FEP 2.01.58 Transanal Radiofrequency Treatment of Fecal Incontinence

Effective Date: April 15, 2018

Related Policies: None

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.

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.

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).

RATIONALE
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...
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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. 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. These briefings aim to aid in the decision-making process by describing the technology, its role in the treatment pathway, a review of 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.” 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. 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


The policies contained in the FEP Medical Policy Manual are developed to assist in administering contractual benefits and do not constitute medical advice. They are not intended to replace or substitute for the independent medical judgment of a practitioner or other health care professional in the treatment of an individual member. The Blue Cross and Blue Shield Association does not intend by the FEP Medical Policy Manual, or by any particular medical policy, to recommend, advocate, encourage or discourage any particular medical technologies. Medical decisions relative to medical technologies are to be made strictly by members/patients in consultation with their health care providers. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that the Blue Cross and Blue Shield Service Benefit Plan covers (or pays for) this service or supply for a particular member.
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POLICY HISTORY

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<thead>
<tr>
<th>Date</th>
<th>Action</th>
<th>Description</th>
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<tbody>
<tr>
<td>June 2012</td>
<td>New Policy</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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<tr>
<td>December 2014</td>
<td>Update Policy</td>
<td>Policy updated with literature review; reference 6 added; no change in policy statement.</td>
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<tr>
<td>March 2017</td>
<td>Update Policy</td>
<td>Policy updated with literature review through November 2, 2016; references 2, 13, and 15 added. Policy statement changed from not medically necessary to investigational.</td>
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