Policy Number	**SUR710.021**
Policy Effective Date	**04/01/2025**
Policy End Date	**12/31/2025**

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 (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.**

Policy Guidelines

None.

Description

Stress urinary incontinence (SUI), 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 (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. 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. (3) Product code: NVJ. (7)

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 policy was originally created in 2005 and has been updated regularly with searches of the PubMed database. The most recent literature search was performed through February 9, 2024. Following is a summary of the key literature to date.

Medical policies assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function-including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, two domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Transvaginal Radiofrequency Remodeling (e.g., SURx® Transvaginal System)
Dmochowski and colleagues reported on a multi-institutional prospective case series of 120 consecutive women with urinary stress incontinence who underwent transvaginal RF bladder neck suspension. (8) Enrolled patients had failed at least a 3-month trial of conservative

therapy, including pelvic floor muscle exercises or pelvic floor stimulation. Follow-up examinations at 1, 3, 6, and 12 months consisted of a history, physical examination, and urodynamic studies. In addition, each patient completed a voiding diary and quality of life questionnaire. A cure was defined as a negative Valsalva maneuver; improvement was defined as decreased daily episodes of pad use. A total of 73% of patients were considered cured or improved at 12 months. More than 68% of patients reported satisfaction with the treatment. The authors concluded that the results were encouraging and that a 73% 12-month success rate suggested that this procedure had applicability for women with refractory incontinence who did not wish to undergo a more complicated surgical procedure, although this study was limited by its lack of a comparison group.

Ross and colleagues conducted a multicenter, prospective single-arm study that included 94 women with stress incontinence. (9) At 1 year, the objective cure rate was 79%, based on a negative leak point pressure. Assessment of quality of life was also significantly improved. Larger controlled studies with longer follow-up were needed to further evaluate this procedure. As noted in a review of laparoscopic bladder neck suspension, initial promising results at 12 months declined to a 30% success rate at 45 months. (10) These authors suggested that any new surgical technique for the treatment of stress incontinence should have more than 2 years of follow-up.

In 2007, Buchsbaum et al. published a retrospective follow-up of the transvaginal RF procedure in 18 patients, 11 with genuine stress urinary incontinence (SUI) and 7 with mixed incontinence. (11) At an unspecified time, greater than 3 months following treatment, 6 of the 18 patients reported no urine loss and were satisfied with the outcome, 2 patients were lost to follow-up, and 10 reported continuing symptoms of incontinence. The relation between diagnosis (i.e., genuine stress-induced or mixed incontinence) and outcome was not presented.

UpToDate

In 2023, UpToDate (12) evaluated available treatment options for female urinary incontinence; transvaginal radiofrequency remodeling was not specifically mentioned.

Transurethral Radiofrequency Remodeling (e.g., Lyrette™ Transurethral SUI System; Previously Known as Renessa)

The policy was expanded in 2006 to include transurethral RF remodeling, also known as transurethral radiofrequency collagen denaturation. The 2006 literature search identified 2 publications from a single company sponsored RCT of the transurethral RF procedure. (13, 14) Quality of life measures did not differ between the RF group (110 subjects) and the sham-control group (63 subjects) at 12 months; however, a subgroup analysis showed benefit in patients with moderate to severe SUI. The study was limited by the post hoc subgroup analysis, loss to follow-up of nearly 20%, and lack of investigator blinding. Longer-term follow-up, identification of the patient population that might benefit from the procedure and independent replication is needed.

In 2007, Appell and colleagues published 3-year follow-up data from the industry-sponsored study described above. (15) Of 110 treated patients, 26 (24%) were available for evaluation; control subjects were not contacted. Of the 26, 5 had obtained other treatments and were not included in the analysis (not counted as failures). An additional 3 patients were not included since they had no episodes of incontinence at baseline. The authors reported that of the 18 (16%) included patients, 50% had reductions in incontinence episodes of greater than 50% (average of 3.5 daily incontinence episodes at baseline to 1.8 at 3 years after treatment). It should be noted that inclusion of all of the 26 subjects who had been contacted would result in a positive response rate of 38%. Interpretation of this study is limited due to the absence of the control group and inadequate numbers of treated patients in follow-up, along with excluding some patients from data analysis.

