2.01.58 Transanal Radiofrequency Treatment of Fecal Incontinence

Policy Statement

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.

Coding

Effective in 2017, there is no specific CPT code for this procedure. It would be reported with the following CPT code:

- **46999**: Unlisted procedure, anus

Prior to 2017, there was a CPT category III code specific to the procedure:

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

Description

Radiofrequency 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, 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 improving continence.

Related Policies

- Biofeedback as a Treatment of Fecal Incontinence or Constipation

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)] prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of the FDA-approved technologies on the basis of medical necessity alone.

Regulatory Status

In 2002, the Secca™ System (Mederi Therapeutics) was cleared for marketing by the U.S. Food and Drug Administration 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.”

Food and Drug Administration product code: GEI.
Rationale

Background

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. Radiofrequency (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.

Literature Review

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 radiofrequency (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 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
score. Authors’ conclusions on the actual clinical significance of this improvement were uncertain. 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 radiofrequency 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.

Supplemental Information
Practice Guidelines and Position Statements
National Institute for Health and Care Excellence
The National Institute for Health and Care Excellence (NICE) issued guidance on radiofrequency 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.”

In 2016, NICE published a Medtech innovation briefing on the Secca system for fecal incontinence. These briefings aim to aid in the decision-making process by describing the technology, its role in the treatment pathway, a review of 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, noted: “Application of temperature-controlled radiofrequency energy to the sphincter complex may be used to treat fecal incontinence. Grade of Recommendation: Weak recommendation based on moderate-quality evidence, 2B.” The guidelines also stated: “Because of the limitations in the available data, alternative treatments should be pursued before considering radiofrequency energy delivery.”

American College of Gastroenterology
The American College of Gastroenterology published guidelines on the management of benign anorectal disorders in 2014. The guidelines indicated that there is insufficient evidence to recommend radiofrequency ablation to the anal sphincter as treatment for fecal incontinence. The College also asserted that the biologic rationale for this type of treatment is unproven.
U.S. Preventive Services Task Force Recommendations
Not applicable.

Medicare National Coverage
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.

Ongoing and Unpublished Clinical Trials
A search of ClinicalTrials.gov in November 2016 did not identify any ongoing or unpublished trials that would likely influence this review.

References

2.01.58 Transanal Radiofrequency Treatment of Fecal Incontinence


**Documentation for Clinical Review**

- No records required

**Coding**

This Policy relates only to the services or supplies described herein. Benefits may vary according to product 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 may be considered investigational.

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<tr>
<th>Type</th>
<th>Code</th>
<th>Description</th>
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<td>CPT®</td>
<td>0288T</td>
<td>Anoscopy, with delivery of thermal energy to the muscle of the anal canal (e.g., for fecal incontinence)</td>
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<td>46999</td>
<td>Unlisted procedure, anus</td>
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<td>HCPCS</td>
<td>None</td>
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<td>ICD-10 Procedure</td>
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<td>Destruction of Anal Sphincter, Percutaneous Approach</td>
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<td>All Diagnoses</td>
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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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<tbody>
<tr>
<td>07/06/2012</td>
<td>BCBSA Medical Policy adoption</td>
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<tr>
<td>08/21/2012</td>
<td>Coding Update</td>
<td>Administrative Review</td>
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<td>01/30/2015</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 (as applicable to your plan) |

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 be directed to the Prior Authorization Department. Please call (800) 541-6652 or visit the provider portal at www.blueshieldca.com/provider.

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.