Anthem

Medical Policy

Subject: Transanal Radiofrequency Treatment of Fecal Incontinence
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Description/Scope

This document addresses the use of transanal radiofrequency energy to treat 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. Radiofrequency energy (for example, the Secca™ System, Mederi Therapeutics, Norwalk, CT) has been investigated as a minimally invasive treatment of fecal incontinence. 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.

Note: For information about sacral nerve stimulation and percutaneous tibial nerve stimulation for fecal incontinence, please see the following:

- CG-SURG-95 Sacral Nerve Stimulation and Percutaneous or Implantable Tibial Nerve Stimulation for Urinary and Fecal Incontinence; Urinary Retention

Position Statement

Investigational and Not Medically Necessary:

Transanal radiofrequency therapy for the treatment of fecal incontinence is considered**investigational and not medically necessary.**

Rationale

Lefebure and colleagues (2008) reported the results of a nonrandomized, prospective study of 15 individuals who underwent the Secca procedure at a single institution between March 2005 and March 2006. All had experienced fecal incontinence for at least 3 months and had attempted, but were unsatisfied with the results of, surgical and/or medical interventions. The goal of the study was to evaluate changes in the Fecal Incontinence Quality of Life (FIQL) questionnaire scores between the baseline and follow-up intervals. At 12 months post-procedure, all 15 individuals were alive and in contact with the investigational site. Investigators reported no long-term complications. The mean Wexner score improved from 14.07 (± 4.5) at baseline to 12.33 (± 4.6) at 1 year (p=0.02). The mean FIQL score improved only in the depression subscore. There were no changes in endoanal ultrasound and anorectal manometry. Researchers concluded that while the study confirmed the safety of the Secca procedure, most individuals remained in the moderate incontinence category as defined by the scoring system and did not improve their FIQL except in the depression subscore. Limitations of this study include its small, single institution, non- randomized design and follow up period of only 12 months. Although the authors report a statistically significant difference in mean Wexner scores between baseline and follow-up, there is broad overlap in the confidence intervals between these time periods. Additionally, limitations of the Wexner scoring system should also be taken into consideration. In his evaluation of various scoring systems and methods for therapeutic interventions for the treatment of fecal incontinence, Rao (2016) states the following regarding the Wexner scale:

> This scale is anchor-based and derived from a patient perspective and not distribution based i.e., was not based on exceeding a minimum clinically important improvement threshold derived from either standard duration or standard error of the mean. Also it is not weighted, does not assess urgency, and the use of pads was weighted equally with stool loss and may not be an accurate measure of incontinence but more of personal hygiene. Because of these inherent weaknesses and high risk of bias, several trials that have used this score as the primary outcome measure have often reported positive results in favor of the treatment but have been seldom replicated (Rao, 2016).

Takahashi-Monroy and colleagues (2008) evaluated the long-term (5 years) durability of radiofrequency energy delivery for fecal incontinence in 19 (18 females and 1 male) individuals. This study was an extension of the follow-up from an earlier prospective study in which individuals who suffered from fecal incontinence were treated with the Secca procedure. The Cleveland Clinic Florida Fecal Incontinence Scale (CCF-FI; 0-20), FIQL score, and the Medical Outcomes Study Short-Form 36 were administered to all participants up to 5 years after the procedure. Differences between baseline and follow-up were analyzed by using paired t-test: the mean duration for fecal incontinence was 7.1 (range, 1-21) years. At the 5-year follow-up, the mean fecal incontinence score had improved from 14.37 to 8.26 ($p<0.00025$) with 16 individuals (84.2%) demonstrating a greater than 50% improvement. All FIQL scores (coping, depression, embarrassment) improved. The social function component of the Short-Form 36 improved from 38.3 to 60 ($p<0.05$). There was a pattern of improvement in the mental component summary of the Short-Form 36 from 38.1 to 48.14. No long-term complications were reported. The researchers concluded that significant and sustained improvements in FIQL were seen at 5 years after treatment with the Secca System. The results of this study are also limited by its small sample number, uncontrolled, non-randomized design.

