

MEDICAL POLICY

POLICY TITLE	TRANSVAGINAL AND TRANSURETHRAL RADIOFREQUENCY TISSUE REMODELING FOR URINARY STRESS INCONTINENCE
POLICY NUMBER	MP 4.034

CLINICAL BENEFIT	☒ MINIMIZE SAFETY RISK OR CONCERN. ☒ MINIMIZE HARMFUL OR INEFFECTIVE INTERVENTIONS. ☐ ASSURE APPROPRIATE LEVEL OF CARE. ☐ ASSURE APPROPRIATE DURATION OF SERVICE FOR INTERVENTIONS. ☐ ASSURE THAT RECOMMENDED MEDICAL PREREQUISITES HAVE BEEN MET. ☐ ASSURE APPROPRIATE SITE OF TREATMENT OR SERVICE.
Effective Date:	RETIRED 9/1/2026

I. POLICY

Transvaginal radiofrequency bladder neck suspension as a treatment of urinary stress incontinence is considered **investigational**, as there is insufficient evidence to support a general conclusion concerning the health outcomes or benefits associated with this procedure.

Transurethral radiofrequency tissue remodeling as a treatment of urinary stress incontinence is considered **investigational**, as there is insufficient evidence to support a general conclusion concerning the health outcomes or benefits associated with this procedure.

Cross-references:

MP 1.033 Sacral Nerve Neuromodulation-Stimulation

MP 2.064 Biofeedback and Neurofeedback Therapy

MP 4.012 Injectable Bulking Agents for the Treatment of Urinary and Fecal Incontinence

PRODUCT VARIATIONS

This policy is only applicable to certain programs and products administered by Capital Blue Cross and subject to benefit variations. Please see additional information below.

FEP PPO - Refer to FEP Medical Policy Manual. The FEP Medical Policy manual can be found at:

<https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies>.

DESCRIPTION/BACKGROUND

Radiofrequency (RF) tissue remodeling with specially designed devices has been explored as a minimally invasive treatment option for urinary stress incontinence. It involves using nonablative levels of RF energy to shrink and stabilize the endopelvic fascia.

Urinary stress incontinence, defined as the involuntary loss of urine from the urethra due to an increase in intra-abdominal pressure, is a common condition, affecting an estimated 15 million

MEDICAL POLICY

POLICY TITLE	TRANSVAGINAL AND TRANSURETHRAL RADIOFREQUENCY TISSUE REMODELING FOR URINARY STRESS INCONTINENCE
POLICY NUMBER	MP 4.034

women in the U.S. Conservative therapy usually includes pelvic floor muscle exercises and behavioral therapy.

Biofeedback, pelvic electrical stimulation, medications or periurethral bulking agents such as collagen might also be tried. Various surgical options are considered when conservative therapy fails, including most prominently various types of bladder suspension procedures, which intend to reduce bladder neck and urethra hypermobility by tightening the endopelvic fascia.

Recently, the use of nonablative levels of RF energy has been investigated as a technique to shrink and stabilize the endopelvic fascia, thus improving the support for the urethra and bladder neck. Two RF devices have been specifically designed for the treatment of urinary stress incontinence, which may be performed as outpatient procedures under general anesthesia.

SURx Transvaginal System

This involves making an incision through the vagina lateral to the urethra, exposing the endopelvic fascia. Radiofrequency energy is then applied over the endopelvic fascia in a slow sweeping manner, resulting in blanching and shrinkage of the tissue. As of 2006, the SURx device is no longer marketed in the U.S.

Lyrette™ (formerly The Renessa® procedure)

The procedure involves passing a radiofrequency probe through the urethral opening into the urethra and then into the bladder. Once the probe is in position, a small balloon is inflated to keep it stationary during the procedure. Radiofrequency energy is used to generate controlled heat at low temperatures in tissue targets within the lower urinary tract. The heat denatures collagen in the tissue at multiple small treatment sites.

Regulatory Status

In 2002, the SURx Transvaginal System received marketing clearance through the U.S. Food and Drug Administration (FDA) 510(k) process. According to the FDA, the device "is indicated for shrinkage and stabilization of female pelvic tissue for treatment of Type II stress urinary incontinence due to hypermobility in women not eligible for major corrective surgery." As of 2006, the SURx is no longer marketed in the U.S.

In 2005, Novasys Medical received clearance to market the Renessa® transurethral radiofrequency system through the FDA 510(k) process. The device is indicated for the transurethral treatment of stress urinary incontinence due to hypermobility.

