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



**EFFECTIVE DATE:** 02 | 07 | 2009

POLICY LAST REVIEWED: 03 | 20 | 2024

### **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.

#### **MEDICAL CRITERIA**

Not applicable

# **PRIOR AUTHORIZATION**

Not applicable

### **POLICY STATEMENT**

# Medicare Advantage Plans

Transvaginal radiofrequency bladder neck suspension and transurethral radiofrequency tissue remodeling is not covered as the evidence is insufficient to determine the effects of the technology on health outcomes.

#### **Commercial Products**

Transvaginal radiofrequency bladder neck suspension and transurethral radiofrequency tissue remodeling is not medically necessary as the evidence is insufficient to determine the effects of the technology on health outcomes.

# **COVERAGE**

Benefits may vary between groups/contracts. Please refer to the appropriate section of the Benefit Booklet or Subscriber Agreement for services not medically necessary.

### **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.

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. At present, the literature and scientific evidence supporting the use of radiofrequency micro-remodeling by a transurethral, transvaginal, or paraurethral approach, (Renessa<sup>TM</sup> and similar devices) is insufficient.

### **CODING**

Transurethral radiofrequency tissue remodeling:

The following code is not covered for Medicare Advantage Plans and considered not medically necessary for Commercial Products for transurethral radiofrequency tissue remodeling:

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

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, May 2024 Provider Update, June 2023 Provider Update, July 2022 Provider Update, March 2021 Provider Update, June 2020

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