MEDICAL POLICY

POLICY TITLE	BIOFEEDBACK AND NEUROFEEDBACK THERAPY
POLICY NUMBER	MP 2.064

CLINICAL BENEFIT	☐ MINIMIZE SAFETY RISK OR CONCERN. ☐ MINIMIZE HARMFUL OR INEFFECTIVE INTERVENTIONS. ☒ ASSURE APPROPRIATE LEVEL OF CARE. ☐ ASSURE APPROPRIATE DURATION OF SERVICE FOR INTERVENTIONS. ☐ ASSURE THAT RECOMMENDED MEDICAL PREREQUISITES HAVE BEEN MET. ☐ ASSURE APPROPRIATE SITE OF TREATMENT OR SERVICE.
Effective Date:	**3/1/2024**

I. POLICY

Biofeedback for Migraine and Tension-Type Headache
Biofeedback may be considered **medically necessary** as part of the overall treatment plan for migraine and tension-type headache.

Biofeedback for Cancer Pain
Biofeedback may be considered **medically necessary** for the treatment of cancer related pain.

Biofeedback for Chronic Pain
Biofeedback may be considered **medically necessary** for chronic back and neck pain.

Biofeedback may be considered **medically necessary** for chronic proctalgia (i.e. levator ani syndrome).

Biofeedback for Constipation
Biofeedback for constipation in adults may be considered **medically necessary** for patients with dyssynergia-type constipation. (see Policy Guidelines)

Biofeedback is considered **not medically necessary** as a treatment of constipation in adults and children in all other situations.

Biofeedback for Fecal Incontinence
Biofeedback for fecal incontinence in adults may be considered **medically necessary** for patients with incontinence and some preserved voluntary sphincter contraction.

Biofeedback for Urinary Incontinence

Biofeedback may be considered **medically necessary** for the treatment of stress and/or urge incontinence in cognitively intact adult patients who have failed a documented trial of pelvic muscle exercise (PME) training.

Failure is defined as no clinically significant improvement in urinary continence after completing 4 weeks of an ordered regimen of PMEs.
Biofeedback may be considered **medically necessary** for children in the treatment of non-neurogenic dysfunctional voiding (i.e. abnormal contraction of the sphincter and/or pelvic floor musculature during voiding).

Biofeedback for Miscellaneous Conditions

Biofeedback is considered **investigational** as a treatment of the following (but not limited to) miscellaneous conditions:

- Addictions
- Allergy
- Anger management
- Anxiety disorders
- As a rehabilitation modality for spasmodic torticollis, spinal cord injury, or following knee surgeries
- Asthma
- Attention deficit hyperactivity disorder (ADHD)
- Balance training (with tongue-place electrotactile biofeedback or visual interactive biofeedback Card)
- Bell's palsy
- Cardiovascular diseases (e.g. heart failure)
- Childhood apraxia of speech
- Chronic abacterial prostatitis
- Chronic fatigue syndrome
- Cleft palate speech (nasopharyngoscopic biofeedback)
- Cluster headaches
- Depression
- Diabetes
- Dyssynergia
- Epilepsy
- Essential hypertension
- Facial pain
- Fecal incontinence in children
- Fecal incontinence in adults (other than the indication listed above)
- Functional dysphonia
- 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

- Panic disorders (e.g., FreeSpria breathing system)
- Peripheral arterial disease (e.g. intermittent claudication)
- Posttraumatic stress disorder
- Prevention of preterm birth
- Psychosomatic conditions
- Raynaud's disease
- Sleep bruxism
- Spasticity secondary to cerebral palsy
- Toe-out gait modification in people with knee osteoarthritis
- Tinnitus
- Tourette's syndrome
- Tremor
- Type 2 diabetes
- Vaginal tear
- Vaginismus
- Vertigo/disequilibrium
- Visual disorders
- Vulvodynia

There is insufficient evidence to support a conclusion general concerning the health outcomes or benefits associated with this procedure for the above indications.

