Transanal radiofrequency for fecal incontinence

Clinical Policy ID: CCP.1404

Recent review date: 1/2025

Next review date: 5/2026

Policy contains: Bowel control disorder; fecal incontinence; SECCA; transanal radiofrequency/anal sphincter remodeling.

First Choice Next has developed clinical policies to assist with making coverage determinations. First Choice Next's clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of "medically necessary," and the specific facts of the particular situation are considered, on a case by case basis, by First Choice Next when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. First Choice Next's clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. First Choice Next's clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, First Choice Next will update its clinical policies as necessary. First Choice Next's clinical policies are not guarantees of payment.

Coverage policy

Transanal radiofrequency (also called anal sphincter remodeling) is investigational/not clinically proven and, therefore, not medically necessary.

Limitations
All other uses of transanal radiofrequency treatment are not medically necessary.

Unlisted procedure codes are reviewed for medical necessity and standard of care.

Alternative covered services

- Conservative treatment (e.g., lifestyle and dietary modifications, patient education, pelvic floor exercises, rectal irrigation, biofeedback, and pharmaceuticals) per standards of care (Paquette, 2015; Wald, 2014; 2016).
- Peristeen® anal irrigation system.
- Surgical treatment per standards of care (Paquette, 2015; Wald, 2014; 2016).

Background

Fecal incontinence is a clinical diagnosis primarily based on history and examination (National Institute of Diabetes and Digestive and Kidney Diseases, 2017). The strongest risk factors are diarrhea, strong urge, and chronic illnesses (e.g., irritable bowel syndrome, diabetes, and neurological impairment of the pelvic floor). Bowel

disturbances such as constipation may occur with or without fecal impaction or overflow diarrhea and without evidence of a structural or biochemical explanation (Bharucha, 2015).

Initial treatment typically begins with conservative approaches (e.g., patient education, pelvic floor exercises, biofeedback, and pharmaceuticals), which can improve symptoms by about 60% and achieve continence in an estimated 20% of patients (Whitehead, 2016). For fecal incontinence refractory to conservative treatment or for colonic pseudo-obstruction, more invasive options such as electrical stimulation implants, injectable bulking agents, and surgery may be indicated.

Transanal radiofrequency (also called anal sphincter remodeling) delivers thermo-controlled radiofrequency energy to the internal anal sphincter muscle, with the intent of improving muscle structure and sphincter function. The U.S. Food and Drug Administration issued 501(k) clearance to the SECCA® system (Curon Medical, Fremont, California) for treating patients with incontinence to solid or liquid stool at least once per week and who have failed conservative therapy (Food and Drug Administration, 2002).

SECCA represents a nonsurgical option for treating fecal incontinence caused by anal sphincter muscle weakness. The procedure can be performed in an outpatient setting in approximately 60 minutes.

Findings

For this policy, we included an Agency for Healthcare Research and Quality comparative effectiveness review of fecal incontinence treatments (Forte, 2016); results from a randomized sham-controlled trial (Visscher, 2017) and a small, prospective, single-center, observational study (Frascio, 2017); and two clinical practice guidelines (Paquette, 2015; Wald, 2014). Forte (2016) found insufficient evidence of effectiveness of transanal radiofrequency for fecal incontinence, as no controlled studies had been published at the time the review was undertaken, whereas results from randomized controlled trials supported the effectiveness of other established procedures for fecal incontinence, although the quality of that evidence was quite variable.

The results from Visscher (2017) and Frascio (2017) offer inadequate evidence to inform clinicians of the effectiveness of the SECCA procedure relative to other noninvasive or invasive options. The clinical significance of reported symptom improvement in the absence of any objective improvement in anorectal function (e.g., manometry or endoanal ultrasonography) is unclear, and patient-related factors associated with treatment success need to be determined from prospective study. An early study of 31 patients pointed out only 22% had sustained long-term response (followed a median of 40 months) (Abbas, 2012).

A systematic review and network meta-analysis of 47 randomized controlled trials (n = 3,748) comparing fecal incontinence treatments found that radiofrequency had more adverse events compared with placebo. No treatment ranked better or worse than others on outcomes (Similis, 2019).

An earlier review of 10 studies (n = 220) showed the SECCA system to be an effective treatment of symptoms of mild or moderate fecal incontinence, reflected in reductions in the Wexner incontinence and improvement in quality-of-life scores (Frascio, 2014). Another review of 10 studies (n = 150) concluded SECCA was safe and well-tolerated, easy to perform, and without any serious complications, but with only a moderate clinical effect that declines over time (Felt-Bersma, 2014).

The American Society of Colon and Rectal Surgeons offered a weak recommendation for the procedure to treat fecal incontinence after conservative options have failed, based on limited evidence (Paquette, 2015). The American College of Gastroenterology found insufficient evidence to recommend transanal radiofrequency ablation treatment; results were conflicting and studies reported no change in anorectal manometric measurement and persistent significant fecal incontinence after the procedure (Wald, 2014; 2016).

In 2020, we identified no newly published, relevant literature to add to the policy.

In 2021, we added one new reference (Vergara-Fernandez, 2020) to the policy, which concluded any improvements in transanal radiofrequency could not be maintained. No policy changes are warranted.

In 2022, we added four references to the policy, two of which were relatively large reviews (Felt-Bersma, 2014; Frascio, 2014).

In 2023, we added a study (n = 31) that found a clinically significant response rate after treatment with SECCA of 16%, 10% and 6% at six months, one year, and three years after baseline, described by authors as "disappointing" (Lam, 2014).

In 2024, we added a guideline from the American College of Gastroenterology on benign anorectal disorders, which noted that early positive results using SECCA had been replaced by mostly poor results in long-term studies (Wald, 2021).

We also added a review of treating fecal incontinence in children and adolescents. Authors state that no consensus guidelines exist. While radiofrequency is listed as one potential option, the article notes the limited efficacy in studies to date (Shen, 2022).

In 2025, no relevant studies were found and no policy changes were warranted.

References

On December 6, 2024, we searched PubMed and the databases of the Cochrane Library, the U.K. National Health Services Centre for Reviews and Dissemination, the Agency for Healthcare Research and Quality, and the Centers for Medicare & Medicaid Services. Search terms were "fecal incontinence/therapy" (MeSH), "catheter ablation, radiofrequency" (MeSH), and the free-text terms "SECCA" and "transanal radiofrequency." We included the best available evidence according to established evidence hierarchies (typically systematic reviews, meta-analyses, and full economic analyses, where available) and professional guidelines based on such evidence and clinical expertise.

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Policy updates

11/2018: initial review date and clinical policy effective date: 2/2019

1/2020: Policy references updated.

1/2021: Policy references updated.

1/2022: Policy references updated.

1/2023: Policy references updated.

1/2024: Policy references updated.

1/2025: Policy references updated.