



BlueCross BlueShield  
of Alabama

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**Name of Policy:**

**Transanal Radiofrequency Treatment of Fecal Incontinence**

Policy #: 163  
Category: Medical

Latest Review Date: September 2014  
Policy Grade: B

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**Background/Definitions:**

*As a general rule, benefits are payable under Blue Cross and Blue Shield of Alabama health plans only in cases of medical necessity and only if services or supplies are not investigational, provided the customer group contracts have such coverage.*

*The following Association Technology Evaluation Criteria must be met for a service/supply to be considered for coverage:*

- 1. The technology must have final approval from the appropriate government regulatory bodies;*
- 2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes;*
- 3. The technology must improve the net health outcome;*
- 4. The technology must be as beneficial as any established alternatives;*
- 5. The improvement must be attainable outside the investigational setting.*

*Medical Necessity means that health care services (e.g., procedures, treatments, supplies, devices, equipment, facilities or drugs) that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury or disease or its symptoms, and that are:*

- 1. In accordance with generally accepted standards of medical practice; and*
- 2. Clinically appropriate in terms of type, frequency, extent, site and duration and considered effective for the patient's illness, injury or disease; and*
- 3. Not primarily for the convenience of the patient, physician or other health care provider; and*
- 4. Not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.*

## **Description of Procedure or Service:**

Radiofrequency (RF) energy has been investigated as a minimally invasive treatment of fecal incontinence, a procedure referred to as the Secca procedure. In this outpatient 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. This procedure is very similar in concept to the Stretta procedure for the treatment of gastroesophageal reflux disease (GERD).

RF energy is a commonly used 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 of GERD, 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.

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. 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.

## **Policy:**

**Transanal Radiofrequency Treatment of Fecal Incontinence does not meet Blue Cross and Blue Shield of Alabama's medical criteria for coverage and is considered **investigational**.**

*Blue Cross and Blue Shield of Alabama does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Cross and Blue Shield of Alabama administers benefits based on the members' contract and corporate medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.*

### **Key Points:**

No trials comparing transanal radiofrequency (RF) treatment of fecal incontinence with available alternative treatments have been identified. The literature search to date has identified eight nonrandomized studies on this procedure; seven studies published between 2003 and 2010, and one study published in 2012.

Abbas et al (2012) published results of their retrospective review of 27 patients who underwent the Secca™ procedure during a six-year period (2004-2010) at Kaiser Permanente Los Angeles Medical Center. Thirty-one procedures were performed for moderate to severe fecal incontinence. Most study patients were women with a mean age of 64 years, and the most common cause of 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 incontinence. No major complications occurred after 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 was 16 at baseline and 10.9 3 months postoperatively. Previous studies have suggested that a CCF-FI of greater than nine indicates a significant impairment of quality of life. However, in the Abbas et al study, 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 2003, Efron et al published an open-label, single-arm, nonrandomized study of 50 patients who underwent the Secca procedure and were followed-up for six 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 the 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 six-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 nine, a total of 15 (34%) achieved CCF-FI less than 10 at six months. Improvement also was assessed using the Medical Outcomes Study Short Form-36, 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 nine parameters; for example, 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 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. 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.

Felt-Bersma et al (2007) published results of an uncontrolled study on the Secca procedure in 11 women with fecal incontinence that underwent baseline and posttreatment testing. Six patients (55%) 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 eight patients (73%), moderate in two, and severe in one. Investigators suggested that this procedure merited further testing and noted that a randomized, controlled trial was underway. Lam et al (2014) reported three-year outcomes of this cohort plus 20 other patients who underwent the Secca procedure for fecal incontinence. Of the total cohort of 31 patients, five (16%) maintained a clinically significant response (defined as >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.

Ruiz et al (2010) reported on one-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 patients (67%). Mean CCF-FI score improved from 15.6 at baseline to 12.9 at 12 months (p=0.035). 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 performed outside the United States. 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, short-term follow-up), efficacy of RF therapy for fecal incontinence is not supported in the literature.

### **Summary**

Studies described in this policy include a small number of patients, and estimates of treatment differences are very imprecise. Study follow-up periods are variable and need to be considerably longer in larger numbers of patients to properly evaluate long-term outcomes. No new studies on this procedure have been published since the last update; three-year follow-up of a small cohort of patients 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 or physical therapies or as an adjunct treatment option for fecal incontinence. Given the insufficient evidence available to evaluate the impact of the technology on net health outcome, this surgical procedure is considered investigational.

### **Practice Guidelines and Position Statements**

The United Kingdom's National Institute for Health and Care Excellence (NICE) issued guidance on RF treatment for fecal incontinence in 2011. 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."

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. This statement was based on level IV evidence (grade of recommendation C) because of the limited data available on this treatment modality.

### **U.S. Preventive Services Task Force Recommendations**

RF treatment of fecal incontinence is not a preventive service.

### **Key Words:**

Transanal radiofrequency therapy, radiofrequency energy, fecal incontinence, the Secca System

### **Approved by Governing Bodies:**

In 2002, the Secca™ System (Curon Medical; Sunnyvale, CA) received 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.”

### **Benefit Application:**

Coverage is subject to member’s specific benefits. Group specific policy will supersede this policy when applicable.

ITS: Home Policy provisions apply

FEP contracts: FEP does not consider investigational and will be reviewed for medical necessity.

### **Current Coding:**

CPT Code:

**0288T** Anoscopy, with delivery of thermal energy to the muscle of the anal canal (e.g., for fecal incontinence)

HCPCS Code:

**C9716** Creation of thermal anal lesions by radiofrequency energy

### **References:**

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## **Policy History:**

Medical Policy Group, May 2004 (1)

Medical Policy Administration Committee May 2004

Available for comment June 1-July 15, 2004

Medical Policy Group, May 2006 (1)

Medical Policy Group, May 2008 (1)

Medical Policy Group, May 2010 (1): Key Points updated, no policy change

Medical Policy Group, November 2011 (3): Code 0288T added

Medical Policy Group, January 2012 (2): Updated Key Points 2011 Update & References

Medical Policy Panel, November 2012

Medical Policy Group, November (2): No change in policy statement. Approved by Governing Bodies, Key Points, References updated with new information from 2012 literature search  
HCPCS code C9716 added

Medical Policy Panel, September 2013

Medical Policy Group, October 2013 (2): No new literature identified. No change to policy statement

Medical Policy Panel, September 2014

Medical Policy Group, September 2014 (1): Update to Key Points and References; no change to policy statement

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*This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member's plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.*

*This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield's administration of plan contracts.*