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.

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

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<td>Individuals: • With urinary incontinence (women)</td>
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<tr>
<td>Individuals: • With post-prostatectomy urinary incontinence</td>
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<td>Individuals: • Who are scheduled for radical prostatectomy</td>
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<td>Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life</td>
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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 that the technology results in an improvement in the net health outcome.

For individuals who have post-prostatectomy urinary incontinence, the evidence includes an RCT and systematic reviews that compared PFMT with or without biofeedback. Relevant outcomes are symptoms, functional outcomes, and quality of life. Results of these data were mixed, and 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 that the technology results in an improvement in the net health outcome.

For individuals who will undergo radical prostatectomy, RCTs have evaluated the efficacy of biofeedback with PFMT compared with PFMT without biofeedback for prevention of prostatectomy-related urinary incontinence. These trials generally did not report improved outcomes with biofeedback added to the intervention. The timing and delivery of the intervention were not well-defined. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

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 not medically necessary.

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

Biofeedback is 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 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, non-arousing environment. Subjects are instructed to use mental techniques to affect the physiologic variable monitored, and feedback is provided for the 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 biofeedback methods that may be employed to treat urinary incontinence, including vaginal cones or weights, perineometers, and electromyographic 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 electromyographic 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 1 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.

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

   https://www.auanet.org/guidelines/incontinence-after-prostate-treatment
   https://www.nice.org.uk/guidance/ng123
26. 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), Revision Effective Date For services performed on or after 01/01/2020.