

Corporate Medical Policy

Transanal Radiofrequency Treatment of Fecal Incontinence

File Name:	transanal_radiofrequency_treatment_of_fecal_incontinence
Origination:	8/2009
Last CAP Review:	11/2019
Next CAP Review:	11/2020
Last Review:	11/2019

Description of Procedure or Service

Radiofrequency energy is a commonly used surgical tool that has been used for tissue ablation and more recently for tissue remodeling. For example, radiofrequency energy has been investigated as a treatment of gastroesophageal reflux disease (GERD), i.e., the Stretta® procedure, in which radiofrequency 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 (IDET) procedure, in which the treatment is intended in part to modify and strengthen the disc annulus. In all of these procedures, nonablative levels of radiofrequency thermal energy are used to alter collagen fibrils, which then result in a healing response characterized by fibrosis. Recently, radiofrequency energy has also been investigated as a minimally invasive treatment of 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.

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.

Regulatory Status

In 2002, the Secca™ System (Mederi Therapeutics) received U.S. Food and Drug Administration (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.”

*****Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.**

Transanal Radiofrequency Treatment of Fecal Incontinence

Policy

Transanal Radiofrequency therapy is considered investigational for the treatment of fecal incontinence. BCBSNC does not provide coverage for investigational services or procedures.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When Transanal Radiofrequency Treatment of Fecal Incontinence is covered

Not applicable.

When Transanal Radiofrequency Treatment of Fecal Incontinence is not covered

Transanal radiofrequency treatment of fecal incontinence is considered investigational.

Policy Guidelines

The evidence for transanal radiofrequency treatment in patients who have fecal incontinence 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 properly evaluate long-term outcomes. Three-year follow-up of a small cohort of patients 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.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcsnc.com. They are listed in the Category Search on the Medical Policy search page.

Effective 1/1/2017, there is no specific CPT code for this procedure. It would be reported with the unlisted code 46999. Prior to 2017, there was a CPT category III code specific to the procedure.

Applicable service codes: 46999

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

Transanal Radiofrequency Treatment of Fecal Incontinence

BCBSA Medical Policy Reference Manual, 2.01.58, 3/12/2009
Senior Medical Director review 6/2009
BCBSA Medical Policy Reference Manual, 2.01.58, 3/11/2010
BCBSA Medical Policy Reference Manual, 2.01.58, 3/10/2011
BCBSA Medical Policy Reference Manual, 2.01.58, 7/12/2012
Specialty Matched Consultant Advisory Panel 10/2012
BCBSA Medical Policy Reference Manual, 2.01.58, 11/8/2012
BCBSA Medical Policy Reference Manual, 2.01.58, 9/12/13
Specialty Matched Consultant Advisory Panel 10/2013
BCBSA Medical Policy Reference Manual, 2.01.58, 9/11/14
Specialty Matched Consultant Advisory Panel 11/2014
Senior Medical Director review 12/2014
Specialty Matched Consultant Advisory Panel 11/2015
Senior Medical Director review 11/2015
BCBSA Medical Policy Reference Manual, 2.01.58, 12/10/15
Specialty Matched Consultant Advisory Panel 11/2016
Medical Director review 11/2016
BCBSA Medical Policy Reference Manual, 2.01.58, 11/2016
Specialty Matched Consultant Advisory Panel 11/2017
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BCBSA Medical Policy Reference Manual, 2.01.58, 11/2018
Specialty Matched Consultant Advisory Panel 11/2019
Medical Director review 11/2019
BCBSA Medical Policy Reference Manual, 2.01.58, 11/2019

Policy Implementation/Update Information

8/3/09	New policy adopted from the BCBS Association. Transanal radiofrequency treatment of fecal incontinence is considered investigational. BCBSNC does not cover investigational services. Reviewed by Senior Medical Director 6/23/09. Notice given 8/3/2009. Policy effective date is 11/9/2009. (btw)
6/22/10	Policy Number(s) removed (amw)
11/23/10	Specialty Matched Consultant Panel Advisory review 10/28/10. Policy accepted as written. (adn)
11/8/11	Routine annual review. Description section and Policy Guidelines section updated. No change in policy statement. (adn)

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- 1/1/12 CPT Codes 0288T and C9716 added to the Billing/Coding section. (adn)
- 10/30/12 Specialty Matched Consultant Advisory Panel review 10/17/12. No change to policy statement. (sk)
- 1/15/13 Reference added. Policy Guidelines section updated. No change to policy statement. (sk)
- 11/26/13 Reference added. Specialty Matched Consultant Advisory Panel review 10/16/13. No change to policy statement. (sk)
- 1/13/15 References updated. Related Policy added. Specialty Matched Consultant Advisory Panel review 11/2014. Senior Medical Director review 12/2014. (td)
- 12/30/15 References updated. Specialty Matched Consultant Advisory Panel review 11/18/2015. Senior Medical Director review 11/2015. (td)
- 2/29/16 Description section updated. Policy Guidelines revised. References updated. (td)
- 12/30/16 Code section updates with deletion of 0288T and added language pertaining to no specific CPT code for this procedure, to report with unlisted code 46999. Specialty Matched Consultant Advisory Panel review 11/2016. Medical Director review 11/2016. (jd)
- 12/15/17 References updated. Specialty Matched Consultant Advisory Panel 11/2017. Medical Director review 11/2017. (jd)
- 12/14/18 Minor revisions. Referenes updated. Specialty Matched Consultant Advisory Panel 11/2018. Medical Director review 11/2018. (jd)
- 12/31/19 Removed Related Policies section and updated References. Specialty Matched Consultant Advisory Panel 11/2019. Medical Director review 11/2019. (jd)

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.