Policy Number	**SUR710.021**
Policy Effective Date	**5/7/2026**

Radiofrequency Energy Therapy for Stress Urinary Incontinence

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Related Policies (if applicable)
None

Disclaimer

Carefully check state regulations and/or the member contract.
Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

Coverage

Transvaginal radiofrequency bladder neck suspension as a treatment of stress urinary incontinence **is considered experimental, investigational and/or unproven.**

Transurethral radiofrequency tissue remodeling as a treatment of SUI **is considered experimental, investigational and/or unproven.**

Endovaginal cryogen-cooled, monopolar radiofrequency remodeling (e.g., Viveve® System) as a treatment of SUI **is considered experimental, investigational and/or unproven.**

Policy Guidelines

None.

Description

Stress urinary incontinence, defined as the involuntary loss of urine from the urethra due to an increase in intra-abdominal pressure and is the most common type of urinary incontinence in women. Conservative therapy includes pelvic floor muscle exercises, pessary devices, behavioral therapy, biofeedback, pelvic electrical stimulation, or periurethral bulking agents such as collagen. 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. (1) For example, for colposuspension (i.e., the Burch procedure), sutures are placed intravaginally on either side of the urethra and fixed to supportive ligaments therefore elevating the vagina and supporting the urethra. (2)

The use of nonablative levels of 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. RF devices have been specifically designed for the treatment of SUI, which may be performed as an outpatient procedure.

SURx® Transvaginal System
This procedure involves making an incision through the vagina lateral to the urethra, exposing the endopelvic fascia. RF energy is then applied over the endopelvic fascia in a slow sweeping manner, resulting in blanching and shrinkage of the tissue.

Lyrette™ Transurethral SUI System (Previously Known as Renessa)
This transurethral radiofrequency collagen denaturation procedure involves passing a specially designed 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. Controlled RF energy is applied through the probe RF 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 to remodel the damaged collagen. (3)

Cryogen-Cooled, Monopolar Radiofrequency Remodeling (e.g., Viveve® System)
The Viveve® System, a monopolar radiofrequency remodeling device for SUI, involves placement of a probe into the vagina that emits cryogen-cooled RF energy. The intention is for the cryogen cooling to protect the tissue from damage while the RF energy delivers energy into the tissue resulting in coagulation and/or hemostasis. (4)

Regulatory Status
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 SUI due to hypermobility in women not eligible for major corrective surgery." (5) As of 2006, the SURx is no longer marketed in the U.S. Product code: MUK. (6)

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 SUI due to hypermobility. (7) In 2013, Verathon acquired Renessa® by Novasys Medical®, and rebranded it as the Lyrette™ transurethral SUI system. Product code: NVJ.

In January 2020, the Viveve® System received FDA clearance under the 510(k) premarket approval process "for use in general surgical procedures for electrocoagulation and hemostasis"; This device is not currently cleared specifically for treatment of urinary incontinence. Product code: GEI. (4)

Rationale

This medical policy is based on Professional Society Guidelines. In addition, the U.S. Food and Drug Administration issued a warning in July 2018 regarding the safety and effectiveness of energy-based devices, including radiofrequency, for indications such as urinary incontinence and vaginal rejuvenation, further discouraging the use of this technology for urinary incontinence. (8)

Practice Guidelines and Position Statements
American Urological Association/Society of Urodynamics and Female Pelvic Medicine & Urogenital Reconstruction
In 2023, the AUA/SUFU updated their recommendations on the surgical treatment of females with stress urinary incontinence (SUI). (9) The AUA/SUFU guideline focuses on established evidence-based treatments (e.g., conservative therapies, urethral bulking agents, and mid-urethral slings) that have robust evidence of efficacy and long-term safety. The guideline does not include transvaginal/transurethral RF remodeling or endovaginal cryogen-cooled monopolar RF remodeling as a treatment option for individuals with SUI. The lack of inclusion in these primary guidelines suggest that these procedures do not meet the necessary criteria for standard of care due to insufficient clinical evidence.

American Urogynecologic Society
In 2022, the AUGS published an evidence-based consensus statement specific to vaginal EBDs. (10) The AUGS was in consensus that the overall efficacy of EBD therapy compared with pelvic floor exercise or mid-urethral slings for the treatment of SUI has not yet fully

been elucidated (Statement Q16). Prospective case series and placebo/sham-controlled studies on EBD have shown conflicting results and there is no evidence that RF offers any significant benefit. Clinical trials comparing EBD therapy with standard of care treatment modalities such as pelvic floor exercises or mid-urethral slings in women with SUI are lacking.

In addition, the AUGS acknowledged the FDA's 2018 prior safety warning about the use of EBDs and emphasized that the FDA has not approved their use for any specific gynecologic indication.

National Institute for Health and Care Excellence

In 2021, NICE published guidance related to the use of transvaginal laser therapy for individuals with SUI. (11) Guidance indicates that the evidence on long-term safety and efficacy is inadequate in quality and quantity. Therefore, this procedure should only be used in the context of research. NICE recommends further research should report long-term safety and efficacy outcomes, the type of laser and energy used, treatment protocols, and patient selection including age, menopausal status, and severity of SUI.

American College of Obstetricians and Gynecologists

In 2020, the ACOG noted that the FDA's 2018 safety communication warns against the use of EBDs (commonly RF or laser) to perform vaginal "rejuvenation," cosmetic vaginal procedures, or nonsurgical vaginal procedures to treat symptoms related to menopause, urinary incontinence, or sexual function. (12) Prospective studies that use validated measures of quality of life, body image, and sexual function are needed to understand the true benefits and harms of these procedures as the FDA has not cleared or approved any EBDs for the treatment of vaginal symptoms related to menopause, urinary incontinence or sexual function.

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	53860, 53899, 0672T
HCPCS Codes	None

*Current Procedural Terminology (CPT®) ©2025 American Medical Association: Chicago, IL.

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Centers for Medicare & Medicaid Services

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare & Medicaid Services does not have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been developed since this medical policy document was written. See Medicare's National Coverage at cms.hhs.gov.

Policy History/Revision

Date	Description of Change
TBD	New medical document. Transvaginal radiofrequency bladder neck suspension as a treatment of stress urinary incontinence (SUI) is considered experimental, investigational and/or unproven. Transurethral radiofrequency tissue remodeling as a treatment of SUI is considered experimental, investigational and/or unproven. Endovaginal cryogen-cooled, monopolar radiofrequency remodeling (e.g., Viveve® System) as a treatment of SUI is considered experimental, investigational and/or unproven.