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Transanal Radiofrequency (RF) Treatment of Fecal 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

Transanal radiofrequency (RF) therapy **is considered experimental, investigational and/or unproven** as a treatment of fecal incontinence.

Policy Guidelines

There is no specific CPT code for this procedure. It may be reported with the unlisted code 46999.

Description

Radiofrequency (RF) energy has been investigated as a minimally invasive treatment of fecal incontinence, in a procedure referred to as the Secca procedure. In this outpatient procedure using conscious sedation, RF 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 improving continence.

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. Etiologies vary and include injury from vaginal delivery, anal surgery, neurologic disease, and the normal aging process. Estimated prevalence is 8% of the adult population.

Treatment

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 for mild incontinence; bowel management programs, commonly used in patients with spinal cord injuries; and biofeedback. Surgical approaches primarily include sphincteroplasty, although more novel approaches, such as sacral neuromodulation or creation of an artificial anal sphincter, may be attempted in patients whose only other treatment option is the creation of a stoma.

RF energy also has been investigated as a minimally invasive treatment of fecal incontinence, a procedure referred to as the Secca procedure. In this outpatient procedure using conscious sedation, RF 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.

RF energy is a surgical tool that has been used for tissue ablation and more recently for tissue remodeling. For example, RF energy has been investigated as a treatment for gastroesophageal reflux disease (i.e., the Stretta procedure), in which RF 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 procedure, in which the treatment is intended in part to modify and strengthen the disc annulus. In all these procedures, non-ablative levels of RF thermal energy are used to alter collagen fibrils, which results in a healing response characterized by fibrosis. Recently, RF energy has been explored as a minimally invasive treatment option for fecal incontinence.

Regulatory Status

In 2002, the Secca® System (Mederi Therapeutics) was cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process 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.” (1) FDA product code: GEI.

Rationale

This policy was created in 2005 and has been updated regularly with searches of the PubMed database. The most recent literature update was performed through April 11, 2024.

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, 2 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 is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. Randomized controlled trials 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.

Fecal Incontinence

Clinical Context and Therapy Purpose

The purpose of transanal radiofrequency (RF) in individuals who have fecal incontinence is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following PICO was used to select literature to inform this policy.

Populations

The relevant population of interest is individuals with fecal incontinence who have failed conservative treatment.

Interventions

The therapy being considered is transanal RF.

Comparators

The following therapies are currently being used to treat fecal incontinence: medical management, biofeedback, and sphincteroplasty.

Outcomes

The general outcomes of interest are the frequency of incontinent episodes and the impact on quality of life.

A beneficial outcome would be elimination of incontinence, reductions in the frequency of incontinence, and improvements in quality of life.

A harmful outcome would be damage to the anal sphincter and an increase in incontinence frequency.

Procedural morbidity would be assessed within 30 days after the procedure. The impact of the treatment on incontinence would be assessed after 3 months to allow for remodeling, and after 3 to 5 years to assess durability.

Systematic Reviews

An Agency for Healthcare Research and Quality Comparative Effectiveness Review, conducted by Forte et al. (2016), assessed surgical treatments for fecal incontinence, including transanal RF treatment. (2) 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.

Simillis et al. (2019) performed a systematic review of the literature to compare the clinical outcomes and effectiveness of treatments available for fecal incontinence. (3) Forty-seven RCTs were included comparing 37 treatments and reporting on 3748 participants. No treatment ranked best or worst with high probability for any outcome of interest. No significant difference was identified between treatments for frequency of fecal incontinence per week, or in changing the resting pressure, maximum resting pressure, squeeze pressure, and maximum squeeze pressure. RF resulted in more adverse events compared to placebo. No difference was identified in incontinence episodes, no treatment ranked best persistently or persistently improved outcomes, and many included treatments did not significantly benefit patients compared to placebo. Large multicenter RCTs with long-term follow-up and standardized inclusion criteria and outcome measures are needed.

Noncomparative Studies

Abbas et al. (2012) retrospectively reviewed 27 patients who underwent the Secca procedure during a 6-year period (2004-2010) at a single medical center. (4) Thirty-one procedures were performed for moderate-to-severe fecal incontinence. Most patients were women (mean age, 64 years), and the most common cause of incontinence was obstetrical injury. The 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 incontinence. No major complications occurred after the Secca procedure, and minor complications were observed in 5 (19%) patients (anal bleeding in 4, vulvar swelling in 1). A treatment response was noted in 21 (78%); mean Cleveland Clinic Florida Fecal Incontinence (CCF-FI) score was 16 at baseline and 10.9 at 3 months postoperatively. Studies have suggested that a CCF-FI score greater than 9

indicates a significant impairment of quality of life. (5) However, in the Abbas study, only 6 (22%) patients had a sustained long-term response without any additional intervention, and 14 (52%) patients underwent or were awaiting additional intervention for persistent or recurrent incontinence over a mean follow-up period of 40 months.

