Effective Date: May 3, 2017

Subject: Transurethral Radiofrequency Micro-Remodeling for female stress urinary incontinence

Background: Stress urinary incontinence is unintentional urination caused by physical activity putting pressure on a person's bladder, as well as the condition of being predisposed to such events. While the condition can usually be controlled with therapies and behavior modifications meant to control bladder pressure and strengthen the tissue responsible for resisting urinary pressure, surgical interventions are sometimes necessary. In transurethral radiofrequency micro-remolding, brand name Renessa® System, four needles are deployed via probe into urethral or bladder neck tissue to deliver pulses of radiofrequency energy and thereby denature distributed subsections of submucosal collagen. After recovery, the urethral tissue displays increased strength and resistance to involuntary opening, which is hoped to be a sustained rather than transitory improvement. While the procedure is less invasive than other surgical interventions and appears to be safe, additional studies are needed to establish whether it is effective.

Policy and Coverage Criteria:

Supporting Information:
Hayes Inc. 2012 describes the procedure as the use of a low level and low temperature radiofrequency (RF) generator and probe. The probe is inserted through the urethra into the bladder, and is anchored in the bladder outlet by inflation of a balloon at its tip. Four needles arranged around the probe shaft are deployed into the tissue to deliver pulses of RF energy for 60 to 90 seconds. The RF energy raises the temperature near the needle tips to 65°C to 75°C, which breaks down a small area of urethral tissue. As it heals, the urethral tissue becomes firmer and less likely to open involuntarily. Published reports show good results at 12-month follow-up, particularly on the subject of adverse events. However, limitations of these studies include small sample sizes, lack of controls, lack of blinding, lack of long-term data, and the lack of urodynamic testing at baseline or follow-up.

A 2015 systematic review by Kang et al found only one comparative trial of useable quality, and that the trial was not large enough to detect rare serious adverse events or establish a difference in efficacy or incontinence-related quality of life from sham treatments, and that quality of evidence was low in general due to opportunity for bias and imprecision. Additionally, the trial was against sham treatment rather than established treatments, so that the non-inferiority of the procedure cannot be determined. A 2012 review by Lukban evaluated clinical studies published between 2005 and 2010 assessing the efficacy of transurethral radiofrequency tissue remodeling. The author found the outcomes of the studies showed the procedure to be a safe, nonsurgical in-office procedure for the treatment of female SUI but did not establish efficacy.

Elser et al. (2009) reported on 12-month results of 136 women treated with the Renessa system for stress urinary incontinence. The report is part of a prospective, 36-month, open-label, single-arm clinical trial. Women eligible for the trial had stress urinary incontinence secondary to bladder outlet hypermobility for 12 months or longer who failed earlier conservative treatments. Patients also had not undergone earlier surgical or bulking.
agent therapy. Significant improvements occurred in median scores on the Incontinence Quality of Life scale and in mean scores on the Urogenital Distress Inventory scale. These early results led researchers to conclude treatment using Renessa results in significant improvement in activity-related leaks and quality of life.

A 2011 update by Elser et al. discussed the 36-month results of their study. Mean improvement in quality of life score improved by 17 points from baseline (p=.0004) while the mean urogenital distress inventory score improved 19 points (p=.0005). The authors concluded transurethral collagen denaturation results in durable quality of life improvements in a significant portion of women for as long as 3 years.

Davila (2011) published a review of non-surgical outpatient therapies for management of female stress urinary incontinence. A literature search and review found that minimally invasive, nonsurgical transurethral radiofrequency collagen denaturation is an effective option for patients with SUI due to urethral hypermobility who have failed pelvic floor rehabilitation and who cannot or choose not to undergo surgery. Evidence suggests generally good safety and benefits that persist for at least 3 years for the majority of patients who undergo this procedure.

Dillon and Dmochowski (2009) noted the transurethral approach of radiofrequency treatment for SUI is appealing because it can be performed in an office setting with the use of oral sedation and local anesthesia. Data also suggests that the treatment has promising efficacy and minimal risk of adverse events. However, they caution further randomized studies with longer follow-up are needed to fully assess the ultimate role of the procedure in SUI treatment.

A retrospective study by Appell et al. (2007) evaluated long-term safety and efficacy in 21 patients from a 12-month, randomized controlled trial utilizing 3-day diaries and the Incontinence Quality of Life (I-QOL) survey. Significant increases in overall I-QOL scores 3 years or more post treatment was the primary end point. Secondary end points were reductions in frequency and severity of incontinence episodes. After 3 years, mean overall I-QOL score improvement was 12.7 (+/-26); 56% of patients achieved 50% or more reduction in frequency. No new adverse events occurred. Appell et al. concluded radiofrequency collagen denaturation is safe and provides durable efficacy.

An earlier report by Appell et al. on the same set of patients found transurethral radiofrequency collagen micro-remodeling to be safe and effective after performing a prospective, randomized, controlled clinical trial. At 12 months, there was no significant difference in the safety profiles of the two arms of the study. Results showed that women with moderate to severe SUI had a significant improvement in quality of life. Women who underwent the therapy also demonstrated a significant elevation in mean leak point pressure at 12-months.

**Coding:**

Codes are listed below for informational purposes only, and do not guarantee member coverage or provider reimbursement. The list may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible.

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<tr>
<th>CPT® Code</th>
<th>Description</th>
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<tr>
<td>53860</td>
<td>Transurethral micro-remodeling of the female bladder neck and proximal urethra for stress urinary incontinence</td>
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**References:**


**HPHC Clinical Medical Policy**

Transurethral Radiofrequency Micro-Remodeling for female stress urinary incontinence

HPHC policies are based on medical science, and written for the majority of people with a given condition.

Coverage described in this policy is standard under most HPHC plans. Specific benefits may vary by product and/or employer group. Please reference appropriate member materials (e.g., Benefit Handbook, Certificate of Coverage) for member-specific benefit information.


**Summary of Changes:**

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<tr>
<th>Date</th>
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<tbody>
<tr>
<td>5/ 2/ 17</td>
<td>References and supporting information updated</td>
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**Approved by UMCPC: 5/ 2/ 17**

**Reviewed/Revised: 6/ 10; 6/ 12; 6/ 14; 5/ 17**

**Initiated: 6/ 10**