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Reviewed: 05/23/24

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Subject: Transvaginal Radiofrequency Bladder Neck Suspension and Transurethral Radiofrequency Tissue Remodeling for Urinary Stress Incontinence

THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS MEDICAL COVERAGE GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.

DESCRIPTION:

Radiofrequency (RF) tissue remodeling with specially designed devices has been investigated 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 is defined as the involuntary loss of urine. Treatment for SUI includes conservative therapy and surgery. Conservative therapy includes pelvic floor muscle exercises, biofeedback, pelvic electrical stimulation, or periurethral bulking agents such as collagen. Various surgical options (e.g., bladder suspension) are considered when conservative therapy fails. 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; transvaginal and transurethral radiofrequency.

The SURx Transvaginal System® is a radiofrequency device that has been specifically designed as a transvaginal treatment of stress urinary incontinence (SUI) 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. In 2002, the SURx Transvaginal System received marketing clearance through the U.S. Food and Drug Administration (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.

The Novasys Transurethral RF System (Renessa® System, Novasys Medical, Inc.) procedure involves passing a small probe through the urethra. The treatment can be performed in the physician's office or other outpatient setting. There are no incisions and bandages and dressings are not required. The Renessa® procedure uses radiofrequency energy (RF) to generate controlled heat at low temperatures in tissue targets within the lower urinary tract. The heat denatures collagen in the tissue at multiple small treatment sites. In 2005, Novasys Medical received clearance to market the Novasys Transurethral RF system (Renessa through the U.S. Food and Drug Administration (FDA) 510(k) process). 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.

Summary and Analysis of Evidence: An UpToDate review "Female urinary incontinence: Treatment" (Lukacz) states that "Transurethral radiofrequency collagen denaturation has been proposed as a minimally invasive device-based intervention to treat urinary incontinence. A systematic review and meta-analysis were able to find only one trial of 173 women that assessed this technology and concluded that it was not known if radiofrequency denaturation improved urinary incontinence symptoms because that outcome was not assessed. In addition, the meta-analysis concluded that there was insufficient evidence to determine if the procedure improved disease-specific quality of life." Limited data are available for transurethral radiofrequency collagen denaturation. The safety and long-term efficacy of transvaginal radiofrequency bladder neck suspension and transurethral radiofrequency tissue remodeling (e.g., Renessa®) on health outcomes is limited; randomized controlled studies with longer follow-up are needed.

POSITION STATEMENT:

Transvaginal radiofrequency bladder neck suspension (e.g., SURx) is considered **experimental or investigational**, as there is limited evidence in the published peer-reviewed literature that supports the use of transvaginal radiofrequency bladder neck suspension as a treatment for female stress urinary incontinence. The safety and long-term efficacy of transvaginal radiofrequency bladder neck suspension on health outcomes is limited, randomized controlled studies with longer follow-up are needed.

Transurethral radiofrequency tissue remodeling (e.g., Renessa®) is considered **experimental or investigational**, as there is limited evidence in the published peer-reviewed literature that supports the use of transurethral radiofrequency tissue remodeling (e.g., Renessa®) as a treatment for female stress urinary incontinence. The safety and long-term efficacy of transurethral radiofrequency tissue remodeling (e.g., Renessa®) on health outcomes is limited; randomized controlled studies with large sample size and longer follow-up are needed.

BILLING/CODING INFORMATION:

CPT Coding:

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

REIMBURSEMENT INFORMATION:

Refer to section entitled **POSITION STATEMENT**.

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Advantage products: No National Coverage Determination (NCD) and/or Local Coverage Determination (LCD) were found at the time of the last guideline reviewed date.

DEFINITIONS:

No guideline specific definitions apply.

RELATED GUIDELINES:

None applicable.

OTHER:

Other names used to report transvaginal radiofrequency bladder neck suspension for urinary stress incontinence:

Lyrette System™ (transurethral stress urinary incontinence system)

SURx procedure

Transvaginal radiofrequency

Transurethral radiofrequency energy therapy (Renessa® System)

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COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy and Coverage Committee on 05/23/24.

GUIDELINE UPDATE INFORMATION:

05/15/04	New Medical Coverage Guideline.
12/15/04	Scheduled review. No change in investigational status, updated references.
01/01/06	Scheduled review. No change in investigational status. Added FDA information to description for SURx transvaginal system. Updated references.
09/15/06	Scheduled review. No change in investigational status. Updated references.
07/15/07	Annual review, investigational status maintained, description section updated, guideline reformatted, references updated.
10/15/08	Scheduled review. No change in transvaginal radiofrequency bladder neck suspension position statement. Updated title to include the text: and Transurethral Radiofrequency Tissue Remodeling. Added position statement (experimental or investigational) for transurethral radiofrequency tissue remodeling as a treatment or urinary stress incontinence. Updated references.
01/01/09	Annual HCPCS coding update: added 0193T.
08/15/09	Annual review, experimental or investigational status maintained. Revised description and position statement. Added Medicare program exception. Updated references.
08/15/10	Annual review. Updated references.
01/01/11	Annual HCPCS coding update: deleted 0193T. Added 53860. Revised Medicare Advantage products program exception.
08/15/11	Scheduled review; maintain experimental or investigational position statement. Updated references.
09/15/12	Scheduled review; position statements maintained; description section and references updated.
12/15/13	Scheduled review. No change in position statement. Added Medicare Advantage products program exception. Updated references.
11/01/15	Revision: ICD-9 Codes deleted.
09/15/17	Review; no change in position statement. Updated references.

03/15/18	Review; no change in position statement. Updated references
04/15/21	Review; no change in position statement.
06/15/23	Review; no change in position statement. Updated references.
06/15/24	Review; no change in position statement. Updated references.