Policy Number	**SUR701.036**
Policy Effective Date	**02/15/2025**
Policy End Date	**12/31/2025**

Transperineal Implantation of a Permanent Adjustable Balloon Continence Device

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Related Policies (if applicable)
None

Disclaimer

Carefully check state regulations and/or the member contract.
Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

Coverage

This medical policy has become inactive as of the end date above. There is no current active version and this policy is not to be used for current claims adjudication or business purposes.

Transperineal implantation of a permanent adjustable balloon continence device for the treatment of urinary incontinence **is considered experimental, investigational and/or unproven**.

Policy Guidelines

None.

Description

Urinary incontinence is the involuntary leakage of urine with loss or weakened control over the urinary sphincter. It is believed that urinary incontinence is underdiagnosed and an underreported problem. Typically, urinary incontinence increases with age and is more common in females than in males. (1)

Background

It is estimated that around 423 million people (20 years and older) worldwide experience some form of urinary incontinence, with approximately 13 million of those individuals in the United States alone. (2)

There are several types of urinary incontinence (2):

- Stress: Urine leakage associated with weak pelvic muscles and increased abdominal pressure from laughing, sneezing, coughing, climbing stairs, or other physical stressors on the abdominal cavity and, thus, the bladder.
- Urge: Involuntary leakage accompanied by or immediately preceded by urgency. The contractions may be caused by bladder irritation or loss of neurologic control.
- Mixed: A combination of stress and urge incontinence, marked by involuntary leakage associated with urgency and with exertion, effort, sneezing, or coughing.
- Functional: The inability to hold urine due to environmental or physical barriers to toileting. This type of incontinence is sometimes referred to as toileting difficulty. The history may suggest physical or cognitive impairment.
- Overflow: The bladder is overdistended due to impaired detrusor contractility and/or bladder outlet obstruction. Neurologic diseases such as spinal cord injuries, multiple sclerosis, and diabetes can impair detrusor function. Bladder outlet obstruction can be caused by external compression by abdominal or pelvic masses and pelvic organ prolapse, among other causes. A common cause in men is benign prostatic hyperplasia.

Treatment and management are dependent on the type of urinary incontinence. Urinary incontinence is treated with a variety of modalities and therapies, including medications, physiotherapy, behavioral programs, lifestyle changes, surgical corrections, and/or devices (e.g., absorbent products, catheterization regimens/diversions, etc.).

The ProACT™ adjustable continence therapy system for men and the ACT™ adjustable continence therapy system for women are indicated for the treatment of stress urinary incontinence (SUI) arising from intrinsic sphincter deficiency (ISD). (3) For adult men, SUI has been ongoing for at least 12 months' duration following radical prostatectomy or transurethral resection of the prostate and have failed to respond adequately to conservative therapy. For adult women, SUI has been the result from ISD or a previously failed surgical repair. (4)

The ProACT™ devices consists of 2 adjustable balloon implants placed via perineal approach bilaterally in a periurethral position at the bladder neck or at the apex of the prostatic remnant. The implant procedure is minimally invasive and may be performed with general or local anesthesia in approximately 30 minutes. Titanium ports attached via tubing to each balloon are placed in the scrotum, allowing for transcutaneous, post-operative volume adjustment.

Increasing the balloon volumes will increase the joining balloon pressure of the urethra, lifting the bladder neck. This lift will improve continence. Further adjustments can be made to meet the needs of the patient. The ACT™ devices essentially is placed the same way as the ProACT™ devices with 2 differences: 1) Balloons are placed only at the bladder neck; and 2) The titanium ports are located in the labia majora.

Regulatory Status

Uromedica, Inc. (Plymouth, MN) has developed long-term implantable balloon therapy systems to treat male and female SUI. ProACT™ (the adjustable continence therapy system for men) was approved by the U.S. Food and Drug Administration (FDA) premarket approval process on November 24, 2015. (3) However, ACT™ (the adjustable continence therapy system for women) has not been approved by the FDA. Both device systems are available outside of the U.S.
FDA Product Code: EZY.

Rationale

This policy originated in 2017 and is based on a literature search of PubMed database through January 8, 2024. The following is a summary of the key literature to date.

