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## Medical Policy



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**\*Current Policy Effective Date: 5/1/24**  
(See policy history boxes for previous effective dates)

### **Title: ProACT™ Adjustable Continence Therapy**

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#### **Description/Background**

ProACT™ adjustable continence device for men was developed to treat adult men who have developed stress urinary incontinence after prostate surgery. Prostate surgery may cause a weakening or loss of control of urinary continence. Most men with incontinence are conservatively treated using absorbent products such as pads, adult diapers, and bed protection. Right after surgery, a condom catheter, indwelling catheter, or penile clamps may be used.

The ProACT adjustable continence system consists of two postoperatively adjustable silicone balloons placed under fluoroscopic guidance at the prostatic apex (in post-TURP individuals), or at the vesico-urethral anastomosis (in post prostatectomy subjects) in males. Balloon titration is via tubing connected to a titanium port in the scrotum to enable post-implantation adjustments. The balloons are filled with isotonic solution following implantation; 1 ml can be titrated monthly until optimum continence is achieved. Improvement in urinary continence may take six months or longer to reach maximum effectiveness. It is also possible that no improvement may be seen.

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#### **Regulatory Status**

ProACT™ adjustable continence therapy (Uromedica Inc.) for men received FDA premarket approval on November 24, 2015.

Product code: EZY

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## Medical Policy Statement

The ProACT™ adjustable continence therapy device is experimental/investigational. It has not been scientifically demonstrated to be as safe and effective as conventional treatment.

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## Inclusionary and Exclusionary Guidelines

N/A

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**CPT/HCPCS Level II Codes** *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure.)*

### Established codes:

N/A

### Other codes (investigational, not medically necessary, etc.):

53451

53452

53453

53454

*Note: Individual policy criteria determine the coverage status of the CPT/HCPCS code(s) on this policy. Codes listed in this policy may have different coverage positions (such as established or experimental/investigational) in other medical policies.*

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## Rationale

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function—including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition.

Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

## **Clinical Context and Therapy Purpose**

The purpose of ProACT™ adjustable continence device for men was developed as a possible treatment option for men who have developed stress urinary incontinence after prostate surgery.

The following **PICO** were used to select literature to inform this review.

## **Populations**

The relevant population of interest are male individuals with stress urinary incontinence after prostate surgery.

## **Interventions**

The ProACT™ adjustable continence device is being considered.

## **Comparators**

Conservative treatments include absorbent products, when those fail, surgical treatment consists of implantable devices (e.g., artificial urinary sphincter, the male sling and bulk injections).

## **Outcomes**

The primary endpoint is urinary continence. The secondary endpoints include 50% decrease in pads per day usage and increases in the Incontinence Quality of Life Score (IQOL).

## **Review of Evidence**

In 2006, Rocha et al examined a new prosthesis ProACT to determine its ability to effectively treat post radical prostatectomy urinary incontinence.<sup>1</sup> From November 2000 to March 2004, 25 patients with severe post radical prostatectomy urinary incontinence were treated using the ProACT device. The preoperative evaluation included pad count, Valsalva leak point pressure determination, and Incontinence Quality-of-Life scores. In the follow-up, the same parameters, as well as complications, were analyzed and compared with the baseline measurements to assess the efficacy. The follow-up period was 6 to 48 months (mean 22.4). Of the 25 patients, 23 had follow-up data available for analysis. The improvements in pad count, Incontinence Quality-of-Life score, and Valsalva leak point pressures from baseline to the last follow-up examination were all significant ( $P < 0.05$ ). Overall, of the 23 patients followed up, 15 (65.2%) were continent using 0 to 1 pad daily and satisfied, 3 (13%) were improved but unsatisfied, and 5 (22%) did not have any improvement. Balloon adjustments were performed in all patents to achieve continence. Revision surgery was required in 4 (17%) of 23 patients.

Martens et al (2009) presented the first series of implantations of ProACT in the Netherlands.<sup>2</sup> A non-validated questionnaire was sent to 29 male patients implanted with ProACT to determine Stamey incontinence score, pad count and questions about quality of life and satisfaction. Complications, revisions and explantations were registered. Mean follow-up was 41 months. Based on Stamey score four patients are continent at the end and nine patients according to the pad count. The average pad count also decreased. Remarkable was the high rate of dislocations and revisions and patients' satisfaction.