Home Use of Biofeedback

Unsupervised home use of biofeedback is considered **not medically necessary**.

Neurofeedback

Neurofeedback and EMG controlled neuromuscular electrical stimulation are considered **investigationa**l, as there is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

POLICY GUIDELINES

Rome IV diagnostic criterion for dyssynergic defecation includes: Diagnostic Criteria for Dyssynergic Defecation

- "Inappropriate contraction of the pelvic floor as measured with anal surface EMG [electromyography] or manometry with adequate propulsive forces during attempted defecation."[c]

[c] These criteria are defined by age- and sex-appropriate normal values for the technique.

Dyssynergic constipation may be coded as outlet dysfunction constipation. Outlet dysfunction constipation, also known as pelvic floor dysfunction, is defined as incoordination of the muscles of the pelvic floor during attempted evacuation.

Cross-reference:

MP 1.033 Sacral Nerve Neuromodulation/Stimulation and Pelvic Floor Stimulation Devices
MP 2.062 Temporomandibular Joint Dysfunction (TMJ)
MP 2.096 Electromyography (EMG) (Needle and Non-Needle) of the anal or urethral sphincter
MP 2.304 Autism Spectrum Disorders
MP 4.012 Injectable Bulking Agents for the Treatment of Urinary and Fecal Incontinence
MP 6.020 Transcutaneous Electrical Nerve Stimulation

II. PRODUCT VARIATIONS TOP

This policy is only applicable to certain programs and products administered by Capital Blue Cross. Please see additional information below, and subject to benefit variations as discussed in Section VI below.

FEP PPO:

Refer to FEP Medical Policy Manual. The FEP Medical Policy manual can be found at: https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies .

III. DESCRIPTION/BACKGROUND TOP

Biofeedback

Biofeedback involves the feedback of a variety of types of physiologic information not normally 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 some specific way. Biofeedback training is done either in individual or group sessions, alone or in combination with other behavioral therapies designed to teach relaxation. A typical program consists of 10 to 20 training sessions of 30 to 60 minutes each. Training sessions are performed in a quiet, nonarousing environment. Subjects are instructed to use mental techniques to affect the physiologic variable monitored, and feedback is provided for successful alteration of the physiologic parameter. This feedback may be signals such as lights or tone, verbal praise, or other auditory or visual stimuli.

Biofeedback as a Treatment of Headache

The various forms of biofeedback differ mainly in the nature of the disease or disorder under treatment, the biologic variable that the subject attempts to control, and the information that is fed back to the subject. Biofeedback techniques include peripheral skin temperature feedback, blood-volume-pulse feedback (vasoconstriction and dilation), vasoconstriction training (temporalis artery), and electromyographic biofeedback; these may be used alone or in conjunction with other therapies (eg, relaxation, behavioral management, medication). In general, electromyographic biofeedback is used to treat tension headaches. With this procedure, electrodes are attached to the temporal muscles, and the patient attempts to reduce muscle tension. Feedback on achievement of a decrease in muscle tension is provided to the subject, reinforcing those activities (behaviors or thoughts) that are effective. Thermal biofeedback, in which patients learn to increase the temperature of their fingertips through the

use of imagery and relaxation, is a commonly employed technique for migraine headaches. In this technique, a temperature sensor is placed on the finger, and the subject is taught to increase peripheral vasodilation by providing feedback on skin temperature, an effect that is mediated through sympathetic activity. The combination of thermal biofeedback and relaxation training has also been used to improve migraine symptoms. The pulse amplitude recorded from the superficial temporal artery has also been used to provide feedback. Temporal pulse amplitude biofeedback has been used to treat both chronic tension-type headaches and migraine headaches.

Regulatory Status

A variety of biofeedback devices are cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. These devices are designated by FDA as class II with special controls and are exempt from premarket notification requirements. FDA defines a biofeedback device as “an instrument that provides a visual or auditory signal corresponding to the status of one or more of a patient's physiological parameters (eg, brain alpha wave activity, muscle activity, skin temperature) so that the patient can control voluntarily these physiological parameters.” FDA product code: HCC.

