

## Corporate Medical Policy

### Radiofrequency Tissue Remodeling for Urinary Stress Incontinence

<b>File Name:</b>	radiofrequency_tissue_remodeling_for_urinary_stress_incontinence
<b>Origination:</b>	6/2005
<b>Last CAP Review:</b>	11/2011
<b>Next CAP Review:</b>	11/2012
<b>Last Review:</b>	4/2012

#### **Description of Procedure or Service**

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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.

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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.

## Related policies:

Periurethral Bulking Agents for the Treatment of Urinary Incontinence  
Pelvic Floor Stimulation as a Treatment of Urinary Incontinence

***\*\*\*Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.***

## Policy

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**Transvaginal and Transurethral Radiofrequency Tissue Remodeling for Urinary Stress Incontinence are considered investigational. BCBSNC does not cover investigational services.**

## Benefits Application

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This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

## When Radiofrequency Tissue Remodeling for Urinary Stress Incontinence is covered

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Not Applicable

## When Radiofrequency Tissue Remodeling for Urinary Stress Incontinence is not covered

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Transvaginal radiofrequency bladder neck suspension as a treatment of urinary stress incontinence is considered investigational.

Transurethral radiofrequency tissue remodeling as a treatment of urinary stress incontinence is considered investigational.

## Policy Guidelines

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There remains 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.

## Billing/Coding/Physician Documentation Information

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This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at [www.bcbsnc.com](http://www.bcbsnc.com). They are listed in

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the Category Search on the Medical Policy search page.

*Applicable service codes: 53860*

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

## **Scientific Background and Reference Sources**

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### **Policy entitled: Urinary Incontinence Treatment**

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.69, 7/15/04.

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.01.17, 4/15/04.

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.60, 11/9/04.

Specialty Matched Consultant Advisory Panel - 5/2005

### **New policy entitled: Radiofrequency Tissue Remodeling for Urinary Stress Incontinence**

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.60, 8/17/05.

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.60, 12/12/06.

Specialty Matched Consultant Advisory Panel - 5/8/07

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.

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):493-9.  
McDougall EM, Heidorn CA, Portis AJ et al. Laparoscopic bladder neck suspension fails the test of time. *J Urol* 1999; 162(6):2078-81.

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* 2006; Epub ahead of print.

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.

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):1995-2001.

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.

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*

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Invasive Gynecol 2009; 16(1):56-62.

Karliner L; California Technology Assessment Forum. Radiofrequency micro-remodeling for the treatment of female stress urinary incontinence. October 2008. Retrieved on May 1, 2009 from <http://www.ctaf.org/content/general/detail/930>.

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.60, 2/14/08.

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.60, 12/11/09.

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.60, 2/12/09.

Specialty Matched Consultant Advisory Panel - 9/2009

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.60, 2/11/10

Specialty Matched Consultant Advisory Panel review 12/2010

Elser DM, Mitchell GK, Miklos JR et al. Nonsurgical transurethral collagen denaturation for stress urinary incontinence in women: 18-month results from a prospective long-term study. *Neurourol Urodyn*. 2010; 29(8):1424-8.

American College of Obstetricians and Gynecologists (ACOG). Urinary incontinence in women 2005 (reaffirmed in 2009). Retrieved on April 1, 2011 from <http://www.guideline.gov/content.aspx?id=10931>

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.60, 3/10/11

Specialty Matched Consultant Advisory Panel review 11/2011

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.60, 3/8/12

Medical Director review 4/2012

## **Policy Implementation/Update Information**

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### **Policy entitled: Urinary Incontinence Treatment**

6/16/05 Specialty Matched Consultant Advisory Panel review 5/24/05. Section I - Periurethral Injection of Implant Material for the Treatment of Urinary Incontinence; description revised, included biocompatible copolymer implant (e.g., URYX) in description; For "When Covered"- 2.d. "Cross-linked collagen or carbon-coated beads are used as the implantable material." pulled out as a separate sentence so need 1 or 2 and use of listed materials; also added biocompatible copolymers as one of the approved materials; For "When not Covered" added "The use of autologous fat and autologous ear chondrocytes as periurethral bulking agents are considered investigational and are not covered."; For "Policy Guidelines" removed sentence re: "15 ml of paste are injected..." since the procedure is included in the description. Section II - Sacral Nerve Modulation/Stimulation...description of procedure revised to provide additional information; For "When Covered" - changed #2 to indicate that the urinary incontinence conditions listed in #1 should not be related to a neurologic condition; #3 now reads: "Medical records document that the patient has failed at least a 3 month trial of conservative treatment such as behavioral therapy (i.e., diet modification, bladder training, biofeedback, Kegel exercises) and/or pharmacotherapy (i.e., 2 or more anti-

