

MEDICAL POLICY

**SUBJECT: RADIOFREQUENCY TREATMENT
FOR FECAL INCONTINENCE**

EFFECTIVE DATE: 12/16/04
REVISED DATE: 10/20/05, 10/19/06, 09/20/07, 08/21/08
ARCHIVED DATE: 07/16/09
**EDITED DATE: 07/15/10, 06/16/11, 06/21/12, 06/20/13,
06/19/14, 06/18/15, 06/16/16, 06/15/17,
10/18/18**

POLICY NUMBER: 7.01.66
CATEGORY: Technology Assessment

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- *If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.*
- *If a commercial product (including an Essential Plan product) or a Medicaid product covers a specific service, medical policy criteria apply to the benefit.*
- *If a Medicare 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.*

POLICY STATEMENT:

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

Refer to Corporate Medical Policy #11.01.03 regarding Experimental and Investigational Services.

POLICY GUIDELINES:

The Federal Employees Health Benefit Program (FEHBP/FEP) requires that procedures, devices or laboratory tests approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational and thus these procedures, devices or laboratory tests may be assessed only on the basis of their medical necessity.

DESCRIPTION:

Fecal incontinence is defined as the involuntary leakage of stool from the rectum and anal canal. Fecal continence depends on a several mechanisms that include 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 and entails delivery of radiofrequency energy to the sphincteric complex of the anal canal to create discrete thermal lesions. It is thought 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 FDA clearance through Investigational Device Exemption in March of 2002, consists of a hand-held anosopic device with electrodes and a radiofrequency generator. Per FDA label indications, the Secca™ System is intended for use specifically in the treatment of fecal incontinence in those patients with incontinence of stool (solid or liquid) at least once per week and who have failed conservative therapy.

Literature consists of small nonrandomized studies with outcomes of improved symptoms in fecal incontinence and quality of life. The clinical response rates using subjective measurements (greater than 10% improvement) were 60%-80% in these studies. In contrast to these subjective findings, there were no differences in the objective measurements of the anal sphincter (e.g., manometry measures, rectal sensation volumes, pudendal nerve motor latency, or sphincter defects). While these findings are promising, the evidence remains inadequate to allow conclusions regarding long-term outcomes. The findings in these studies need to be validated by well-designed, randomized, controlled studies with a larger sample population and longer-term follow-up.

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CODES: Number Description

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: No specific codes; may be reported with unlisted code 46999

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HCPCS: No specific codes

ICD10: R15.0-R15.9 Fecal incontinence (code range)

REFERENCES:

BlueCross BlueShield Association. Transanal radiofrequency treatment of fecal incontinence. Medical Policy Reference Manual Policy # 201.58. 2016 Nov 10.

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*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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KEY WORDS:

Secca procedure

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CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

Based on our review, radiofrequency ablation of fecal incontinence is not specifically addressed in National CMS or Regional Medicare coverage determinations or policies.