

Protocol

Biofeedback as a Treatment of Urinary Incontinence in Adults

(20127)

Medical Benefit		Effective Date: 01/01/10	Next Review Date: 09/17
Preauthorization	No	Review Dates: 01/08, 11/08, 09/09, 09/10, 09/11, 09/12, 09/13, 09/14, 09/15, 09/16	

This Protocol considers this test or procedure investigational. If the physician feels this service is medically necessary, preauthorization is recommended.

The following Protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. 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.

Populations	Interventions	Comparators	Outcomes
Patients/individuals with: <ul style="list-style-type: none">• Adult-associated urinary incontinence	Interventions of interest are: <ul style="list-style-type: none">• Biofeedback in outpatient clinic or home settings using an FDA-cleared device with PFMT	Comparators of interest are: <ul style="list-style-type: none">• PFMT without biofeedback	Relevant outcomes include: <ul style="list-style-type: none">• Change in disease severity• Symptoms

PFMT: pelvic floor muscle training.

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.

Summary of Evidence

There is a lack of consistent evidence from randomized controlled trials (RCTs) that biofeedback improves incontinence outcomes in women or in men after prostate surgery compared with pelvic floor muscle exercises alone. No published evidence supports the unsupervised home use of biofeedback for treatment of urinary incontinence. The body of evidence consists of RCTs that have conflicting results.

Policy

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.

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

Medicare Advantage Policy Guidelines

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.

Biofeedback is not a treatment, per se, but a tool to help patients learn how to perform PME. Patient selection is a major part of the process and the patient should be motivated, cognitively intact, and compliant. In addition, there must be assurance that the pelvic floor musculature is intact.

Biofeedback may be used as an initial incontinence treatment modality only when, in the opinion of the physician, that approach is most appropriate and there is documentation of medical justification and rationale for why a PME trial was not attempted first.

Patients not showing improvement after five to six visits of retraining with biofeedback are not likely to improve with additional sessions and therefore additional documentation is necessary to justify services beyond five to six visits.

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 postprostatectomy 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 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, 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 subject attempts to control, and the information that is fed back to the subject. 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 FDA's 510(k) process. 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." FDA product code: KPI.

Related Protocols

Injectable Bulking Agents for the Treatment of Urinary and Fecal Incontinence

Pelvic Floor Stimulation as a Treatment of Urinary and Fecal Incontinence

Percutaneous Tibial Nerve Stimulation

Sacral Nerve Neuromodulation/Stimulation

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.

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