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.

OBJECTIVE
The objective of this evidence review is to determine whether transanal radiofrequency treatment for fecal incontinence improves the net health outcome compared with alternatives.

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).

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.” Food and Drug Administration product code: GEI.
FEP 2.01.58 Transanal Radiofrequency Treatment of Fecal Incontinence

RATIONALE

Summary of Evidence
For individuals who have fecal incontinence who receive transanal RF 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.”

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, 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


POLICY HISTORY

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<tr>
<td>June 2012</td>
<td>New Policy</td>
<td>Policy updated with literature review, no references added, no change in policy statement</td>
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<tr>
<td>December 2013</td>
<td>Update Policy</td>
<td>Policy updated with literature review; no references added, no change in policy statement</td>
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<td>December 2014</td>
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<tr>
<td>March 2017</td>
<td>Update Policy</td>
<td>Policy updated with literature review through November 10, 2016; references 2, 13, and 15 added. Policy statement changed from not medically necessary to investigational.</td>
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<td>March 2019</td>
<td>Update Policy</td>
<td>Policy updated with literature review through September 4, 2018; no references added. Policy statement unchanged.</td>
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