

## ***Transanal Radiofrequency Treatment of Fecal Incontinence***

**Effective:** February 1, 2019

**Next Review:** December 2019

**Last Review:** January 2019

### **IMPORTANT REMINDER**

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

### **DESCRIPTION**

Radiofrequency (RF) energy is used to create lesions that, when healed, cause local tissue contraction in an effort to improve symptoms of fecal incontinence.

### **MEDICAL POLICY CRITERIA**

Transanal radiofrequency therapy is considered **investigational** as a treatment of fecal incontinence.

*NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.*

### **CROSS REFERENCES**

1. [Pelvic Floor Stimulation as a Treatment of Urinary and Fecal Incontinence](#), Allied Health, Policy No. 04
2. [Sacral Nerve Modulation/Stimulation for Pelvic Floor Dysfunction](#), Surgery, Policy No. 134

### **BACKGROUND**

Radiofrequency energy is a commonly used surgical tool that has been used for tissue ablation and more recently for tissue remodeling. For example, radiofrequency energy has been investigated as a treatment of gastroesophageal reflux disease (GERD) (i.e., the Stretta

procedure) in which radiofrequency lesions are designed to alter the biomechanics of the lower esophageal sphincter, in orthopedic procedures to remodel the joint capsule, or in an intradiscal electrothermal annuloplasty (IDET) procedure, in which the treatment is intended in part to modify and strengthen the disc annulus. In all of these procedures, nonablative levels of radiofrequency thermal energy are used to alter collagen fibrils, which then result in a healing response characterized by fibrosis. Recently, radiofrequency energy has been explored as a minimally invasive treatment option for fecal incontinence.

Fecal incontinence is the involuntary leakage of stool from the rectum and anal canal. Fecal continence depends on a complex interplay of anal sphincter function, pelvic floor function, stool transit time, rectal capacity, and sensation. In this outpatient procedure using conscious sedation, radiofrequency energy is delivered to the sphincteric complex of the anal canal to create discrete thermal lesions. Over several months, these lesions heal and the tissue contracts, changing the tone of the tissue, which may improve continence.

There are a variety of etiologies, including injury from vaginal delivery, anal surgery, neurologic disease, and the normal aging process. It is estimated that the disorder affects some 8% of the adult population. Medical management includes dietary measures, such as the addition of bulk-producing agents to the diet and elimination of foods associated with diarrhea. Antidiarrheal drugs can be used for mild degrees of incontinence. Bowel management programs, commonly used in patients with spinal cord injuries, may also be effective in patients with fecal incontinence. Biofeedback has been investigated as well. Surgical approaches primarily include a sphincteroplasty, although more novel approaches may be attempted in those patients whose only other treatment option is the creation of a stoma. These novel approaches include an artificial anal sphincter or sacral neuromodulation. Radiofrequency energy has also been investigated as a minimally invasive treatment of fecal incontinence, referred to as the Secca procedure. In this outpatient procedure using conscious sedation, radiofrequency energy is delivered to the sphincteric complex of the anal canal to create discrete thermal lesions. Over several months, these lesions heal and the tissue contracts, changing the tone of the tissue and potentially improving continence.

## **REGULATORY STATUS**

In 2002, the Secca™ System received U.S. Food and Drug Administration (FDA) clearance through the 510(k) process with the following labeled indication:

“The Secca™ System is intended for general use in the electrosurgical coagulation of tissue and is intended for use specifically in the treatment of fecal incontinence in those patients with incontinence to solid or liquid stool at least once per week and who have failed more conservative therapy.”

## **EVIDENCE SUMMARY**

The principal outcomes associated with treatment of fecal incontinence may include: a reduction of days with incontinence, improved functional level, and improved sphincter muscle measurements. Relief from fecal incontinence is a subjective outcome that is typically measured through patient questionnaires and journals and is therefore subject to placebo effect. Therefore, data from adequately powered, blinded, randomized controlled trials (RCTs) are required to control for the placebo effect, determine its magnitude, and determine whether any treatment effect from radiofrequency therapy provides a significant advantage over the placebo.

Treatment with radiofrequency therapy must also be evaluated in general groups of patients against the existing standard of care for the condition being treated. For example, in patients with fecal incontinence, treatment with radiofrequency therapy should be compared to one or more forms of conservative therapy. No trials comparing the outcomes of transanal radiofrequency treatment of fecal incontinence to alternative treatments have been identified.