Biofeedback as a Treatment of Chronic Pain

Treatment for chronic pain is often multimodal and typically includes psychological therapy. Psychological techniques vary but may include cognitive therapy, which teaches subjects the ability to cope with stressful stimuli by attempting to alter negative thought and dysfunctional attitudes, and behavioral approaches to reduce muscle tension and break the pain cycle. Relaxation, using any of a variety of techniques including meditation or mental imagery, is considered a behavioral therapy that may be used alone or as a component of a cognitive-behavioral therapy (CBT) program. Electromyography (EMG) biofeedback has also been used for the treatment of chronic pain, with the assumption that the ability to reduce muscle tension will be improved through feedback of data to the subject regarding degree of muscle tension. While some consider EMG biofeedback to be a method to obtain relaxation, others consider biofeedback to be distinct from other relaxation techniques.

Biofeedback as a Treatment of Fecal Incontinence and Constipation

Adults

Fecal incontinence in adults is the recurrent uncontrolled passage of fecal material. Pathophysiology of the disorder ranges from abnormalities in intestinal motility (diarrhea or constipation) to poor rectal compliance, impaired rectal sensation, or weak or damaged pelvic floor muscles. There is no increase in mortality attributable to fecal incontinence. Morbidity includes skin breakdown and urinary tract infections. Fecal incontinence may affect the quality of life by restricting work, recreation, and activities related to “getting out of the house,” impaired social role function, diminished sexual activity, and increase of social isolation due to embarrassment. Fecal incontinence can bring about the loss of independence and mobility. It is the second most common reason for elderly institutionalization. The most common causes of fecal incontinence in adults are obstetric trauma coupled with age-related degeneration, previous anorectal surgery, rectal prolapse, and perineal trauma. In many individuals, the

condition is multifactorial, involving a combination of structural, physiological, and psychosocial factors. Conventional interventions to treat fecal incontinence include dietary recommendations (eg, fiber), bowel and toilet scheduling, and medications (eg, bulking or antidiarrheal agents).

Constipation refers to infrequent bowel movements and difficulty expelling stool during defecation. Primary constipation is categorized into 3 groups. The most common type is normal-transit constipation in which there is a normal rate of stool movement, but patients feel constipated and may complain of abdominal pain and/or bloating. In the second type, slow-transit constipation, stool moves more slowly through the colon and individuals often experience a limited urge to defecate. The third type, dyssynergic defecation, refers to a loss of ability to coordinate contractions of the pelvic floor muscles and to relax the anal sphincter during defecation. Patients often report an inability to defecate despite the urge to do so. There are also secondary causes of constipation such as the use of certain medications, including opioids and psychoactive drugs; neurologic, endocrine, or metabolic disorders; structural abnormalities; and lifestyle factors. Conventional treatment includes dietary changes (ie, adequate fiber and fluid intake), use of supplemental bulking substances, exercises, and medications.

Children

In children, most cases of fecal incontinence and constipation are functional in which structural, endocrine, or metabolic diseases have been ruled out. Factors contributing to functional incontinence and constipation are fear and/or pain associated with large, hard stools. This leads to retentive posturing in approximately half the children with chronic constipation (ie, the avoidance of defecation by purposefully contracting the external anal sphincter, also termed anismus or paradoxical sphincter contraction). Customary or conventional medical intervention includes dietary changes, bowel and toilet scheduling, softening agents, and education. Behavioral interventions aim to restore normal bowel habits through toilet training, reward and incentive contingency management programs, desensitization of phobia and fear, or skill-building and goal-setting techniques with home practice. Counseling and psychotherapy provide support to the child and address social and psychological problems.

Biofeedback

Biofeedback training for fecal incontinence focuses on improving the ability to voluntarily contract the external anal sphincter and puborectalis muscles in response to rectal filling and to decrease delay in response to a sensation of distension. For constipation, biofeedback aims to teach patients how to tighten and relax their external anal sphincter to pass bowel movements.

