

Protocol

Biofeedback as a Treatment of Urinary Incontinence in Adults

(20127)

Medical Benefit		Effective Date: 01/01/10	Next Review Date: 09/14
Preauthorization	No	Review Dates: 01/08, 11/08, 09/09, 09/10, 09/11, 09/12, 09/13	

*The following Protocol contains medical necessity criteria that apply for this service. It is applicable to Medicare Advantage products unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. **Preauthorization is not required but recommended if, despite this Protocol position you feel this service is medically necessary; supporting documentation must be submitted to Utilization Management.** Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.*

Description

Biofeedback is a technique to teach patients self-regulation of physiologic processes not generally considered to be under voluntary control; a variety of approaches and devices are available. Biofeedback, in conjunction with pelvic floor muscle training (PFMT), is proposed as a treatment of urinary incontinence.

Background

Urinary Incontinence is a common condition defined as an involuntary leakage of urine. Women are twice as likely to be affected as men, and prevalence increases with age. The severity of incontinence affects quality of life and treatment decisions. The types of urinary incontinence include stress, urge, overflow, functional, and post-prostatectomy incontinence. Nonsurgical treatment options may include pharmacologic treatment, pelvic muscle exercises, bladder training exercises, electrical stimulation, and neuromodulation.

Biofeedback is a technique intended to teach patients self-regulation of certain physiologic processes not normally considered to be under voluntary control. The technique involves the feedback of a variety of types of information not commonly available to the patient, followed by a concerted effort on the part of the patient to use this feedback to help alter the physiologic process in some specific way. Biofeedback has been proposed as a treatment for a variety of diseases and disorders, including anxiety, headaches, hypertension, movement disorders, incontinence, pain, asthma, Raynaud's disease, and insomnia. Biofeedback training is done either in individual or group sessions and as a single therapy or in combination with other therapies designed to teach relaxation. A typical program consists of 10 to 20 training sessions of 30 minutes each. Training sessions are performed in a quiet, nonarousing environment. Subjects are instructed to use mental techniques to affect the physiologic variable monitored, and feedback is provided for successful alteration of the physiologic parameter. This feedback may be in the form of signals, such as lights or tone, verbal praise, or other auditory or visual stimuli.

Biofeedback, in conjunction with pelvic floor muscle training (PFMT), is a possible treatment modality for stress, urge, mixed, and overflow urinary incontinence because it may enhance awareness of body functions and the learning of exercises to train pelvic muscles. There are several proposed methods of biofeedback that may be employed for the treatment of urinary incontinence, including vaginal cones or weights, perineometers, and electromyographic (EMG) systems with vaginal and rectal sensors.

The various forms of biofeedback mainly differ in the nature of the disease or disorder under treatment, the biologic variable that the individual attempts to control, and the information that is fed back to the individual. Biofeedback techniques include peripheral skin temperature feedback, blood-volume-pulse feedback

(vasoconstriction and dilation), vasoconstriction training (temporalis artery), and EMG biofeedback; these may be used alone or in conjunction with other therapies (e.g., relaxation, behavioral management, medication).

Regulatory Status

A variety of biofeedback devices are cleared for marketing through the U.S. Food and Drug Administration's (FDA) 510(k) process. The FDA defines a biofeedback device as "an instrument that provides a visual or auditory signal corresponding to the status of one or more of a patient's physiological parameters (e.g., brain alpha wave activity, muscle activity, skin temperature, etc.) so that the patient can control voluntarily these physiological parameters".

Related Protocols:

Pelvic Floor Stimulation as a Treatment of Urinary Incontinence

Injectable Bulking Agents for the Treatment of Urinary and Fecal Incontinence

Sacral Nerve Neuromodulation/Stimulation

Posterior Tibial Nerve Stimulation for Voiding Dysfunction

Corporate Medical Guideline

Biofeedback in the outpatient setting is considered **investigational** as a treatment of urinary incontinence in adults.