Venturino et al (2015) evaluated the functional results, morbidity and quality of life of the ProACT treatment of male stress urinary incontinence after prostate surgery.<sup>3</sup> Between 2002

and 2012, twenty-two consecutive male patients were implanted with the ProACT device. Continence was defined by the use of 0 pads daily, and the quality of life was assessed by validated questionnaires. Only 1 patient (4.5%) was immediately continent after ProACT implantation, and the other 21 men (95.5%) needed  $\geq 1$  balloon refills postoperatively. The baseline daily pad number decreased from a mean of 5.9 pads (range, 3-12 pads) to a mean of 1.7 pads (range, 0-5 pads) per day after refilling but increased to a mean of 3.9 (range, 0-10) at the last follow-up visit. After balloon adjustments, 4 patients (18%) were continent and 18 patients (82%) showed an improvement with a 95% rate of subjective satisfaction. Revision and explantation rates were 73% and 55%, respectively. At a median follow-up of 57 months, only 1 patient (4.5%) remained dry, and only 10 patients (45%) remained satisfied with the procedure, whereas 12 patients (55%) were unchanged and dissatisfied.

Nicolas et al (2019) also evaluated the efficacy of ProACT in the second line treatment for non-severe post radical prostatectomy urinary incontinence after male sling failure.<sup>4</sup> This single center retrospective study of patients treated with male sling (17 Advance™, 1 TOMS™) between 2009 and 2015. The continence results were evaluated by the number of pad per day and the quality of life assessment by the I-QOL questionnaire. The "cure" was defined as no pad and "improved" as decreased more than 50% of pads use. Eighteen patients were included with median follow-up of 21.5 [14-44] months. Two patients (11.1 %) had a past history of pelvic radiotherapy. The median pads per day used was 2 [1-3] after male sling insertion and before Pro-ACT device insertion. After Pro-ACT device insertion, the median pads per day used was 0 [0-1], with 77.7 % of patients cured and 22.2 % improved. The median quality of life score I-QOL, was 52.2 [23.3-62.6] and 83 [31.8-97.7], respectively before and after Pro-ACT device insertion ( $P < 0.001$ ). Nine (60 %) patients rated their incontinence severity as mild, four (26.6 %) as middle and two (13.3 %) as severe, after balloon insertion. The median volume of adjustment was 3 [2-6] mL.

Nestler et al (2019) published long-term results of ProACT device implantation.<sup>5</sup> In May 2017, follow-up of all patients who underwent ProACT implantation between 2003 and 2013 was obtained. Parameters were numbers of pads used, filling volume of balloons, and patient-reported satisfaction. Furthermore, revisions were noted. Between 2003 and 2013, 134 patients were implanted a ProACT system. Median age was 71 years; median follow-up was 118 months. One hundred twelve 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  $p > 0.7$ ).

Finally, Munier et al (2020) analyzed the cumulative experience of 2 center with offering ProACT device implantation for stress urinary incontinence (SUI) after radical prostatectomy (RP) in patients with insufficient improvement from slings.<sup>6</sup> This retrospective study reviewed all patients implanted with second line ProACT. The primary endpoint was continence, defined as 0 pads per day (PPD). The secondary endpoints were 50% decrease in PPD and increases in the Incontinence Quality of Life score (IQOL). Refilling and complications were reported. Between 2007 and 2016, 26 patients were implanted. Five patients have had adjuvant radiotherapy (18%). The mean follow-up was 36 months ( $\pm 20$ ; min 14-max 128). All patient presented with persistent SUI, using 2.3 PPD ( $\pm 1$ ; min 1-max 6), and only one sling was removed due to infection. After ProACT with an average 3 mL refilling ( $\pm 1.2$  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 IQOL 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%). Three patients (14.8%) needed ProACT device replacement.

## **SUMMARY OF EVIDENCE**

For individuals who have male stress urinary incontinence after prostate surgery the evidence includes several single armed studies and a systematic review. In the single armed studies, complication rates and/or need for revision surgery tended to be high. In the Nestler (2019) 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. Venturino (2015) noted that in the short term the ProACT device appeared to be safe and efficacious; however, in the long term the ProACT does not appear to be an ideal device for durable continence and patients' satisfaction. The systematic review by Angulo (2019) comparing results of the ATOMS procedure to ProACT concluded that despite the many limitations in these studies, the ATOMS procedure was found to be more efficacious, with higher patient satisfaction and better durability than ProACT to treat male stress incontinence. Additional studies preferably controlled and ideally, random controlled trials are needed. The evidence is insufficient to determine the effects of the technology on health outcomes.