Biofeedback attempts to improve rectal sensory perception, strength, coordination, or some combination of these 3 components. Sensory training involves inducing intrarectal pressure using a balloon feedback device. A manometric balloon probe is inserted into the rectum, and the balloon is filled with air to produce a sensation of rectal filling. Strength training uses either anal canal pressure (manometric) or intra-anal electromyography feedback of pelvic floor muscles. The purpose is to strengthen the force of the pelvic floor muscles contraction without including rectal distention. Some training increases endurance (duration of external anal sphincter contraction) as well as peak strength. Coordination training uses pressure feedback of intrarectal balloon distention with a water-perfused catheter or Schuster-type balloon probe and pelvic floor muscles contractions in a simultaneous feedback display. The purpose of

coordination training is to synchronize the contraction of the external anal sphincter with the relaxation of the internal anal sphincter.

Biofeedback techniques convert the physiologic measures from an intra-anal electromyography sensor, anal manometric probe (measuring intra-anal pressure), or perianal surface electromyography electrodes to either a visual or audio display for feedback. Ultrasound has also been used to show patients' contraction of the anal sphincter on a screen. Biofeedback training is done alone or in combination with other behavioral therapies designed to teach relaxation. Training sessions are performed in a quiet, nonarousing environment.

Regulatory Status

A variety of biofeedback devices have been cleared for marketing by the U.S. Food and Drug Administration through the 510(k) process. These devices are designated by the U.S. Food and Drug Administration as class II with special controls and are exempt from premarket notification requirements. The Food and Drug Administration defines a biofeedback device as "an instrument that provides a visual or auditory signal corresponding to the status of 1 or more of a patient's physiological parameters (e.g., brain alpha wave activity, muscle activity, skin temperature, etc.) so that the patient can control voluntarily these physiological parameters."

Biofeedback as a Treatment of Urinary Incontinence in Adults

Urinary incontinence is a common condition defined as an involuntary leakage of urine. Women are twice as likely to be affected as men, and prevalence increases with age. The severity of incontinence affects the quality of life and treatment decisions. The types of urinary incontinence include stress, urge, overflow, functional, and post-prostatectomy incontinence.

Biofeedback

Biofeedback, in conjunction with pelvic floor muscle training, is a possible treatment modality for stress, urge, mixed, and overflow urinary incontinence because it may enhance awareness of body functions and the learning of exercises to train pelvic muscles. Several proposed biofeedback methods that may be employed to treat urinary incontinence, including vaginal cones or weights, perineometers, and electromyographic systems with vaginal and rectal sensors.

Biofeedback for Miscellaneous Indications

Biofeedback has been proposed as a treatment for a variety of diseases and disorders including addictions, allergy, anger management, anxiety, as a rehabilitation modality for spasmodic torticollis, spinal cord injury or following knee surgeries, asthma, attention deficit hyperactivity disorder (ADHD), asthma, balance training, Bell's palsy, cardiovasuclar diseases, childhood apraxia or speech, chronic abacterial prostatitis, chronic fatigue syndrome, chronic musculoskeletal pain, cleft palate speech, cluster headaches, depression, diabetes, epilepsy, essential hypertension, facial pain, fecal incontinence in adults and children, functional dysphonia, 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, panic disorders, peripheral arteria disease, posttraumatic stress disorder, prevention of preterm birth, psychosomatic conditions, Raynaud's disease, sleep bruxism, spasticity secondary to cerebral palsy, toe-gait modification in people with knee

osteoarthritis, tinnitus, Tourette's syndrome, tremor, Type 2 diabetes, vaginal tear, vaginismus, vertigo, disequilibrium, visual disorders and vulvodynia. The type of feedback used in an intervention (e.g., visual, auditory, etc.) depends on the nature of the disease or disorder under treatment.

Regulatory Status

Since 1976, a large number of biofeedback devices have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. FDA Product Code: HCC.

Neurofeedback

Various of 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 (eg, 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 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.

