

Policy: MP154

Section: Medical Benefit Policy

Subject: Transanal Radiofrequency Therapy for Fecal Incontinence (Secca®)

I. Policy: Transanal Radiofrequency Therapy for Fecal Incontinence (Secca®)

II. Purpose/Objective:

To provide a policy of coverage regarding Transanal Radiofrequency Therapy for Fecal Incontinence (Secca®)

III. Responsibility:

- A. Medical Directors
- B. Medical Management

IV. Required Definitions

1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions

Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

- a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- b. provided for the diagnosis, and the direct care and treatment of the Member's condition, illness disease or injury;
- c. in accordance with current standards of good medical treatment practiced by the general medical community.
- d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
- e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

Medicaid Business Segment

Medical Necessity shall mean a service or benefit that is compensable under the Medical Assistance Program and if it meets any one of the following standards:

- (i) The service or benefit will, or is reasonably expected to, prevent the onset of an illness, condition or disability.
- (ii) The service or benefit will, or is reasonably expected to, reduce or ameliorate the physical, mental or development effects of an illness, condition, injury or disability.
- (iii) The service or benefit will assist the Member to achieve or maintain maximum functional

capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for members of the same age.

DESCRIPTION: Radiofrequency energy delivered to the sphincteric complex via an anoscopic device is being purported as a treatment for fecal incontinence. The device (Secca® system) creates thermal lesions in the mucosa of the anal canal. It is theorized that as these lesions heal over time and the tissue contracts, it may change the tone of the tissue and improve continence.

EXCLUSIONS: The Plan does **NOT** provide coverage for Transanal radiofrequency therapy (Secca®) as a treatment for fecal incontinence because it is considered **experimental, investigational or unproven**. The Geisinger Technology Assessment Committee evaluated this technology and concluded that there is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of this test on health outcomes when compared to established tests or technologies.

Note: A complete description of the process by which a given technology or service is evaluated and determined to be experimental, investigational or unproven is outlined in MP 15 - Experimental Investigational or Unproven Services or Treatment.

CODING ASSOCIATED WITH: Transanal Radiofrequency Therapy for Fecal Incontinence (Secca®)
The following codes are included below for informational purposes and may not be all inclusive. Inclusion of a procedure or device code(s) does not constitute or imply coverage nor does it imply or guarantee provider reimbursement. Coverage is determined by the member specific benefit plan document and any applicable laws regarding coverage of specific services. Please note that per Medicare coverage rules, only specific CPT/HCPCS Codes may be covered for the Medicare Business Segment. Please consult the CMS website at www.cms.gov or the local Medicare Administrative Carrier (MAC) for more information on Medicare coverage and coding requirements.

46999 Unlisted procedure, anus

Current Procedural Terminology (CPT®) © American Medical Association: Chicago, IL

LINE OF BUSINESS:

Eligibility and contract specific benefits, limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy. For Medicare, applicable LCD's and NCD's will supercede this policy. For PA Medicaid Business segment, this policy applies as written.

REFERENCES:

Geisinger Technology Assessment Committee Triage Group. March 2005

Efron JE. The SECCA(tm) Procedure: A New Therapy for Treatment of Fecal Incontinence. Surg Technol Int. 2004;13:107-10.

Efron JE, Corman ML, Fleshman J, Barnett J, Nagle D, Birnbaum E, Weiss EG, Nogueras JJ, Sligh S, Rabine J, Wexner SD. Safety and effectiveness of temperature-controlled radio-frequency energy delivery to the anal canal (Secca procedure) for the treatment of fecal incontinence. Dis Colon Rectum. 2003 Dec;46(12):1606-16; discussion 1616-8.

Takahashi T, Garcia-Osogobio S, Valdovinos MA, Belmonte C, Barreto C, Velasco L. Extended two-year results of radio-frequency energy delivery for the treatment of fecal incontinence (the Secca procedure). Dis Colon Rectum. 2003 Jun;46(6):711-5

Takahashi T, Garcia-Osogobio S, Valdovinos MA, Mass W, Jimenez R, Jauregui AL, Bobadilla J, Belmonte C, Edelstein PS, Utley DS. Radiofrequency Energy Delivery to the Anal Canal for the Treatment of fecal Incontinence. Dis Colon Rectum 2002;45:915-922.

New Studies Reveal Benefits of Radiofrequency for Treatment of Fecal Incontinence. Results to be Presented at American Society of Colon and Rectal Surgeons Annual Meeting June 3-8

Curon Medical Manufacturer's website

www.curonmedical.com/Physicians/secca_fi.html - 20k -

Takahashi-Monroy T, Morales M, Garcia-Osogobio S, Valdovinos MA, Belmonte C, Barreto C, Zarate X, Bada O, Velasco L. SECCA(R) Procedure for the Treatment of Fecal Incontinence: Results of Five-Year Follow-Up. *Dis Colon Rectum*. 2008 Mar;51(3):355-9.

Tjandra JJ, Dykes SL, Kumar RR, Ellis CN, Gregorcyk SG, Hyman NH, Buie WD; Standards Practice Task Force of The American Society of Colon and Rectal Surgeons. Practice parameters for the treatment of fecal incontinence. *Dis Colon Rectum*. 2007 Oct;50(10):1497-507. Accessed May 11, 2010. Available at URL address: http://www.fascrs.org/physicians/practice_parameters/

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Abbas MA, Tam MS, Chun LJ. Radiofrequency treatment for fecal incontinence: Is it effective long-term? *Dis Colon Rectum*. 2012;55(5):605-610

Lam TJ, Visscher AP, Meurs-Szojda MM, Felt-Bersma RJ. Clinical response and sustainability of treatment with temperature-controlled radiofrequency energy (Secca) in patients with faecal incontinence: 3 years follow-up. *Int J Colorectal Dis*. 2014;29(6):755-761

Paquette, IM, Varma, MG, Kaiser, AM, Steele, SR, Rafferty, JF. The American Society of Colon and Rectal Surgeons' Clinical Practice Guideline for the Treatment of Fecal Incontinence. United States, 2015. p. 623-36.

This policy will be revised as necessary and reviewed no less than annually.

Devised: 5/05

Revised: 5/10 (refs)

Reviewed: 5/06; 6/07; 6/08; 6/09; 5/11, 5/12, 5/13, 5/14; 5/15, 5/16, 4/17, 4/18