Kim and colleagues (2009) evaluated the safety and effectiveness of the Secca procedure as a treatment for fecal incontinence in 8 individuals. Measurements at baseline and after the procedure were assessed using the Fecal Incontinence Severity Index (FISI) score and the FIQL scale. Anorectal manometry and endoanal ultrasound also were used. The median age of the individuals was 59 years (range, 28-73 years) and 7 of the 8 were women. At 6 months after the procedure, the mean FISI score and all of the parameters in the FIQL scale with the exception of the embarrassment scale did not improve significantly. Researchers did not observe any changes in the anal manometry and endoanal ultrasound parameters. When compared to other studies, the participants in this study experience higher rated of complications. In 7 of the 8 participants, complications included anal bleeding, local hematoma, laxative-associated diarrhea, anal pain, and anal mucosal discharge after the procedure. In this study, the Secca procedure resulted in relatively poor treatment outcomes. Similar to some of the studies discussed above, limitations of this study include the small sample size, nonrandomized, uncontrolled design and short follow-up.

Ruiz and colleagues (2010) reported the 1-year outcomes of individuals who underwent the Secca procedure as a treatment for fecal incontinence at a single institution between March 2003 and June 2004. A total of 24 individuals were enrolled in the study, but only 16 were available at the 12-month follow-up visit. The main causes of fecal incontinence were obstetric injury, aging, trauma from previous anorectal surgeries, or idiopathic. The mean CCF-FI score improved from a mean of 15.6 (± 3.2) at baseline to 12.9 (± 4.6) at 12 months (p=0.035). The CCF-FI score also indicated that 4 participants (25%) experienced a worsening of their fecal incontinence, and 2 individuals (12.5%) showed no improvement. Of the 10 participants (62.5%) with improvement, 2 (12.5%) had at least a 50% improvement in the CCF-FI score at the 12-month follow-up, and 7 participants (43.8%) demonstrated a 20% or more improvement. Overall, 10 of the 16 participants had a score less than 15, indicating moderate fecal incontinence. At 1 year post-treatment, the mean CCF-FI score was reduced from severe to moderate incontinence. The mean FIQL score improved in all subsets except for the depression subscore which did not reach significance (p=0.58). The authors acknowledged that some of the limitations of this study included a small sample size, the lack of physiologic study data, and the loss to follow-up of 33% of the participants. The follow-up period for this study is shorter than the study conducted by Takahashi-Monroy (2008) and many of the participants continued to experience fecal incontinence.

Lam and colleagues (2014) reported 3-year outcomes for 31 individuals who underwent the Secca treatment for fecal incontinence between 2005 and 2010. In order to study severe fecal incontinence, the researchers included participants with a Vaizey score (VS) of 12 or higher. A clinically significant response to Secca was defined as ≥ 50% reduction in the VS at 6 months. The impact of fecal incontinence was measured using the FIQL score, and data was acquired on four occasions: at baseline, at 6 months, at 1 year, and at 3 years. Anal manometry and anal endosonography were carried out at 3 months and compared to baseline. During the follow-up period, 5/31 (6%) of the participants sustained a clinically significant response after the transanal radiofrequency procedure for 6 months. A total of 3/31 (10%) maintained response for 1 year and 2/31 (6%) retained response for 3 years. No escalations in anorectal pressures or improvements in rectal compliance were observed. The results of this prospective, non-randomized trial suggest that for the majority of participants in this study, the clinically significant response to transanal radiofrequency therapy was at best, temporary in nature. This study is also limited by it uncontrolled, nonrandomized design and small population.

Frascio and colleagues (2017) conducted a prospective, single-center, observational study on the 1-year outcomes of the Secca procedure for 21 individuals, all of whom had failed conservative treatment and had fecal incontinence for at least 6 months. Of the 21 individuals included in the original study, 19 (90%) were available to complete the 1-year follow-up. Study outcomes included the CCF-FI score, FIQL score, anorectal manometry, and endoanal ultrasound. At 1 year, participants' CCF-FI improved from 14.5 points to 12.9 points. The FIQL score, which included lifestyle, coping, depression, and embarrassment, only significantly improved in the embarrassment category (p<0.05). Although manometry measurements initially improved after the procedure, the improvements were not sustained at the 1-year follow-up. Endoanal ultrasound did not show any sphincter defects at baseline or at 1 year. No complications occurred except for one intra-anal submucosal abscess that was successfully treated. Limitations of the study included a small sample size, all female participants, and a loss to follow-up for 2 participants.

