APPENDIX to Transanal Radiofrequency Treatment of Fecal Incontinence Policy

Prior Authorization Requirements

This service (or procedure) is considered **investigational** in all instances. If you would like to submit additional information please forward to the Prior Authorization Department.

Within five days before the actual date of service, the Provider MUST confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should also be directed to the Prior Authorization Department. Please call 1-800-541-6652 or visit the Provider Portal www.blueshieldca.com/provider.

Evidence Basis for the Policy

Rationale

Radiofrequency (RF) energy is a commonly used 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 gastroesophageal reflux disease (GERD), i.e., the Stretta™ (Curon Medical, Fremont, CA) procedure, in which RF lesions are designed to alter the biomechanics of the lower esophageal sphincter. It has also been used in orthopedic procedures to remodel the joint capsule, or in an intradiscal electrothermal annuloplasty (IDET) procedure, in which the treatment is intended in part to modify and strengthen the disc annulus. In all of these procedures, non-ablative 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.

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. There are a variety of etiologies, including injury from vaginal delivery, anal surgery, neurologic disease, and the normal aging process. It is estimated that the disorder affects eight percent of the adult population. Medical management includes dietary measures, such as the addition of bulk-producing agents to the diet and elimination of foods associated with diarrhea. Anti-diarrheal drugs can be used for mild degrees of incontinence. Bowel management programs, commonly used in patients with spinal cord injuries, may also be effective in patients with fecal incontinence. Biofeedback has been

investigated as well. Surgical approaches primarily include a sphincteroplasty, although more novel approaches may be attempted in those patients whose only other treatment option is the creation of a stoma. These novel approaches include an artificial anal sphincter or sacral neuromodulation. Radiofrequency energy has also been investigated as a minimally invasive treatment of fecal incontinence, a procedure referred to as the Secca™ (Curon Medical, Freemont, CA) procedure.

Regulatory Status

In 2002, the Secca™ System received U.S. Food and Drug Administration (FDA) clearance through the 510(k) process with the following labeled indication:

> The Secca System is intended 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.

As of April 2012, no trials allowing comparison of outcomes of transanal RF treatment of fecal incontinence to available alternative treatments have been identified.

Clinical Studies

One published study of the Secca procedure (Efron et al., 2003), which appears to be the clinical study that was submitted as part of the FDA approval process, consisted of an open-label, single-arm, non-randomized clinical study of 50 subjects who were treated and followed up for six months. Patients served as their own controls. The study assessed changes in fecal incontinence symptom scores and quality of life between the baseline and follow-up intervals. Fecal incontinence was assessed with the Cleveland Clinic Florida Fecal Incontinence (CCF-FI) score, and quality of life was assessed with the Fecal Incontinence Quality of Life (FIQL) score. Both the CCF-FI and FIQL scores improved in a steady gradual manner over a six-month period, from 14.6 to 11.1 for the CCF-FI and 2.5 to 3.1 for the FIQL. Previous studies have suggested that a CCF-FI of greater than nine indicates a significant impairment of quality of life (Rothbarth et al., 2001). Of the 44 patients with an initial baseline CCF-FI score greater than nine, a total of 15 (34%) achieved a CCF-FI less than 10 at six months. Improvement was also assessed using the Medical Outcomes Study Short Form-36 (SF-36), focusing on mental and social parameters. The mean social function subscore improved from 64.3 to 34.4, while the mental health subscore improved from 65.8 to 73.8. Fourteen-day diary data demonstrated significant improvement in all nine parameters. For example, the days with any fecal incontinence dropped from 10 in a 14-day period to seven. In contrast, there were no differences in objective measures of anal sphincter, i.e., there were no differences based on manometry measures, rectal sensation volumes, pudendal nerve motor latency, or internal or external sphincter defects, as noted on endo-anal ultrasound. The authors noted that determining the mechanism of action for the procedure was not an objective of the study. Three significant procedure-related complications occurred during the trial. Two patients developed anal ulceration, and one developed bleeding from a hemorrhoidal vein. Twenty-six minor adverse events occurred, including minor bleeding in five patients, transient worsening of incontinence in four patients, and anal pain in five patients.

In another uncontrolled study on the Secca procedure, 11 women with fecal incontinence underwent baseline and post-treatment testing (Felt-Bersma et al., 2007). Six (55%) patients reported improvement; Vaizey scores decreased 13%, and no changes were observed in anal manometry, rectal compliance measurement, or three-dimensional anal ultrasound. Postoperative pain was reported to be slight in eight (73%), moderate in two (18%) and severe in one (9%) patient. The investigators suggested that this procedure merited further testing and noted that a randomized, controlled trial was underway.

A search of the MEDLINE database from February 2010 through April 2012 found one paper reporting on one-year quality-of-life and continence outcomes for a series of 24 patients treated with RF energy for fecal incontinence in 2003 to 2004 (Ruiz et al., 2010). Twelve-month results were available for 16 of the 24 patients (67%). The mean CCF-FI score improved from 15.6 at baseline to 12.9 at 12 months (p=0.035). The mean FIQL Questionnaire score improved in all subsets except for the depression subscore. The authors commented that the actual clinical significance of this improvement needed to be determined.

Three additional very small case series (n=15, 19, 8) were performed outside the U.S (Lefebure et al., 2008; Takahashi-Monroy et al., 2008; Kim et al., 2009). In two of these small trials, no clear benefit was noted for the procedure.

Summary

Given the small number of studies that have been conducted and the limitations of those trials (i.e., small number of patients, lack of control arm and randomization, inconsistencies with inclusion and exclusion criteria, and short-term follow-up), the efficacy of RF therapy for fecal incontinence is not supported in the literature. Therefore because there is insufficient evidence available to evaluate the impact of the technology on net health outcome, this surgical procedure is considered investigational.

Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program (FEP)) prohibit Plans from denying Food and Drug Administration (FDA) - approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

This Policy relates only to the services or supplies described herein. Benefits may vary according to benefit design; therefore, contract language should be reviewed before applying the terms of the Policy. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement.

Type	Number	Description
CPT	0288T	Anoscopy, with delivery of thermal energy to the muscle of the anal canal (eg, for fecal incontinence)
	46999	Unlisted procedure, anus
HCPC	None	
ICD9 Procedure	None	
ICD9 Diagnosis	All Diagnoses	
Place of Service	All Places of Service	

Tables

N/A

Definitions

N/A

Index / Cross Reference of Related BSC Medical Policies

N/A

Key / Related Searchable Words

- Fecal incontinence
- Radiofrequency treatment
- Secca procedure

References

- Blue Cross Blue Shield Association. Medical Policy Manual, No, 2.01.58 (November 2011).
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- Rothbarth J, Bemelman WA, Meijerick WJ et al. What is the impact of fecal incontinence on the quality of life. Dis Colon Rectum. 2001; 44(1):67-71.
- Ruiz D, Pinto RA, Hull TL et al. Does the radiofrequency procedure for fecal incontinence improve quality of life and incontinence a 1-year follow-up? Dis Colon Rectum. 2010; 53(7):1041-6.
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Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

Effective Date	Action	Reason
7/6/2012	BCBSA Medical Policy adoption	Medical Policy Committee
8/21/2012	Coding Update	Administrative Review

The materials provided to you are guidelines used by this plan to authorize, modify, or deny care for persons with similar illness or conditions. Specific care and treatment may vary depending on individual need and the benefits covered under your contract. These Policies are subject to change as new information becomes available.

Click here to view the policy statement for this policy

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