## **SUPPLEMENTAL INFORMATION**

### **Practice Guidelines and Position Statements**

#### **AMERICAN UROLOGICAL ASSOCIATION (AUA)/SOCIETY OF URODYNAMICS, FEMALE PELVIC MEDICINE & UROGENITAL RECONSTRUCTION (SUFU) GUIDELINE<sup>9</sup>**

A set of 2019 guidelines published by a panel comprised of AUA and SUFU members recommend that adjustable balloon devices are an appropriate treatment strategy for patients with post-prostate surgery–induced, mild SUI (evidence level, grade B), but that an artificial urinary sphincter (AUS) is a more preferred surgical management option (evidence level, grade C).

#### **INTERNATIONAL CONTINENCE SOCIETY<sup>10</sup>**

A 2023 review of SUI treatments for men reported that The proACT™ balloon technique appears to be a feasible procedure to improve the continence in short and median term, with better results occurring with more operator experience. Similar to the male sling procedure, appropriate candidates include those with mild to moderate leakage due to intrinsic sphincter deficiency, and no previous radiation. The benefit of an adjustable system should be weighed against the need for multiple sessions of refilling the balloon, and with reported rate of peri-operative and post-operative complications. Longer followup is needed before definitive comparison to male sling or artificial sphincter can be made. No recommendation is possible due to variable data on complication rates (12-58%). (Level 3, Grade D).

### **Ongoing and Unpublished Clinical Trials**

Some currently unpublished trials that might influence this review are listed in Table 1.

**Table 1. Summary of Key Trials**

NCT Number	Title	Enrollment	Completion Date
NCT03767595	ProACT post-approval study, 5 year prospective, open lable multi-center study	145	Dec 2027
NCT01500603	ProACT™ balloons vs. Retrourethral AdvanceXP™ male sling for post-prostatectomy incontinence.	6	Terminated

NCT: national clinical trial

## Government Regulations

### National:

National Coverage Determination: publication 100-3, manual section 230.10, section title Incontinence Control Devices. Effective date: 10/07/1996.<sup>11</sup>

### A. Mechanical/Hydraulic INCONTINENCE Control Devices

Mechanical/hydraulic **INCONTINENCE** control devices are accepted as safe and effective in the management of urinary **INCONTINENCE** in patients with permanent anatomic and neurologic dysfunctions of the bladder. This class of devices achieves control of urination by compression of the urethra. The materials used and the success rate may vary somewhat from device to device. Such a device is covered when its use is reasonable and necessary for the individual patient.

### B. Collagen Implant

A collagen implant, which is injected into the submucosal tissues of the urethra and/or the bladder neck and into tissues adjacent to the urethra, is a prosthetic device used in the treatment of stress urinary **INCONTINENCE** resulting from intrinsic sphincter deficiency (ISD). ISD is a cause of stress urinary **INCONTINENCE** in which the urethral sphincter is unable to contract and generate sufficient resistance in the bladder, especially during stress maneuvers. Prior to collagen implant therapy, a skin test for collagen sensitivity must be administered and evaluated over a 4 week period.

In male patients, the evaluation must include a complete history and physical examination and a simple cystometrogram to determine that the bladder fills and stores properly. The patient then is asked to stand upright with a full bladder and to cough or otherwise exert abdominal pressure on his bladder. If the patient leaks, the diagnosis of ISD is established.

In female patients, the evaluation must include a complete history and physical examination (including a pelvic exam) and a simple cystometrogram to rule out abnormalities of bladder compliance and abnormalities of urethral support. Following that determination, an abdominal leak point pressure (ALLP) test is performed. Leak point pressure, stated in cm H<sub>2</sub>O, is defined as the intra-abdominal pressure at which leakage occurs from the bladder (around a catheter) when the bladder has been filled with a minimum of 150 cc fluid. If the patient has an ALLP of less than 100 cm H<sub>2</sub>O, the diagnosis of ISD is established.

