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
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

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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. Several meta-analyses and at least 3 additional moderately sized RCTs (n range, 144-172 patients) have compared neurofeedback with methylphenidate, biofeedback, cognitive behavioral therapy, cognitive training, physical activity, or sham neurofeedback. Collectively, these studies found either small or no benefit of neurofeedback. A meta-analysis also found no effect of neurofeedback on objective measures of attention and inhibition. 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. Also, the beneficial effects of neurofeedback are more likely to be reported by evaluators unblinded to treatment (parents) than by evaluators blinded to treatment (teachers), suggesting bias in the nonblinded evaluations. Additional research with blinded evaluation of outcomes is needed to demonstrate the effect of neurofeedback on ADHD. However, the completion dates for some registered trials of neurofeedback in ADHD have passed without publication of results, suggesting the potential for publication bias. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have disorders other than ADHD (e.g., chronic insomnia, epilepsy, substance abuse, pediatric brain tumors, and post-traumatic stress disorder) who receive neurofeedback, the evidence includes case reports, case series, comparative cohorts, small RCTs, and systematic reviews. 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. However, the completion dates for some registered trials of neurofeedback in disorders other than ADHD have passed without publication of results, suggesting the potential for publication bias. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

POLICY
Neurofeedback is considered investigational.

BACKGROUND
DISORDERS OF THE CENTRAL NERVOUS SYSTEM
Various disorders involve abnormal brain activity, 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, tinnitus, and attention-deficit/hyperactivity disorder.

Treatment
Neurofeedback is being investigated for the treatment of a variety of disorders. 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, 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 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. Up-regulating or downregulating neural activity with real-time feedback of functional magnetic resonance imaging signals is also being explored.

Two EEG-training protocols (training of SCPs, theta/beta training) are typically used in children with attention-deficit/hyperactivity disorder. 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 a reduction of cortical excitation 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 (4-8 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 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.

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.


42. Nan W, Dias APB, Rosa AC. Neurofeedback Training for Cognitive and Motor Function Rehabilitation in Chronic Stroke: Two Case Reports. Front Neurol. 2019;10:800. PMID 31396152