



Medical Coverage Policy

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Coverage Policy Number 0576

Radiofrequency Therapy for Fecal Incontinence

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INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer’s particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer’s benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer’s benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see “Coding Information” below). When billing, providers

must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

This Coverage Policy addresses radiofrequency therapy for fecal incontinence (e.g., SECCA procedure, Secca[®] System).

Coverage Policy

Radiofrequency therapy for fecal incontinence is considered experimental, investigational, or unproven.

Health Equity Considerations

Health equity is the highest level of health for all people; health inequity is the avoidable difference in health status or distribution of health resources due to the social conditions in which people are born, grow, live, work, and age.

Social determinants of health are the conditions in the environment that affect a wide range of health, functioning, and quality of life outcomes and risks. Examples include safe housing, transportation, and neighborhoods; racism, discrimination and violence; education, job opportunities and income; access to nutritious foods and physical activity opportunities; access to clean air and water; and language and literacy skills.

General Background

Fecal incontinence is the inability to control the passage of gas, liquid and/or solid feces due to the loss of the coordinated function of the muscles and/or nerves of the rectum, anal canal, and pelvic floor. Treatment of minor incontinence (i.e., incontinence to flatus and occasional seepage of liquid stool) may be controlled by changes in diet and dietary habits, medication (e.g., bulking agents, antidiarrheal drugs), and bowel training (e.g., Kegel exercises, biofeedback). In the case of major incontinence (i.e., frequent loss of solid waste material) or incontinence unresponsive to conservative measures, surgical intervention may be indicated. In the event of an isolated sphincter defect, the standard surgical treatment is sphincteroplasty. Other surgical procedures include repair of rectocele or rectal prolapse and, in severe cases, fecal diversion (i.e., colostomy) (Kim, et al., 2009; Lefebure, et al., 2008; Rao, 2004; Wexner and Sands, 2003; Takahashi, et al., 2002).

Transanal radiofrequency therapy (e.g., Secca[®] procedure) is a proposed alternative therapy for the treatment of fecal incontinence for patients who have not responded to medical therapy and are not good surgical candidates or have failed surgical intervention. The Secca procedure is noninvasive, typically takes 30–45 minutes, and is performed in an outpatient setting under local anesthesia and sedation. It is also proposed that there are fewer complications following the Secca procedure compared to invasive surgical procedures.

Radiofrequency therapy is based on the theory that “collagen deposition and subsequent scarring may increase one’s ability to recognize and retain stool and permit improved continence” (Parisien and Corman, 2005). An anoscopic device uses four electrodes to deliver controlled radiofrequency energy to the sphincter muscles surrounding the anal canal. The energy creates precise, submucosal burn lesions, triggering collagen contraction. The lesions are subsequently resorbed, remodeling the tissue. The remodeling is proposed to improve barrier function of the anal sphincter (Efron, et al., 2003; Takahashi, et. al., 2002).

U.S. Food and Drug Administration (FDA)

The Secca® System (Curon Medical Inc., Sunnyvale, CA) was approved by the FDA as a 510(k) Class II device for general use for electrosurgical coagulation and “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 treatment” (FDA, 2002).

Literature Review

There is insufficient evidence in the published peer-reviewed scientific literature to support the effectiveness of transanal radiofrequency therapy (e.g., Secca procedure) for the treatment of fecal incontinence. Studies are primarily in the form of prospective case series with small patient populations (n=8–50). With the exception of Takahashi-Monroy et al. (2008) (19 patients, 5 year study) and Lam et al. (2014) (31 patients, 3 year study), follow-ups were short-term, ranging from 6–12 months. Various questionnaires (e.g., Fecal Incontinence Severity Index, Fecal Incontinence-related Quality of Life questionnaire, Vaizey scale) were utilized to measure quality of life (e.g., coping, depression, embarrassment) outcomes and results were inconsistent. Typically there were no significant improvements in physical component outcomes, such as anorectal manometry parameters, pudendal nerve motor latency, endoanal ultrasound results, and the thickness of internal anal sphincters. Some studies reported numerous complications while others reported no complications (Ruiz, et al., 2010; Kim, et al., 2009; Lefebure, et al., 2008; Takahashi-Monroy, et al., 2008; Felt-Bersma, et al., 2007; Efron, et al., 2003; Takahashi, et al., 2003). Simillis et al. (2019) reported on a meta-analysis of RCTs that compare the clinical outcomes and effectiveness of treatments for fecal incontinence. The review found that pairwise comparisons of the treatments demonstrated significantly more adverse events with transanal delivery of radiofrequency energy compared to placebo. Studies comparing the use of transanal radiofrequency therapy to established medical and surgical treatment options are lacking.

Professional Societies/Organizations

American College of Gastroenterology (ACG): The ACG clinical guideline for management of benign anorectal disorders (Wald, et al., 2021) addresses Radiofrequency stimulation (SECCA procedure), stating that the 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 (Wald, 2021).

American Society of Colon and Rectal Surgeons: The American Society of Colon and Rectal Surgeons' 2023 Clinical Practice Guidelines for the Management of Fecal Incontinence states:

- Application of temperature-controlled radiofrequency energy to the sphincter complex is not recommended to treat fecal incontinence.

Based on the available data, radiofrequency energy delivery is not recommended for the treatment of FI. Additionally, no new studies evaluating this modality have been published since 2014 (Bordeianou, et al., 2023).

American Gastroenterological Association: The AGA 2017 Clinical Practice Update: Expert Review on Surgical Interventions and the Use of Device-Aided Therapy for the Treatment of Fecal Incontinence and Defecatory Disorders states that 'Radiofrequency Anal Sphincter Remodeling' procedure involves delivering temperature-controlled radiofrequency energy to the anorectal junction with a goal of remodeling, scarring, and causing contraction of the collagen tissues in the anal region. The SAGA notes that "Most studies included small numbers of patients, and most were studies conducted more than 8 years ago. There are no randomized controlled trials, but it has been FDA approved since 2002 for patients who have failed conservative therapy for FI" (Bharucha, et al., 2017).

Medicare Coverage Determinations

	Contractor	Determination Name/Number	Revision Effective Date
NCD	National	No determination found.	
LCD		No determination found.	

Note: Please review the current Medicare Policy for the most up-to-date information. (NCD = National Coverage Determination; LCD = Local Coverage Determination)

Coding Information

Notes:

1. This list of codes may not be all-inclusive since the American Medical Association (AMA) and Centers for Medicare & Medicaid Services (CMS) code updates may occur more frequently than policy updates.
2. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Considered Experimental/Investigational/Unproven when used to report transanal radiofrequency therapy for fecal Incontinence (e.g., SECCA procedure):

CPT®* Codes	Description
46999	Unlisted procedure, anus

***Current Procedural Terminology (CPT®) ©2023 American Medical Association: Chicago, IL.**

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Revision Details

Type of Revision	Summary of Changes	Date
Annual review	<ul style="list-style-type: none"> • No clinical policy statement changes. 	10/15/2024

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