

Medical Policy Manual

Topic: Transanal Radiofrequency Treatment of Fecal Incontinence

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Section: Surgery

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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^[1]

Radiofrequency energy has 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, which may improve continence. This procedure is very similar in concept to the Stretta procedure for treatment of gastroesophageal reflux disease (GERD).

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 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. 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.”

MEDICAL POLICY CRITERIA

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

SCIENTIFIC EVIDENCE

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 (RCT) 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.

Nonrandomized Trials

- In 2012, Abbas et al. published results of their retrospective review of 27 patients who underwent the Secca™ procedure over a 6-year period (2004-2010) at Kaiser Permanente Los Angeles Medical Center^[2]. 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 3 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 5 patients (19%; anal bleeding in 4 and swelling of the vulva in 1). A treatment response was noted in 21 patients (78%) (mean Cleveland Clinic Florida Fecal Incontinence [CCF-FI] Score: 16 [baseline] and 10.9 [3 months postoperatively]). Previous studies have suggested that a CCF-FI of greater than 9 indicates a significant impairment of quality of life.^[3] However in the study by Abbas et al. only 6 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.
- A published study of the Secca procedure by Efron et al. in 2003^[4], appears to be the clinical study that was submitted as part of the FDA approval process.^[5] The study consists of an open-label, single-arm, non-randomized clinical study that included 50 subjects who were treated and followed up for 6 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 6-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 6 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 73.8, while the mental health subscore improved from 65.8 to 73.8. Fourteen-day diary data demonstrated significant improvement in all 9 parameters; for example, the days with any fecal incontinence dropped from 10 in a 14-day period to 7. 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 1 developed bleeding from a hemorrhoidal vein. Twenty-six minor adverse events occurred, including minor bleeding in 5 patients, transient worsening of incontinence in 4 patients, and anal pain in 5 patients.
- In 2007, Felt-Bersma et al. published the results of an uncontrolled study on the Secca procedure in eleven women with fecal incontinence who underwent baseline and post-treatment testing.^[6] Six (55%) patients reported improvement; Vaisey scores decreased 13%, and no changes were observed in anal manometry, rectal compliance measurement, or 3-dimensional anal ultrasound. Postoperative pain was reported to be slight in 8 (73%), moderate in 2, and severe in 1 patient. The investigators suggested that this procedure merits further testing, and noted that a randomized controlled trial was underway.

- In 2010, Ruiz et al. published a paper reporting on 1-year quality-of-life and continence outcomes for a series of 24 patients treated with RF energy for fecal incontinence in 2003 to 2004.^[7] 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.
- Three additional very small case series (n = 15, 19, 8) were also performed outside the United States.^[8-10] In 2 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.

Clinical Practice Guidelines

American Society of Colon and Rectal Surgeons

The American Society of Colon and Rectal Surgeons, in their 2007 practice parameters for the treatment of fecal incontinence, classified the Secca™ procedure as a potentially useful treatment intervention for selected patients with moderate fecal incontinence.^[11] This statement was based on level IV evidence (grade of recommendation C) because of the limited data available on this treatment modality.

Summary

The trials described in this policy include a small number of patients, and the estimates of treatment differences are very imprecise. The study follow-up periods are variable and need to be considerably longer for a proper evaluation of long-term success. Multicenter randomized controlled trials with sufficient power are required to evaluate the use of this procedure as an alternative to other surgical interventions or physical therapies or as an adjunct treatment option for fecal incontinence. Given the insufficient evidence available to evaluate the impact of transanal radiofrequency treatment on net health outcomes, transanal radiofrequency therapy is considered investigational as a treatment of fecal incontinence.

REFERENCES

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CROSS REFERENCES

[Transvaginal and Transurethral Radiofrequency Tissue Remodeling for Urinary Stress Incontinence](#), Surgery, Policy No. 130

[Sacral Nerve Modulation/Stimulation for Pelvic Floor Dysfunction](#), Surgery, Policy No. 134

CODES	NUMBER	DESCRIPTION
CPT	0288T	Anoscopy, with delivery of thermal energy to the muscle of the anal canal (eg, for fecal incontinence)
HCPCS	C9716	Creations of thermal anal lesions by radiofrequency energy