Transvaginal and Transurethral Radiofrequency Tissue Remodeling for Urinary Stress Incontinence

Policy # 00254
Original Effective Date: 03/13/2010
Current Effective Date: 09/19/2018

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc.(collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Services Are Considered Investigational
Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers transvaginal radiofrequency (RF) bladder neck suspension as a treatment of urinary stress incontinence to be **investigational.***

Based on review of available data, the Company considers transurethral radiofrequency (RF) tissue remodeling as a treatment of urinary stress incontinence to be **investigational.***

Background/Overview

Radiofrequency 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.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)
In 2002, the SURx Transvaginal System received marketing clearance through the 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.

In 2005, Novasys Medical received clearance to market the Renessa transurethral RF system through the FDA 510(k) process. The device is indicated for the transurethral treatment of stress urinary incontinence due to hypermobility.

Centers for Medicare and Medicaid Services (CMS)
No national coverage determination.

Rationale/Source

Transvaginal Radiofrequency Remodeling

At the time this policy was created, the minimal published literature regarding the transvaginal RF bladder neck suspension was inadequate to permit scientific conclusions regarding the safety and long-term efficacy of this procedure. Dmochowski and colleagues reported on a multi-institutional prospective case series of 120 consecutive women with urinary stress incontinence who underwent transvaginal RF bladder neck suspension. Enrolled patients had failed at least a 3-month trial of conservative therapy, including most commonly, pelvic floor muscle exercises or pelvic floor stimulation. Follow-up examinations at 1, 3, 6, and 12 months consisted of a history, physical examination, and urodynamic studies. In addition, each patient completed a voiding diary and quality-of-life questionnaire. A cure was defined as a negative Valsalva maneuver; improvement was defined as decreased daily episodes of pad use. A total of 73% of patients were considered cured or improved at 12 months. More than 68% of patients reported satisfaction with the treatment. The authors concluded that the results were encouraging and that a 73% 12-month success rate suggested that this procedure had applicability for women with refractory incontinence who did not wish to undergo a more complicated surgical procedure. Ross and colleagues conducted a multicenter, prospective single-arm study that included 94 women with stress incontinence. At 1 year, the objective cure rate was 79%, based on a negative leak point pressure. Assessment of quality of life was also significantly improved. Larger controlled studies with longer follow-up were needed to further evaluate this procedure.

As noted in a review of laparoscopic bladder neck suspension, initial promising results at 12 months declined to a 30% success rate at 45 months. These authors suggested that any new surgical technique for the treatment of stress incontinence should have more than 2 years of follow-up.

Updated searches of the literature identified only case series. In 2007, Buchsbaum and colleagues published a retrospective follow-up of the transvaginal RF procedure in 18 patients, 11 with genuine stress urinary incontinence and 7 with mixed incontinence. At an unspecified time greater than 3 months following treatment, 6 of the 18 patients reported no urine loss and were satisfied with the outcome, 2 patients were lost to follow-up, and 10 reported continuing symptoms of incontinence. The relation between diagnosis (i.e., genuine stress-induced or mixed incontinence) and outcome was not presented.

Transurethral Radiofrequency Remodeling

The policy was expanded in 2006 to include transurethral RF remodeling. The 2006 literature search identified 2 publications from a single company-sponsored randomized controlled trial (RCT) of the transurethral RF procedure. Quality-of-life measures did not differ between the RF group (110 subjects) and the sham-control group (63 subjects) at 12 months; however, a subgroup analysis showed benefit in patients with moderate to severe stress urinary incontinence. The study was limited by the post hoc subgroup analysis, loss to follow-up of nearly 20%, and lack of investigator blinding. Longer-term follow-up, identification of the patient population that might benefit from the procedure, and independent replication were needed. In 2007, Appell and colleagues published 3-year follow-up data from the industry-sponsored study described above. Of 110 treated patients, 26 (24%) were available for evaluation; control subjects were not contacted. Of the 26, 5 had obtained other treatments and were not included in the analysis (not counted as failures). An additional 3 patients were not included since they had no episodes of incontinence at baseline. The authors reported that of the 18 (16%) included patients, 50% had reductions in incontinence episodes of greater than 50% (average of 3.5 daily incontinence episodes at baseline to 1.8 at 3 years after treatment). It should be noted that inclusion of all of the 26 subjects who had been contacted would result in a positive response rate of 38%. Interpretation of this study is limited due to the absence of the control group and inadequate numbers of treated patients in follow-up, along with excluding some patients from data analysis.

