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

EFFECTIVE DATE: 02|07|2009
POLICY LAST UPDATED: 05|18|2022

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.

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. At present, the literature and scientific evidence supporting the use of radiofrequency micro-remodeling by a transurethral, transvaginal, or paraurethral approach, (Renessa™ 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

Not applicable

PUBLISHED

Provider Update, July 2022
Provider Update, March 2021
Provider Update, June 2020
Provider Update, June 2019
Provider Update, November 2018

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