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<b>Medical Benefit</b>		<b>Effective Date:</b> 04/01/16	<b>Next Review Date:</b> 01/20
<b>Preauthorization</b>	No	<b>Review Dates:</b> 11/08, 09/09, 09/10, 09/11, 05/12, 05/13, 05/14, 01/15, 01/16, 01/17, 01/18, 01/19	

***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 anxiety disorders	Interventions of interest are: • Biofeedback	Comparators of interest are: • Standard care	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life
Individuals: • With asthma	Interventions of interest are: • Biofeedback	Comparators of interest are: • Standard care	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life
Individuals: • With Bell palsy	Interventions of interest are: • Biofeedback	Comparators of interest are: • Standard care	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life
Individuals: • With depression	Interventions of interest are: • Biofeedback	Comparators of interest are: • Standard care	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life
Individuals: • With hypertension	Interventions of interest are: • Biofeedback	Comparators of interest are: • Standard care	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life
Individuals: • With motor dysfunction after stroke	Interventions of interest are: • Biofeedback	Comparators of interest are: • Standard care	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life
Individuals: • With motor dysfunction after lower-limb injury or surgery	Interventions of interest are: • Biofeedback	Comparators of interest are: • Standard care	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life
Individuals: • With multiple sclerosis	Interventions of interest are: • Biofeedback	Comparators of interest are: • Standard care	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life

Populations	Interventions	Comparators	Outcomes
Individuals: • With orthostatic hypotension due to spinal cord injury	Interventions of interest are: • Biofeedback	Comparators of interest are: • Standard care	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life
Individuals: • Who need pain management during labor	Interventions of interest are: • Biofeedback	Comparators of interest are: • Standard care	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life
Individuals: • With posttraumatic stress disorder	Interventions of interest are: • Biofeedback	Comparators of interest are: • Standard care	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life
Individuals: • Who are susceptible to preterm birth	Interventions of interest are: • Biofeedback	Comparators of interest are: • Standard care	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life
Individuals: • With Raynaud disease	Interventions of interest are: • Biofeedback	Comparators of interest are: • Standard care	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life
Individuals: • With sleep bruxism	Interventions of interest are: • Biofeedback	Comparators of interest are: • Standard care	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life
Individuals: • With tinnitus	Interventions of interest are: • Biofeedback	Comparators of interest are: • Standard care	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life

## DESCRIPTION

Biofeedback is a technique intended to teach patients self-regulation of certain physiologic processes that are otherwise impossible or extremely difficult to control. This review focuses on the use of biofeedback for treating miscellaneous indications—specifically, indications other than urinary and fecal incontinence, headache, and chronic pain.

## SUMMARY OF EVIDENCE

For individuals with anxiety disorders who receive biofeedback, the evidence includes two systematic reviews and a randomized controlled trial (RCT) published after the review. Relevant outcomes are symptoms, functional outcomes, and quality of life. The systematic reviews and observational trial on heart rate variability biofeedback and the RCT on diaphragmatic breathing relaxation reported the positive effects of these treatments on anxiety. However, the trials had small sample sizes (median, 14 participants) and study quality was generally poor. Additional limitations included improper randomization, allocation concealment, and inadequate descriptions of randomization or missing data. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with asthma who receive biofeedback, the evidence includes three RCTs. Relevant outcomes are symptoms, functional outcomes, and quality of life. Each RCT used a different biofeedback technique, which provided patients with information on carbon dioxide, heart rate, and respiratory sinus arrhythmia. While the

