Protocol

Biofeedback as a Treatment of Urinary Incontinence in Adults

(20127)

Medical Benefit		**Effective Date**: 01/01/10	**Next Review Date**: 09/19
Preauthorization	No	**Review Dates**: 01/08, 11/08, 09/09, 09/10, 09/11, 09/12, 09/13, 09/14, 09/15, 09/16, 09/17, 09/18	

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
Individuals: • With urinary incontinence (women)	Interventions of interest are: • Biofeedback with pelvic floor muscle training	Comparators of interest are: • Pelvic floor muscle training without biofeedback	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life
Individuals: • With post-prostatectomy urinary incontinence	Interventions of interest are: • Biofeedback with pelvic floor muscle training	Comparators of interest are: • Pelvic floor muscle training without biofeedback	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life
Individuals: • Who are scheduled for radical prostatectomy	Interventions of interest are: • Biofeedback with pelvic floor muscle training	Comparators of interest are: • Pelvic floor muscle training without biofeedback	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life

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

For individuals who have urinary incontinence (women) who receive biofeedback with PFMT, the evidence includes randomized controlled trials (RCTs) and systematic reviews. Relevant outcomes are symptoms, functional outcomes, and quality of life. A comparative effectiveness review did not find a statistically significant difference in continence rates when patients received PFMT with or without biofeedback. Other systematic reviews evaluating biofeedback and/or verbal feedback as part of treatment for urinary incontinence found improvement in some outcomes, but not others. There is a lack of consistent evidence from well-designed trials that biofeedback effectively treats urinary incontinence. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have post-prostatectomy urinary incontinence or who are scheduled for radical prostatectomy who receive biofeedback with PFMT, the evidence includes RCTs and systematic reviews. Relevant outcomes are symptoms, functional outcomes, and quality of life. Several RCTs have compared PFMT with or without biofeedback in men undergoing radical prostatectomy, and in men with post-prostatectomy urinary incontinence. These trials had mixed findings, but did not consistently report significantly improved outcomes when biofeedback was added to the intervention. The timing and delivery of the intervention were not well-defined. Additional well-designed trials are needed that demonstrate the superiority of biofeedback with PFMT over PFMT alone. The evidence is insufficient to determine the effects of the technology on health outcomes.

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 feedback on a variety of types of infor-

mation 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. Several proposed methods of biofeedback that may be employed to treat 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; they may be used alone or in conjunction with other therapies (e.g., relaxation, behavioral management, medication).

REGULATORY STATUS

A variety of biofeedback devices have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 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.” 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.

1. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Biofeedback. TEC Assessments. 1995;Volume 10:Tab 25.
2. Moroni RM, Magnani PS, Haddad JM, et al. Conservative treatment of stress urinary incontinence: a systematic review with meta-analysis of randomized controlled trials. Rev Bras Ginecol Obstet. Feb 2016;38(2):97-111. PMID 26883864
3. 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 (AHRQ Pub. No. 11(12)-EHC074-1). Rockville (MD): Agency for Healthcare Research and Quality; 2012.
4. 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. PMID 21735442
5. 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. Nov 13 2002;288(18):2293-2299. PMID 12425706
6. 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. Nov 2006;98(5):1043-1050. PMID 17034605
7. 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. Aug 2013;24(8):1347-1354. PMID 23306768
8. Pereira VS, de Melo MV, Correia GN, et al. Vaginal cone for postmenopausal women with stress urinary incontinence: randomized, controlled trial. Climacteric. Feb 2012;15(1):45-51. PMID 22066898
9. Anderson CA, Omar MI, Campbell SE, et al. Conservative management for postprostatectomy urinary incontinence. Cochrane Database Syst Rev. 2015;1:CD001843. PMID 25602133
10. Hsu LF, Liao YM, Lai FC, et al. Beneficial effects of biofeedback-assisted pelvic floor muscle training in patients with urinary incontinence after radical prostatectomy: A systematic review and metaanalysis. Int J Nurs Stud. Aug 2016;60:99-111. PMID 27297372
11. 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. Jul 2007;100(1):76-81. PMID 17433028
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. Jan 12 2011;305(2):151-159. PMID 21224456
13. 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. Oct 2012;110(7):1004-1010. PMID 22332815
14. Wille S, Sobottka A, Heidenreich A, et al. Pelvic floor exercises, electrical stimulation and biofeedback after radical prostatectomy: results of a prospective randomized trial. J Urol. Aug 2003;170(2 Pt 1):490-493. PMID 12853806
15. Bales GT, Gerber GS, Minor TX, et al. Effect of preoperative biofeedback/pelvic floor training on continence in men undergoing radical prostatectomy. Urology. Oct 1 2000;56(4):627-630. PMID 11018619
16. American Urological Association. Diagnosis and Treatment of Overactive Bladder (Non-Neurogenic) in Adults: AUA/SUFU Guideline. https://www.auanet.org/education/guidelines/overactive-bladder.cfm. Accessed November, 2016.
17. Qaseem A, Dallas P, Forciea MA, et al. Nonsurgical management of urinary incontinence in women: a clinical practice guideline from the American College of Physicians. Ann Intern Med. Sep 16 2014;161(6):429-440. PMID 25222388

18. National Institute for Health and Clinical Excellence (NICE). Urinary incontinence in women: management [CG171]. 2015; https://www.nice.org.uk/Guidance/CG171. Accessed December 16, 2016.
19. Canadian Urological Association. Guidelines for adult urinary incontinence collaborative consensus document. 2012; http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3478335/. Accessed November, 2016.
20. Shamilyan T, Wyman J, Bliss DZ, et al. Prevention of urinary and fecal incontinence in adults. Evidence Reports/Technology Assessments No. 161 (AHRQ Publication No. 08-E003). Rockville (MD) Agency for Healthcare Research and Quality; 2007.
21. Centers for Medicare and Medicaid Services. National coverage decision for biofeedback therapy for the treatment of urinary incontinence (Publication No. 100-3, Section 30.1.1). 2001; http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=42&ncdver=1&CoverageSelection=National&KeyWord=Biofeedback+Urinary+Incontinence&KeyWordLookUp=Title&KeyWordSearchType=And&bc=gAAAABAAAAAAAA%3d%3d&. Accessed November, 2016.
22. National Coverage Determination (NCD) for Biofeedback Therapy for the Treatment of Urinary Incontinence (30.1.1), Effective Date of this Version 7/1/2001.
23. National Government Services, Inc. (Primary Geographic Jurisdiction 06 & K - Illinois, Minnesota, Wisconsin, Connecticut, New York - Entire State, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont) Local Coverage Determination (LCD): Outpatient Physical and Occupational Therapy Services (L33631), For services performed on or after 01/01/2018.