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

EFFECTIVE DATE: 02|17|2009
POLICY LAST UPDATED: 02|02|2015

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.

PRIOR AUTHORIZATION

Not applicable

POLICY STATEMENT

BlueCHiP for Medicare and Commercial

Transvaginal radiofrequency bladder neck suspension and Transurethral radiofrequency tissue remodeling as a treatment of urinary stress incontinence is not medically necessary as there is insufficient peer reviewed literature that demonstrates that these procedures are effective.

MEDICAL CRITERIA

None

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.

COVERAGE

Benefits vary between groups/contracts. Please refer to the appropriate Evidence of Coverage or Subscriber Agreement for applicable not medically necessary benefits/ coverage.

CODING

Blue CHiP for Medicare and Commercial

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

53860

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

None

PUBLISHED

Provider Update	Apr 2015
Provider Update	June 2014
Provider Update	May 2013
Provider Update	April 2012
Provider Update	April 2011
Provider Update	April 2010

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, 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.

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-femalestress- 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