Transvaginal and Transurethral Radiofrequency Tissue Remodeling for Urinary Stress Incontinence

Policy # 00254
Original Effective Date: 03/13/2010
Current Effective Date: 09/11/2019

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 (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.

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.

**Rationale/Source**

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
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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.

Supplemental Information
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 and 2 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.

Medicare National Coverage
No national coverage determination.

References

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03/05/2010 Medical Policy Committee approval
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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
09/08/2016 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.
09/05/2019 Medical Policy Committee review

Next Scheduled Review Date: 09/2020

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