In 2009, Elser and colleagues published findings from an industry-sponsored prospective case series. This was a 36-month multicenter study of transurethral RF remodeling in 136 women with stress urinary incontinence caused by bladder outlet hypermobility who had failed nonsurgical treatment and were not candidates for surgical therapy. Exclusion criteria included urge incontinence or stress urinary incontinence caused by intrinsic sphincter deficiency. By 12 months, 25 patients withdrew consent, 19 were lost to follow-up, and 17 reported lack of response, resulting in 75 patients (55%) who were evaluated at the 12-month follow-up. Efficacy, based on the percentage of patients with a 50% or greater reduction from baseline in daily incontinence episodes, was reported in 68 (50%) patients. Of the 75 evaluated at 12 months, 69% (38% of 136) reported at least a 50% reduction in leaked urine (median of 15 g) from baseline, and 45% (25% of 136) were dry. One patient reported increased leaking. No serious adverse events were reported.

The most common adverse events at day 3 included dysuria (5%), urinary retention (4%), post-procedure pain (3%), and urinary tract infection (3%).

Eighteen-month and 3-year follow-up data have been published. Sixty-three of 136 (46%) women who received treatment completed the 18-month follow-up, and data were available on 60 women (44% of the study population). Thirty-one of the 60 evaluable women (61.7%) reported a reduction of at least 50% from baseline in leaks due to activity. In an intention-to-treat (ITT) analysis of data from all 136 participants (last observation carried forward), 46.7% reported at least a 50% reduction in leaks from baseline. A total of 41 women (30% of the study population) completed the 3-year follow-up evaluation. According to diary data, available for 39 women, 24 (62%) reported at least a 50% reduction in leaks per day. In an ITT analysis with multiple imputations of missing data, 60% of women had at least a 50% reduction in leaks. The study is limited by a low long-term follow-up rate and lack of a control or comparison group.

Summary

Transvaginal and transurethral radiofrequency tissue remodeling involves the use of nonablative levels of radiofrequency energy to shrink and stabilize the endopelvic fascia and are potential minimally invasive treatment options for urinary stress incontinence. There is 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.

References

1. Blue Cross and Blue Shield Association, Medical Policy Reference Manual, “Transvaginal and Transurethral Radiofrequency Tissue Remodeling for Urinary Stress Incontinence”, 2.01.60, 3:2013-Archived Policy.
2. 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.
3. 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.
4. McDougall EM, Heidorn CA, Portis AJ et al. Laparoscopic bladder neck suspension fails the test of time. J Urol 1999; 162(6):2078-81.
5. 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.
6. 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.
7. 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.
8. 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.
9. 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.
10. 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.

11. Elser DM, Mitchell GK, Miklos JR et al. Nonsurgical transurethral radiofrequency collagen denaturation: results at three years after treatment. Adv Urol 2011; 2011:872057.
12. 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.
13. 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.

Policy History

Original Effective Date: 03/13/2010
Current Effective Date: 09/19/2018

03/05/2010	Medical Policy Committee approval
03/19/2010	Medical Policy Implementation Committee approval. New policy.
04/07/2011	Medical Policy Committee approval
04/13/2011	Medical Policy Implementation Committee approval. No change to coverage.
04/12/2012	Medical Policy Committee review
04/25/2012	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
04/04/2013	Medical Policy Committee review
04/24/2013	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
03/06/2014	Medical Policy Committee review
03/19/2014	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
08/03/2015	Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed.
09/03/2015	Medical Policy Committee review
09/23/2015	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
09/08/2016	Medical Policy Committee review
09/21/2016	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/01/2017	Coding update: Removing ICD-9 Diagnosis Codes
09/07/2017	Medical Policy Committee review
09/20/2017	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
09/06/2018	Medical Policy Committee review
09/19/2018	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 09/2019

Coding

The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2017 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

The responsibility for the content of Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines is with Blue Cross and Blue Shield of Louisiana and no endorsement by the AMA is intended or should be implied. The AMA disclaims responsibility for any consequences or liability attributable or related to any use, nonuse or interpretation of information contained in Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense

medical services. The AMA assumes no liability for data contained or not contained herein. Any use of CPT outside of Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines should refer to the most current Current Procedural Terminology which contains the complete and most current listing of CPT codes and descriptive terms. Applicable FARS/DFARS apply.

CPT is a registered trademark of the American Medical Association.

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	53860, 53899
HCPCS	No codes
ICD-10 Diagnosis	N39.3

*****Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. FDA and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
    2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    3. Reference to federal regulations.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.