BlueCross BlueShield of Alabama

Name of Policy:

Transvaginal and Transurethral Radiofrequency Tissue Remodeling for Urinary Stress Incontinence

Policy #: 296
Category: Medicine

Latest Review Date: March 2013
Policy Grade: B

Background/Definitions:

As a general rule, benefits are payable under Blue Cross and Blue Shield of Alabama health plans only in cases of medical necessity and only if services or supplies are not investigational, provided the customer group contracts have such coverage.

The following Association Technology Evaluation Criteria must be met for a service/supply to be considered for coverage:

1. *The technology must have final approval from the appropriate government regulatory bodies;*
2. *The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes;*
3. *The technology must improve the net health outcome;*
4. *The technology must be as beneficial as any established alternatives;*
5. *The improvement must be attainable outside the investigational setting.*

Medical Necessity means that health care services (e.g., procedures, treatments, supplies, devices, equipment, facilities or drugs) that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury or disease or its symptoms, and that are:

1. *In accordance with generally accepted standards of medical practice; and*
2. *Clinically appropriate in terms of type, frequency, extent, site and duration and considered effective for the patient's illness, injury or disease; and*
3. *Not primarily for the convenience of the patient, physician or other health care provider; and*
4. *Not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.*

Description of Procedure or Service:

Radiofrequency energy is a commonly used surgical tool that has been used for tissue ablation and more recently for tissue remodeling. For example, radiofrequency energy has been investigated as a treatment of gastroesophageal reflux disease (GERD), i.e., the Stretta procedure, where radiofrequency lesions are designed to alter the biomechanics of the lower esophageal sphincter. Radiofrequency energy has also been used in orthopedic procedures to remodel the joint capsule or in the intradiscal electrothermal annuloplasty (IDET) procedure where the treatment is intended in part to modify and strengthen the disc annulus. In all of these procedures, non-ablative levels of radiofrequency thermal energy are used to alter collagen fibrils, which then result in a healing response characterized by fibrosis. Recently, radiofrequency energy has been explored as a minimally invasive treatment option for urinary stress incontinence.

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 United States. Conservative therapy includes pelvic floor muscle exercises, biofeedback, pelvic electrical stimulation, or periurethral bulking agents such as collagen. Various surgical options are considered when conservative therapy fails, including most prominently various different types of bladder suspension procedures, which intends to reduce bladder neck and urethra hypermobility by tautening 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 radiofrequency energy has been investigated as a technique to shrink and stabilize the endopelvic fascia, thus improving the support for the urethra and bladder neck. The SURx Transvaginal System is a radiofrequency device that has been specifically designed as a transvaginal treatment of urinary stress incontinence that can be performed as an outpatient procedure under general anesthesia. An incision is made 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. This procedure is similar in concept to thermal capsulorrhaphy as a treatment of shoulder instability. The Renessa procedure (Novasys Medical) induces collagen denaturation in the urethra with a specially designed four needle radiofrequency probe. It does not require an incision and can be performed in an outpatient or office setting under local anesthesia. As of 2006, the SURx is no longer marketed in the United States.

The SURx Transvaginal System received clearance to market through the U.S. Food and Drug Administration (FDA 510(k)) process in 2002. 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".

Novasys Medical received clearance to market the Renessa transurethral RF system through the U.S. Food and Drug Administration 510(k) process in 2005. The device is indicated for the transurethral treatment of stress urinary incontinence due to hypermobility.

Policy:

Transvaginal radiofrequency bladder neck suspension and/or transurethral radiofrequency tissue remodeling as a treatment of urinary stress incontinence **do not** meet Blue Cross and Blue Shield of Alabama's medical criteria for coverage and are considered **investigational**.

Blue Cross and Blue Shield of Alabama does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Cross and Blue Shield of Alabama administers benefits based on the members' contract and corporate medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

Key Points:

Transvaginal Radiofrequency Procedure

The minimal published literature regarding transvaginal radiofrequency bladder neck suspension is inadequate to permit scientific conclusions regarding the safety and long-term efficacy of this procedure. Some of the articles are summarized below.

Dmochowski et al (2003), reported on a multi-institutional prospective case series of 120 consecutive women with urinary stress incontinence who underwent transvaginal radiofrequency 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. At 12 months, 73% of patients were considered cured or improved. More than 68% of patients reported satisfaction with the treatment. The authors conclude that the results are encouraging and that a 73% 12 month success rate suggests that this procedure has applicability for women with refractory incontinence. They also stated that ongoing analysis of the data has indicated opportunities for improvement of this new surgical technique that could result in higher efficacy rates without compromising safety. Further long-term evaluation is being conducted to assess chronic durability of this procedure.

Ross, et al (2002), reported on a multicenter, prospective, single-arm, longitudinal study of 94 women undergoing laparoscopic treatment for genuine stress incontinence (GSI). Patients underwent RF bipolar treatment of paravaginal tissue to induce tissue shrinkage causing bladder neck elevation. At one year, the objective cure rate was 79% based on a negative leak point pressure, and improvement in quality of life by questionnaire was 81%, and patient satisfaction was 83%. The authors concluded that this procedure appears to be a safe and efficient means to treat mild to moderate GSI, but long-term follow-up is necessary.

