Protocol

Neurofeedback

(20128)

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

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 attention-deficit/ hyperactivity disorder	Interventions of interest are: • Neurofeedback	Comparators of interest are: • Psychological therapy • Pharmacologic therapy	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life
Individuals: • With disorders other than attention-deficit/hyperactivity disorder	Interventions of interest are: • Neurofeedback	Comparators of interest are: • Psychological therapy • Pharmacologic therapy	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life

DESCRIPTION

Neurofeedback describes techniques for providing feedback about neuronal activity, as measured by electro-encephalogram 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 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 (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.

1. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Neurofeedback. TEC Assessments 1997; Volume 12: Tab 21.
2. Cortese S, Ferrin M, Brandeis D, et al. Neurofeedback for attention-deficit/hyperactivity disorder: meta-analysis of clinical and neuropsychological outcomes from randomized controlled trials. J Am Acad Child Adolesc Psychiatry. Jun 2016; 55(6):444-455. PMID 27238063
3. Gevensleben H, Holl B, Albrecht B, et al. Is neurofeedback an efficacious treatment for ADHD? A randomised controlled clinical trial. J Child Psychol Psychiatry. Jul 2009; 50(7):780-789. PMID 19207632
4. Gevensleben H, Holl B, Albrecht B, et al. Neurofeedback training in children with ADHD: 6-month follow-up of a randomised controlled trial. Eur Child Adolesc Psychiatry. May 25, 2010; 19(9):715-724. PMID 20499120
5. Steiner NJ, Frenette EC, Rene KM, et al. In-school neurofeedback training for ADHD: sustained improvements from a randomized control trial. Pediatrics. Mar 2014; 133(3):483-492. PMID 24534402
6. Duric NS, Assmus J, Gundersen D, et al. Neurofeedback for the treatment of children and adolescents with ADHD: a randomized and controlled clinical trial using parental reports. BMC Psychiatry. 2012; 12:107. PMID 22877086

7. Bink M, van Nieuwenhuizen C, Popma A, et al. Behavioral effects of neurofeedback in adolescents with ADHD: a randomized controlled trial. Eur Child Adolesc Psychiatry. Sep 2015; 24(9):1035-1048. PMID 25477074
8. Gelade K, Janssen TW, Bink M, et al. Behavioral effects of neurofeedback compared to stimulants and physical activity in attention-deficit/hyperactivity disorder: a randomized controlled trial. J Clin Psychiatry. Oct 2016; 77(10):e1270-e1277. PMID 27631143
9. Duric NS, Assmus J, Elgen IB. Self-reported efficacy of neurofeedback treatment in a clinical randomized controlled study of ADHD children and adolescents. Neuropsychiatr Dis Treat. 2014; 10:1645-1654. PMID 25214789
10. Bink M, Bongers IL, Popma A, et al. 1-year follow-up of neurofeedback treatment in adolescents with attention-deficit hyperactivity disorder: randomised controlled trial. BJPsych Open. Mar 2016; 2(2):107-115. PMID 27703763
11. Tan G, Thornby J, Hammond DC, et al. Meta-analysis of EEG biofeedback in treating epilepsy. Clin EEG Neurosci. Jul 2009; 40(3):173-179. PMID 19715180
12. Sokhadze TM, Cannon RL, Trudeau DL. EEG biofeedback as a treatment for substance use disorders: review, rating of efficacy, and recommendations for further research. Appl Psychophysiol Biofeedback. Mar 2008; 33(1):1-28. PMID 18214670
13. de Ruiter MA, Oosterlaan J, Schouten-van Meeteren AY, et al. Neurofeedback ineffective in paediatric brain tumour survivors: Results of a double-blind randomised placebo-controlled trial. Eur J Cancer. Sep 2016; 64:62-73. PMID 27343714
14. Schoenberg PL, David AS. Biofeedback for psychiatric disorders: a systematic review. Appl Psychophysiol Biofeedback. Jun 2014; 39(2):109-135. PMID 24806535
15. Jarusiewicz B. Efficacy of neurofeedback for children in the autism spectrum: a pilot study. J Neurother. 2002; 6(4):39-49. PMID
16. Sokhadze EM, El-Baz AS, Tasman A, et al. Neuromodulation integrating rTMS and neurofeedback for the treatment of autism spectrum disorder: an exploratory study. Appl Psychophysiol Biofeedback. Dec 2014; 39(3-4):237-257. PMID 25267414
17. Kim DY, Yoo SS, Tegethoff M, et al. The inclusion of functional connectivity information into fMRI-based neurofeedback improves its efficacy in the reduction of cigarette cravings. J Cogn Neurosci. Mar 11 2015:1-21. PMID 25761006
18. Linden DE, Habes I, Johnston SJ, et al. Real-time self-regulation of emotion networks in patients with depression. PLoS One. 2012; 7(6):e38115. PMID 22675513
19. Choobforoushzadeh A, Neshat-Doost HT, Molavi H, et al. Effect of neurofeedback training on depression and fatigue in patients with multiple sclerosis. Appl Psychophysiol Biofeedback. Mar 2015; 40(1):1-8. PMID 25362584
20. Kayiran S, Dursun E, Dursun N, et al. Neurofeedback intervention in fibromyalgia syndrome; a randomized, controlled, rater blind clinical trial. Appl Psychophysiol Biofeedback. Dec 2010; 35(4):293-302. PMID 20614235
21. Cortoos A, De Valck E, Arns M, et al. An exploratory study on the effects of tele-neurofeedback and tele-biofeedback on objective and subjective sleep in patients with primary insomnia. Appl Psychophysiol Biofeedback. Jun 2010; 35(2):125-134. PMID 19826944
22. Walker JE. QEEG-guided neurofeedback for recurrent migraine headaches. Clin EEG Neurosci. Jan 2011; 42(1):59-61. PMID 21309444
23. Moshkani Farahani D, Tavallaie SA, Ahmadi K, et al. Comparison of neurofeedback and transcutaneous electrical nerve stimulation efficacy on treatment of primary headaches: a randomized controlled clinical trial. Iran Red Crescent Med J. Aug 2014; 16(8):e17799. PMID 25389484
24. Chirita-Emandi A, Puiu M. Outcomes of neurofeedback training in childhood obesity management: a pilot study. J Altern Complement Med. Nov 2014; 20(11):831-837. PMID 25188371

