MEDICAL POLICY STATEMENT
Marketplace

Policy Name & Number	Date Effective
ProACT Adjustable Continence Therapy-MP-MM-1304	IN, GA, WV, KY: 07/01/2022-06/30/2023 OH: 08/01/2022-07/31/2023
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.

This policy applies to the following Marketplace(s):				
☒ **Georgia**	☒ **Indiana**	☒ **Kentucky**	☒ **Ohio**	☒ **West Virginia**

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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** – The involuntary leakage of urine. After prostate surgery, men can develop one or a combination of the following types of incontinence:
  - **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. UUI is typically associated with bladder outlet obstruction or detrusor overactivity.
  - **Overflow Urinary Incontinence (OUI)** – Occurs when urine is retained in the bladder due to incomplete voiding after an attempt to urinate. OUI can be caused by bladder outlet obstruction or detrusor underactivity.
  - **Mixed Urinary Incontinence** – A combination of stress urinary incontinence and urge urinary incontinence, occurs 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

NA

F. Related Policies/Rules

NA

G. Review/Revision History

	DATE	ACTION
Date Issued	04/13/2022	NEW POLICY
Date Revised		
Date Effective	GA, IN, KY, WV: 07/01/2022 OH: 08/01/2022	
Date Archived	IN, GA, WV, KY: 06/30/2023 OH: 07/31/2023	This Policy is no longer active and has been archived. Please note that there could be other Policies that may have some of the same rules incorporated and CareSource reserves the right to follow CMS/State/NCCI guidelines without a formal documented Policy.

H. References

1. Angulo JC, 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:e0225762.
2. Clemens JQ. Urinary incontinence in men. (2022 January 3). UpToDate. Retrieved March 23, 2022 from www.uptodate.com.
3. Comiter CV, Speed J. (2021 May 24). Urinary incontinence after prostate treatment. UpToDate. Retrieved March 23, 2022 from www.uptodate.com.
4. Finazzi Agro 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.
5. Health Technology Assessment. ProACT adjustable continence therapy (Uromedica) for treatment of post-surgical incontinence in men. Hayes. Updated 06/07/2021. Retrieved February 2, 2022 from www.evidence.hayesinc.com.
6. 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; 38:2051.
7. 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.
8. Premarket Approval (PMA) P130018: FDA Summary of Safety and Effectiveness Data. (2015 November 24). Retrieved March 28, 2022 from www.accessdata.fda.gov.
9. ProACT: Patient Brochure. Plymoth, MN; Uromedica. P130018C. Retrieved March 28, 2022 from www.accessdata.fda.gov.
10. ProACT: Physician Instructions for Use. Plymouth, MN; Uromedica. P130018D. Retrieved March 28, 2022 from www.accessdata.fda.gov.
11. Sandhu JS, et al. Incontinence after prostate treatment: AUA/SUFU guideline. J Urol. 2019 Aug;202:369-378. Doi: 10/1097/ju.0000000000000314.
12. Singla N, Singla AK. Post-prostatectomy incontinence: etiology, evaluation, and management. Turk J Urol. 2014 Mar;40(1):1-8. Doi: 10.5152/tud.2014.222014.
13. Uromedica announces launch of ProACT adjustable continence therapy for men with FDA approval and reimbursement coding. Businesswire. 07/11/2017. Retrieved February 2, 2022 from www.businesswire.com.

I. State-Specific Information

A. Georgia
   1. Effective: 07/01/2022

B. Indiana
   1. Effective: 07/01/2022

C. Kentucky
   1. Effective: 07/01/2022

D. Ohio
   1. Effective: 08/01/2022

E. West Virginia
   1. Effective: 07/01/2022

The MEDICAL Policy Statement detailed above has received due consideration as defined in the MEDICAL Policy Statement Policy and is approved.