McDougall, et al (1999), reported on a study that compared long-term success rates of laparoscopic and transvaginal Raz bladder neck suspension. The results showed that at a mean of 45 months follow-up, only 30% of the laparoscopy group and 35% of the transvaginal group were completely continent. These authors suggested that any new surgical technique for treatment of stress urinary incontinence should have a mean follow-up of more than two years to determine true clinical efficacy.

More recently, two small retrospective studies were published to assess the outcomes of transvaginal radiofrequency for the treatment of women with stress incontinence.

Buchsbaum, et al (2007), reported on a retrospective chart review of 18 women (11 with genuine SUI and 7 with mixed incontinence) who were treated with the transvaginal RF procedure and noted a low cure rate and low patient satisfaction. They reported that post-op, two patients were continent, four were improved, and 10 were unimproved. They also reported that five patients were extremely satisfied, one patient was satisfied, and 10 patients were not satisfied with the results. There were seven patients who sought additional treatment within one year. The authors noted that the low cure rate, low patient satisfaction, and high rate of additional treatment led them to discontinue this transvaginal RF procedure.

Ismail (2008) reported on a study of 24 patients who were treated with the transvaginal radiofrequency remodeling for SUI and demonstrated low effectiveness. A rising failure rate was noted at three months post-op. At 12 months, the cumulative cure rate was 45.8% and the reoperation rate was 37.5%. These researchers have also discontinued this procedure as a treatment option.

Transurethral Radiofrequency Procedure
There are a few recently published studies evaluating the transurethral RF tissue micro-remodeling procedure to treat SUI. Some of these studies are summarized below.

Sotomayor, et al (2005), reported on a pilot clinical trial that analyzed the outcomes of four different treatment regimens using transurethral RF micro-remodeling in 41 women with SUI. The results showed the incidence of quality of life score improvement at 12 months ranged from 75% to 78%, and statistically significant incontinence episode frequency reduction was demonstrated by three of four treatment groups. At 12 months, the procedure demonstrated safety, quality of life improvement, and incontinence episode frequency reduction. The authors noted that this trial was not controlled, there were few subjects in any one treatment group, and diagnosis and follow-up evaluation lacked urodynamic testing. This study was sponsored by Novasys Medical, Inc., the company that makes the RF device.

Appell et al (2006), reported on a randomized, controlled clinical trial that evaluated the safety and efficacy of transurethral RF collagen micro-remodeling in women with SUI. There were 110 women who underwent RF micro-remodeling and 63 who underwent sham treatment. The results showed 74% of women with moderate to severe baseline SUI had a statistically significant improvement in quality of life. This study is limited by the post-hoc subgroup analysis, loss to follow-up of nearly 20%, and lack of investigator binding. This study was sponsored by Novasys Medical, Inc., the company that makes the RF device.

Appell, et al (2007), reported on a three year retrospective study on the long-term safety and efficacy of transurethral radiofrequency collagen denaturation to treat SUI due to bladder outlet hypermobility. The original 12-month study was conducted in 173 women and is previously summarized. This two-year extension evaluated only 21 patients at three or more years post-treatment. The results showed the mean I-QOL score improvement at three years was 12.7 (± 26) and 56% of patients achieved a 50% or greater reduction in frequency at three years. There were no new adverse events reported. This study was sponsored by Novasys Medical, Inc., the company that makes the Renessa system.

Lenihan et al (2005), reported on a retrospective review that looked at the effect of menopause and hormone replacement therapy in women with moderate to severe SUI after transurethral RF tissue micro-remodeling. The results showed RF micro-remodeling resulted in 81% of subjects achieving 10 point or greater I-QOL score improvement vs. 49% of sham subjects at 12 months. Outcomes did not differ statistically when premenopausal (85%), post-menopausal using HRT (70%), and post-menopausal not using HRT (71%) groups were compared. This study was sponsored by Novasys Medical, Inc., the makers of the RF micro-remodeling probe.

Lenihan et al (2005), reported on the feasibility, safety, and patient comfort associated with non-surgical RF tissue micro-remodeling in women with SUI given oral and local anesthesia. Sixteen women underwent the procedure using oral plus local anesthesia without IV sedation. Two patients experienced nausea and vomiting when drinking immediately after treatment, and one of these patients had urinary retention. Just before discharge, the patients classified their pain on a scale from 0 (no pain) to 10 (terrible pain). The mean score was 1.8, with 38% selecting 0. This was a small study group and was supported by Novasys Medical, Inc., the company that makes the Renessa system.

Wells et al (2007), reported on the use of an oral sedation and local anesthetic regimen in performing RF collagen denaturation. This study enrolled 33 women with SUI due to hypermobility. They were pretreated with an oral sedative (diazepam) and lidocaine. Then, transurethral RF collagen denaturation was performed in the office. The mean VAS pain score prior to discharge was 1.4 (range 0-6), with 42% of women rating their pain as 0. This research was supported by Novasys Medical, Inc., the maker of Renessa.

