Transanal Radiofrequency Treatment of Fecal Incontinence

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Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc.(collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Services Are Considered Investigational
Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers transanal radiofrequency (RF) therapy as a treatment of fecal incontinence to be **investigational.***

Policy Guidelines

The Secca procedure may be performed on an outpatient basis using conscious sedation and a local anesthetic.

Background/Overview

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 of these procedures, nonablative 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.

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FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

In 2002, the Secca System (Mederi Therapeutics) was cleared for marketing by the U.S. 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." FDA product code: GEI.

Centers for Medicare and Medicaid Services (CMS)

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

Rationale/Source

Assessment of efficacy for therapeutic intervention involves a determination of whether an intervention improves health outcomes. The optimal study design for this purpose is a randomized controlled trial that includes clinically relevant measures of health outcomes. Intermediate outcome measures, also known as surrogate outcome measures, may also be adequate if there is an established link between the intermediate outcome and true health outcomes. Nonrandomized comparative studies and uncontrolled studies can sometimes provide useful information on health outcomes but are prone to biases such as noncomparability of treatment groups, placebo effect, and variable natural history of the condition. The following is the summary of the key literature to date.

FECAL INCONTINENCE

No trials comparing transanal RF treatment of fecal incontinence with available alternative treatments have been identified. The literature search to date has identified 8 nonrandomized studies on this procedure.

Systematic Reviews

In 2016, an Agency for Healthcare Research and Quality Comparative Effectiveness Review assessed surgical treatments for fecal incontinence, including transanal RF treatment. 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.

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. 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 four, swelling of the vulva in one). A treatment response was noted in 21 (78%); mean Cleveland Clinic Florida Fecal Incontinence (CCF-FI) score was 16 at baseline and 10.9 3 months postoperatively. Previous studies have suggested that a CCF-FI score greater than 9

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indicates a significant impairment of quality of life. 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.

In 2003, Efron et al published an open-label, single-arm, nonrandomized study of 50 patients who underwent the Secca procedure and was followed for 6 months. 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 Fecal Incontinence Quality of Life (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 subscore improved from 64.3 to 34.4, and mental health subscore 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.

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. 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. Investigators suggested that this procedure merited further testing. Lam et al (2014) reported 3-year outcomes of this cohort plus 20 other patients who underwent the Secca procedure for fecal incontinence. 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.

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. 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 FIQL score improved in all subsets except for the depression subscore. Authors' conclusions on the actual clinical significance of this improvement were uncertain.

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

Section Summary: Noncomparative Studies
A small body of observational studies or noncomparative, 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.

SUMMARY OF EVIDENCE
For individuals who have fecal incontinence who receive transanal RF treatment, the evidence includes 8 nonrandomized studies. 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.

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Policy History

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01/17/2018 Medical Policy Implementation Committee approval. New policy.
Next Scheduled Review Date: 01/2019

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Code Type	Code
CPT	46999
HCPCS	No codes
ICD-10 Diagnosis	All related diagnoses

*****Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

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A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
    2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    3. Reference to federal regulations.

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