Unsupervised home use of biofeedback for treatment of urinary incontinence is **investigational**.

Medicare Advantage

Biofeedback is **medically necessary** for the treatment of stress and/or urge incontinence in cognitively intact patients who have failed a documented trial of pelvic muscle exercise (PME) training when rendered by a practitioner in an office or other facility setting. It is not a treatment, per se, but a tool to help patients learn how to perform PME. A failed trial of PME training is defined as no clinically significant improvement in urinary incontinence after completing four weeks of an ordered plan of pelvic muscle exercises to increase periurethral muscle strength.

Home use of biofeedback therapy is **investigational**.

Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this Protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

References

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

1. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Biofeedback. TEC Assessments 1995; Volume 10, Tab 25.
2. Shamliyan T, Wyman J, Kane RL et al. Nonsurgical treatments for urinary incontinence in adult women: diagnosis and comparative effectiveness. Comparative Effectiveness Review No. 36. (Prepared by the University of Minnesota Evidence-based Practice Center under Contract No. HHS 290-2007-10064-I.). 2012. Available online at: http://effectivehealthcare.ahrq.gov/ehc/products/169/834/CER36_UrinaryIncontinence_FinalReport_20120517.pdf. Last accessed June, 2013.
3. Herderschee R, Hay-Smith EJ, Herbison GP et al. Feedback or biofeedback to augment pelvic floor muscle training for urinary incontinence in women. *Cochrane Database Syst Rev* 2011; (7):CD009252.
4. Burgio KL, Goode PS, Locher JL et al. Behavioral training with and without biofeedback in the treatment of urge incontinence in older women: a randomized controlled trial. *JAMA* 2002; 288(18):2293-9.
5. Williams KS, Assassa RP, Gillies CL et al. A randomized controlled trial of the effectiveness of pelvic floor therapies for urodynamic stress and mixed incontinence. *BJU Int* 2006; 98(5):1043-50.
6. Hirakawa T, Suzuki S, Kato K et al. Randomized controlled trial of pelvic floor muscle training with or without biofeedback for urinary incontinence. *Int Urogynecol J* 2013.
7. Pereira VS, de Melo MV, Correia GN et al. Vaginal cone for postmenopausal women with stress urinary incontinence: randomized, controlled trial. *Climacteric* 2012; 15(1):45-51.
8. MacDonald R, Fink HA, Huckabay C et al. Pelvic floor muscle training to improve urinary incontinence after radical prostatectomy: a systematic review of effectiveness. *BJU Int* 2007; 100(1):76-81.
9. Campbell SE, Glazener CM, Hunter KF et al. Conservative management for postprostatectomy urinary incontinence. *Cochrane Database Syst Rev* 2012; 1:CD001843.
10. Tienforti D, Sacco E, Marangi F et al. Efficacy of an assisted low-intensity programme of perioperative pelvic floor muscle training in improving the recovery of continence after radical prostatectomy: a randomized controlled trial. *BJU Int* 2012; 110(7):1004-10.
11. Mariotti G, Sciarra A, Gentilucci A et al. Early recovery of urinary continence after radical prostatectomy using early pelvic floor electrical stimulation and biofeedback associated treatment. *J Urol* 2009; 181(4):1788-93.
12. Goode PS, Burgio KL, Johnson TM, 2nd et al. Behavioral therapy with or without biofeedback and pelvic floor electrical stimulation for persistent postprostatectomy incontinence: a randomized controlled trial. *JAMA* 2011; 305(2):151-9.
13. National Institute for Health and Clinical Excellence (NICE). Urinary incontinence: the management of urinary incontinence in women. 2006. Available online at: www.nice.org.uk. Last accessed May, 2013.
14. Centers for Medicare and Medicaid Services. National coverage decision for biofeedback therapy for the treatment of urinary incontinence. Available online at: www.cms.hhs.gov. Last accessed June, 2013.