

Medical Coverage Policy | Transvaginal and
Transurethral Radiofrequency Tissue Remodeling for Urinary
Stress Incontinence



EFFECTIVE DATE: 02|07|2009

POLICY LAST UPDATED: 04|02|2020

OVERVIEW

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.

This policy is applicable to Commercial Products only. For Blue CHIP for Medicare, see related policy section.

MEDICAL CRITERIA

Not applicable

PRIOR AUTHORIZATION

Not applicable

POLICY STATEMENT

Commercial Products

Transvaginal radiofrequency bladder neck suspension and transurethral radiofrequency tissue remodeling is not medically necessary as the evidence is insufficient to determine the effects of the technology on health outcomes.

COVERAGE

Benefits may vary between groups/contracts. Please refer to the appropriate section of the Benefit Booklet or Subscriber Agreement for services not medically necessary.

BACKGROUND

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. At present, the literature and scientific evidence supporting the use of radiofrequency micro-remodeling by a transurethral, transvaginal, or paraurethral approach, (Renessa™ and similar devices) is insufficient. Therefore, these services are considered not medically necessary for Commercial products.

CODING

Commercial Products

Transurethral radiofrequency tissue remodeling:

The following code is considered not medically necessary for transurethral radiofrequency tissue remodeling:

53860 Transurethral, radiofrequency micro-remodeling of the female bladder neck and proximal urethra for stress urinary incontinence

Transvaginal radiofrequency bladder neck suspension:

There are no specific CPT codes describing the bladder neck suspension procedure. CPT code 53899 (unlisted procedure, urinary system) would be used.

RELATED POLICIES

BlueCHiP for Medicare National and Local Coverage Determinations

PUBLISHED

Provider Update, June 2020

Provider Update, June 2019

Provider Update, November 2018

Provider Update, September 2017

Provider Update, November 2016

Provider Update, April 2015

Provider Update, June 2014

Provider Update, May 2013

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):1028-3
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.

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