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cholinergic drugs or a combination of an anti-cholinergic and a tricyclic anti-depressant); #4 is now re: the percutaneous test stimulation. For "When not Covered" #1 - added several examples of conditions "Any conditions other than those listed above including but not limited to the following: stress incontinence, urge incontinence due to a neurologic condition (e.g., detrusor hyperreflexia, multiple sclerosis or spinal cord injury), other types of chronic voiding dysfunction, patients with mechanical urethral obstruction such as benign prostatic hypertrophy, cancer or urethral stricture." Section III - Pelvic Floor Stimulation...added policy guidelines re: investigational status: "Available data are insufficient to determine whether this treatment is as effective as alternatives. Additionally, the treatments lack standardization of delivery. There are minimal data for magnetic stimulation and no randomized trials. There is insufficient medical and scientific evidence to permit the Plan to evaluate the therapeutic value of pelvic floor stimulation as a treatment of urinary incontinence. For further information, please refer to separate policy number MED1263, Investigational (Experimental) Services." Added - Section IV re: Transvaginal Radiofrequency Bladder Neck Suspension for Urinary Stress Incontinence as investigational. Notice given 6/16/05. Effective date 8/18/05.

- 1/5/06 Removed deleted codes E0752, E0756, E0757, E0758 & E0759 from appropriate Billing/Coding sections.
- 2/26/07 Added HCPCS codes L8680, L8681, L8682, L8683, L8685, L8686, L8687, L8688, L8689 to Section II - Sacral Nerve Modulation/Stimulation for Urinary Incontinence. (pmo)

## **New policy entitled: Radiofrequency Tissue Remodeling for Urinary Stress Incontinence**

- 6/4/07 Notification that Section IV (Transvaginal Radiofrequency Bladder Neck Suspension for Urinary Stress Incontinence) of the policy entitled "Urinary Incontinence, Treatment " will be issued as a separate policy entitled "Radiofrequency Tissue Remodeling for Urinary Stress Incontinence". Policy to be effective 8/13/07. Information regarding Renessa Transurethral Radiofrequency System added to "Description" section. Transvaginal radiofrequency bladder neck suspension as a treatment of urinary stress incontinence is currently considered investigational. Added criteria that transurethral radiofrequency tissue remodeling as a treatment of urinary stress incontinence is considered investigational. Policy Guidelines section updated to include transurethral radiofrequency tissue remodeling. Notification given 6/4/07. Effective date 8/13/07. (pmo)
- 1/05/09 CPT code 0193T effective January 1, 2009 added to Billing/Coding section. (pmo)
- 9/28/09 Description and Policy Guidelines sections revised. Under Billing/Coding section, added information re: coding for the bladder neck suspension procedure. Medical terms and Reference sources added. (pmo)
- 6/22/10 Policy Number(s) removed (amw)
- 1/18/11 Specialty Matched Consultant Advisory Panel review 12/2010. References updated. Policy Guidelines updated. Added the following statement to Description section: "As of 2006, the SURx Transvaginal System is no longer marketed in the U.S." Added new CPT code 53860 and deleted 0193T.(mco)
- 5/24/11 References updated. Policy guidelines updated. No changes to policy statements. (mco)
- 12/20/11 Specialty Matched Consultant Advisory Panel review 11/2011. References updated. No

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changes in Policy Statements. (mco)

- 5/1/12 Description section updated. Policy statement revised to state: "Transvaginal and Transurethral Radiofrequency Tissue Remodeling for Urinary Stress Incontinence are considered investigational. BCBSNC does not cover investigational services." Policy Guidelines updated. References updated. Medical Director review 4/2012. (mco)

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Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.