MEDICAL POLICY STATEMENT
Marketplace

Policy Name & Number	Date Effective
ProACT Adjustable Continence Therapy-MP-MM-1304	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 f81Mc7.(n)145 482.71 Th0 G[19 156.i ((5e)4(9T6y3a, f539.88 434.59 0.47998 0.47998 ref72.024 412.5

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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-ac

Date Effective	05/01/2024	
Date Archived		

I. References

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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 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. 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
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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 Ch74(od)3( )-4(an)3(d)1 79205 324.50 g0 G[-)]TJETQqETQqETQqjq0e sysrety sse

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