

# MEDICAL POLICY

MEDICAL POLICY DETAILS	
Medical Policy Title	Radiofrequency Treatment for Fecal Incontinence
Policy Number	7.01.66
Category	Technology Assessment
Original Effective Date	12/16/04
Committee Approval Date	10/20/05, 10/19/06, 09/20/07, 08/21/08
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Product Disclaimer	<ul style="list-style-type: none"> <li>• <i>Services are contract dependent; if a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.</i></li> <li>• <i>If a commercial product (including an Essential Plan or Child Health Plus product), medical policy criteria apply to the benefit.</i></li> <li>• <i>If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.</i></li> <li>• <i>If a Medicare product (including Medicare HMO-Dual Special Needs Program (DSNP) product) covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.</i></li> <li>• <i>If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.</i></li> </ul>

## POLICY STATEMENT

Based upon our criteria and assessment of the peer-reviewed literature, radiofrequency treatment of fecal incontinence has not been medically proven to be effective and, therefore, is considered **investigational**.

*Refer to Corporate Medical Policy #11.01.03 Experimental or Investigational Services*

## DESCRIPTION

Fecal incontinence is defined as the involuntary leakage of stool from the rectum and anal canal. Fecal continence depends on several mechanisms, including anal sphincter function, pelvic floor function, stool transit time, rectal capacity, and sensation. There are a variety of etiologies that can cause fecal incontinence, which include injury from vaginal delivery, anal surgery, and neurologic disease. Treatment depends on the cause and severity of incontinence. Less invasive treatment methods may include medication, dietary changes, biofeedback, and exercise programs to strengthen anal and pelvic muscles. Surgical interventions include sphincteroplasty and the placement of an artificial anal sphincter.

Radiofrequency energy has been investigated as a minimally invasive treatment for fecal incontinence in patients who have failed conservative therapies. The procedure is usually performed on an outpatient basis under conscious sedation/local anesthesia. It entails delivery of radiofrequency energy to the sphincteric complex of the anal canal, to create discrete thermal lesions. Proponents suggest that, over a period of several months, as these lesions heal and the tissue contracts, the tone of the tissue increases or tightens, thereby improving barrier function and continence.

## RATIONALE

The Secca System (Curon Medical, Inc.), which received U.S. Food and Drug Administration (FDA) clearance under the investigational device exemption in March of 2002, consists of a hand-held anosopic device with electrodes and a

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radiofrequency generator. Per FDA label indications, the Secca System is intended for use specifically in the treatment of fecal incontinence in patients who experience incontinence of stool (solid or liquid) at least once per week and who have failed conservative therapy.

Literature is limited, without any more recent publications, and consists of small, non-randomized 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 (Abbas et al., 2012; Ruiz et al., 2010; Felt-Bersmaet et al., 2007; Effron et al., 2003). One randomized sham-controlled clinical trial was conducted with 40 patients in the Netherlands, with researchers concluding that although findings were statistically significant, clinical impact for most of the patients was negligible. Therefore, the radiofrequency energy procedure should not be recommended for patients with fecal incontinence until patient-related factors associated with treatment success are known (Visscher 2017).

The 2021 American College of Gastroenterology (ACG) Clinical Guidelines for Management of Benign Anorectal Disorders does not include a recommendation guideline for radiofrequency stimulation for the treatment of fecal incontinence. Rather, the guidelines indicate that despite initial positive studies more recent reports suggest poor long-term results (Wald 2021).

### CODES

- Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.
- **CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.**
- Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.
- Code Key: Experimental/Investigational = (E/I), Not medically necessary/ appropriate = (NMN).

#### CPT Codes

Code	Description
No specific codes	
46999 (E/I*)	Unlisted procedure, anus <b>*E/I when billed as radiofrequency treatment of fecal incontinence</b>

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#### HCPCS Codes

Code	Description
No specific codes	

#### ICD10 Codes

Code	Description
R15.0 - R15.9	Fecal incontinence (code range)

### REFERENCES

\*Abbas MA, et al. Radiofrequency treatment for fecal incontinence: is it effective long-term? Dis Colon Rectum 2012 May;55(5):605-10.

\*Efron JE, et al. Safety and effectiveness of temperature-controlled radiofrequency energy delivery to the anal canal (Secca procedure) for the treatment of fecal incontinence. Dis Colon Rectum 2003 Dec;46(12):1606-16.

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Food and Drug Administration (FDA). Center for Devices and Radiological Health. 510(k) Summary Secca System. [[https://www.accessdata.fda.gov/cdrh\\_docs/pdf/K014216.pdf](https://www.accessdata.fda.gov/cdrh_docs/pdf/K014216.pdf)] accessed 09/07/23.

\*Ruiz D, et al. Does the radiofrequency procedure for fecal incontinence improve quality of life and incontinence at 1-year follow-up? Dis Colon Rectum 2010 Jul;53(7):1041-1046.

\*Takahashi T, et al. Extended two-year results of radiofrequency energy delivery for the treatment of fecal incontinence (Secca procedure). Dis Colon Rectum 2003 Jun;46(6):711-5.

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Vergara-Fernandez O, et al. Long-term outcomes of radiofrequency treatment for fecal incontinence: are the results maintainable? Int J Colorectal Dis 2020;35(1):173-176.

\*Wald A, et al. ACG clinical guideline: Management of benign anorectal disorders. Am J Gastroenterol 2021 Oct 1;116(10):1987-2008.

\*Key Article

**KEY WORDS**

Secca procedure, fecal incontinence

**CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS**

Based on our review, radiofrequency therapy for fecal incontinence is not addressed in National or Regional Medicare coverage determinations or policies.