IV. RATIONALE

TOP

Biofeedback as Treatment of Headache

Summary of Evidence

For individuals who have migraine or tension-type headache who receive biofeedback, the evidence includes randomized controlled trials and systematic reviews of these trials. Relevant outcomes are symptoms, functional outcomes, and quality of life. The literature, which includes meta-analyses of a large number of controlled and uncontrolled studies, has suggested that this treatment can reduce the frequency and/or severity of migraine and tension-type headaches. Biofeedback, along with other psychologic and behavioral techniques (eg, relaxation training) may be particularly useful for children, pregnant women, and other adults who are not able to take medications. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have cluster headache who receive biofeedback, the evidence includes case reports and small case series. Relevant outcomes are symptoms, functional outcomes, and quality of life. No controlled trials were identified on biofeedback for cluster headache. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Biofeedback as a Treatment of Chronic and Cancer Pain

Summary of Evidence

For individuals who have chronic pain who receive biofeedback, the evidence includes multiple RCTs for different pain syndromes. Relevant outcomes are symptoms, functional outcomes, quality of life, and medication use. In a meta-analysis on the efficacy of biofeedback for chronic back pain, Sielski and colleagues (2017) evaluated 21 studies (n=1062). They found a significant small to medium effect size for pain intensity reduction (Hedges' g=0.60; 95% CI, 0.44 to 0.76) that was stable with a significant small-to-large effect size (Hedges' g=0.62; 95% CI, 0.40 to 0.84) over an average of 8-months follow-up. The researchers also found improvement in depression, disability, muscle tension, and coping. They concluded that biofeedback improved short and long-term pain-related outcomes for chronic back pain. In a

clinical practice guideline on treatments for back pain (Qaseem, 2017), the ACP recommends that clinicians should initially prescribe nonpharmacologic treatment for chronic low back pain, including electromyography biofeedback (Grade: strong recommendation).In their guidelines on adult cancer pain (V.1.2022), the National Comprehensive Cancer Network (NCCN) recommends biofeedback as an evidence-based treatment modality (2A recommendation).

Biofeedback as a Treatment of Fecal Incontinence or Constipation

Summary of Evidence

For individuals who have fecal incontinence who receive biofeedback, the evidence includes RCTs and systematic reviews. Relevant outcomes are symptoms, functional outcomes, and quality of life. Whereas an RCT found that there was a significantly greater decrease in fecal incontinence symptoms with biofeedback plus exercise training than with exercise training alone, most trials did not show a significant benefit. Systematic reviews have not found that biofeedback provides additional benefit when offered in conjunction with conventional therapy compared with conventional therapy alone. Input from The American Society of Colon and Rectal Surgeons' Clinical Practice Guideline for the Treatment of Fecal Incontinence and The American College of Gastroenterology Clinical Guideline: Management of Benign Anorectal Disorders support biofeedback for fecal incontinence. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have constipation other than dyssynergia-type constipation who receive biofeedback, the evidence includes RCTs and systematic reviews. Relevant outcomes are symptoms, functional outcomes, and quality of life. A systematic review of RCTs found a benefit of biofeedback as a treatment for constipation in adults. Conclusions of the systematic review were limited by variability in patient populations, comparator groups, and outcome measures, and biofeedback was not clearly beneficial for any other type of constipation. There are positive results, however, in small trials that biofeedback can be beneficial to individuals with irritable bowel syndrome.

For individuals who have dyssynergia-type constipation who receive biofeedback, the evidence includes RCTs and systematic reviews. Relevant outcomes are symptoms, functional outcomes, and quality of life. Several well-conducted RCTs focusing on patients with dyssynergia-type constipation have reported benefits in a subgroup of patients meeting well-defined criteria. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

Biofeedback as a Treatment of Miscellaneous Conditions

Summary of Evidence

For individuals with anxiety disorders 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 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 that the technology results in an improvement in the net health outcome.

For individuals with asthma who receive biofeedback, the evidence includes 3 RCTs. Relevant outcomes are symptoms, functional outcomes, and quality of life. Each RCTs 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 on 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 that the technology results in an improvement in the net health outcome.

