 observational studies (n=13,100) were included, three addressing bulking agents, 35 addressing male synthetic slings, ten addressing ACTs, and 37 addressing artificial urinary sphincters (AUSs). Cure rate, defined as one or fewer pads per day, was 26.1% (95% confidence interval [CI]: 10.6 to 51.4, I^2=92.8%, very-low-quality evidence) for bulking agents, 58.6% (95% CI: 51.3 to 65.5, I^2=89.1%, low-quality evidence) for slings, 63.2% (95% CI: 57.6 to 68.5, I^2 = 22.5%, very-low-quality evidence) for ACT, and 74.0% (95% CI:61.2 to 83.7, I^2 = 92.1%, very-low-quality evidence) for AUS. Estimated rates of reoperation were 5.8% (95% CI: 1.9 to 11.6, I^2 = 94.1%, moderate-quality evidence) for slings, 23.8% (95% CI: 5.9 to 61.0, I^2 = 95.5%, low-quality evidence) for ACT, and 22.2% (95% CI: 15.2 to 31.3, I^2 = 92.3%, high-quality evidence) for AUS. Ultimately, the authors conclude “available evidence regarding the benefits of surgeries to treat postprostatectomy urinary incontinence remains mainly uncertain while suggesting important harms.”

Larson (2019) performed a systematic review and meta-analysis of adjustable continence therapy for the treatment of male stress urinary incontinence.[5] Nineteen studies (N=1264) met inclusion criteria. No randomized controlled trials were identified. Patients used 4.0 (95% confidence interval [CI] 2.6 to 5.4) pads per day prior to implantation and 1.1 (95% CI 0.5 to 1.7) pads per day post-implantation. Incontinence quality of life improved by 30.8 points from

baseline to post-implantation. Post-implantation, 60.2% of patients were considered "dry" and 81.9% of patients were considered "dry" or improved greater than 50%. The rate of intraoperative perforation of the bladder or urethra was 5.3%, the rate of infection was 2.2%, and the rate of urinary retention was 1.5%. The estimated overall all-cause revision rate was 22.2% during a mean follow-up of 3.6 years. No data from any comparison intervention were reported.

Randomized Controlled Trials

There are no randomized controlled trials for this indication.

Nonrandomized Studies

Ruggiero (2022) conducted a single-center retrospective study that evaluated long-term durability of peri-urethral balloons administered for neurogenic or non-neurogenic stress urinary incontinence in 177 male and female patients.[6] The most common causes of stress urinary incontinence were radical prostatectomy (n=82, 46.3%), idiopathic intrinsic sphincter deficiency (n=55, 31.1%) and neurogenic sphincter deficiency (n=32, 18.1%). Mean follow-up occurred at five years. Complete continence (no pad necessary) was achieved for 109 patients (61.6%). At follow-up, the peri-urethral balloon global survival rate was 47.5% (median=57.8 months), and the survival rate without balloon failure was 68.4%. The mean balloon survival duration was 116.19 months. This study is limited by lack of a comparison group.

Guerry (2022) presented a multicentric retrospective study to assess the effectiveness, safety and risk factors of failure and complications associated with Adjustable Continence Therapy (ACT®) balloons as a treatment for female stress urinary incontinence (SUI).[7] All women implanted with ACT® balloons between 2000 and 2018 were considered eligible for this study (n=281). Effectiveness and safety were assessed at 1 year, and risk factors for failure and complications were sought. One hundred and four (37.0%), 94 (33.5%) and 83 (29.5%) of the women were categorized as success, improvement, and failure, respectively. Intra-, early and late postoperative complications occurred in 13 (4.6%), 35 (12.5%) and 75 (26.7%) women, respectively. The authors recommend ACT balloons as a therapeutic arsenal for female SUI.

Another retrospective study that by Demeestere (2022) also looked at efficacy and safety after adjustable continence therapy (ACT®) balloons implantation to treat stress urinary incontinence (SUI) due to intrinsic sphincter deficiency, but specifically in neurogenic and non-neurogenic women.[8] Among the 277 included women, 51 presented with a neurologic underlying disease. Mean age at implantation was 68.5 years. There was no significant difference in efficacy between neurogenic and non-neurogenic women with a success rate of 39.2% and 36.3%, respectively (p=0.69).