ProACT™

Case Series/Retrospective Studies

Several early case series were identified during the literature review. Significant improvements were measured in pads per day (PPD), which generally meant most patients used a precautionary/safety absorbent pad daily. Table 1 shows the outcomes measurements following ProACT™ implantation.

Table 1. Efficacy Outcomes Following ProACT™ Implantation

Study	No. of Pts	Follow Up Time	Continence Achieved % (PPD Count)	Significantly Improved %	No Improvement %	Quality of Life Measurement
Hübner, et al. 2005 (5)	117	24 mo	67% (baseline 6 PPD to 1 PPD at 2 yrs post operatively)	92%	8%	At baseline, 34.7 to 66.3 after 2 yrs
Kocjancic, et al. 2007 (6)	64	12 mo	67% (43 pts) (baseline 5.2 PPD to 1.54 PPD at 12 mo)	66% (42 pts)	17% (11 pts)	At baseline, 31.7 to 62.5 at 6 mo, and 71.1 at 12 mo)

Lebret, et al. 2008 (7)	62	12 mo	30% (baseline 4.6 PPD to 1.06 PPD at 12 mo)	59%	83%	At baseline 48 to 67 at 12 mo
Trigo-Rocha, et al. 2006 (8)	23	48 mo	65.2% (15 pts)	13% (3 pts)	22% (5 pts)	N/R

mo: months; No.: number; N/R: not reported; Pts: patients; PPD: pads per day; yrs: years.

In 2018, Nash et al. presented 18-month follow-up results for patients enrolled in a pivotal study evaluating the safety and efficacy of the ProACT Adjustable Continence Therapy for the treatment of post-prostatectomy stress urinary incontinence (SUI). (9) The clinical study involved 11 clinical sites and enrolled 160 subjects. A total of 124 subjects met study criteria and 123 underwent ProACT implantation, of whom 98 completed 18-month follow-up. 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. 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 count. One procedure-related serious adverse event (SAE), retention, was reported among the 124 subjects; the SAE was resolved without clinical meaningful sequalae.

Follow-up results were again presented by Nash et al. in 2019, for 68 patients who completed 4-year follow-up visits. (10) 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. The authors concluded that these results confirm the long-term safety and efficacy of this newly FDA-approved therapy, showing significant improvements in both objective and subjective measures of SUI in mild, moderate, and severely incontinent male patients. They also note that the implant procedure is minimally invasive, and complications are generally mild and easily resolvable. These findings are limited by the lack of a comparison group and a large loss to follow-up.

Ronzi et al. (2019) conducted a retrospective cohort study on 102 patients to assess the effectiveness and complications of treatment for neurogenic stress urinary incontinence (nSUI) by adjustable continence therapy (ACT™ and ProACT™). (11) Mean (SD) age at implantation was 48.4 (16.5) years. Patients were followed-up for a mean 2.7 (2.3) years. After implantation, 5.9% of patients were totally continent, 51.2% had an improvement in symptoms of at least

50% (including 14.6% with improvements of at least 90%), 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 states that despite the multicenter study design and the learning curves for this surgery, they did not find a place for ACT™/ProACT™ in nSUI therapy, and that the small number of patients and their heterogeneity did not enable subgroup analyses.

Nestler et al. (2019) conducted a retrospective study to evaluate the success and revision rate of ProACT over long-term follow-up and if repeat ProACT implantation after failure would be a reasonable strategy. (12) Follow-up of 134 patients who underwent ProACT implantation between 2003 and 2013 was obtained. 112 implantations were successful (82.6%) and the number of pads used decreased significantly ($p < 0.005$). Sixty-three patients were revised and 49 were successful (77.8%). No differences in success rate, pads used, or filling volume were seen (all $p > 0.8$). In a second revision, again, no differences in success rate or pads used were noted (all $p > 0.7$). Patients' personal satisfaction was high despite the high revision rate. Study findings are limited by the lack of a comparison group.

