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

**Individuals:**
- With attention-deficit/hyperactivity disorder

**Individuals:**
- With disorders other than attention-deficit/hyperactivity disorder

### Interventions

**Interventions of interest are:**
- Neurofeedback

### Comparators

**Comparators of interest are:**
- Psychological therapy
- Pharmacologic therapy

### Outcomes

**Relevant outcomes include:**
- Symptoms
- Functional outcomes
- Quality of life

### DESCRIPTION

Neurofeedback describes techniques for providing feedback about neuronal activity, as measured by electroencephalogram biofeedback, functional magnetic resonance imaging, or near-infrared spectroscopy, to teach patients to self-regulate brain activity. Neurofeedback may use several techniques in an attempt to normalize unusual patterns of brain function in patients with various psychiatric and central nervous system disorders.

### SUMMARY OF EVIDENCE

For individuals who have attention-deficit/hyperactivity disorder (ADHD) who receive neurofeedback, the evidence includes randomized controlled trials (RCTs) and meta-analyses. Relevant outcomes are symptoms, functional outcomes, and quality of life. At least five moderately sized RCTs (N range, 90-102 patients) have compared neurofeedback with methylphenidate, attention skills training, or cognitive therapy. These trials found either small or no benefit of neurofeedback. Studies that used active controls have suggested that, at least part of the effect of neurofeedback may be due to attention skills training, relaxation training, and/or other nonspecific effects. In addition, the beneficial effects are more likely to be reported by evaluators unblinded to treatment (parents) than by evaluators blinded (teachers) to treatment, suggesting bias in the nonblinded evaluations. The meta-analysis also found no effect of neurofeedback on objective measures of attention and inhibition. Additional research with blinded evaluation of outcomes is needed to demonstrate an effect of
neurofeedback on ADHD. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have disorders other than ADHD (e.g., epilepsy, substance abuse, pediatric brain tumors) who receive neurofeedback, the evidence includes case reports, case series, comparative cohorts, and small RCTs. Relevant outcomes are symptoms, functional outcomes, and quality of life. For these other disorders, including psychiatric, neurologic, and pain syndromes, the evidence is poor and several questions concerning clinical efficacy remain unanswered. Larger RCTs that include either a sham or active control are needed to evaluate the effect of neurofeedback for these conditions. The evidence is insufficient to determine the effects of the technology on health outcomes.

POLICY

Neurofeedback is considered investigational.

BACKGROUND

Neurofeedback may be conceptualized as a type of biofeedback that has traditionally used the electroencephalogram (EEG) as a source of feedback data. Neurofeedback differs from established forms of biofeedback in that the information fed back to the patient (via EEG tracings, functional magnetic resonance imaging [fMRI], near-infrared spectroscopy) is a direct measure of global neuronal activity, or brain state, compared with feedback of the centrally regulated physiologic processes, such as tension of specific muscle groups or skin temperature. The patient may be trained to either increase or decrease the prevalence, amplitude, or frequency of specified EEG waveforms (e.g., alpha, beta, theta waves), depending on the changes in brain function associated with the particular disorder. It has been proposed that training of slow cortical potentials (SCPs) can regulate cortical excitability and that using the EEG as a measure of central nervous system functioning can help train patients to modify or control their abnormal brain activity. Upregulating or downregulating neural activity with real-time feedback of fMRI signals is also being explored.

Neurofeedback is being investigated for the treatment of a variety of disorders including autism spectrum disorder, insomnia and sleep disorders, learning disabilities, Tourette syndrome, traumatic brain injury, seizure disorders, premenstrual dysphoric disorder, menopausal hot flashes, depression, stress management, panic and anxiety disorders, posttraumatic stress disorder, substance abuse disorders, eating disorders, migraine headaches, stroke, Parkinson disease, fibromyalgia, and tinnitus. Two EEG-training protocols (training of SCPs, theta/beta training) are typically used in children with ADHD. For training of SCPs, surface-negative and surface-positive SCPs are generated over the sensorimotor cortex. Negative SCPs reflect increased excitation and occur during states of behavioral or cognitive preparation, while positive SCPs are thought to indicate reduction of cortical excitability of the underlying neural networks and appear during behavioral inhibition. In theta/beta training, the goal is to decrease activity in the EEG theta band (four to eight Hz) and increase activity in the EEG beta band (13-20 Hz), corresponding to an alert and focused but relaxed state. Alpha-theta neurofeedback is typically used in studies on substance abuse. Neurofeedback protocols for depression focus on alpha interhemispheric asymmetry and theta/beta ratio within the left prefrontal cortex. Neurofeedback for epilepsy has focused on sensorimotor rhythm up-training (increasing 12-15 Hz activity at motor strip) or altering SCPs. It has been proposed that learned alterations in EEG patterns in epilepsy are a result of operant conditioning and are not conscious or voluntary. A variety of protocols have been described for treatment of migraine headaches.

REGULATORY STATUS

A number of electroencephalogram (EEG) feedback systems (EEG hardware and computer software programs)
have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. For example, the BrainMaster™ 2E (BrainMaster Technologies) is “...indicated for relaxation training using alpha EEG Biofeedback. In the protocol for relaxation, BrainMaster™ provides a visual and/or auditory signal that corresponds to the patient’s increase in alpha activity as an indicator of achieving a state of relaxation.” Although devices used during neurofeedback may be subject to FDA regulation, the process of neurofeedback itself is a procedure, and, therefore, not subject to FDA approval. FDA product codes: HCC, GWQ.

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
Biofeedback for Miscellaneous Indications

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.