25. Koprivova J, Congedo M, Raszka M, et al. Prediction of treatment response and the effect of independent component neurofeedback in obsessive-compulsive disorder: a randomized, sham-controlled, double-blind study. Neuropsychobiology. Apr 27 2013; 67(4):210-223. PMID 23635906
26. Deng X, Wang G, Zhou L, et al. Randomized controlled trial of adjunctive EEG-biofeedback treatment of obsessive-compulsive disorder. Shanghai Arch Psychiatry. Oct 2014; 26(5):272-279. PMID 25477720
27. Subramanian L, Hindle JV, Johnston S, et al. Real-time functional magnetic resonance imaging neurofeedback for treatment of Parkinson's disease. J Neurosci. Nov 9 2011; 31(45):16309-16317. PMID 22072682
28. Cho HY, Kim K, Lee B, et al. The effect of neurofeedback on a brain wave and visual perception in stroke: a randomized control trial. J Phys Ther Sci. Mar 2015; 27(3):673-676. PMID 25931705
29. Zhuo C, Li L. The application and efficacy of combined neurofeedback therapy and imagery training in adolescents with Tourette syndrome. J Child Neurol. Jul 2014; 29(7):965-968. PMID 23481449
30. Subcommittee on Attention-Deficit/Hyperactivity Disorder, Steering Committee on Quality Improvement Management, Wolraich M, et al. ADHD: clinical practice guideline for the diagnosis, evaluation, and treatment of attention-deficit/hyperactivity disorder in children and adolescents. Pediatrics. Nov 2011; 128(5):1007-1022. PMID 22003063
31. National Institute for Health and Caare Excellence. Autism: the management and support of children and young people on the autism spectrum [CG170]. 2013; https: //www.nice.org.uk/guidance/cg170. Accessed January 20, 2017.
32. Hammond DC, Bodenhamer-Davis G, Gerald Gluck G, et al. Standards of practice for neurofeedback and neurotherapy: a position paper of the International Society for Neurofeedback & Research. J Neurother. 26 Feb 2011; 15(1):54-64. PMID
33. Verdellen C, van de Griendt J, Hartmann A, et al. European clinical guidelines for Tourette syndrome and other tic disorders. Part III: behavioural and psychosocial interventions. Eur Child Adolesc Psychiatry. Apr 2011; 20(4):197-207. PMID 21445725
34. American Psychological Association. Getting in touch with your inner brainwaves through biofeedback. 2003 November; http://www.apa.org/research/action/biofeedback.aspx. Accessed January 20, 2017.