In 2009, Elser and colleagues published findings from an industry-sponsored prospective case series. (16) This was a 36-month multicenter study of transurethral RF remodeling in 136 women with SUI caused by bladder outlet hypermobility who had failed nonsurgical treatment and were not candidates for surgical therapy. Exclusion criteria included urge incontinence or SUI caused by intrinsic sphincter deficiency. By 12 months, 25 patients withdrew consent, 19 were lost to follow-up, and 17 reported a lack of response, resulting in 75 patients (55%) who were evaluated at the 12-month follow-up. Efficacy, based on the percentage of patients with a 50% or greater reduction from baseline in daily incontinence episodes, was reported in 68 (50%) patients. Of the 75 evaluated at 12 months, 69% (38% of 136) reported at least a 50% reduction in leaked urine (median of 15 g) from baseline, and 45% (25% of 136) were dry. One patient reported increased leaking. No serious adverse events were reported. The most common adverse events at day 3 included dysuria (5%), urinary retention (4%), post-procedure pain (3%), and urinary tract infection (3%). Limitations of this study include the dropout rate with regard to individuals completing all of the in-office assessments and lack of a control group.

In 2010, Elser et al. published 18 month and 3-year follow-up data. Sixty-three of 136 (46%) women who received treatment completed the 18-month follow-up, and data were available on 60 women (44% of the study population). (17) Thirty-one of the 60 evaluable women (61.7%) reported a reduction of at least 50% from baseline in leaks due to activity. In an intention-to-treat (ITT) analysis of data from all 136 participants (last observation carried forward), 46.7% reported at least a 50% reduction in leaks from baseline. A total of 41 women (30% of the study population) completed the 3-year follow-up evaluation. (18) According to diary data, available for 39 women, 24 (62%) reported at least a 50% reduction in leaks per day. In an ITT analysis with multiple imputations of missing data, 60% of women had at least a 50% reduction in leaks. The study is limited by a low long-term follow-up rate and lack of a control or comparison group.

In 2015, a meta-analysis by Kang et al. was able to find only one trial of 173 women that assessed this RF energy technology, concluding that it was not known if RF 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. The author also noted: "It is not known whether transurethral radiofrequency collagen denaturation, as compared with sham treatment, improves patient-reported symptoms of urinary incontinence. Evidence is insufficient to show whether the procedure improves disease-specific quality of life. Evidence is also insufficient to show whether the procedure causes serious adverse events or other adverse events in comparison with sham treatment, and no evidence was found for comparison with any other method of treatment for urinary incontinence." (19)

UpToDate

In 2023, UpToDate (12) reviewed available treatment options for female urinary incontinence and found 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 located one trial (Kang et al. described above) that assessed this technology and concluded that it was not known if RF 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.

Endovaginal Cryogen-Cooled, Monopolar Radiofrequency Remodeling (e.g., Viveve® System)

Endovaginal cryogen-cooled, monopolar radiofrequency remodeling delivers cryogen-cooled, monopolar RF remodeling endovaginally and is a proposed treatment in women with SUI.

In 2017, Lalji and Lozanova (20) conducted a prospective, multi-center, non-randomized study evaluating the safety and efficacy of monopolar RF treatment for addressing mild to moderate SUI as well as vulvo-vaginal laxity. The study included 27 women who were treated with 3 once-weekly sessions that included intra-vaginal treatment then treatment of labia majora and the perineum. The authors noted that the treatments were well tolerated with no adverse events observed. Improvement in the SUI condition was evaluated weekly and at a 1-month follow-up visit. Sixteen women (59.3%) reporting decrease in the amount of leakage with 15 women (55.6%) becoming leak free at the 1-month visit. They stated that future studies with longer follow-up are warranted to understand how the results develop as the collagen remodeling process takes up to 90 days to fully complete, and that further controlled studies are needed to confirm the data and evaluate the long-term effects. Limitations of the study include the small sample size, the short follow-up period, and the lack of a control group.

In 2020, Allan et al. (21) conducted a 12-month single site, randomized, unblinded feasibility study investigating the effectiveness of non-ablative, cryogen-cooled, monopolar RF as a treatment for female SUI. This small study included 35 women with 21 receiving 1 treatment and 14 receiving 2 treatments. Twenty-five women completed the 12-month follow-up, with 9 women dropping out of the first group and 3 women dropping out of the second group. The authors concluded that this feasibility study indicates there is promising efficacy and safety of a cryogen-cooled, monopolar RF therapy for treating SUI although there was a decrease in efficacy noted between 6 months and 12 months post-procedure; however, this study did not show benefit from a second cryogen-cooled, monopolar RF therapy treatment at 6 weeks. The

percentage of women showing more than 50% reduction from baseline in leakage volume at 12 months was similar between groups. Limitations of this study include the age and weight disparity between the groups in that the first group had a mean age of 41.0 years and a lower body mass index (BMI 24.5) while the second group was older with a mean age of 46.1 years and an average BMI of 26.0. In addition, there were 3 women in group 2 who were post-menopausal while group 1 had none. The authors recommend additional larger, long-term randomized and sham controlled studies. In addition, this study lacked a comparison group of individuals who did not receive Viveve treatment. Additional studies to investigate optimal timing between procedures are also needed.

