

Blue Cross Blue Shield of Massachusetts is an Independent Licenses of the Blue Cross and Blue Shield Association

# **Medical Policy**

# Transvaginal and Transurethral Radiofrequency Tissue Remodeling for Urinary Stress Incontinence

## **Table of Contents**

Policy: Commercial

- Coding Information
- Information Pertaining to All Policies

Policy: Medicare

- Description
- References

- Authorization Information
- Policy History

# **Policy Number: 523**

BCBSA Reference Number: 2.01.60A (For Plan internal use only)

#### **Related Policies**

- Periurethral Bulking Agents for the Treatment of Urinary Incontinence, #471
- Biofeedback as a Treatment of Urinary Incontinence in Adults, #173
- Pelvic Floor Stimulation as a Treatment of Urinary Incontinence, #470

## **Policy**

# Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity

Transvaginal radiofrequency bladder neck suspension as a treatment of urinary stress incontinence is **INVESTIGATIONAL**.

Transurethral radiofrequency tissue remodeling as a treatment of urinary stress incontinence is **INVESTIGATIONAL**.

#### **Prior Authorization Information**

## Inpatient

 For services described in this policy, precertification/preauthorization <u>IS REQUIRED</u> if the procedure is performed inpatient.

## Outpatient

• For services described in this policy, see below for situations where prior authorization might be required if the procedure is performed outpatient.

	Outpatient
Commercial Managed Care (HMO and POS)	This is <b>not</b> a covered service.
Commercial PPO and Indemnity	This is <b>not</b> a covered service.

## **CPT Codes / HCPCS Codes / ICD Codes**

Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

The following CPT code is considered investigational for <u>Commercial Members: Managed Care</u> (<u>HMO and POS</u>), <u>PPO, Indemnity, Medicare HMO Blue and Medicare PPO Blue:</u>

#### **CPT Codes**

CPT codes:	Code Description
53860	Transurethral, radiofrequency micro-remodeling of the female bladder neck and proximal urethra for stress urinary incontinence

### **Description**

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 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.

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, thus improving the support for the urethra and bladder neck.

Examples of RF devices for the treatment of urinary stress incontinence include the SURx Transvaginal System and Renessa® transurethral radiofrequency system from Novasys Medical Inc. All RF devices for the treatment of urinary stress incontinence are considered investigational regardless of the commercial name, the manufacturer, or FDA approval status.

#### **Summary**

There remains insufficient evidence from well-conducted, randomized, controlled trials that either transvaginal or transurethral radiofrequency tissue remodeling improves the net health outcome compared to a sham procedure or another treatment for stress urinary incontinence. Thus, the treatments are considered investigational.

#### **Policy History**

Date	Action
1/2021	Medicare information removed. See MP #132 Medicare Advantage Management for local coverage determination and national coverage determination reference.
3/2020	Policy updated with literature review through March 1, 2020, no references added.
	Policy statements unchanged.
12/2015	Clarified coding information.
7/2014	Updated Coding section with ICD10 procedure and diagnosis codes. Effective
	10/2015.
5/2013	Annual policy review. New references added.
11/2011-4/2012	Medical policy ICD 10 remediation: Formatting, editing and coding updates. No
	changes to policy statements.
1/1/2012	New policy describing ongoing non-coverage. Effective 1/1/2011.

# Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:

Medical Policy Terms of Use

Managed Care Guidelines
Indemnity/PPO Guidelines
Clinical Exception Process
Medical Technology Assessment Guidelines

#### 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.
- 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.
- 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.
- 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 microremodeling 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.
- 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.
- 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.
- 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.
- California Technology Assessment Forum (CTAF). Radiofrequency Micro-remodeling for the Treatment of Female Stress Urinary Incontinence. Available online at: http://ctaf.org/assessments/radiofrequency-micro-remodeling-treatment-female-stress-urinary-incontinence. Last accessed January, 2013.
- 12. American College of Obstetricians and Gynecologists (ACOG). Urinary incontinence in women. Available online at: http://www.guidelines.gov/content.aspx?id=10931. Last accessed January, 2013.