Ruiz et al. (2010) reported on 1-year quality of life and continence outcomes for a series of 24 patients treated with RF energy for fecal incontinence between 2003 and 2004. (6) Twelve-month results were available for 16 (67%) patients. Mean CCF-FI score improved from 15.6 at baseline to 12.9 at 12 months (p=0.035). Mean Fecal Incontinence Quality of Life (FIQL) score improved in all subsets except for the depression subscore. Authors' conclusions on the actual clinical significance of this improvement were uncertain.

Felt-Bersma et al. (2007) published results of an uncontrolled study on the Secca procedure in 11 women with fecal incontinence who underwent baseline and posttreatment testing. (7) Six (55%) patients reported improvement; Vaizey Incontinence Questionnaire scores improved 13%, but 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%) patients, moderate in 2, and severe in 1. Lam et al. (2014) reported 3-year outcomes of this cohort plus 20 other patients who underwent the Secca procedure for fecal incontinence. (8) Of the total cohort of 31 patients, 5 (16%) maintained a clinically significant response (defined as ≥50% reduction in Vaizey Incontinence Questionnaire score) for 6 months, 3 (10%) maintained response for 1 year, and 2 (6%) maintained response for 3 years. Improvements from baseline in anal manometry (increased anorectal pressures or enhanced rectal compliance) were not observed.

Efron et al. (2003) published an open-label, single-arm, nonrandomized study of 50 patients who underwent the Secca procedure and was followed for 6 months. (9) Patients served as their own controls. The study assessed change in fecal incontinence symptom scores and quality of life between baseline and follow-up. Fecal incontinence was assessed with CCF-FI score, and quality of life was assessed with the FIQL score. 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 from 2.5 to 3.1 for the FIQL. Of 44 patients who had an initial baseline CCF-FI score greater than 9, a total of 15 (34%) achieved CCF-FI score less than 10 at 6 months. Improvement also was assessed using the Medical Outcomes Study 36-Item Short-Form Health Survey, focusing on mental and social parameters. Mean social function sub-score improved from 64.3 to 34.4, and mental health sub-score improved from 65.8 to 73.8. Fourteen-day diary data demonstrated significant improvement in all 9 parameters (e.g., 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 function (i.e., there were no differences in manometry measures, rectal sensation volumes, pudendal nerve motor latency, or internal or external sphincter defects), as noted on endoanal ultrasound. Authors noted that determining the mechanism of action for the procedure was not a study objective. 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 5 patients, transient worsening of incontinence in 4 patients, and anal pain in 5 patients.

Three other very small case series (n=15, 19, 8) were performed outside the United States. (10-12) In two, no clear benefit was noted for the procedure.

Frascio et al. (2017) conducted a prospective, single-center, observational study to assess the one-year follow-up results following the RF procedure for fecal incontinence. (13) Twenty-one patients underwent the Secca® RF procedure, 19 of whom completed the one-year of follow-up (CCF-FI score, FIQL), anorectal manometry, and endoanal ultrasound). The mean CCF-FI significantly improved at three months' follow-up from 14.5 prior to treatment to 11.9 post-treatment and was maintained at 6 months. A slight decrease was observed at one year, which had no impact on the global satisfaction. During the same period, only 1/4 subsets of the FIQL score improved. Manometry and endoanal ultrasound did not show significant changes post procedure. Researchers concluded that RF is a valid treatment option for patients with mild-to-moderate fecal incontinence. This treatment has demonstrated clinically significant improvements in symptoms, as demonstrated by statistically significant reductions in the CCF-FI as well as significant improvements in FIQL scores at six months, with a slight, though not clinically significant, decrease at one year follow-up. Limitations of the study included a small sample size, all female subjects, and a loss to follow-up for 2 participants.

Section Summary: Noncomparative Studies

A small body of observational studies or non-comparative, single-arm trials have reported on changes in incontinence symptoms after the Secca procedures. Given the small number of studies 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, short-term follow-up), the efficacy of RF therapy for fecal incontinence is not supported in the literature.

