



MASSACHUSETTS

Blue Cross Blue Shield of Massachusetts is an Independent Licensee 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](#)
- [Policy: Medicare](#)
- [Authorization Information](#)
- [Coding Information](#)
- [Description](#)
- [Policy History](#)
- [Information Pertaining to All Policies](#)
- [References](#)

Policy Number: 523

BCBSA Reference Number: 2.01.60A

NCD/LCD: Local Coverage Determination (LCD): Non-covered Services (L33629)

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**.

Medicare HMO BlueSM and Medicare PPO BlueSM Members

This is not a covered service.

Medical necessity criteria and coding guidance for **Medicare Advantage members living in Massachusetts** can be found through the link(s) below.

[Local Coverage Determinations \(LCDs\) for National Government Services, Inc.](#)

Local Coverage Determination (LCD): Non-covered Services (L33629)

Note: To review the specific LCD, please remember to click “accept” on the CMS licensing agreement at the bottom of the CMS webpage.

For medical necessity criteria and coding guidance for **Medicare Advantage members living outside of Massachusetts**, please see the Centers for Medicare and Medicaid Services website at <https://www.cms.gov> for information regarding your specific jurisdiction.

Prior Authorization Information

Inpatient

- For services described in this policy, precertification/preauthorization **IS REQUIRED** 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 not a covered service.
Commercial PPO and Indemnity	This is not a covered service.
Medicare HMO BlueSM	This is not a covered service.
Medicare PPO BlueSM	This is not 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 Commercial Members: Managed Care (HMO and POS), PPO, Indemnity, Medicare HMO Blue and Medicare PPO Blue:

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
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	New references from BCBSA National medical policy.
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, Korn 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.
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.
11. 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.