Visscher and colleagues (2017) performed a randomized sham-controlled trial to differentiate between the benefits and placebo effect of the Secca procedure. The researchers randomized 40 individuals 1:1 to either receive the Secca procedure or an inactive sham procedure. At 6 months post-procedure, the researchers found that the VS decreased a mean of –3.6 points for the Secca group and –1.2 points for the sham group (p=0.02). Only 2 participants in the Secca group met the primary outcome of a decrease in VS of at least 50%, but the researchers could not identify why these individuals had a successful outcome compared to other study participants. The researchers did not find a statistically significant difference between the Secca and sham group for the FIQL score or for anorectal manometry measurements. No serious adverse events were reported, and side effects included minor bleeding or hematoma, temporary discharge of mucus, and diarrhea from the pre-procedure antibiotic. Limitations of the study included the inclusion of severely incontinent individuals and the powering of the study against an older pilot study. The authors concluded that "the Secca procedure should not be recommended for patients with FI [fecal incontinence] until patient-related factors associated with treatment success are known."

Other Considerations

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

In a clinical practice guideline for the treatment of fecal incontinence (Paquette, 2015), the American Society of Colon and Rectal Surgeons (ASCRS) concluded that the reported evidence for radiofrequency treatment is relatively sparse and has relevant limitations. Most studies reviewed have been small, single-center series with short-term follow-up. In addition, the authors observed that while long-term follow-up is very limited, any clinical benefit achieved in the short term appears to be sustained in the long term. The authors also noted that individuals with inflammatory bowel disease (IBD), chronic constipation, diarrhea, and history of pelvic radiation were not included in the studies reviewed. They stated that "because of the limitations in the available data, alternative treatments should be pursued before considering radiofrequency energy delivery."

The Agency for Healthcare Research and Quality (AHRQ) published a systematic review on treatments for fecal incontinence (Forte, 2016). The authors found a lack of comparative studies on Secca and concluded that the evidence for the procedure was insufficient.

Summary

In order to determine the long-term efficacy of transanal radiofrequency therapy as a treatment of fecal incontinence, it should be compared to conservative therapies that are considered standard of care for this condition. The peer-reviewed literature on this topic consists primarily of non-randomized uncontrolled trials, none of which compared transanal radiofrequency treatment to conservative treatments or alternative treatments. Additionally, most of the peer-reviewed literature consists of small studies with short-term follow-up. Studies to date have not distinguished between the five types of fecal incontinence (stress, urge, overflow, functional and mixed incontinence). Larger, prospective randomized trials comparing transanal radiofrequency treatment to other conservative or alternative treatments of fecal incontinence and demonstrating long-term improved patient outcomes are needed to accurately determine the efficacy of this treatment and identify which population of individuals with fecal incontinence might benefit from this treatment.

Background/Overview

Fecal incontinence is the inability to control the bowels, which results in leakage of stool or gas. There are many causes of fecal incontinence, including injury from childbirth, injury from a previous surgery, nerve-related diseases, and age-related changes in muscle tone. Fecal incontinence affects between 2-8% of the U.S. adult population. Seven percent of the otherwise healthy individuals over age 65 who are living at home experience fecal incontinence at least once per week or need to use a pad. Females are affected more frequently than males.

Management of fecal incontinence is provided in a tiered approach, beginning with lifestyle modification or pharmacologic therapy

followed by selectively offering various modalities and surgery to eligible individuals. Selection of which treatment modality to be employed depends on a number of aspects, such as severity of symptoms, availability of methods, and the individual's adherence to treatment. Moreover, concomitant use of different methods can improve results and is usually applied.

The Secca procedure is a minimally invasive, outpatient procedure that represents a less-invasive option for the treatment of fecal incontinence, as compared to surgery. The Secca System, which received U.S. Food and Drug Administration (FDA) approval in March 2002, consists of the control module, a four-channel radiofrequency generator, and the Secca hand piece, which is a single-use device used to deliver energy to the muscles of the anal canal. The physician places the device into the anal canal, deploys the electrodes into the tissue, and initiates radiofrequency energy delivery. Discrete thermal lesions are created in the tissue surrounding each electrode. Over time, the treated areas resorb and the tissue contracts, changing the tone of the tissue and improving continence in most individuals. Potential complications include stricture, pain, and constipation. Additional studies are needed to examine long-term outcomes and the development of complications.

Definitions

Fecal incontinence (also known as bowel incontinence): The loss of bowel control, leading to an involuntary passage of stool. This can range from occasionally leaking a small amount of stool and passing gas, to completely losing control of bowel movements.

Radiofrequency: Relating to, using, or induced by using heat produced by high-frequency radio waves.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. 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.

When Services are Investigational and Not Medically Necessary:
When the code describes a procedure indicated in the Position Statement section as investigational and not medically necessary.