Elser et al (2008), reported the 12-month results of a continuing, prospective 36-month clinical trial. Women with SUI secondary to bladder outlet hypermobility for 12 months or longer and had failed earlier conservative treatment and had not received earlier surgical or bulking agent therapy were treated with the Renessa procedure. There were 136 women who underwent the procedure and 75 patients were evaluable at 12 months. The results showed 50% (68 patients) experienced a 50% or greater reduction versus baseline in number of leaks caused by activity/day and activity/week. Stress pad weight tests showed that 69% of women had 50% or more reduction in leaked urine; 45% were dry; 29% had no leaks. The I-QOL (Incontinence Quality of Life) scores showed significant improvement at 12 months, with 50.3% of patients reporting a $\geq$ 10 point improvement. UDI-6 (Urogenital Distress Inventory) scores showed that 61.8% of patients reported any improvement. The PGI-I scores showed that at 12 months, 50% of patients reported their SUI symptoms were better. The authors concluded that these are the 12 month

results of a 36-month trial of Renessa. Continuing evaluation of this study population during a 36-month period will further assess the long-term durability of this treatment.

Larger studies with long-term follow-up, identification of the patient population that might benefit from the procedure and independent replication are needed. There is minimal evidence within the peer-reviewed literature that provides support for the use of transvaginal radiofrequency surgery or transurethral radiofrequency tissue micro-remodeling. The efficacy and long-term effectiveness of these modalities for the treatment of urinary incontinence has not been determined. Transvaginal and transurethral RF treatment for stress urinary incontinence are considered investigational.

2010 Update
There remains 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 United States. Thus, the policy statements are unchanged; the treatments remain investigational.

2011 Update
Eighteen month follow-up data were published in 2010. 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. The 60 evaluable patients reported a median improvement of 9.5 stress leaks per week. High drop-out rate and lack of a control or comparison group are limitations of this study.

2012 Update
The 36 month followup data has now been published from the Elser et al study. A total of 41 women (30% of the study population) completed the three-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.

2013 Update
No new information available.

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 still remains 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. Thus, the policy statements are unchanged and the treatments remain investigational.

Practice Guidelines and Position Statements
In 2008, the California Technology Assessment Forum (CTAF) completed a review of radiofrequency remodeling for the treatment of female stress urinary incontinence. The evidence for SURx was found to not meet the CTAF criteria. The evidence for Renessa consisted of the single industry-sponsored randomized, controlled trial with 12-month follow-up and post-hoc analysis (reviewed above, reference 8) and two observational pilot studies. The CTAF Assessment concluded that although the benefits are clearly not as great as with the available gold standard (i.e., surgical approaches), the benefit-to-risk ratio was favorable for transurethral radiofrequency remodeling and did provide options for women with stress urinary incontinence, particularly for those not eligible for surgical intervention.

The American College of Obstetricians and Gynecologists' (ACOG) recommendations on treating urinary incontinence in women (reaffirmed in 2009) do not mention transvaginal or transurethral radiofrequency remodeling.

Key Words:
Transvaginal radiofrequency bladder neck suspension, transurethral radiofrequency tissue remodeling, urinary stress incontinence

Approved by Governing Bodies:
The SURx Transvaginal System received clearance to market through the U.S. Food and Drug Administration (FDA) 510(k) process in 2002. 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".

Novasys Medical received clearance to market the Renessa transurethral RF system through the U.S. FDA 510(k) process in July 2005. The device "is indicated for the transurethral treatment of female stress urinary incontinence due to hypermobility in women who have failed conservative treatment and who are not candidates for surgical therapy".

Benefit Application:
Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

ITS: Home Policy provisions apply
FEP does not consider investigational if FDA approved. Will be reviewed for medical necessity.
Pre-certification requirements: Not applicable

Current Coding:

CPT Codes:	**53899**	Unlisted procedure, urinary system
	53860	Transurethral radiofrequency micro-remodeling of the female bladder neck and proximal urethra for stress urinary incontinence **(Effective 01/01/11)**

Previous Coding:

	0193T	Transurethral, radiofrequency micro-remodeling of the female bladder neck and proximal urethra for stress urinary incontinence **(Effective 01/01/09) (Deleted January 1, 2011)**

References:

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Policy History:

Medical Policy Group, December 2006
Medical Policy Administration Committee, January 2007
Available for comment January 30-March 8, 2007
Medical Policy Group, January 2009
Medical Policy Group, March 2010 **(3)**
Medical Policy Group, December 2010 – 2011 Code updates
Medical Policy Group, July 2011; Key Points & References
Medical Policy Group March 2012**(3)**: 2012 Update to Key Points & References
Medical Policy Panel, March 2013

Medical Policy Group, March 2013 **(3)**: 2013 Update to Key Points; no change in policy statement

This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member's plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield's administration of plan contracts.