01-91000-07

Original Effective Date: 12/15/03

Reviewed: 10/24/24

Revised: 11/15/24

Subject: Transanal Radiofrequency Therapy as a Treatment of Fecal Incontinence

THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS MEDICAL COVERAGE GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.

Position Statement	Billing/Coding	Reimbursement	Program Exceptions	Definitions	Related Guidelines
Other	References	Updates			

DESCRIPTION:

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.

Radiofrequency (RF) energy has been investigated as a minimally invasive treatment of fecal incontinence; a procedure referred to as the Secca procedure. In this 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.

Summary and Analysis of Evidence: Visscher et al (2017) conducted a randomized sham-controlled clinical study (2008-2015) to determine whether the clinical response to the radiofrequency energy procedure is superior to sham in patients with fecal incontinence. Forty patients with fecal incontinence in whom maximal conservative management had failed were randomly assigned to receiving either radiofrequency energy or sham procedure. Patients with severe fecal incontinence were included in the study, thus making it difficult to generalize the results. The authors concluded “(b)oth radiofrequency energy and sham procedure improved the fecal incontinence score, the radiofrequency energy procedure more than sham. Although statistically significant, the 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.” National Institute for Health and Care Excellence Medtech innovation briefing titled “Secca System for faecal incontinence” (NICE, 2016) states “(t)he Secca System is a device that is used to apply

radiofrequency energy to the internal anal sphincter muscle in the anal canal (known as Secca Therapy) to treat faecal incontinence. The available evidence, which is of limited quality, quantity and generalisability, shows short-term improvements in both faecal incontinence and quality of life, with no significant improvements in the relevant patient-reported scores in the medium and long term (1 and 3 years)." The briefing further states "(t)here is a lack of comparative data showing the advantages of Secca Therapy over other minimally invasive or surgical treatment options, or when the placebo effect is accounted for." The American College of Gastroenterology (ACG), in a clinical guideline on the management of benign anorectal disorders (Wald et al, 2021) stated "(t)he SECCA procedure involves radiofrequency stimulation of the muscles in the anal canal to increase muscle connective tissue ratio and scarring via a probe with needles in the anal canal performed under local anesthesia and sedation. Despite initial positive studies including a multi-center trial from 2003, more recent reports suggest poor long-term results." UpToDate review "Fecal Incontinence in adults: Management" (Lembo, Spivak, 2024) states "(r)adiofrequency ablation (RFA) is a procedure that involves delivering temperature-controlled radiofrequency energy to the anorectal junction to create thermal lesions in the muscle while preserving mucosal integrity. RFA is no longer recommended for treatment of fecal incontinence as long-term results have demonstrated conflicting results and limited efficacy, and randomized trials are lacking."

POSITION STATEMENT:

Transanal radiofrequency therapy for the treatment of fecal incontinence is considered **experimental or investigational**, as the available clinical data are insufficient to determine effectiveness of this treatment.

BILLING/CODING INFORMATION:

There is no specific code for reporting transanal radiofrequency therapy.

REIMBURSEMENT INFORMATION:

Refer to section entitled **POSITION STATEMENT**.

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Advantage products: No National Coverage Determination (NCD) and/or Local Coverage Determination (LCD) were found at the time of the last guideline reviewed date.

If this Medical Coverage Guideline contains a step therapy requirement, in compliance with Florida law 627.42393, members or providers may request a step therapy protocol exemption to this requirement if based on medical necessity. The process for requesting a protocol exemption can be found at Coverage Protocol Exemption Request.

DEFINITIONS:

None applicable.

RELATED GUIDELINES:

Injectable Bulking Agents for the Treatment of Urinary and Fecal Incontinence, 09-A9000-03

Pelvic Floor Stimulation as a Treatment of Incontinence, 01-97000-06

OTHER:

Indexing terms:

Note: 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.

Secca procedure

Secca™ System

REFERENCES:

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COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy and Coverage Committee on 10/24/24.

GUIDELINE UPDATE INFORMATION:

12/15/03	New Medical Coverage Guideline Developed.
10/15/04	Scheduled review; no change in coverage statement.
01/01/06	Scheduled review; no change in coverage statement; updated references.
11/15/06	Scheduled review; no change in coverage statement; updated references.
08/15/07	Scheduled review; reformatted guideline; updated references.
11/15/08	Scheduled review; no change in position statement; updated references.
10/15/09	Scheduled review; no change in position statement; updated references.
01/01/12	Annual HCPCS coding update: added 0288T.
05/11/14	Revision: Program Exceptions section updated.
05/15/14	Revision: Program Exceptions section updated.
01/01/17	Annual CPT/HCPCS update. Deleted 0288T.
03/15/19	Scheduled review. Revised description and updated references.
11/15/20	Scheduled review. Maintained position statement and updated references.
08/15/22	Scheduled review. Maintained position statement and updated references.
05/22/23	Update to Program Exceptions section.
01/01/24	Position statements maintained.

11/15/24	Scheduled review. Revised description, maintained position statement and updated references.