## **SYSTEMATIC REVIEW**

In 2016, an Agency for Healthcare Research and Quality comparative effectiveness systematic review assessed surgical treatments for fecal incontinence, including transanal RF treatment.<sup>[1]</sup> Reviewers identified only case series, which they addressed only under a key question related to adverse effects, not a key question related to comparative effectiveness. Reviewers concluded that the evidence for transanal RF treatment was insufficient to support its use for fecal incontinence.

## **RANDOMIZED CONTROLLED TRIAL**

In 2017, Visscher reported on a randomized, controlled trial of radiofrequency treatment of fecal incontinence.<sup>[2]</sup> Forty patients for whom maximal conservative management had failed were enrolled and randomized to the radiofrequency or sham groups. The Vaizey incontinence score was 16.8 (SD 2.9) pre-treatment and at six months post-treatment it was 13.2 (SD 3.1) in the radiofrequency group and 15.6 (SD 3.3) in the sham group. The difference between the groups at six months was statistically significant. There was no statistically significant difference in the fecal incontinence quality-of-life score at six months and no difference in anorectal function was reported.

## **NONRANDOMIZED STUDIES**

A 2017 publication by Frascio reported the outcomes of a nonrandomized prospective observational study of Secca for fecal incontinence at one year following the procedure.<sup>[3]</sup> The study included 21 patients who underwent the procedure and 19 who completed the follow-up at one year. The Fecal Incontinence Score was measured pre-treatment and at three months, six months, and one year and was reported as 14.5, 11.9, 12, and 12.9, respectively. Only one of the four subsets of the Fecal Incontinence Quality of Life score improved over the same time points. No changes were reported in Manometry or endoanal ultrasound.

In 2012, Abbas published results of their retrospective review of 27 patients who underwent the Secca™ procedure over a six-year period (2004-2010) at Kaiser Permanente Los Angeles Medical Center<sup>[4]</sup>. Thirty-one procedures were performed for moderate to severe fecal incontinence. The majority of study patients were women with a mean age of 64 years, and the most common cause of the incontinence was obstetrical injury. Median length of symptoms was three years. Biofeedback had failed in more than half of patients, and more than 20% of patients had previous surgical intervention to treat the incontinence. No major complications occurred following the Secca procedure, and minor complications were observed in five patients (19%; anal bleeding in four and swelling of the vulva in one). A treatment response was noted in 21 patients (78%) (mean Cleveland Clinic Florida Fecal Incontinence [CCF-FI] Score: 16 [baseline] and 10.9 [three months postoperatively]). Previous studies have suggested that a CCF-FI of greater than nine indicates a significant impairment of quality of life.<sup>[5]</sup> However in the study by Abbas only six patients (22%) had a sustained long-term response without any additional intervention, and 14 patients (52%) underwent or are awaiting additional intervention for persistent or recurrent incontinence over a mean follow-up period of

40 months.

In 2010, Ruiz published a paper reporting on one-year quality-of-life and continence outcomes for a series of 24 patients treated with radiofrequency (RF) energy for fecal incontinence in 2003 to 2004.<sup>[6]</sup> Twelve-month results were available for 16 of the 24 patients (67%). The mean CCF-FI score improved from 15.6 at baseline to 12.9 at 12 months ( $p=0.035$ ). The mean FIQL Questionnaire score improved in all subsets except for the depression subscore. The authors comment that the actual clinical significance of this improvement needs to be determined.

In 2007, Felt-Bersma published the results of an uncontrolled study on the Secca procedure in eleven women with fecal incontinence who underwent baseline and post-treatment testing.<sup>[7]</sup> Six (55%) patients reported improvement; Vaisey scores decreased 13%, and no changes were observed in anal manometry, rectal compliance measurement, or three-dimensional anal ultrasound. Postoperative pain was reported to be slight in eight (73%), moderate in two, and severe in one patient. The investigators suggested that this procedure merits further testing, and noted that a RCT was underway. In 2014, Lam reported on three-year outcomes of this cohort plus 20 other patients who underwent the Secca procedure for fecal incontinence.<sup>[8]</sup> Of the total cohort of 31 patients, five (16%) maintained a clinically significant response (defined as  $\geq 50\%$  reduction in Vaizey score) for six months, three (10%) maintained response for one year, and two (6%) maintained response for three years. Improvements from baseline in anal manometry (increased anorectal pressures or enhanced rectal compliance) were not observed.

