MEDICAL POLICY

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

Original Issue Date (Created):	**12/1/2013**
Most Recent Review Date (Revised):	**8/11/2020**
Effective Date:	**12/1/2020**

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 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 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 please see additional information below, and subject to benefit variations as discussed in Section VI below.

FEP PPO - The FEP program dictates that all drugs, devices or biological products approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational. Therefore, FDA-approved drugs, devices or biological products may be assessed on the basis of medical necessity.

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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 6.5 million women in the U.S. Conservative therapy usually includes pelvic floor muscle exercises. Biofeedback, pelvic electrical stimulation, 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. For example, for colposuspension (i.e., the Burch procedure), sutures are placed in the endopelvic fascia and fixed to Cooper's ligament or retropubic periosteum, which in turn creates a floor or hammock underneath the bladder neck and urethra.

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.

Lyrette™ (formerly The Renessa® procedure):

The procedure involves passing a specially designed 4-needle RF 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 then delivered for 60 seconds to the 4 needles, which are deployed from the probe into the tissue of the bladder neck and upper urethra. Tissue temperatures of 65 to 75 degrees Celsius are generated; at this temperature, focal microscopic denaturation of collagen occurs. The procedure is repeated 9 times so that collagen is denatured at 36 tissue 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.

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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. Moreover, no device designed for transvaginal tissue remodeling is currently available in the U.S. Thus, the treatments are considered investigational.

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:

CPT Codes®								
53860								

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

CPT Codes®								
53899								

IX. REFERENCES

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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.*
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.*
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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.*
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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.*
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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). Available at https://core.ac.uk/download/pdf/42130441.pdf. Accessed August 11, 2020.*
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Other Sources:

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X. POLICY HISTORY

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MP 4.034	**CAC 9/24/13 Minor review.** Extracted information regarding transvaginal and transurethral radiofrequency tissue remodeling for urinary stress incontinence from MP 4.012 Injectable Bulking Agents for the Treatment of Urinary and Fecal Incontinence (formerly Urinary Incontinence Treatment (Including Periurethral Bulking Agents) and this separate policy was created. Added rationale section. No change to policy statements. Policy coded.
	CAC 9/30/14 Consensus review. No change to policy statements. Reference and rationale sections reviewed. Deleted reference to LCD L30547 – retired 10/31/13. No NCD.
	CAC 9/29/15 Consensus review. No changes to the policy statements. Rationale and reference update. FEP variation revised as FEP policy was archived. Coding reviewed
	CAC 9/27/16 Consensus review. No changes to the policy statements. Rationale and Reference sections updated. Coding reviewed. Variation reformatting completed.
	CAC 11/28/17 Consensus review. No change to policy statements. References and rationale reviewed. Coding reviewed.
	10/10/18 Consensus review. No change to policy statements. References reviewed. Rationale condensed.
	8/2/19 Consensus review. No change to policy statements. References and summary reviewed.
	8/11/20 Consensus review. No change to policy statements. References updated.

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