MEDICAL POLICY STATEMENT
Ohio Medicaid

Policy Name & Number	Date Effective
ProACT Adjustable Continence Therapy-OH MCD-MM-1305	05/01/2024
Policy Type	
MEDICAL	

Medical Policy Statement prepared by CareSource and its affiliates are derived from literature based on and supported by clinical guidelines, nationally recognized utilization and technology assessment guidelines, other medical management industry standards, and published MCO clinical policy guidelines. Medically necessary services include, but are not limited to, those health care services or supplies that are proper and necessary for the diagnosis or treatment of disease, illness, or injury and without which the patient can be expected to suffer prolonged, increased or new morbidity, impairment of function, dysfunction of a body organ or part, or significant pain and discomfort. These services meet the standards of good medical practice in the local area, are the lowest cost alternative, and are not provided mainly for the convenience of the member or provider. Medically necessary services also include those services defined in any Evidence of Coverage documents, Medical Policy Statements, Provider Manuals, Member Handbooks, and/or other policies and procedures.

Medical Policy Statements prepared by CareSource and its affiliates do not ensure an authorization or payment of services. Please refer to the plan contract (often referred to as the Evidence of Coverage) for the service(s) referenced in the Medical Policy Statement. If there is a conflict between the Medical Policy Statement and the plan contract (i.e., Evidence of Coverage), then the plan contract (i.e., Evidence of Coverage) will be the controlling document used to make the determination. According to the rules of Mental Health Parity Addiction Equity Act (MHPAEA), coverage for the diagnosis and treatment of a behavioral health disorder will not be subject to any limitations that are less favorable than the limitations that apply to medical conditions as covered under this policy.

Table of Contents

A. Subject

ProACT Adjustable Continence Therapy

B. Background

Urinary incontinence is a known complication of prostate surgery which can impact quality of life. The incidence of incontinence varies by procedure, but it is transient for most individuals. Incontinence after prostate surgery is a dynamic condition that can greatly improve in the first one to two years with conservative therapies. Conservative management may include lifestyle modification, pads, compression, catheters, and pelvic floor exercises. An estimated 5% of men whose incontinence fails to resolve undergo an additional procedure for the treatment of incontinence. Surgical management, which is usually deferred for at least 12 months post-prostatectomy, may involve adjustable balloon devices for mild stress incontinence, male slings for mild to moderate stress incontinence, and artificial urinary sphincters for severe stress incontinence.

ProACT is a minimally invasive adjustable continence therapy for stress urinary incontinence utilizing a proprietary balloon device. Under fluoroscopic guidance, implantation instruments are advanced via transverse perineal incisions to the area of the bladder neck. The tissue is then dilated to create space for the balloon device. A balloon is inserted bilaterally and inflated with isotonic solution. Titanium ports are placed under the skin to allow for future inflation or deflation of the balloons. While the device has demonstrated efficacy in peer-reviewed medical literature, device migration requiring revision surgery or explantation has also been documented. A shared decision-making approach between physician and patient is recommended.

C. Definitions

- **Urinary Incontinence** – Involuntary leakage of urine, including the following types:
  - **Stress Urinary Incontinence (SUI)** – Occurs in the absence of a bladder contraction due to inadequate urethral sphincter function, either from mechanical damage to the urethral sphincter or from physiologic effects that limit sphincter function.
  - **Urge Urinary Incontinence (UUI)** – A sudden and compelling desire to pass urine that is difficult to defer and is accompanied by involuntary leakage, typically associated with bladder outlet obstruction or detrusor overactivity.
  - **Overflow Urinary Incontinence (OUI)** – Urine is retained in the bladder due to incomplete voiding after an attempt to urinate, potentially caused by bladder outlet obstruction or detrusor underactivity.
  - **Mixed Urinary Incontinence** – A combination of stress urinary incontinence and urge urinary incontinence, occurring when both the bladder and urinary sphincter have impaired function.

D. Policy

I. CareSource considers ProACT adjustable continence therapy medically necessary when **ALL** the following clinical criteria are met:

A. Member is at least 45 years of age.
B. Member underwent radical prostatectomy or transurethral resection of the prostate at least 12 months prior without radiation therapy.
C. Member has documented primary stress urinary incontinence arising from intrinsic sphincter deficiency of at least 12 months duration.
D. Member has documentation of conservative therapy failure.
E. Member experiences at least 3 incontinence episodes per day.
F. Member has positive 24-hour pad weight test (at least 8-gram pad weight increase demonstrated in two 24-hour pad weight tests).

