

(20153)

Medical Benefit		Effective Date: 04/01/16	Next Review Date: 01/18
Preauthorization	No	Review Dates: 11/08, 09/09, 09/10, 09/11, 05/12, 05/13, 05/14, 01/15, 01/16, 01/17	

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: <ul style="list-style-type: none"> With mood disorders, behavioral conditions, pain, movement or motor disorders, or other conditions potentially treatable with self-regulation of physiologic processes^a 	Interventions of interest are: <ul style="list-style-type: none"> Biofeedback 	Comparators of interest are: <ul style="list-style-type: none"> Standard care 	Relevant outcomes include: <ul style="list-style-type: none"> Symptoms Functional outcomes Quality of life

^a Urinary and fecal incontinence, headache, and chronic pain are addressed elsewhere (see Related Protocols listing).

Description

Biofeedback is a technique intended to teach patients self-regulation of certain physiologic processes not normally considered to be under voluntary control. This protocol focuses on the use of biofeedback for treating miscellaneous indications. Specifically, these are indications other than urinary and fecal incontinence, headache, and chronic pain.

Summary of Evidence

The evidence for the use of biofeedback in individuals with Bell's palsy, hypertension, motor function after stroke, injury or lower-limb surgery, multiple sclerosis, prevention of preterm birth, posttraumatic stress disorder, Raynaud disease, tinnitus, or sleep bruxism includes one or more randomized controlled trials (RCTs) on each indication. Relevant outcomes are symptoms, functional outcomes, and quality of life. The available RCTs either failed to show any beneficial impact of biofeedback or had design flaws that create uncertainty about the contribution of nonspecific factors such as attention or placebo effects versus the specific effect of biofeedback. Moreover, the trials are generally of short duration and the durability of benefits reported is unclear. The evidence is insufficient to determine the effects of the technology on health outcomes.

The evidence for the use of biofeedback in individuals with asthma, insomnia, movement disorders, or orthostatic hypotension associated with spinal cord injury includes a TEC Assessment or other systematic review of the literature. Relevant outcomes are symptoms, functional outcomes, and quality of life. The systematic

reviews did not find sufficient evidence that biofeedback benefited these conditions. The evidence is insufficient to determine the effects of the technology on health outcomes.

The evidence for the use of biofeedback in individuals with anxiety or depression includes no published peer-reviewed studies. Relevant outcomes are symptoms, functional outcomes, and quality of life. The evidence is insufficient to determine the effects of the technology on health outcomes.

Policy

Biofeedback is considered **investigational** as a treatment of the following miscellaneous conditions:

- anxiety disorders
- asthma
- Bell palsy
- depression
- hypertension
- insomnia
- motor function after stroke, injury or lower-limb surgery
- movement disorders
- multiple sclerosis
- orthostatic hypotension in patients with spinal cord injury
- pain management during labor
- posttraumatic stress disorder
- prevention of pre-term birth
- Raynaud disease
- sleep bruxism
- tinnitus

Background

Biofeedback is a technique intended to teach patients self-regulation of certain unconscious or involuntary physiologic processes. The technique involves the feedback of a variety of types of information not usually 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 a 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. The type of feedback used in an intervention (e.g., visual, auditory) depends on the nature of the disease or disorder under treatment. This protocol focuses on the use of biofeedback for the treatment of hypertension, anxiety, insomnia, asthma, movement disorders, and other miscellaneous applications (i.e., conditions not addressed in other protocols on biofeedback).

This protocol addresses biofeedback devices that measure and provide feedback on physiologic process such as heart rate, muscle tension, skin temperature, and blood flow. Electroencephalographic biofeedback, also called neurofeedback, which measures brainwave activity, is addressed elsewhere.

Regulatory Status

A large number of biofeedback devices have been cleared through the U.S. Food and Drug Administration's 510(k) process since 1976.

Related Protocols

Biofeedback as a Treatment of Chronic Pain
Biofeedback as a Treatment of Fecal Incontinence or Constipation
Biofeedback as a Treatment of Headache
Biofeedback as a Treatment of Urinary Incontinence in Adults
Neurofeedback
Treatment of Tinnitus

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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