A published study of the Secca procedure by Efron in 2003<sup>[9]</sup>, appears to be the clinical study that was submitted as part of the FDA approval process. The study consists of an open-label, single-arm, non-randomized clinical study that included 50 subjects who were treated and followed up for six months. Patients served as their own control. The study assessed changes in fecal incontinence symptom scores and quality of life between the baseline and follow-up intervals. Fecal incontinence was assessed with the CCF-FI score and quality of life was assessed with the Fecal Incontinence Quality of Life Score (FIQL). Both the CCF-FI and FIQL scores improved in a steady gradual manner over a six-month period, from 14.6 to 11.1 for the CCF-FI and 2.5 to 3.1 for the FIQL. Of the 44 patients with an initial baseline CCF-FI score greater than 9, a total of 15 (34%) achieved a CCF-FI less than 10 at six months. Improvement was also assessed using the Medical Outcomes Study Short Form-36 (SF-36), focusing on mental and social parameters. The mean social function subscore improved from 64.3 to 74.4, while the mental health subscore improved from 65.8 to 73.8. Fourteen-day diary data demonstrated significant improvement in all nine parameters; for example, the days with any fecal incontinence dropped from 10 in a 14-day period to seven. In contrast, there were no differences in objective measures of anal sphincter, i.e., there were no differences based on manometry measures, rectal sensation volumes, pudendal nerve motor latency, or internal or external sphincter defects, as noted on endoanal ultrasound. The authors noted that determining the mechanism of action for the procedure was not an objective of the study. Three significant procedure-related complications occurred during the trial. Two patients developed anal ulceration, and one developed bleeding from a hemorrhoidal vein. Twenty-six minor adverse events occurred, including minor bleeding in five patients, transient worsening of incontinence in four patients, and anal pain in five patients.

Three additional very small case series ( $n = 15, 19, 8$ ) were also performed outside the United States.<sup>[10-12]</sup> In two of these small trials, no clear benefit was noted for the procedure. Given the

small number of studies that have been conducted and the limitations of those trials (i.e., small number of patients, lack of control arm and randomization, inconsistencies with inclusion and exclusion criteria, and short-term follow-up, the efficacy of radiofrequency therapy for fecal incontinence is not supported in the literature.

## PRACTICE GUIDELINE SUMMARY

### NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

The United Kingdom’s National Institute for Health and Care Excellence (NICE) issued guidance on radiofrequency treatment for fecal incontinence in 2011.<sup>[13]</sup> NICE concluded that “evidence on endoscopic radiofrequency therapy of the anal sphincter for [fecal] incontinence raises no major safety concerns. There is evidence of efficacy in the short term, but in a limited number of patients. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research.”

### AMERICAN SOCIETY OF COLON AND RECTAL SURGEONS

In 2015, The American Society of Colon and Rectal Surgeons, updated their 2007 practice guidelines for the treatment of fecal incontinence.<sup>[14]</sup> The guidelines say “the application of temperature-controlled radiofrequency energy to the sphincter complex may be used to treat fecal incontinence. Grade recommendation based on moderate-quality evidence, 2B.” The guidelines also state “Because of the limitations in the available data, alternative treatments should be pursued before considering radiofrequency energy delivery.”

### AMERICAN COLLEGE OF GASTROENTEROLOGY

The American College of Gastroenterology (ACG) published guidelines on the management of benign anorectal disorders in 2014.<sup>[15]</sup> The guidelines indicated that there is insufficient evidence to recommend radiofrequency ablation to the anal sphincter as treatment for fecal incontinence. ACG also asserted that the biologic rationale for this type of treatment is unproven.

## SUMMARY

There is not enough research to show that transanal radiofrequency therapy improves health outcomes for people with fecal incontinence. No clinical guidelines based on research recommend transanal radiofrequency therapy for people with fecal incontinence. Therefore, transanal radiofrequency therapy is considered investigational for all indications, including but not limited to fecal incontinence.

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## CODES

Codes	Number	Description
CPT	46999	Unlisted procedure, anus
HCPCS	None	

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