Medical Coverage Policy

Transvaginal and Transurethral Radiofrequency Tissue Remodeling for Urinary Stress Incontinence

❑ Device/Equipment  ❑ Drug  ❑ Medical  ❑ Surgery  ❑ Test  ❑ Other

Effective Date: 2/17/2009  Policy Last Updated: 2/7/2012

❑ Prospective review is recommended/required. Please check the member agreement for preauthorization guidelines.

❑ Prospective review is not required.

Description:
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), in orthopedic procedures to remodel the joint capsule, or in intradiscal electrothermal annuloplasty (IDET) procedure. In all of these procedures, nonablative 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 which affects 6.5 million women in the United States.

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. Two radiofrequency devices have been specifically designed for the treatment of urinary stress incontinence, which may be performed as outpatient procedures under general anesthesia. With the SURx Transvaginal System, 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. The Renessa® procedure (Novasys Medical) induces collagen denaturation in the urethra with a specially designed 4 needle radiofrequency probe.

The minimal published literature regarding both transvaginal radiofrequency bladder neck suspension is inadequate to permit scientific conclusions regarding the safety and long-term efficacy of this procedure. In 2008 the California Technology Assessment Forum completed a review of radiofrequency remodeling for the treatment of female stress urinary incontinence. The evidence for the Renessa® consisted of a single industry-sponsored randomized controlled trial with a one year follow-up and post-hoc analysis; and two observational pilot studies. The assessment concluded that the Renessa® may provide options for women with stress urinary incontinence, especially those not eligible for surgical intervention. However the outcomes of the Renessa® are clearly not as great as with the available gold standard (surgical approaches). The evidence for SURx did not meet the California Technology Assessment Forum criteria. Further research is needed.

Medical Criteria:
Not applicable.

Policy:
Transvaginal and transurethral radiofrequency tissue remodeling for urinary stress incontinence is considered **not medically necessary** as the published literature regarding both transvaginal radiofrequency bladder neck suspension is inadequate to permit scientific conclusions regarding the safety and long-term efficacy of this procedure.

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

**Coding:**
The following code should be used for transurethral radiofrequency tissue remodeling:

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

The following code should be used for all other procedures:

**53899 Unlisted procedure, urinary system**

**Also Known As:**
Renessa®
SURx®

**Published:**
Provider Update, April 2010
Provider Update, April 2011
Provider Update, April 2012

**References:**


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