To use a collagen implant, physicians must have urology training in the use of a cystoscope and must complete a collagen implant training program.

Coverage of a collagen implant, and the procedure to inject it, is limited to the following types of patients with stress urinary **INCONTINENCE** due to ISD:

- Male or female patients with congenital sphincter weakness secondary to conditions such as myelomeningocele or epispadias;
- Male or female patients with acquired sphincter weakness secondary to spinal cord lesions;
- Male patients following trauma, including prostatectomy and/or radiation; and
- Female patients without urethral hypermobility and with abdominal leak point pressures of 100 cm H<sub>2</sub>O or less.

Patients whose **INCONTINENCE** does not improve with 5 injection procedures (5 separate treatment sessions) are considered treatment failures, and no further treatment of urinary **INCONTINENCE** by collagen implant is covered. Patients who have a reoccurrence of **INCONTINENCE** following successful treatment with collagen implants in the past (e.g., 6-12 months previously) may benefit from additional treatment sessions. Coverage of additional sessions may be allowed but must be supported by medical justification.

### **Local:**

NO LCD on this topic

*(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)*

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### **Related Policies**

- Magnetic Pelvic Floor Stimulation for Urinary Incontinence
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### **References**

1. Rocha FL, Gomes CM, Pompeo AC, et al. Prospective study evaluating efficacy and safety of adjustable continence therapy (PROACT) for post radical prostatectomy urinary incontinence. *Urology*, May 2006; 67(5):965-969.
2. Martens FM, Lampe MI, Heesakkers PFA. ProAct for stress urinary incontinence after radical prostatectomy. *Urol Int*. June 2009; 82(4):394-398.
3. Venturino L, Dalpiaz O, Pummer K, Primus G. Adjustable continence balloons in men: adjustments do not translate into long-term continence. *Urology*, June 2015;85(6): 1448-1452.
4. Nicolas M, Droupy S, Costa P. ProACT device implantation efficiency in second line treatment of post radical prostatectomy urinary incontinence after sub-urethral male sling failure. *Prog Urol*. January 2019; 29(1):36-44.
5. Nestler S, Thomas C, Neisius A, et al. Long-term results of ProACT primary and repeat implantation for treatment of stress urinary incontinence in men. *World J Urol*. June 2019; 37(6): 1173-1179.
6. Munier P, Nicolas M, Tricard T, et al. What if artificial urinary sphincter is not possible? Feasibility and effectiveness of ProACT for patients with persistent stress urinary

incontinence after radical prostatectomy treated by sling. *Neurourol Urodyn*. June 2020. 39(5): 1417-1422.

7. American Urological Association (AUA)/Society of Urodynamics (SUFU). Incontinence after prostate treatment guideline. Published 2019. <https://auanet.org/>. Accessed January 2023.
8. International Continence Society. Surgical treatment of urinary incontinence in men. Published in 2010. <https://ics.org/>. Accessed January 2024.
9. Centers for Medicare and Medicaid Services (CMS). National Coverage Determination. Incontinence Control Devices. <https://CMS.gov/>. Accessed January 2024.

*The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through January 2024, the date the research was completed.*



### Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
3/1/22	12/14/21		Joint policy established
3/1/23	2/15/22		Deleted T codes, added codes 53451-53454 as E/I effective 1/1/22.
5/1/23	2/21/23		Routine policy maintenance, no change in policy status. (ds)
5/1/24	2/20/24		Routine policy maintenance, no change in policy status. Vendor managed: N/A (ds)

Next Review Date:            1<sup>st</sup> Qtr. 2025

### Pre-Consolidation Medical Policy History

Original Policy Date	Comments
BCN:	Revised:
BCBSM:	Revised:

**BLUE CARE NETWORK BENEFIT COVERAGE  
POLICY: PROACT™ ADJUSTABLE CONTINENCE THERAPY**

**I. Coverage Determination:**

<b>Commercial HMO (includes Self-Funded groups unless otherwise specified)</b>	Not covered
<b>BCNA (Medicare Advantage)</b>	See government section
<b>BCN65 (Medicare Complementary)</b>	Coinsurance covered if primary Medicare covers the service.

**II. Administrative Guidelines:**

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the individual member's certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.
- Duplicate (back-up) equipment is not a covered benefit.