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:	**3/1/2024**

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 and Pelvic Floor Stimulation Devices
MP 2.064 Biofeedback and Neurofeedback Therapy
MP 4.012 Injectable Bulking Agents for the Treatment of Urinary and Fecal Incontinence

II. PRODUCT VARIATIONS

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This policy is only applicable to certain programs and products administered by Capital BlueCross and subject to benefit variations as discussed in Section VI. 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.

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III. DESCRIPTION/BACKGROUND

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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 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.

IV. RATIONALE

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Summary

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.

V. DEFINITIONS

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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.

VI. BENEFIT VARIATIONS

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The existence of this medical policy does not mean that this service is a covered benefit under the member's health benefit plan. Benefit determinations should be based in all cases on the applicable health benefit plan language. Medical policies do not constitute a description of benefits. A member's health benefit plan governs which services are covered, which are

excluded, which are subject to benefit limits and which require preauthorization. There are different benefit plan designs in each product administered by Capital BlueCross. Members and providers should consult the member's health benefit plan for information or contact Capital BlueCross for benefit information.

VII. DISCLAIMER

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Capital BlueCross's medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. If a provider or a member has a question concerning the application of this medical policy to a specific member's plan of benefits, please contact Capital BlueCross' Provider Services or Member Services. Capital BlueCross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

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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							

IX. REFERENCES

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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, Korni 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*
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. Blue Cross Blue Shield Association Medical Policy Reference Manual. 2.01.60, Transvaginal and Transurethral Radiofrequency Tissue Remodeling for Urinary Stress Incontinence. Archived March 2013.

X. POLICY HISTORY

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MP 4.034	**8/11/20 Consensus review.** No change to policy statements. References updated.
	8/11/2021 Consensus review. No change to policy statement. References and coding reviewed.
	12/1/2021 Administrative review. Added 0672T. Effective date 1/1/2022
	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.

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