MEDICAL POLICY

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

Original Issue Date (Created):	**September 24, 2013**
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Effective Date:	**December 1, 2013**

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 Modulation/Stimulation for Pelvic Floor Dysfunction
MP-2.064 Biofeedback
MP-4.012 Injectable Bulking Agents for the Treatment of Urinary and Fecal Incontinence

II. PRODUCT VARIATIONS

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[N] = No product variation, policy applies as stated
[Y] = Standard product coverage varies from application of this policy, see below

[N] Capital Cares 4 Kids
[N] PPO
[N] HMO
[N] SeniorBlue HMO
[N] SeniorBlue PPO
[N] Indemnity
[N] SpecialCare
[N] POS
[Y] FEP PPO*

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* Refer to FEP Medical Policy Manual MP-2.01.60 Transvaginal and Transurethral Radiofrequency Tissue Remodeling for Urinary Stress Incontinence. The FEP Medical Policy manual can be found at: http://www.fepblue.org/medical-policies.jsp

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.

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.

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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This policy was updated regularly with searches of the MEDLINE database. The most recent literature search was performed for the period January 2012 through February 1, 2013. Following is a summary of the key literature to date:

Transvaginal Radiofrequency Remodeling

At the time this policy was created, the minimal published literature regarding the transvaginal radiofrequency (RF) bladder neck suspension was inadequate to permit scientific conclusions regarding the safety and long-term efficacy of this procedure. Dmochowski and colleagues reported on a multi-institutional prospective case series of 120 consecutive women with urinary stress incontinence who underwent transvaginal RF bladder neck suspension. (1) Enrolled patients had failed at least a 3-month trial of conservative therapy, including most commonly, pelvic floor muscle exercises or pelvic floor stimulation. Follow-up examinations at 1, 3, 6, and 12 months consisted of a history, physical examination, and urodynamic studies. In addition, each patient completed a voiding diary and quality-of-life questionnaire. A cure was defined as a negative valsalva maneuver; improvement was defined as decreased daily episodes of pad use. A total of 73% of patients were considered cured or improved at 12 months. More than 68% of patients reported satisfaction with the treatment. The authors concluded that the results were encouraging and that a 73% 12-month success rate suggested that this procedure had applicability for women with refractory incontinence who did not wish to undergo a more complicated surgical procedure. Ross and colleagues conducted a multicenter, prospective single-arm study that included 94 women with stress incontinence. (2) At 1 year, the objective cure rate was 79%, based on a negative leak point pressure. Assessment of quality of life was also significantly improved. Larger controlled studies with longer follow-up were needed to further evaluate this procedure. As noted in a review of laparoscopic bladder neck suspension, initial promising results at 12 months declined to a 30% success rate at 45 months. (3) These authors suggested that any new surgical technique for the treatment of stress incontinence should have more than 2 years of follow-up.

Updated searches of the literature identified only case series. In 2007, Buchsbaum and colleagues published a retrospective follow-up of the transvaginal RF procedure in 18 patients, 11 with genuine stress urinary incontinence and 7 with mixed incontinence. (4) At an unspecified time greater than 3 months following treatment, 6 of the 18 patients reported no

urine loss and were satisfied with the outcome, 2 patients were lost to follow-up, and 10 reported continuing symptoms of incontinence. The relation between diagnosis (i.e., genuine stress-induced or mixed incontinence) and outcome was not presented.

Transurethral Radiofrequency Remodeling

The policy was expanded in 2006 to include transurethral RF remodeling. The 2006 literature search identified 2 publications from a single company-sponsored randomized controlled trial (RCT) of the transurethral RF procedure. (5, 6) Quality-of-life measures did not differ between the RF group (110 subjects) and the sham-control group (63 subjects) at 12 months; however, a subgroup analysis showed benefit in patients with moderate to severe stress urinary incontinence. The study was limited by the post hoc subgroup analysis, loss to follow-up of nearly 20%, and lack of investigator blinding. Longer-term follow-up, identification of the patient population that might benefit from the procedure, and independent replication were needed. In 2007, Appell and colleagues published 3-year follow-up data from the industry-sponsored study described above. (7) Of 110 treated patients, 26 (24%) were available for evaluation; control subjects were not contacted. Of the 26, 5 had obtained other treatments and were not included in the analysis (not counted as failures). An additional 3 patients were not included since they had no episodes of incontinence at baseline. The authors reported that of the 18 (16%) included patients, 50% had reductions in incontinence episodes of greater than 50% (average of 3.5 daily incontinence episodes at baseline to 1.8 at 3 years after treatment). It should be noted that inclusion of all of the 26 subjects who had been contacted would result in a positive response rate of 38%. Interpretation of this study is limited due to the absence of the control group and inadequate numbers of treated patients in follow-up, along with excluding some patients from data analysis.

