



BlueCross BlueShield
of Alabama

Name of Blue Advantage Policy:

Transanal Radiofrequency Treatment of Fecal Incontinence

Policy #: 163
Category: Medical

Latest Review Date: December 2020
Policy Grade: B

BACKGROUND:

Blue Advantage medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:

1. *Safe and effective;*
2. *Not experimental or investigational*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*
 - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
 - *Furnished in a setting appropriate to the patient's medical needs and condition*
 - *Ordered and furnished by qualified personnel;*
 - *One that meets, but does not exceed, the patient's medical need; and*
 - *At least as beneficial as an existing and available medically appropriate alternative.*

Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill **Original Medicare for covered services that are related to **clinical trials** that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

POLICY:

Effective for dates of service on or after July 1, 2005:

Blue Advantage will treat transanal radiofrequency treatment of fecal incontinence as a non-covered benefit and as investigational.

Blue Advantage does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Advantage administers benefits based on the members' contract and medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

DESCRIPTION OF PROCEDURE OR SERVICE:

Radiofrequency (RF) energy has been investigated as a minimally invasive treatment of fecal incontinence, a procedure referred to as the Secca procedure. In this outpatient 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 improving continence.

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. 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.

Radiofrequency (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 of GERD (i.e., 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.

KEY POINTS:

The most recent literature review was updated through August 20, 2020.

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.

Practice Guidelines and Position Statements

National Institute for Health and Care Excellence (NICE)

NICE issued guidance on RF treatment for fecal incontinence in 2011. 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.”

In 2016, NICE published a Medtech innovation briefing (MIB) on the Secca system for fecal incontinence. The aim of an MIB is to aid in the decision-making process by providing a description of the technology, its role in the treatment pathway, a review of relevant published evidence, and cost information. MIBs do not contain recommendations. The MIB notes 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 which conservative management options have not controlled symptoms.

American Society of Colon and Rectal Surgeons

The American Society of Colon and Rectal Surgeons, in their 2015 clinical practice guideline notes, “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.” The guidelines also state “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 (ACG) published guidelines on the management of benign anorectal disorders in 2014. The guideline indicated that there is insufficient evidence to recommend radiofrequency ablation to the anal sphincter as treatment for fecal incontinence. ACG also asserted that the biological rationale for this type of treatment is unproven.

U.S. Preventive Services Task Force Recommendations

Not applicable

KEY WORDS:

Transanal radiofrequency therapy, radiofrequency energy, fecal incontinence, the Secca System

APPROVED BY GOVERNING BODIES:

In 2002, the Secca™ System (Mederi Therapeutics) received FDA clearance 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.”

BENEFIT APPLICATION:

Coverage is subject to member’s specific benefits. Group specific policy will supersede this policy when applicable.

CURRENT CODING:

Effective in 2017, there is no specific CPT code for this procedure. It would be reported with the following unlisted code:

46999	Unlisted procedure, anus
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PREVIOUS CODING:

0288T	Anoscopy, with delivery of thermal energy to the muscle of the anal canal (e.g., for fecal incontinence) (Deleted 12/31/16)
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POLICY HISTORY:

Adopted for Blue Advantage, March 2005
 Available for comment May 1-June 14, 2005
 Medical Policy Group, May 2008
 Medical Policy Group, May 2010
 Medical Policy Group, November 2011
 Medical Policy Group, January 2012
 Medical Policy Group, November 2012
 Medical Policy Group, October 2013
 Medical Policy Group, October 2014
 Medical Policy Group, December 2015
 Medical Policy Group, November 2016
 Medical Policy Group, December 2017
 Medical Policy Group, December 2018
 Medical Policy Group, November 2019
 Medical Policy Group, December 2020

This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member's plan in effect as of the date

services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield's administration of plan contracts.