

# Protocol

## Transanal Radiofrequency Treatment of Fecal Incontinence

(20158)

<b>Medical Benefit</b>		<b>Effective Date:</b> 10/01/09	<b>Next Review Date:</b> 03/19
<b>Preauthorization</b>	No	<b>Review Dates:</b> 05/09, 05/10, 05/11, 05/12, 05/13, 05/14, 05/15, 11/15, 11/16, 03/17, 03/18	

***This protocol considers this test or procedure investigational. If the physician feels this service is medically necessary, preauthorization is recommended.***

*The following protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.*

Populations	Interventions	Comparators	Outcomes
Individuals: <ul style="list-style-type: none"><li>• With fecal incontinence</li></ul>	Interventions of interest are: <ul style="list-style-type: none"><li>• Transanal radiofrequency treatment</li></ul>	Comparators of interest are: <ul style="list-style-type: none"><li>• Medical management</li><li>• Biofeedback</li><li>• Sphincteroplasty</li></ul>	Relevant outcomes include: <ul style="list-style-type: none"><li>• Symptoms</li><li>• Change in disease status</li><li>• Quality of life</li><li>• Treatment-related morbidity</li></ul>

### 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.

### Summary of Evidence

For individuals who have fecal incontinence who receive transanal radiofrequency treatment, the evidence includes eight 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.

### 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.

**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.

**Regulatory Status**

In 2002, the Secca™ System (Mederi Therapeutics) was cleared for marketing by the U.S. Food and Drug Administration (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.”<sup>1</sup> FDA product code: GEI.

**Related Protocol**

Biofeedback as a Treatment of Fecal Incontinence or Constipation

---

Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are

considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

## References

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

1. Food and Drug Administration (FDA). Attachment 14: 510(k) Summary. Curon Medical, Inc.'s Secca™ System. 2002; [http://www.accessdata.fda.gov/cdrh\\_docs/pdf/k014216.pdf](http://www.accessdata.fda.gov/cdrh_docs/pdf/k014216.pdf). Accessed October 25, 2017.
2. Forte ML, Andrade KE, Butler M, et al. Treatments for Fecal Incontinence (Comparative Effectiveness Review No. 165). Rockville, MD: Agency for Healthcare Research and Quality; 2016.
3. Abbas MA, Tam MS, Chun LJ. Radiofrequency treatment for fecal incontinence: is it effective long-term? *Dis Colon Rectum*. May 2012; 55(5):605-610. PMID 22513440
4. Rothbarth J, Bemelman WA, Meijerink WJ, et al. What is the impact of fecal incontinence on quality of life? *Dis Colon Rectum*. Jan 2001; 44(1):67-71. PMID 11805565
5. Efron JE, Corman ML, Fleshman J, et al. Safety and effectiveness of temperature-controlled radio-frequency energy delivery to the anal canal (Secca procedure) for the treatment of fecal incontinence. *Dis Colon Rectum*. Dec 2003; 46(12):1606-1616; discussion 1616-1608. PMID 14668584
6. 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*. Jul 2007; 19(7):575-580. PMID 17556904
7. Lam TJ, Visscher AP, Meurs-Szojda MM, et al. Clinical response and sustainability of treatment with temperature-controlled radiofrequency energy (Secca) in patients with faecal incontinence: 3 years follow-up. *Int J Colorectal Dis*. Jun 2014; 29(6):755-761. PMID 24805249
8. Ruiz D, Pinto RA, Hull TL, et al. Does the radiofrequency procedure for fecal incontinence improve quality of life and incontinence at 1-year follow-up? *Dis Colon Rectum*. Jul 2010; 53(7):1041-1046. PMID 20551757
9. Lefebure B, Tuech JJ, Bridoux V, et al. Temperature-controlled radio frequency energy delivery (Secca procedure) for the treatment of fecal incontinence: results of a prospective study. *Int J Colorectal Dis*. Oct 2008; 23(10):993-997. PMID 18594840
10. 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*. Mar 2008; 51(3):355-359. PMID 18204954
11. Kim DW, Yoon HM, Park JS, et al. Radiofrequency energy delivery to the anal canal: is it a promising new approach to the treatment of fecal incontinence? *Am J Surg*. Jan 2009; 197(1):14-18. PMID 18614149
12. National Institute for Health and Care Excellence (NICE). Endoscopic radiofrequency therapy of the anal sphincter for faecal incontinence [IPG393]. 2011; <https://www.nice.org.uk/guidance/ipg393>. Accessed October 25, 2017.
13. National Institute for Health and Care Excellence (NICE). Secca System for faecal incontinence [MIB66]. 2016; <https://www.nice.org.uk/advice/mib66/chapter/summary>. Accessed October 25, 2017.
14. 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*. Jul 2015; 58(7):623-636. PMID 26200676
15. Wald A, Bharucha AE, Cosman BC, et al. ACG clinical guideline: management of benign anorectal disorders. *Am J Gastroenterol*. Aug 2014; 109(8):1141-1157; (Quiz) 1058. PMID 25022811