Randomized Controlled Trials

Visscher et al. (2017) performed a randomized sham-controlled clinical trial to determine whether the clinical response to the RF energy procedure is superior to sham in patients with fecal incontinence. (14) Forty patients with fecal incontinence in whom maximal conservative management had failed were randomly assigned to receiving either RF energy or sham procedure. At baseline, Vaizey incontinence score was 16.8 (SD 2.9). At t = 6 months, the RF energy group improved by 2.5 points on the Vaizey incontinence score compared with the sham group (13.2 (SD 3.1), 15.6 (SD 3.3), p = 0.02). The FIQL score at t = 6 months was not statistically different. Anorectal function did not show any alteration. Investigators concluded that both RF energy and sham procedure improved the fecal incontinence score, the RF energy procedure more than sham. Although statistically significant, the clinical impact for most of the patients was negligible. Therefore, the RF energy procedure should not be recommended for patients with fecal incontinence until patient-related factors associated with treatment success are known.

Summary of Evidence

For individuals who have fecal incontinence who receive transanal radiofrequency (RF) treatment, the evidence includes systematic reviews, nonrandomized studies and a randomized clinical trial. Relevant outcomes are symptoms, change in disease status, quality of life, and treatment-related morbidity. Studies include a small number of patients and estimates of treatment differences are very imprecise. Study follow-up periods vary and need to be considerably longer and involve larger numbers of patients to evaluate long-term outcomes properly. Three-year follow-up of a small cohort showed decrement in response over time. Multicenter randomized controlled trials with sufficient power are required to evaluate the continuing use of this procedure as an alternative to other surgical interventions, physical therapies, or as an adjunctive treatment option for fecal incontinence. The evidence is insufficient to determine the effects of the technology on health outcomes.

Practice Guidelines and Position Statements

National Institute for Health and Care Excellence

The National Institute for Health and Care Excellence (NICE) issued guidance on RF treatment for fecal incontinence in 2011. (15) 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. Further research into endoscopic radiofrequency therapy of the anal sphincter for [fecal] incontinence should clearly define the patient groups being treated. It should also report the clinical impact in terms of quality of life and long-term outcomes."

In 2016, NICE published a Medtech innovation briefing on the Secca system for fecal incontinence. (16) These briefings aim to aid in the decision-making process by describing the technology, its role in the treatment pathway, the relevant published evidence, and cost information. These briefings do not contain recommendations. The briefing noted that "Secca therapy is a minimally invasive treatment option available for people with incontinence of solid or liquid stool at least once a week, in whom conservative management options have not controlled symptoms."

American Society of Colon and Rectal Surgeons

The American Society of Colon and Rectal Surgeons, in its 2015 clinical practice guidelines (updated in 2024), noted: "Application of temperature-controlled radiofrequency energy to the sphincter complex is not recommended to treat fecal incontinence." (Conditional strength; quality of evidence very low). (17) The guidelines also state: "The evidence supporting this approach for the management of FI [fecal incontinence] is relatively sparse and has relevant limitations…No new studies evaluating this modality have been published since 2014."

American College of Gastroenterology

In a clinical guideline on the management of benign anorectal disorders (2021), the American College of Gastroenterology (ACG), determined that in spite of initial positive studies on the Secca procedure, more recent reports suggest poor long-term results. (18)

Ongoing and Unpublished Clinical Trials

A search of ClinicalTrials.gov in April 2024 did not identify any ongoing or unpublished trials that would likely influence this policy.

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	46999
HCPCS Codes	None

*Current Procedural Terminology (CPT®) ©2023 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 <http://www.cms.hhs.gov>.

Policy History/Revision

Date	Description of Change
06/15/2024	Document updated with literature review. Coverage unchanged. No new references added; some revised.
06/01/2023	Reviewed. No changes.
12/01/2022	Document updated with literature review. Coverage unchanged. Added references 3, 13, 14, and 18.
02/01/2022	Reviewed. No changes.
03/15/2021	Document updated with literature review. Coverage unchanged. No new references added.
08/15/2020	Reviewed. No changes.
02/15/2019	Document updated with literature review. Coverage unchanged. No references added or deleted.
04/15/2018	Document updated with literature review. Coverage unchanged. References 2, 13 and 15 were added.
04/01/2017	Reviewed. No changes.
04/01/2016	Document updated with literature review. Coverage unchanged.
02/01/2015	Reviewed. No changes.
03/15/2013	Document updated with literature review. Coverage unchanged.
09/01/2011	Document updated with literature review. Coverage unchanged.
07/15/2009	Updated policy with literature review and remains experimental, investigational and unproven.
09/01/2007	Revised/Updated Entire Document
05/01/2005	New Medical Document