BlueCross BlueShield Federal Employee Program.

FEP 2.01.58 Transanal Radiofrequency Treatment of Fecal Incontinence

Effective Date: April 15, 2018

Related Policies: None

Transanal Radiofrequency Treatment of Fecal Incontinence

Description

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.

FDA REGULATORY STATUS

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."[1] Food and Drug Administration product code: GEI.

POLICY STATEMENT

Transanal radiofrequency therapy is considered **investigational** as a treatment of fecal incontinence.

POLICY GUIDELINES

The Secca procedure may be performed on an outpatient basis using conscious sedation and a local anesthetic.

BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

RATIONALE

Summary of Evidence

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.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

National Institute for Health and Care Excellence

The National Institute for Health and Care Excellence (NICE) issued guidance on radiofrequency treatment for fecal incontinence in 2011.[12] NICE concluded that "evidence on endoscopic radiofrequency therapy of the anal sphincter for [fecal] incontinence raises no major safety concerns. There is evidence of efficacy in the short term but in a limited number of patients." [12]

In 2016, NICE published a Medtech innovation briefing on the Secca system for fecal incontinence.[13] These briefings aim to aid in the decision-making process by describing the technology, its role in the treatment pathway, a review of the relevant published evidence, and cost information. These briefings do not contain recommendations. The briefing noted that "Secca therapy is a minimally invasive treatment option available for people with incontinence of solid or liquid stool at least once a week, in whom conservative management options have not controlled symptoms."

American Society of Colon and Rectal Surgeons

The American Society of Colon and Rectal Surgeons, in its 2015 clinical practice guidelines, noted: "Application of temperature-controlled radiofrequency energy to the sphincter complex may be used to treat fecal incontinence. Grade of Recommendation: Weak recommendation based on moderate-quality evidence, 2B."[14] The guidelines also stated: "Because of the limitations in the available data, alternative treatments should be pursued before considering radiofrequency energy delivery."

American College of Gastroenterology

The American College of Gastroenterology published guidelines on the management of benign anorectal disorders in 2014.[15] The guidelines indicated that there is insufficient evidence to recommend radiofrequency ablation to the anal sphincter as treatment for fecal incontinence. The College also asserted that the biologic rationale for this type of treatment is unproven.

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

REFERENCES

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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

POLICY HISTORY

Date	Action	Description
June 2012	New Policy	
December 2013	Update Policy	Policy updated with literature review, no references added, no change in policy statement
December 2014	Update Policy	Policy updated with literature review; reference 6 added; no change in policy statement.
March 2016	Update Policy	Policy updated with literature review through November 10, 2015; reference 12 added. Policy statement unchanged.
March 2017	Update Policy	Policy updated with literature review through November 2, 2016; references 2, 13, and 15 added. Policy statement changed from not medically necessary to investigational.
March 2018	Update Policy	Policy updated with literature review through September 11, 2017; no references added. Policy statement unchanged.