CPT

46999	Unlisted procedure, anus [when specified as delivery of thermal energy to the muscle of the anal canal (e.g., for fecal incontinence)]

ICD-10 Diagnosis

	All diagnoses

References

Peer Reviewed Publications:

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3. Felt-Bersma RJ, Szojda MM, Mulder CJ. Temperature-controlled radiofrequency energy (SECCA) to the anal canal for the treatment of faecal incontinence offers moderate improvement. Eur J Gastroenterol Hepatol. 2007; 19(7):575-580.
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14. Takahashi-Monroy T, Morales M, Garcia-Osogobio S, et al. SECCA procedure for the treatment of fecal incontinence: results of five-year follow-up. Dis Colon Rectum. 2008; 51(3):355-359.
15. Visscher AP, Lam TJ, Meurs-Szojda MM, Felt-Bersma RJF. Temperature-controlled delivery of radiofrequency energy in fecal incontinence: a randomized sham-controlled clinical trial. Dis Colon Rectum. 2017; 60(8):860-865.

Government Agency, Medical Society, and Other Authoritative Publications:

1. Bachoo P, Brazzelli M, Grant A. Surgery for faecal incontinence in adults. Cochrane Database Syst Rev. 1999; (3):CD001757.
2. Forte ML, Andrade KE, Butler M, et al. Treatments for fecal incontinence. Comparative Effectiveness Review No. 165 [Internet]. Rockville (MD): Agency for Healthcare Research and Quality (US); 2016 March. Available at: https://effectivehealthcare.ahrq.gov/sites/default/files/pdf/fecal-incontinence_research.pdf. Accessed on December 19, 2023.
3. Paquette IM, Varma MG, Kaiser AM, et.al. The American Society of Colon and Rectal Surgeons' clinical practice guideline for the treatment of fecal incontinence. Dis Colon Rectum. 2015; 58(7):623-636.
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Websites for Additional Information

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Index

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

Document History

Status	Date	Action
Reviewed	02/15/2024	Medical Policy & Technology Assessment Committee (MPTAC) review. Updated Rationale, References and Websites for Additional Information sections.
Reviewed	02/16/2023	MPTAC review. Updated, References and Websites for Additional Information sections.
Reviewed	02/17/2022	MPTAC review. Updated the review date, Rationale, References and Websites for Additional Information sections.
Reviewed	02/11/2021	MPTAC review. Updated the review date, Rationale, References and Websites for Additional Information.
Reviewed	02/20/2020	MPTAC review. Updated the review date, References and Websites.
Reviewed	03/21/2019	MPTAC review. Description/Scope, References and Websites sections updated.
Reviewed	03/22/2018	MPTAC review. The document header wording updated from “Current Effective Date” to “Publish Date.” The Description/Scope, Rationale, Background, Definitions, References, and Websites sections updated.
Reviewed	05/04/2017	MPTAC review. Updated Rationale, References and Websites sections.
	01/01/2017	Updated Coding section with 01/01/2017 CPT changes; removed code 0288T deleted 12/31/2016.
Reviewed	05/05/2016	MPTAC review. Updated Rationale, References and History sections. Removed ICD-9 codes from Coding section.
Reviewed	05/07/2015	MPTAC review. Updated Rationale, References and History sections.
Reviewed	05/15/2014	MPTAC review. Updated References and History sections.
Reviewed	05/09/2013	MPTAC review. Updated References and History sections.
Reviewed	05/10/2012	MPTAC review. Updated References and History sections. In Description/Scope section, added cross reference to SURG.00017. Updated Coding section; removed code C9716 deleted 12/31/2011.
	01/01/2012	Updated Coding section with 01/01/2012 CPT changes.
Reviewed	05/19/2011	MPTAC review. Updated review date, Rationale, References and History sections.
Reviewed	05/13/2010	MPTAC review. Updated review date, References and History sections.
Reviewed	05/21/2009	MPTAC review. Updated review date, Rationale, References and History sections.
Reviewed	05/15/2008	MPTAC review.
	02/21/2008	The phrase "investigational/not medically necessary" was clarified to read "investigational and not medically necessary." This change was approved at the November 29, 2007 MPTAC meeting.
Reviewed	05/17/2007	MPTAC review. References and Coding updated.
Reviewed	06/08/2006	MPTAC review. Updated References, no change to position statement.
Revised	07/14/2005	MPTAC review. Revision based on Pre-merger Anthem and Pre-merger WellPoint Harmonization.

Pre-Merger Organizations	Last Review Date	Document Number	Title
Anthem, Inc.	01/29/2004	SURG.00056	Transanal Radiofrequency Treatment of Fecal Incontinence
WellPoint Health Networks, Inc.	09/23/2004	2.06.21	Transanal Radiofrequency Therapy

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