Medical Coverage Policy | Transanal Radiofrequency of Fecal Incontinence

EFFECTIVE DATE: 06|01|2019
POLICY LAST REVIEWED: 03|18|2026

OVERVIEW
Radiofrequency energy has been investigated as a minimally invasive treatment of fecal incontinence, in a procedure referred to as the Secca procedure. In this outpatient procedure using conscious sedation, radiofrequency 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.

MEDICAL CRITERIA
Not applicable

PRIOR AUTHORIZATION
Not applicable

POLICY STATEMENT
Medicare Advantage Plans
Transanal radiofrequency therapy is considered not covered as a treatment of fecal incontinence as the evidence is insufficient to determine the effects of the technology on health outcomes.

Commercial
Transanal radiofrequency therapy is considered not medically necessary as a treatment of fecal incontinence as the evidence is insufficient to determine the effects of the technology on health outcomes.

COVERAGE
Benefits may vary between groups/contracts. Please refer to the Evidence of Coverage or Subscriber Agreement for applicable not medically necessary/not covered benefits/coverage.

BACKGROUND
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. Estimated prevalence is 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 for mild incontinence; bowel management programs, commonly used in patients with spinal cord injuries; and biofeedback. Surgical approaches primarily include sphincteroplasty, although more novel approaches, such as sacral neuromodulation or creation of an artificial anal sphincter, may be attempted in patients whose only other treatment option is the creation of a stoma. Radiofrequency (RF) energy also 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 potentially improving continence.

RF energy is a 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 for gastroesophageal reflux disease (ie, 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 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.

In 2002, the Secca™ System (Mederi Therapeutics) was cleared for marketing by the U.S. Food and Drug Administration through the 510(k) process 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."

For individuals who have fecal incontinence who receive transanal radiofrequency treatment, the evidence includes 8 nonrandomized studies. Relevant outcomes are symptoms, change in disease status, quality of life, and treatment-related morbidity. Studies include a small number of patients, and estimates of treatment differences are very imprecise. Study follow-up periods vary and need to be considerably longer and involve larger numbers of patients to evaluate long-term outcomes properly. Three-year follow-up of a small cohort showed decrement in response over time. Multicenter randomized controlled trials with sufficient power are required to evaluate the continuing use of this procedure as an alternative to other surgical interventions, physical therapies, or as an adjunctive treatment option for fecal incontinence. The evidence is insufficient to determine the effects of the technology on health outcomes.

CODING

Medicare Advantage Plans and Commercial Products

There is no specific CPT code(s) for this procedure. It would be reported with the following unlisted CPT code:

46999 Unlisted procedure, anus

RELATED POLICIES

None

PUBLISHED

Provider Update, May 2026
Provider Update, April 2025
Provider Update, April 2024
Provider Update, May 2023
Provider Update, July 2022

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