In 2009, Elser and colleagues published findings from an industry-sponsored prospective case series. (8) This was a 36-month multicenter study of transurethral RF remodeling in 136 women with stress urinary incontinence caused by bladder outlet hypermobility who had failed nonsurgical treatment and were not candidates for surgical therapy. Exclusion criteria included urge incontinence or stress urinary incontinence caused by intrinsic sphincter deficiency. By 12 months, 25 patients withdrew consent, 19 were lost to follow-up, and 17 reported lack of response, resulting in 75 patients (55%) who were evaluated at the 12-month follow-up. Efficacy, based on the percentage of patients with a 50% or greater reduction from baseline in daily incontinence episodes, was reported in 68 (50%) patients. Of the 75 evaluated at 12 months, 69% (38% of 136) reported at least a 50% reduction in leaked urine (median of 15 g) from baseline, and 45% (25% of 136) were dry. One patient reported increased leaking. No serious adverse events were reported. The most common adverse events at day 3 included dysuria (5%), urinary retention (4%), post-procedure pain (3%), and urinary tract infection (3%).

Eighteen-month and 3-year follow-up data have been published. Sixty-three of 136 (46%) women who received treatment completed the 18-month follow-up, and data were available on 60 women (44% of the study population). (9) Thirty-one of the 60 evaluable women (61.7%)

reported a reduction of at least 50% from baseline in leaks due to activity. In an intention-to-treat (ITT) analysis of data from all 136 participants (last observation carried forward), 46.7% reported at least a 50% reduction in leaks from baseline. A total of 41 women (30% of the study population) completed the 3-year follow-up evaluation. (10) According to diary data, available for 39 women, 24 (62%) reported at least a 50% reduction in leaks per day. In an ITT analysis with multiple imputations of missing data, 60% of women had at least a 50% reduction in leaks. The study is limited by a low long-term follow-up rate and lack of a control or comparison group.

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.

Practice Guidelines and Position Statements

In 2008, the California Technology Assessment Forum (CTAF) completed a review of radiofrequency remodeling for the treatment of female stress urinary incontinence. (11) The evidence for SURx was found to not meet the CTAF criteria. The evidence for Renessa consisted of the single industry-sponsored randomized, controlled trial with 12-month follow-up and post-hoc analysis (reviewed above, reference 8) and 2 observational pilot studies. (5,6) The CTAF Assessment concluded that although the benefits are clearly not as great as with the available gold standard (i.e., surgical approaches), the benefit-to-risk ratio was favorable for transurethral radiofrequency remodeling and did provide options for women with stress urinary incontinence, particularly for those not eligible for surgical intervention.

The American College of Obstetricians and Gynecologists' (ACOG) recommendations on treating urinary incontinence in women (reaffirmed in 2009) do not mention transvaginal or transurethral radiofrequency remodeling. (12)

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 contract. Benefit determinations should be based in all cases on the applicable contract language. Medical policies do not constitute a description of benefits. A member's individual or group customer benefits govern which services are covered, which are excluded, and which are subject to benefit limits and which require preauthorization. Members and providers should consult the member's benefit information or contact Capital for benefit information.

VII. DISCLAIMER

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Capital'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. Capital 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.

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Investigational: therefore not covered:

CPT Codes®								
53860	53899							

HCPCS Code	Description
N/A	

ICD-9-CM Diagnosis Code*	Description
N/A	

*If applicable, please see Medicare LCD or NCD for additional covered diagnoses.

The following ICD-10 diagnosis codes will be effective October 1, 2014:

ICD-10-CM Diagnosis Code*	Description
N/A	

*If applicable, please see Medicare LCD or NCD for additional covered diagnoses.

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.*
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.*
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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.*
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.*
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.*
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. *Taber's Cyclopedic Medical Dictionary, 19th edition.*
14. *Novitas Solutions. Local Coverage Determination (LCD) L30547 Radiofrequency Treatment for Urinary Incontinence. Effective 04/02/2012. [Website]: https://www.novitas-solutions.com/policy/mac-ab/l30547-r4.html. Accessed August 7, 2013.*

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X. POLICY HISTORY

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MP 4.034	CAC 9/24/13 Minor. 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.

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