RATIONALE

Summary

MEDICAL POLICY

POLICY TITLE	TRANSVAGINAL AND TRANSURETHRAL RADIOFREQUENCY TISSUE REMODELING FOR URINARY STRESS INCONTINENCE
POLICY NUMBER	MP 4.034

Transvaginal and transurethral radiofrequency tissue remodeling involves the use of nonablative levels of radiofrequency energy to shrink and stabilize the endopelvic fascia and are potential minimally invasive treatment options for urinary stress incontinence. There is insufficient evidence from well-conducted, randomized, controlled trials that either of these treatments improves the net health outcome compared to a sham procedure or another treatment for stress urinary incontinence. The safety and long-term efficacy on health outcomes is limited, and randomized controlled studies with longer follow-up are needed. The evidence is insufficient to determine that the technology results in an improvement in the net health outcomes.

DEFINITIONS

510(K) APPROVAL refers to section 510(k) of the Food, Drug and Cosmetic Act. Under 510(k), before a manufacturer can market a medical device in the United States, they must demonstrate to FDA's satisfaction that it is substantially equivalent (as safe and effective) to a device already on the market.

MIXED INCONTINENCE is a combination of stress and urge incontinence.

OVERFLOW INCONTINENCE is characterized by small frequent voidings due to overfilling of the bladder or to a bladder with pathologically decreased volume.

PESSARY is a device inserted into the vagina to function as a support structure for the uterus.

STRESS INCONTINENCE is an involuntary loss of urine that occurs during physical activity, such as coughing, sneezing, laughing or exercise. This incontinence occurs as a result of weakened pelvic muscles that support the bladder and urethra, or because of malfunction of the urethral sphincter.

URGE INCONTINENCE is a condition characterized by a strong desire to urinate immediately before an involuntary bladder contraction with a loss of a large amount of urine.

DISCLAIMER

Capital Blue Cross' medical policies are used to determine coverage for specific medical technologies, procedures, equipment, and services. These medical policies do not constitute medical advice and are subject to change as required by law or applicable clinical evidence from independent treatment guidelines. Treating providers are solely responsible for medical advice and treatment of members. These policies are not a guarantee of coverage or payment. Payment of claims is subject to a determination regarding the member's benefit program and eligibility on the date of service, and a determination that the services are medically necessary and appropriate. Final processing of a claim is based upon the terms of contract that applies to the members' benefit program, including benefit limitations and exclusions. If a provider or a member has a question concerning this medical policy, please contact Capital Blue Cross' Provider Services or Member Services.

MEDICAL POLICY

POLICY TITLE	TRANSVAGINAL AND TRANSURETHRAL RADIOFREQUENCY TISSUE REMODELING FOR URINARY STRESS INCONTINENCE
POLICY NUMBER	MP 4.034

CODING INFORMATION

Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Transurethral radiofrequency tissue remodeling as a treatment of urinary stress incontinence is considered investigational; therefore, not covered:

Procedure Codes									
53860									

Transvaginal radiofrequency bladder neck suspension as a treatment of urinary stress incontinence is considered investigational; therefore, not covered:

Procedure Codes									
53899	0672T								

REFERENCES

1. Dmochowski RR, Avon M, Ross J et al. Transvaginal radio frequency treatment of the endopelvic fascia: a prospective evaluation for the treatment of genuine stress urinary incontinence. *J Urol* 2003; 169(3):1028-32. PMID: 12576838
2. Ross JW, Galen DI, Abbott K et al. A prospective multisite study of radiofrequency bipolar energy for treatment of genuine stress incontinence. *J Am Assoc Gynecol Laparosc* 2002; 9(4-Jan):493-9. PMID: 12386362
3. McDougall EM, Heidorn CA, Portis AJ et al. Laparoscopic bladder neck suspension fails the test of time. *J Urol* 1999; 162(6):2078-81. PMID: 10569574
4. Buchsbaum GM, McConville J, Korn R et al. Outcome of transvaginal radiofrequency for treatment of women with stress urinary incontinence. *Int Urogynecol J Pelvic Floor Dysfunct* 2007; 18(3):263-5. PMID: 16788852
5. Appell RA, Juma S, Wells WG et al. Transurethral radiofrequency energy collagen micro-remodeling for the treatment of female stress urinary incontinence. *Neurourol Urodyn* 2006; 25(4):331-6. PMID: 16673379
6. Lenihan JP. Comparison of the quality of life after nonsurgical radiofrequency energy tissue micro-remodeling in premenopausal and postmenopausal women with moderate-to-severe stress urinary incontinence. *Am J Obstet Gynecol* 2005; 192(6-Jan):1995-2001. PMID: 15970873
7. Appell RA, Singh G, Klimberg IW et al. Nonsurgical, radiofrequency collagen denaturation for stress urinary incontinence: retrospective 3-year evaluation. *Expert Rev Med Devices* 2007; 4(4):455-61. PMID: 17605681
8. Elser DM, Mitchell GK, Miklos JR et al. Nonsurgical transurethral collagen denaturation for stress urinary incontinence in women: 12-month results from a prospective long-term study. *J Minim Invasive Gynecol* 2009; 16(1):56-62. PMID: 19013110

