

# Protocol

## Transanal Radiofrequency Treatment of Fecal Incontinence

(20158)

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|------------------------|---------------------------------|---|
| <b>Medical Benefit</b> | <b>Effective Date:</b> 10/01/09 | <b>Next Review Date:</b> 05/15                                |
| Preatuthorization      | No                              | <b>Review Dates:</b> 05/09, 05/10, 05/11, 05/12, 05/13, 05/14 |

*The following Protocol contains medical necessity criteria that apply for this service. It is applicable to Medicare Advantage products unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. **Preatuthorization is not required but is recommended if, despite this Protocol position, you feel this service is medically necessary.** 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.*

### 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).

### 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. There are a variety of etiologies, including injury from vaginal delivery, anal surgery, neurologic disease, and the normal aging process. It is estimated that the disorder affects 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 can be used for mild degrees of incontinence. Bowel management programs, commonly used in patients with spinal cord injuries, may also be effective in patients with fecal incontinence. Biofeedback has been investigated as well. Surgical approaches primarily include a sphincteroplasty, although more novel approaches may be attempted in those patients whose only other treatment option is the creation of a stoma. These novel approaches include an artificial anal sphincter or sacral neuromodulation. RF energy has also 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)

### Related Protocol

Biofeedback as a Treatment of Fecal Incontinence or Constipation

### Policy (Formerly Corporate Medical Guideline)

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

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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). 510(k) Summary. Attachment 14. 2002. Available online at: [http://www.accessdata.fda.gov/cdrh\\_docs/pdf/k014216.pdf](http://www.accessdata.fda.gov/cdrh_docs/pdf/k014216.pdf). Last accessed August 2013.
2. Abbas MA, Tam MS, Chun LJ. Radiofrequency treatment for fecal incontinence: is it effective long-term? *Dis Colon Rectum* 2012; 55(5):605-10.
3. Rothbarth J, Bemelman WA, Meijerick WJ et al. What is the impact of fecal incontinence on the quality of life. *Dis Colon Rectum* 2001; 44(1):67-71.
4. 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* 2003; 46(12):1606-18.
5. 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):575-80.
6. 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* 2010; 53(7):1041-6.

7. Lefebvre B, Tuech JJ, Bridoux V et al. Temperature-controlled radiofrequency energy delivery (Secca procedure) for the treatment of fecal incontinence: results of a prospective study. *Int J Colorectal Dis* 2008; 23(10):993-7.
8. 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):355-9.
9. 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* 2009; 197(1):14-8.
10. National Institute for Health and Clinical Excellence (NICE). Endoscopic radiofrequency therapy of the anal sphincter for faecal incontinence (2011). Available online at: <http://www.nice.org.uk/nicemedia/live/13047/54501/54501.pdf>. Last accessed August 2013.
11. Tjandra JJ, Dykes SL, Kumar RR et al. Practice parameters for the treatment of fecal incontinence. *Dis Colon Rectum* 2007; 50(10):1497-507.