II. Limitations/Exclusions

ProACT is contraindicated in patients with any of the following:

A. urge incontinence
B. detrusor instability or over-activity
C. residual volume of at least 100ml or at least 25% of the total bladder capacity after voiding
D. active systemic or urinary tract infections
E. history of bladder stones
F. hemophilia or other bleeding disorders
G. UI resulting from detrusor instability
H. UI resulting from overactive bladder
I. reduced bladder compliance
J. residual urine volume exceeding 100 cubic centimeters after voiding
K. suspected bladder cancer
L. radiotherapy within the past 6 months

E. Conditions of Coverage

N/A

F. Related Policies/Rules

N/A

G. Review/Revision History

	DATE	ACTION
Date Issued	04/13/2022	New Policy
Date Revised	03/29/2023 02/14/2024	Annual review: updated references. Approved at Committee. Annual review: editorial changes to document language and updated references. Approved at Committee.
Date Effective	05/01/2024	
Date Archived		

H. References

1. Angulo JC, Schönburg S, Giammò A, et al. Systematic review and meta-analysis comparing adjustable transobterator male system (ATOMS) and adjustable continence therapy (ProACT) for male stress incontinence. *PLoS One*. 2019;14(12):e0225762. doi:10.1371/journal.pone.0225762
2. Artificial urinary sphincter: A-0267 (AC). MCG. 27th ed. Updated September 21, 2023. Accessed January 23, 2024. www.careweb.careguidelines.com
3. Clemens JQ. Urinary incontinence in men. UpToDate. Updated January 3, 2022. Accessed January 23, 2024. www.uptodate.com
4. Comiter CV, Speed J. Urinary incontinence after prostate treatment. UpToDate. Updated July 1, 2022. Accessed January 23, 2024. www.uptodate.com
5. Finazzi Agrò E, Gregori A, Bianchi D, et al. Efficacy and safety of adjustable balloons (ProACT) to treat male stress urinary incontinence after prostate surgery: medium and long-term follow-up data of a national multicentric retrospective study. *Neurourol Urodyn*. 2019;38(7):1979-1984. doi:10.1002/nau.24103
6. Klock JA, Palacios AR, Leslie SW, et al. Artificial urinary sphincters and adjustable dual-balloon continence therapy in men. Updated November 2, 2023. Accessed January 23, 2024. www.ncbi.nlm.nih.gov
7. Larson T, Jhaveri H, Yeung LL. Adjustable continence therapy (ProACT) for the treatment of male stress incontinence: a systematic review and meta-analysis. *Neurourol Urodyn*. 2019;38(8):2051-2059. doi:10.1002/nau.24135
8. Nash S, Aboseif S, Gilling P, et al. Four-year follow-up on 68 patients with a new post-operatively adjustable long-term implant for post-prostatectomy stress incontinence: ProACT. *Neurourol Urodyn*. 2019;38(1):248-253. doi:10.1002/nau.23838
9. Premarket approval (PMA) P130018: FDA summary of safety and effectiveness data. Food and Drug Administration. November 24, 2015. Accessed January 23, 2024. www.accessdata.fda.gov
10. ProACT: patient brochure. Food and Drug Administration. Accessed January 23, 2024. www.accessdata.fda.gov
11. ProACT: physician instructions for use. Food and Drug Administration. Accessed January 23, 2024. www.accessdata.fda.gov
12. ProACT adjustable continence therapy (Uromedica) for treatment of post-surgical incontinence in men. Hayes. Updated May 24, 2023. Accessed July 17, 2023. www.evidence.hayesinc.com

13. ProACT therapy for the treatment of stress urinary incontinence in males (ProACT). National Library of Medicine. Updated May 31, 2018. Accessed January 24, 2024. clinicaltrials.gov
14. Sandhu JS, Bryer B, Comiter C, et al. Incontinence after prostate treatment: AUA/SUFU guideline. *J Urol*. 2019;202(2):369-378. doi:10/1097/ju.00000000000314
15. Uromedica announces launch of ProACT adjustable continence therapy for men with FDA approval and reimbursement coding. *Businesswire*. July 11, 2017. Accessed January 23, 2024. www.businesswire.com

Independent medical review – April 2022

ODM approved 2/22/2024