Additional Literature Related to RF Energy Therapy

In 2021, Stachowicz et al. (22) performed a comprehensive literature review for articles pertaining to the use of RF energy in women with SUI, genitourinary syndrome of menopause (GSM), female sexual dysfunction (FSD), and overactive bladder (OAB). By altering the approach and location of energy application, many new devices have been marketed for treatment of conditions such as SUI, GSM, FSD, and OAB. Available studies demonstrate promising efficacy and favorable safety; however, interpretation of studies is greatly limited by poor study quality and reporting. The authors note that despite a lack of high-quality evidence for efficacy, safety, and durability in the literature, practitioners continue to promote RF technology for a variety of genitourinary complaints although additional robust data are needed to substantiate evidence-based use.

Summary of Evidence

Transvaginal and transurethral radiofrequency (RF) tissue remodeling and endovaginal cryogen-cooled, monopolar RF remodeling are minimally invasive treatment options for individuals with stress urinary incontinence (SUI). To date, there is insufficient evidence from well-conducted randomized controlled trials that either transvaginal or transurethral RF and/or endovaginal cryogen-cooled, monopolar RF remodeling improves the net health outcome compared to a sham procedure or another treatment for SUI. Larger studies with long-term follow-up, identification of the patient population that might benefit from the procedure and independent replication are needed. There is minimal evidence within the scientific literature that provides support for the use of this technology. The efficacy and long-term effectiveness of these modalities for the treatment of SUI has not been determined therefore, the evidence is insufficient to determine the health effects of this technology.

Practice Guidelines and Position Statements

American Urological Association (AUA) /Society of Urodynamics and Female Pelvic Medicine & Urogenital Reconstruction (SUFU)

In 2023, the AUA/SUFU updated their recommendations on the surgical treatment of females with SUI. (23) The AUA/SUFU guideline does not include transvaginal or transurethral radiofrequency remodeling, or endovaginal cryogen-cooled, monopolar radiofrequency remodeling as a treatment option for individuals with SUI.

National Institute for Health and Care Excellence (NICE)

In 2021, NICE published guidance related to the use of transvaginal laser therapy for individuals with SUI. (24) 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.

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this policy are listed in Table 1. The Viveve System is not currently FDA cleared specifically for the treatment of urinary incontinence although Viveve Medical is expected to seek specific marketing clearance for the treatment of SUI pending results from the PURSUIT clinical trial (NCT04720352).

Table 1. Summary of Key Trials

NCT Number	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT04720352	PURSUIT: Prospective US Radiofrequency SUI Trial	390	Dec 2022 (Unknown status)

NCT: national clinical trial.

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 (SPD) 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®) ©2024 American Medical Association: Chicago, IL.

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Centers for Medicare and Medicaid Services (CMS)

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 and Medicaid Services (CMS) 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 <https://www.cms.hhs.gov>.

Policy History/Revision

Date	Description of Change
04/01/2025	Reviewed. No changes.
04/01/2024	Document updated with literature review. Coverage unchanged. Added references 22, 24; others updated/removed.
05/01/2023	Reviewed. No changes.

12/01/2022	Document updated with literature review. The following change was made in coverage: Added endovaginal cryogen-cooled, monopolar radiofrequency remodeling (e.g., Viveve® System) as a treatment of SUI is considered experimental, investigational and/or unproven. Added references 1-7, 12, 13, 21, 22; others updated.
04/01/2021	Reviewed. No changes.
03/15/2020	Document updated with literature review. Coverage unchanged. No new references added.
04/15/2018	Reviewed. Coverage unchanged.
07/15/2017	Document updated with literature review. Coverage unchanged.
06/01/2016	Reviewed. Coverage unchanged.
04/15/2015	Document updated with literature review. Coverage unchanged.
04/01/2012	Document updated with literature review. Coverage unchanged. Rationale significantly revised.
02/15/2010	Medical document updated with literature review. Coverage unchanged. Transvaginal radiofrequency bladder neck suspension as a treatment of stress urinary incontinence (SUI) is considered experimental, investigational and unproven and transurethral radiofrequency tissue remodeling as a treatment of SUI is considered experimental, investigational and unproven.
08/01/2007	Revised/Updated Entire Document
05/01/2005	New Medical Document