Transanal Radiofrequency Treatment of Fecal Incontinence

Section 2.0 Medicine
Effective Date January 30, 2015

Subsection Original Policy Date July 6, 2012
Next Review Date January 2016

Description
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 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. This procedure is very similar in concept to the Stretta® procedure for treatment of gastroesophageal reflux disease (GERD).

Related Policies
- N/A

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

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

Effective in 2012, there is a specific CPT category III code for this procedure:
- 0288T: Anoscopy, with delivery of thermal energy to the muscle of the anal canal (e.g., for fecal incontinence)

Prior to 2012, there were no specific CPT codes describing this procedure. It was likely that CPT code 46999 (unlisted procedure, anus) would have been used.

Benefit Application
Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program (FEP)) prohibit Plans from denying Food and Drug Administration (FDA) - approved technologies as
investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

**Rationale**

**Background**

Radiofrequency (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 gastroesophageal reflux disease (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 (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 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.

**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.” (1)

FDA product code: GEI

**Literature Review**

No trials allowing comparison of outcomes of transanal radiofrequency (RF) treatment of fecal incontinence to available alternative treatments have been identified. The literature search to date has identified 8 nonrandomized studies on this procedure; 7 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 over a 6-year period (2004-2010) at Kaiser Permanente Los Angeles Medical Center. 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. 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) consists of an open-label, single-arm, nonrandomized clinical study that included 50 subjects who were treated and followed up for 6 months. Patients served as their own controls. 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 (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 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 34.4, 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.

Felt-Bersma et al. (2007) published the results of an uncontrolled study on the Secca procedure in 11 women with fecal incontinence who underwent baseline and post-treatment testing. Six (55%) patients reported improvement; Vaiyey 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 merited further testing and noted that a randomized, controlled trial was underway. 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 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) 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 performed outside the U.S. (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 RF therapy for fecal incontinence is not supported in the literature.

A search of online site clinicaltrials.gov in August 23, 2013 did not identify any clinical trials of RF treatment of fecal incontinence.

Summary

Studies described in this policy include a small number of patients, and the estimates of treatment differences are very imprecise. Study follow-up periods are variable and need to be considerably longer for a proper evaluation of long-term success. No new studies on this procedure have been published since the last update; 3-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 radiofrequency treatment for fecal incontinence in 2011. (11) 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. (11)

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. (12) 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.
Medicare National Coverage

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

References


Documentation Required for Clinical Review

- No records required
This Policy relates only to the services or supplies described herein. Benefits may vary according to benefit design; therefore, contract language should be reviewed before applying the terms of the Policy. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement.

IE

The following services are considered investigational and therefore not covered for any indication.

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<th>Type</th>
<th>Code</th>
<th>Description</th>
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Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

<table>
<thead>
<tr>
<th>Effective Date</th>
<th>Action</th>
<th>Reason</th>
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<tr>
<td>7/6/2012</td>
<td>BCBSA Medical Policy adoption</td>
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<tr>
<td>8/21/2012</td>
<td>Coding Update</td>
<td>Administrative Review</td>
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<tr>
<td>1/30/2015</td>
<td>Policy revision without position change</td>
<td>Medical Policy Committee</td>
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Definitions of Decision Determinations

**Medically Necessary:** A treatment, procedure or drug is medically necessary only when it has been established as safe and effective for the particular symptoms or diagnosis, is not investigational or experimental, is not being provided primarily for the convenience of the patient or the provider, and is provided at the most appropriate level to treat the condition.

**Investigational/Experimental:** A treatment, procedure or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.
**Split Evaluation:** Blue Shield of California / Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a Split Evaluation, where a treatment, procedure or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

**Prior Authorization Requirements**

This service (or procedure) is considered medically necessary in certain instances and investigational in others (refer to policy for details).

For instances when the indication is medically necessary, clinical evidence is required to determine medical necessity.

For instances when the indication is investigational, you may submit additional information to the Prior Authorization Department.

Within five days before the actual date of service, the Provider MUST confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should also be directed to the Prior Authorization Department. Please call 1-800-541-6652 or visit the Provider Portal www.blueshieldca.com/provider.

The materials provided to you are guidelines used by this plan to authorize, modify, or deny care for persons with similar illness or conditions. Specific care and treatment may vary depending on individual need and the benefits covered under your contract. These Policies are subject to change as new information becomes available.