Ricard (2022) assess the mid-term efficacy and safety of adjustable continence therapy (ProACT™) for the treatment of male stress urinary incontinence (SUI) after radical prostatectomy (RP) between 2007 and 2017, mainly with flexible cystoscopic guidance.[9] Two hundred men with a median age of 68 years were included. Seventeen percent (n=34) had had prior radiotherapy and 15.5% (n=31) had had prior SUI surgery. The median follow-up was 43 (19 to 71) months. The severity of SUI was as follows: mild in 119 (59.5%), moderate in 48 (24%), and severe in 33 patients (16.5%). Severe SUI and a history of prior radiotherapy were associated with a lower success rate (p=0.033 and p<0.0001). The overall reoperation rate was 34%, with 5.6% (n=11) requiring a third implantation. Of the At the last follow up, among the overall population, the success rate was 40.1% and the median PII was 18.3%. For

patients in whom the balloons were still in place (n=132), the cumulative success and improvement rate was 78%, with a median PII of 72%.patients, 29.4% (n=58) required an artificial urinary sphincter to treat SUI.

Noordhoff (2019) reported a retrospective study of outcomes of 29 patients implanted with adjustable continence balloons for stress urinary incontinence following transurethral resection of the prostate.[10] Patients were followed for a median of 21 (interquartile range 11 to 43) months. Complications of Clavien-Dindo grade II or lower occurred in 24% of patients within 30 days post-surgery and 24% of patients underwent reintervention. The International Prostate Symptom Score (IPSS) quality of life item improved significantly from five prior to treatment to three and one, respectively, at six and 12 months post-surgery. At the final visit, continence had improved in 76% of patients, with 45% of patients "dry".

Ronzi (2019) performed a retrospective multicenter study of patients with neurological pathologies treated with adjustable continence therapy balloons for neurogenic stress urinary incontinence.[11] A total of 102 patients were implanted and followed for a mean of 2.7 years. Following implantation, 5.9% of patients were fully continent, 51.2% had an improvement in symptoms of at least 50%, and the remainder had improvements of less than 50%, including 7.3% who had treatment failures. Seventy patients experienced treatment failures. Twenty patients underwent permanent removal of the device.

Venturino (2015) examined twenty-two male patients implanted with the ProACT device and followed up to a median of 57 months.[12] Results reported included number of pads used and subjective satisfaction. Revision and explantation rates were 73% and 55%, respectively. At the last follow-up visit, only one patient (4.5%) remained dry, and only 10 patients (45%) remained satisfied with the procedure, whereas 12 patients (55%) were unchanged and dissatisfied.

Utomo (2013) examined 49 implanted male patients who were followed up to a median of nine months. Results reported included urodynamic parameters pre- and post-implantation.[13] Twelve patients were reported to have nonsuccessful clinical outcomes. A longer duration of incontinence, the use of more than five pads daily, and a smaller cystometric bladder capacity were independent predictors of unsuccessful clinical outcomes.

Kjaer (2012) examined 114 implanted male patients with no long-term follow-up. Results reported included preoperative and postoperative pad use and urinary leakage.[14] They reported an overall dry rate (calculated from pad usage and urinary leakage) of 50%. A decrease in urinary leakage > 50% was seen in 72 patients (80%), 23 patients had complications and overall, 50 patients (53%) reported being very or predominantly satisfied.

PRACTICE GUIDELINE SUMMARY

The 2019 American Urological Association Guideline on Incontinence After Prostate Treatment states:[15]

- Adjustable balloon devices may be offered to patients with mild stress urinary incontinence after prostate treatment. (Moderate Recommendation; Evidence Level: Grade B)

- In men with stress urinary incontinence after primary, adjuvant, or salvage radiotherapy who are seeking surgical management, artificial urinary sphincter is preferred over male slings or adjustable balloons. (Moderate Recommendation; Evidence Level: Grade C)

Moderate Recommendations are directive statements that an action should (benefits outweigh risks/burdens) or should not (risks/burdens outweigh benefits) be undertaken because net benefit or net harm is moderate.

Grade B: RCTs with some weaknesses of procedure or generalizability or moderately strong observational studies with consistent findings. Grade C: RCTs with serious deficiencies of procedure or generalizability or extremely small sample sizes or observational studies that are inconsistent, have small sample sizes, or have other problems that potentially confound interpretation of data.

SUMMARY

There is not enough research to show that a transperineally implanted periureteral adjustable balloon continence device improves net health outcomes for people with urinary incontinence. Therefore, use of a transperineally implanted periureteral adjustable balloon continence device is considered investigational as a treatment for urinary incontinence.

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CODES

Codes	Number	Description
CPT	53451	Bilateral periurethral transperineal adjustable balloon continence device
	53452	Unilateral periurethral transperineal adjustable balloon continence device
	53453	Removal of periurethral transperineal adjustable balloon continence device
	53454	Fluid adjustment of periurethral transperineal adjustable balloon continence device
HCPCS	None	

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