

Corporate Medical Policy

Transanal Radiofrequency Treatment of Fecal Incontinence

File Name: transanal_radiofrequency_treatment_of_fecal_incontinence
Origination: 8/2009
Last CAP Review: 10/2011
Next CAP Review: 10/2012
Last Review: 10/2011

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.

Radiofrequency energy has also been investigated as a minimally invasive treatment of fecal incontinence, 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. This procedure is very similar in concept to the Stretta procedure for treatment of gastroesophageal reflux disease (GERD).

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.”

*****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.**

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.

Transanal Radiofrequency Treatment of Fecal Incontinence

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. BCBSNC does not cover investigational services.

Policy Guidelines

A search of the MEDLINE database from February 2010 through January 2011 found one paper published in 2010 reporting on 1-year quality of life and continence outcomes for a series of 24 patients treated with RF energy for fecal incontinence in 2003 to 2004. The authors commented that the actual clinical significance of the study results needs to be determined. A previous literature search found only 3 very small case series (n = 15, 19, 8) from outside the United States. In 2 of these small trials, no clear benefit was noted for the procedure.

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 radiofrequency therapy for fecal incontinence is not supported in the literature. This surgical procedure is considered investigational given the insufficient evidence available to evaluate the impact 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.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable service codes: 0288T, C9716

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

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

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Policy Implementation/Update Information

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| 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) |
| 1/1/12 | CPT Codes 0288T and C9716 added to the Billing/Coding section. (adn) |

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.