In 2019, Noordhoff et al. conducted a retrospective multicenter case series on 29 patients to evaluate the outcome of adjustable continence balloons in the treatment of SUI after transurethral resection of the prostate (TURP). (13) Endpoints were patient-reported changes in pad count and complications. Dry was defined as no pad or one security pad. Preoperative urinary incontinence was mild in 7 (24%), moderate in 12 (41%), and severe in 10 (35%) patients. The median follow-up duration was 21 months. The results showed within 30 days postoperatively, a Clavien-Dindo grade less than or equal to II complication occurred in 24% of the patients. Reintervention rate was 24%. Six and 12 months after implantation, the International Prostate Symptom Score (IPSS) quality-of-life item improved significantly from 5 preoperatively to 3 and 1 respectively. At last visit (median 21 months after implantation), the outcome on continence had improved in 76% of the patients, including, 45% dry patients. After a median follow-up of 28 months, all but one patient reported improvement on the Patient Global Impression of Improvement (PGI-I) scale. In detail, 10 patients reported "very much better" condition compared with before the implantation, 10 patients "much better," two patients "a little better," and one patient "no change." Daily pad use decreased from three (interquartile range [IQR], 2-5) to one (IQR, 0-2) pads/day ($P < 0.001$). According to the authors, this is the first study reporting results of adjustable continence balloons in the treatment of post-TURP SUI. They concluded that the therapy was found to be safe and efficient. These findings are limited by both small sample size and the lack of a comparison group.

In 2020, Munier et al. retrospectively analyzed the cumulate experience of two centers with offering periurethral balloon implantation for SUI post radical prostatectomy (RP) in patients with insufficient improvement from slings. (14) The primary endpoint was continence, defined as 0 pads per day (PPD). The secondary endpoints were 50% decrease in PPD and increases in the I-QOL. Between 2007 and 2016, 26 patients were implanted. Five patients have had adjuvant radiotherapy (18%). The mean follow-up was 36 months (±20; min 14-max 128). All

patient presented with persistent SUI, using 2.3 PPD (±1; min 1-max 6), and only one sling was removed due to infection. 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 PPD decreased from 2.6 to 1. The average I-QOL score of those 8 patients increased by 20 points, from 53.4 up to 74.2 (P = .005). Overall, 26 patients (96.3%) were improved. The remaining patient was not implanted because of an intraoperative urethral injury and is considered a failed case (3.7%). He had instead an artificial urinary sphincter (AUS) implantation. Three patients (14.8%) needed periurethral balloon replacement. The authors concluded that ProACT implantations are effective and without significant complications. These findings are limited by both small sample size and the lack of a comparison group.

Comparative Studies

Hübner et al. in 2007 completed a comparative study of ProACT™'s original 50 patients (group 1) to the most recent 50 patients (group 2), comparing changes in pad use and incontinence QoL. (15) The mean follow-up for group 1 was 23 months and group 2 was 20 months. Overall, group 2 patients obtained more consistent outcomes compared to group 1 (80% versus 60% dry or greater than 50% improved). The authors reported operative time was reduced in group 2 as were the rate and range of complications.

Another comparative study was published in 2008 by Crivellaro et al. (16) The comparison was between ProACT™ and a bone anchored male sling (BAMS) surgical treatment. A total of 84 patients participated in the study following post radical prostatectomy incontinence, with 46 having the ProACT™ system implanted or 38 having BAMS completed. At a mean follow up of 19 and 33 months respectively, 30/44 (68%) patients treated with ProACT™ were dry (0/1 safety pad) in comparison with 23/36 (64%) patients treated with BAMS. Further stratifying the results, ProACT™ had 33/39 (85%) dry patients in severe (greater than 3 PPD) preoperative incontinence whereas BAMS had 21/26 (81%) dry patients in severe preoperative incontinence. The authors concluded when comparing ProACT™ to another surgical treatment for incontinence, the ProACT™ results seem to be the better choice for severe incontinence.

Systematic Reviews

Larson (2019) conducted a systematic review and meta-analysis on ProACT for the treatment of male SUI to evaluate the efficacy associated with the implantation of adjustable balloon devices. (17) The review of literature that consisted of 19 studies included 1264 patients and a mean follow-up time of 3.6 years. The reviewers noted ProACT implantation resulted in an incontinence QoL improvement of 30.8 points from baseline. At baseline patients averaged 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% (95% CI: 54.2%-65.9%) and the number of patients who were found to be either "dry" or improved greater than 50% was 81.9% (95% CI: 74%-87.8%).