trials reported improvements in each parameter for which the patients received biofeedback, the improvements did not impact clinical outcomes such as medication use and forced expiratory volume. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with Bell palsy who receive biofeedback, the evidence includes four RCTs. Relevant outcomes are symptoms, functional outcomes, and quality of life. The RCTs evaluated the efficacy of adding a mirror and/or electromyography biofeedback to facial exercises. Sample sizes were small, and there was heterogeneity across techniques used and length of treatments. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with depression who receive biofeedback, the evidence includes a systematic review. Relevant outcomes are symptoms, functional outcomes, and quality of life. The review only identified two dissertations assessing the use of biofeedback for depression. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with hypertension who receive biofeedback, the evidence includes a systematic review and an RCT published after the review. Relevant outcomes are symptoms, functional outcomes, and quality of life. The systematic review identified 36 RCTs, though sample sizes were small and overall study quality poor. Various biofeedback techniques were used: thermal, galvanized skin response, pulse wave velocity, and heart rate variability. Results across trials did not consistently show a benefit of biofeedback. Conclusions were limited due to the heterogeneity across interventions and the generally poor quality of the trials. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with motor dysfunction after stroke who receive biofeedback, the evidence includes systematic reviews, RCTs published after the systematic reviews and a case series. Relevant outcomes are symptoms, functional outcomes, and quality of life. One systematic review identified 18 high-quality trials using the following biofeedback techniques: weight distribution on a platform sensor, muscle activity from electromyography, linear gait parameters, and joint angle from a goniometer. Feedback was visual, auditory, or both. Outcome measures primarily assessed motor activity in research settings, rather than clinical outcomes such as rates of falls or the ability to perform activities of daily living. Pooled effects showed improvements in motor function in the short term. The evidence is limited due to the variability in type, duration, and intensity of the interventions and lack of long-term outcomes. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with motor dysfunction after lower-limb injury or surgery who receive biofeedback, the evidence includes a systematic review. Relevant outcomes are symptoms, functional outcomes, and quality of life. The systematic review identified four RCTs evaluating the use of electromyography biofeedback. Sample sizes were small, with half of the trials reporting significant benefits of biofeedback and the other half reporting no difference between study groups. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with multiple sclerosis who receive biofeedback, the evidence includes two RCTs. Relevant outcomes are symptoms, functional outcomes, and quality of life. One trial used vibrotactile biofeedback and the other provided patients with heart rate and muscle tension biofeedback. Sample sizes were small, and trialists reported marginally significant differences between study groups. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with orthostatic hypotension due to spinal cord injury who receive biofeedback, the evidence includes a case series and a case report. Relevant outcomes are symptoms, functional outcomes, and quality of life. The case series and a case report collectively provided information on three patients given visual and auditory feedback. Patients were able to raise their systolic blood pressure by an average of 39%. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who need pain management during labor who receive biofeedback, the evidence includes four RCTs. Relevant outcomes are symptoms, functional outcomes, and quality of life. A Cochrane review graded the four trials as having a high risk of bias due to unclear descriptions of blinding and randomization methods. Due to the heterogeneity in biofeedback methods and outcomes measured, pooled analyses could not be performed. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with posttraumatic stress disorder who receive biofeedback, the evidence includes an RCT, a nonrandomized study, and two case series. Relevant outcomes are symptoms, functional outcomes, and quality of life. The studies had small sample sizes and inconsistent results. A systematic review of the four studies rated the evidence a grade C for conflicting scientific evidence. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who are susceptible to preterm birth who receive biofeedback, the evidence includes an RCT. Relevant outcomes are symptoms, functional outcomes, and quality of life. In the RCT, women in the treatment group received heart rate variability biofeedback. Patients receiving the treatment experienced a decrease in perceived chronic stress, but there was no significant difference in the number of preterm births, gestational duration, or birth weight. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with Raynaud disease who receive biofeedback, the evidence includes a systematic review. Relevant outcomes are symptoms, functional outcomes, and quality of life. The systematic review identified five RCTs using biofeedback techniques. Pooled analysis was performed on four of these trials. Reduction in frequency of attacks was significantly lower in the sham-control group. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with sleep bruxism who receive biofeedback, the evidence includes two systematic reviews and an RCT published after the review. Relevant outcomes are symptoms, functional outcomes, and quality of life. One systematic review identified seven randomized and nonrandomized studies using biofeedback techniques and the most recent systematic review identified six additional studies. Studies were generally small, used different techniques, measured different outcomes, and were assessed as having either moderate or high risk of bias. Two studies reported the number of bruxism episodes per hour and a pooled analysis of these studies showed no significant differences between biofeedback groups and control groups. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with tinnitus who receive biofeedback, the evidence includes a single RCT. Relevant outcomes are symptoms, functional outcomes, and quality of life. Treatment consisted of a biofeedback based behavioral intervention over a three-month period. The treatment group experienced improvements in tinnitus annoyance, loudness ratings, controllability, coping cognitions, and depressive symptoms. Additional studies are needed to confirm the results of this single trial. 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
- movement disorders such as motor function after stroke, injury or lower-limb surgery
- multiple sclerosis

- orthostatic hypotension in patients with spinal cord injury
- pain management during labor
- posttraumatic stress disorder
- prevention of preterm birth
- Raynaud disease
- sleep bruxism
- tinnitus

## BACKGROUND

Biofeedback is a technique intended to teach patients self-regulation of certain unconscious or involuntary physiologic processes. Biofeedback equipment converts physiological signals into outputs given to patients. 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 being treated. This protocol focuses on the use of biofeedback for the treatment of hypertension, anxiety, insomnia, asthma, movement disorders (e.g., motor function after stroke, injury, or lower-limb surgery), and other applications (i.e., conditions not addressed in other evidence reviews on biofeedback).

In addition, this protocol focuses on biofeedback devices that measure and provide information on the physiologic processes such as heart rate, muscle tension, skin temperature, and blood flow. Electroencephalographic biofeedback, also called neurofeedback, which measures brainwave activity, is addressed in the Neurofeedback Protocol.

## 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 and Constipation

Biofeedback as a Treatment of Headache

Biofeedback as a Treatment of Urinary Incontinence in Adults

Neurofeedback

Treatment of Tinnitus

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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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