Transanal radiofrequency for fecal incontinence

Clinical Policy ID: CCP.1404

Recent review date: 1/2026

Next review date: 5/2027

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

First Choice VIP Care has developed clinical policies to assist with making coverage determinations. First Choice VIP Care'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 by First Choice VIP Care, on a case by case basis, 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 VIP Care'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 VIP Care's clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, First Choice VIP Care will update its clinical policies as necessary. First Choice VIP Care'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 temperature-controlled radiofrequency energy to the internal anal sphincter muscle, with the intent of improving muscle structure and sphincter function. The United States Food and Drug Administration issued 510(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 (United States Food and Drug Administration, 2002).

The Secca system 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

The evidence base for temperature-controlled transanal radiofrequency delivered to the internal anal sphincter for fecal incontinence remains limited. The most informative evidence consists of a randomized, sham-controlled trial, small observational cohorts with variable follow-up, and evidence syntheses that rely largely on nonrandomized studies with substantial heterogeneity. Across these sources, any reported symptom-score improvements are inconsistent, often modest in magnitude, and are not reliably linked to objective improvements in anorectal physiology or imaging measures, creating uncertainty about clinical utility and mechanism-based benefit. Comparative evidence versus established therapies used after optimized conservative management is lacking, and durability is limited in long-term follow-up, with sustained response occurring in a minority of treated patients.

Clinical practice guidelines

Guidance from the American Society of Colon and Rectal Surgeons does not recommend application of temperature-controlled radiofrequency energy to the anal sphincter complex for fecal incontinence because the evidence does not demonstrate clinically meaningful benefit (Bordeianou, 2023). This recommendation reflects the limited controlled evidence base and the absence of durable benefit demonstrated in long-term follow-up studies (Bordeianou, 2023; Abbas, 2012; Lam, 2014).

Guidance from the American College of Gastroenterology describes early positive reports for this intervention but notes that more recent evidence suggests poor long-term results and does not support routine use for fecal incontinence management (Wald, 2021). In the context of guideline care pathways, conservative management and pelvic floor rehabilitation with biofeedback remain first-line approaches, with escalation to established procedural and surgical options when symptoms remain clinically significant. Temperature-controlled transanal radiofrequency is not positioned as a recommended therapy within these pathways (Bordeianou, 2023; Wald, 2021).

Systematic reviews and meta-analyses

A comparative effectiveness review prepared for the Agency for Healthcare Research and Quality concluded that evidence was insufficient to determine the effectiveness of radiofrequency-based approaches for fecal incontinence, reflecting limited comparative evidence and reliance on small, heterogeneous studies (Forte, 2016). This finding is relevant to medical necessity because insufficient evidence precludes reliable estimation of effect size, durability, patient selection criteria, and comparative value versus established therapies (Forte, 2016).

A systematic review and network meta-analysis comparing multiple fecal incontinence interventions did not demonstrate favorable ranking for radiofrequency approaches across key outcomes and reported a higher adverse-event rate for radiofrequency compared with placebo in pooled comparisons, with important limitations related to indirectness and variability in included trials (Simillis, 2019). Although the certainty of such estimates is constrained by study design and reporting heterogeneity, these findings do not establish a comparative advantage and raise concerns regarding risk-benefit balance relative to other therapies (Simillis, 2019).

Reviews focusing specifically on the temperature-controlled radiofrequency procedure predominantly summarize nonrandomized studies and report improvements in symptom severity scores and some quality-of-life measures, but the evidence base is limited by small sample sizes, variability in patient selection and outcome definitions, and incomplete assessment of durability (Frascio, 2014; Felt-Bersma, 2014). These limitations reduce confidence that observed changes reflect reproducible, clinically meaningful benefit in typical clinical practice (Frascio, 2014; Felt-Bersma, 2014).

Controlled clinical evidence, including sham-controlled evidence

A randomized, sham-controlled trial evaluating temperature-controlled transanal radiofrequency reported limited differences between active treatment and sham treatment and did not demonstrate a pattern consistent with clinically meaningful improvement for most patients at short-term follow-up (Visscher, 2017). The trial results also did not demonstrate consistent improvement in objective anorectal physiology measures, which increases uncertainty regarding the clinical relevance of symptom-score changes and limits inference about durable functional improvement (Visscher, 2017).

The available controlled evidence does not establish comparative effectiveness versus established therapies used after optimized conservative management, such as neuromodulation or structured pelvic floor rehabilitation with biofeedback. In the absence of head-to-head comparative studies or robust indirect evidence, clinical utility and appropriate placement in the care pathway cannot be determined (Forte, 2016; Simillis, 2019; Bordeianou, 2023).

Other evidence: durability, objective testing concordance, and safety reporting limitations

Long-term observational follow-up studies suggest that sustained response occurs in a minority of treated patients and that additional interventions are commonly required over time, indicating limited durability (Abbas, 2012; Lam, 2014; Vergara-Fernandez, 2020). Reported response rates vary across studies, and the evidence does not identify reproducible patient selection criteria associated with durable benefit, including severity thresholds, stool consistency phenotypes, or sphincter integrity characteristics (Abbas, 2012; Lam, 2014; Vergara-Fernandez, 2020).

Across the evidence base, symptom-score improvements are not consistently accompanied by improvements in anorectal manometry or imaging measures such as endoanal ultrasonography. This discordance increases uncertainty regarding whether reported symptom changes reflect durable improvements in anorectal function and limits the ability to use objective testing to confirm or predict clinical benefit (Visscher, 2017; Abbas, 2012; Lam, 2014).

Adverse events are frequently described as transient in published series, but reporting is inconsistent and sample sizes are small, limiting the ability to exclude clinically important harms or to compare safety reliably with established therapies. Evidence syntheses that include placebo comparisons suggest potential for increased

adverse events with radiofrequency approaches, but certainty is limited by heterogeneity and indirectness (Felt-Bersma, 2014; Simillis, 2019).

In 2026, we advise the background and findings sections added the 2023 American Society of Colon and Rectal Surgeons guideline (Bordeianou, 2023).

References

On December 9, 2025, 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.

1/2026: Policy references updated.

Related Codes

Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy CCP.1404. This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill accordingly.

Code	Code Description
46999	Unlisted procedure, anus