ECRI

In a 2021 Clinical Evidence Assessment, ECRI considered the evidence for the ProACT device for male SUI to be "inconclusive". (18) They went on to state that although evidence from many

case series synthesized in a meta-analysis supports limited conclusions on ProACT's safety and effectiveness, failure and complication rates may outweigh benefits for more than one-fifth of treated patients. No evidence is available to compare ProACT with full-cuff AUSs, other adjustable continence balloons, or other devices marketed in the United States for treating SUI in men after prostate surgery.

Professional Guidelines and Position Statements

American Urological Association (AUA)/Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction (SUFU)

In 2019, the AUA/SUFU addressed incontinence following prostate treatment which included the following recommendations (19):

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

Information noted included: "In 2017, adjustable balloon devices became available in the United States for treatment of male intrinsic sphincter deficiency after RP or TURP. While they have been shown to improve incontinence, providers should be aware of an increased incidence of intraoperative complications and need for explant within the first two years compared to the male sling and AUS. Given the limited clinical experience of implanters across the United States, providers should obtain specialty training prior to device implantation."

International Consultation on Incontinence (ICI)

A report from the 6th ICI (2019) (20), regarding the surgical treatment of post-prostatectomy SUI in men, states that an AUS is the preferred treatment for men with moderate to severe SUI after radical prostatectomy. Male slings are an acceptable approach for men with mild to moderate SUI. Injectable agents have a poor success rate in men with SUI. Although there are several series reporting the outcomes of different surgical interventions for post-prostatectomy SUI, there is still a need for prospective randomized clinical trials. Recommendations for future research include standardized workup and outcome measures, and complete reporting of adverse events at long-term.

ACT™

Case Series/Retrospective Studies

As with ProACT™, ACT™ improvement outcomes were measured by PPD or pad weights. Table 2 shows those outcome measurements following ACT™ implantation.

Table 2. Efficacy Outcomes Following ACT™ Implantation

Study	No. of Pts	Follow Up Time	Continence Achieved % (PPD Count or Pad Weight)	Significantly Improved %	No Improvement %	Quality of Life Measurement

Kocjancic, et al. 2008 (21)	49	12 mo	68%	16%	N/R	N/R
Kocjancic, et al. 2010 (22)	57	6 yrs	51% (29 pts) (baseline 5.6 PPD to 0.41 PPD at 12 mo)	N/R	N/R	At 12 mo, 64% very much improved, 23% much improved, and 13% minimally improved
Aboseif, et al. 2009 (23)	140	12 mo	52% dry at 12 mo	80%	N/R	At baseline, 36.5 to 70.7 at 12 mo
Wachter, et al. 2008 (24)	41	Mean follow-up of 25 mo	44%	15% (29% had slight improvement)	12%	N/R
Aboseif, et al. 2011 (25)	77	12 mo	47% (baseline 4.3 PPD to 1.9 PPD at 12 mo)	92%	N/R	At baseline, 33.9 to 71.6 at 12 mo

mo: months; No.: number; N/R: not reported; PPD: pads per day; Pts: patients; yrs; years.

In a single-center retrospective study, Freton et al. (2018) compared the outcomes of the ACT® device with those of the artificial urinary sphincter AMS 800 in the treatment of SUI due to sphincter deficiency in women. (26) Twenty-five patients underwent an ACT® implantation and 36 an AUS implantation. Patients in the AUS group were younger (62.9 vs 70.4 years; $p = 0.03$) with less comorbidity (ASA Score = 3 in 12.1% vs 33.3%; $p = 0.005$). Operative time and hospital stay were shorter in the ACT® group (45.7 vs 206.1 min; $p < 0.001$; 1.7 vs 7 days; $p < 0.001$ respectively). There was a higher rate of intraoperative complications in the AUS group (47% vs 8%; $p < 0.001$) but the rates of postoperative complications were similar between both groups. The ACT® was associated with an increased risk of urinary retention (20% vs 2.8%; $p = 0.04$). Results were in favor of AUS for: decrease in USP stress incontinence subscore (-7.6 vs -3.2; $p < 0.001$), number of pads per 24 h (- 4.6 vs -2.3; $p = 0.002$), PGII scale (PGII = 1: 61.1% vs 12%; $p < 0.001$), and cure rate (71.4% vs 21.7%; $p < 0.001$). The authors concluded that in the present series, keeping in mind the significantly different baseline characteristics, AUS implantation was associated with better functional outcomes than the ACT® in female patients with SUI due to intrinsic sphincter deficiency, but with a higher intraoperative complications rate, longer operative time, and a longer stay.

