



## MASSACHUSETTS

Blue Cross Blue Shield of Massachusetts is an Independent Licensee of the Blue Cross and Blue Shield Association

### Medical Policy

## Transanal Radiofrequency Treatment of Fecal Incontinence

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### Policy Number: 309

BCBSA Reference Number: 2.01.58

NCD/LCD: NA

### Related Policies

Biofeedback as a Treatment of Fecal Incontinence, #[308](#)

### Policy

**Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity Medicare HMO Blue<sup>SM</sup> and Medicare PPO Blue<sup>SM</sup> Members**

Transanal radiofrequency therapy as a treatment of fecal incontinence is [INVESTIGATIONAL](#).

### Prior Authorization Information

#### Inpatient

- For services described in this policy, precertification/preauthorization **IS REQUIRED** for all products if the procedure is performed **inpatient**.

#### Outpatient

- For services described in this policy, see below for products where prior authorization **might be required** if the procedure is performed **outpatient**.

	Outpatient
<b>Commercial Managed Care (HMO and POS)</b>	This is <b>not</b> a covered service.
<b>Commercial PPO and Indemnity</b>	This is <b>not</b> a covered service.
<b>Medicare HMO Blue<sup>SM</sup></b>	This is <b>not</b> a covered service.
<b>Medicare PPO Blue<sup>SM</sup></b>	This is <b>not</b> a covered service.

### CPT Codes / HCPCS Codes / ICD Codes

*Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.*

*Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.*

*The following codes are included below for informational purposes only; this is not an all-inclusive list.*

No specific CPT codes.

## **Description**

### **Fecal Incontinence**

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.

### **Treatment**

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.

## **Summary**

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.

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.

## Policy History

Date	Action
12/2019	BCBSA National medical policy review. Description, summary and references updated. Policy statements unchanged.
1/2019	BCBSA National medical policy review. Description, summary and references updated. Policy statements unchanged.
1/2017	Clarified coding information for the 2017 code changes.
1/2016	New references added from BCBSA National medical policy.
12/2015	Added coding language.
2/2014	New references added from BCBSA National medical policy.
11/2011-4/2012	Medical policy ICD 10 remediation: Formatting, editing and coding updates. No changes to policy statements.
10/2011	Reviewed - Medical Policy Group - GI, Nutrition and Organ Transplantation. No changes to policy statements.
1/21/2011	Medical Policy 309 effective 1/21/2011, describing ongoing non-coverage.

## Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:

[Medical Policy Terms of Use](#)

[Managed Care Guidelines](#)

[Indemnity/PPO Guidelines](#)

[Clinical Exception Process](#)

[Medical Technology Assessment Guidelines](#)

## References

1. Food and Drug Administration (FDA). Attachment 14: 510(k) Summary. Curon Medical, Inc.'s Secca™ System. 2002; [http://www.accessdata.fda.gov/cdrh\\_docs/pdf/k014216.pdf](http://www.accessdata.fda.gov/cdrh_docs/pdf/k014216.pdf). Accessed September, 2019.
2. Forte ML, Andrade KE, Butler M, et al. Treatments for Fecal Incontinence (Comparative Effectiveness Review No. 165). Rockville, MD: Agency for Healthcare Research and Quality; 2016.
3. Abbas MA, Tam MS, Chun LJ. Radiofrequency treatment for fecal incontinence: is it effective long-term? *Dis Colon Rectum*. May 2012;55(5):605-610. PMID 22513440.
4. Rothbarth J, Bemelman WA, Meijerink WJ, et al. What is the impact of fecal incontinence on quality of life? *Dis Colon Rectum*. Jan 2001;44(1):67-71. PMID 11805565.
5. Efron JE, Corman ML, Fleshman J, et al. Safety and effectiveness of temperature-controlled radiofrequency energy delivery to the anal canal (Secca procedure) for the treatment of fecal incontinence. *Dis Colon Rectum*. Dec 2003;46(12):1606-1616; discussion 1616-1608. PMID 14668584.
6. Felt-Bersma RJ, Szojda MM, Mulder CJ. Temperature-controlled radiofrequency energy (SECCA) to the anal canal for the treatment of faecal incontinence offers moderate improvement. *Eur J Gastroenterol Hepatol*. Jul 2007;19(7):575-580. PMID 17556904.
7. Lam TJ, Visscher AP, Meurs-Szojda MM, et al. Clinical response and sustainability of treatment with temperature-controlled radiofrequency energy (Secca) in patients with faecal incontinence: 3 years follow-up. *Int J Colorectal Dis*. Jun 2014;29(6):755-761. PMID 24805249.
8. Ruiz D, Pinto RA, Hull TL, et al. Does the radiofrequency procedure for fecal incontinence improve quality of life and incontinence at 1-year follow-up? *Dis Colon Rectum*. Jul 2010;53(7):1041-1046. PMID 20551757.
9. Lefebure B, Tuech JJ, Bridoux V, et al. Temperature-controlled radio frequency energy delivery (Secca procedure) for the treatment of fecal incontinence: results of a prospective study. *Int J Colorectal Dis*. Oct 2008;23(10):993-997. PMID 18594840.
10. Takahashi-Monroy T, Morales M, Garcia-Osogobio S, et al. SECCA procedure for the treatment of fecal incontinence: results of five-year follow-up. *Dis Colon Rectum*. Mar 2008;51(3):355-359. PMID 18204954.

11. Kim DW, Yoon HM, Park JS, et al. Radiofrequency energy delivery to the anal canal: is it a promising new approach to the treatment of fecal incontinence? *Am J Surg.* Jan 2009;197(1):14-18. PMID 18614149.
12. National Institute for Health and Care Excellence (NICE). Endoscopic radiofrequency therapy of the anal sphincter for faecal incontinence [IPG393]. 2011; <https://www.nice.org.uk/guidance/ipg393>. Accessed September, 2019.
13. National Institute for Health and Care Excellence (NICE). Secca System for faecal incontinence [MIB66]. 2016; <https://www.nice.org.uk/advice/mib66/chapter/summary>. Accessed September, 2019.
14. Paquette IM, Varma MG, Kaiser AM, et al. The American Society of Colon and Rectal Surgeons' clinical practice guideline for the treatment of fecal incontinence. *Dis Colon Rectum.* Jul 2015;58(7):623-636. PMID 26200676.
15. Wald A, Bharucha AE, Cosman BC, et al. ACG clinical guideline: management of benign anorectal disorders. *Am J Gastroenterol.* Aug 2014;109(8):1141-1157; (Quiz) 1058. PMID 25022811.