MEDICAL POLICY

POLICY TITLE	TRANSVAGINAL AND TRANSURETHRAL RADIOFREQUENCY TISSUE REMODELING FOR URINARY STRESS INCONTINENCE
POLICY NUMBER	MP 4.034

9. Elser DM, Mitchell GK, Miklos JR et al. Nonsurgical transurethral collagen denaturation for stress urinary incontinence in women month results from a prospective long-term study. *Neurourol Urodyn* 2010; 29(8):1424-8. PMID: 20976817
10. Elser DM, Mitchell GK, Miklos JR et al. Nonsurgical transurethral radiofrequency collagen denaturation: results at three years after treatment. *Adv Urol* 2011; 2011:872057. PMID: 22190917
11. NCT01455779 Lyrette: Renewing Continence Objective and Subjective Efficacy Study (ROSE)
12. Sand PK, Owens GM, Black EJ, Anderson LH, Martinson MS. Cost effectiveness of radiofrequency microremodeling for stress urinary incontinence. *Int Urogynecol J*. 2014;25(4):517-523. PMID: 24108392
13. Kang D, Han J, Neuberger NM, et al. "Transurethral radiofrequency collagen denaturation for the treatment of women with urinary incontinence." *Cochrane Database of Systematic Reviews* 3 (2015). PMID: 25785555
14. Lukacz, E. Female urinary incontinence: Treatment. In: UpToDate Online Journal [serial online]. Waltham, MA: UpToDate; updated May 25, 2023
15. Kobashi K, Albo M, Dmochowski R, et al., "Surgical Treatment of Female Stress Urinary Incontinence: AUA/SUFU Guideline". *Journal of Urology*. 198: 875-883. PMID: 28625508
16. Davila GW. Review Article Nonsurgical outpatient therapies for the management of female stress urinary incontinence: long-term effectiveness and durability. *Advances in Urology* 2011. PMID: 21738529
17. Dillon B, Dmochowski R. Radiofrequency for the treatment of stress urinary incontinence in women. *Current Urology Reports* 2009; 10: 369-374. PMID: 19709484
18. ACOG Practice Bulletin No. 155: Urinary Incontinence in Women. *Obstet Gynecol*. Nov 2015; 126(5): e66-e81. PMID 26488524
19. Stachowicz AM, Hoover ML, Karram MM. Clinical utility of radiofrequency energy for female genitourinary dysfunction: past, present, and future. *Int Urogynecol J*. 2021 Jun;32(6):1345-1350. PMID 33661319
20. Brasil C, Sodré D, Lemos A, et al. Radiofrequency in the Treatment of urinary incontinence of female stress: a pilot randomized clinical trial. *Research Square* (Research Square). Published online February 9, 2024. doi:10.21203/rs.3.rs-3888375/v1
21. Elfaki S, Hassan S. Radiofrequency in Cosmetic Gynecology, Literature Review 2018-2023. *Obstetrics & Gynecology Open Access*. 2024;8(1). doi:10.29011/2577-2236.100182
22. Lukacz, E. Female Urinary Incontinence: Treatment. In: UpToDate Online Journal [serial online]. Waltham, MA: UpToDate; Updated June 26, 2025. Literature review current through September 2025.

POLICY HISTORY

MP 4.034	08/11/2020 Consensus Review. No change to policy statements. References updated.
-----------------	---

MEDICAL POLICY

POLICY TITLE	TRANSVAGINAL AND TRANSURETHRAL RADIOFREQUENCY TISSUE REMODELING FOR URINARY STRESS INCONTINENCE
POLICY NUMBER	MP 4.034

	08/11/2021 Consensus Review. No change to policy statement. References and coding reviewed.
	12/01/2021 Administrative Update. Added 0672T. Effective date 01/01/2022
	11/22/2022 Consensus Review. No change in policy statement. References updated.
	11/28/2023 Consensus Review. No change to policy statement. Product variation language, Background and Rationale updated. References added.
	10/02/2024 Consensus Review. No change to policy statements. References reviewed and updated. No coding changes.
	10/30/2025 Consensus Review. No change to policy statement. Cross-references and references reviewed and updated. No coding changes.
	05/15/2026 Retirement Review.

Health care benefit programs issued or administered by Capital Blue Cross and/or its subsidiaries, Capital Advantage Insurance Company[®], Capital Advantage Assurance Company[®] and Keystone Health Plan[®] Central. Independent licensees of the Blue Cross BlueShield Association. Communications issued by Capital Blue Cross in its capacity as administrator of programs and provider relations for all companies.