Systematic Reviews

Two systematic reviews were published. ACT™ implantation, along with other types of surgical treatments, was included in a systematic review published in 2015 by Nikolopoulos et al. (27) The studies reviewed had five or more cases each from a period covering 1980-2014. Table 3 lists the different procedures with pooled success rates.

Table 3. Pooled Success Rates Reviewed for Surgical Interventions to Treat Recurrent SUI

Surgical Intervention	**Pooled Success Rate (95% Confidence Interval)**
Colposuspension	76% (±5.04)
Midurethral sling	68.5% (±3.11)
Repeat midurethral sling	66.2% (±4)
Midurethral sling fixation	61% (±10.56)
Pubovaginal sling	79.3% (±6.54)
Adjustable continence therapy AND adjustable slings	53.8% (±5.28)
Urethral bulking injections	38% (±10.7)
Laparoscopic 2-team sling, salvage spiral sling, and artificial urinary sphincter procedures	Promising results, but data is limited

SUI: stress urinary incontinence.

Reviewing the success rates, the use of ACT™ implantation appears to have a lower success rate than other more routinely utilized procedures.

An industry sponsored systematic review was published in 2014 by Phé et al. (28) This review targeted the ACT™ implantation surgical technique and the results of implantation for treatment of SUI. Eight studies were published between 2007 to 2013. The mean follow-up of the studies were 1-6 years. Forty to 100% of the patients had already been treated surgically for SUI. A reduction of PPD were noted in each study following ACT™ implantation. More importantly, the QoL scores improved following implantation. The authors concluded ACT™ implantation was a reasonable treatment for SUI. However, long-term studies need to be analyzed.

Summary of Evidence

The evidence is insufficient to support transperineal implantation of a permanent adjustable balloon continence device for the treatment of urinary incontinence.

For the ProACT™ system, the evidence includes several small cases series/retrospective studies, small comparative studies, and a systematic review, as well as professional guidelines and position statements. Although quality of life (QoL) responses from patients are encouraging and the pads per day (PPD) use diminishes following the implantation, long-term, prospective randomized clinical trials are still needed. Therefore, the use of the ProACT™ system to treat urinary incontinence is considered experimental, investigational and/or unproven.

For the ACT™ system, the evidence includes several small cases series/prospective studies and a couple of systematic reviews. As with ProACT™, QoL responses from patients are positive and the PPD count does decrease, however, long-term, prospective randomized clinical trials are still needed. Additionally, The ACT™ system has still not received U.S. Food and Drug Administration approval. Therefore, the use of the ACT™ system to treat urinary incontinence is considered experimental, investigational and/or unproven.

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	53451, 53452, 53453, 53454
HCPCS Codes	None

*Current Procedural Terminology (CPT®) ©2024 American Medical Association: Chicago, IL.

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Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does not have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been developed since this medical policy document was written. See Medicare's National Coverage at <https://www.cms.hhs.gov>.

Policy History/Revision

Date	Description of Change
12/31/2025	Document became inactive.
02/15/2025	Reviewed. No changes.
03/15/2024	Document updated with literature review. Coverage unchanged. Reference 2 was added, some references were removed.
03/15/2023	Reviewed. No changes.

06/01/2022	Document updated with literature review. Coverage modified without change in intent to: Transperineal implantation of a permanent adjustable balloon continence device for the treatment of urinary incontinence is considered experimental, investigational and/or unproven. The following references were added: 10-15, 19, 21-22, 28, and 32. Title changed from: Implanted Adjustable Continence Therapy.
05/15/2021	Reviewed. No changes.
06/01/2020	Document updated with literature review. Coverage unchanged. The following references were added: 3, 19-21; one reference was removed.
06/15/2018	Reviewed. No changes.
07/01/2017	New medical document. Implanted adjustable continence therapy is considered experimental, investigational and/or unproven as a minimally invasive treatment for urinary incontinence in adult men or women.