For individuals with Bell palsy who receive biofeedback, the evidence includes 4 RCTs. Relevant outcomes are symptoms, functional outcomes, and quality of life. The RCTs evaluated the efficacy of adding 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 that the technology results in an improvement in the net health outcome.

For individuals with depression who receive biofeedback, the evidence includes a systematic review and 2 small RCTs published after the systematic review. Relevant outcomes are symptoms, functional outcomes, and QOL. The review only identified 2 dissertations assessing the use of biofeedback for depression. One RCT found that respiratory and heart rate biofeedback plus usual care reduced BDI scores compared to usual care alone, while the other found that respiratory sinus arrhythmia biofeedback plus usual care was associated with greater improvements in HAM-D scores compared to usual care alone; however, these trials were limited by open-label designs, short follow-up periods, and small sample sizes. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

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 QOL. The systematic review identified 36 RCTs, though sample sizes were small and overall study quality was poor. Various biofeedback techniques were used: thermal, galvanized skin response, pulse wave velocity, and HRV. Results across trials did not consistently show a benefit of biofeedback. Conclusions were limited due to the shortage of studies isolating the effect of biofeedback, the generally poor quality of trials, and heterogeneity across interventions used. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with motor dysfunction after stroke who receive biofeedback, the evidence includes systematic reviews and RCTs published after the systematic reviews. Relevant outcomes are symptoms, functional outcomes, and quality of life. A 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 were primarily assessments of motor activity in research settings, rather than clinical outcomes such as rate of falls or 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 that the technology results in an improvement in the net health outcome.

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 4 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 that the technology results in an improvement in the net health outcome.

For individuals with multiple sclerosis who receive biofeedback, the evidence includes 2 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 that the technology results in an improvement in the net health outcome.

For individuals with orthostatic hypotension due to spinal cord injury who receive biofeedback, the evidence includes a case report and a case series. Relevant outcomes are symptoms, functional outcomes, and quality of life. The case report and case series collectively provided information on 3 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 that the technology results in an improvement in the net health outcome.

For individuals who need pain management during labor who receive biofeedback, the evidence includes 4 RCTs. Relevant outcomes are symptoms, functional outcomes, and quality of life. A Cochrane review assessed the four selected 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 that the technology results in an improvement in the net health outcome.

For individuals with posttraumatic stress disorder who receive biofeedback, the evidence includes an RCT, a nonrandomized study, and 2 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 4 studies rated the evidence a grade C for conflicting scientific evidence. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

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, patients 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 birthweight. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

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 5 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 that the technology results in an improvement in the net health outcome.

For individuals with sleep bruxism who receive biofeedback, the evidence includes 2 systematic reviews and an RCT published after the review. Relevant outcomes are symptoms, functional outcomes, and QOL. One systematic review identified 7 randomized and nonrandomized studies using biofeedback techniques, and the most recent systematic review identified 6 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. An RCT published after the reviews tested a full-occlusion biofeedback splint in 41 patients with sleep bruxism and temporomandibular disorder. The trial found that, compared to an adjusted occlusal splint, the biofeedback splint allowed for greater reductions in pain after 3 months of treatment. However, no significant differences in sleep bruxism episodes were observed. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

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 3-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 that the technology results in an improvement in the net health outcome.

Neurofeedback
Summary of Evidence

For individuals who have ADHD who receive neurofeedback, the evidence includes RCTs and meta-analys es. 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 (eg, chronic insomnia, epilepsy, substance abuse, pediatric brain tumors, andPTSD) 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.

V. DEFINITIONS

TOP

ELECTROENCEPHALOGRAPH (EEG) is an instrument for recording the electrical activity of the brain.

ELECTROMYOGRAM (EMG) is the graphic record of resting and voluntary muscle activities as a result of electrical stimulation.

PHYSIOLOGIC pertains to normal functions of the human body as opposed to pathological.

VI. BENEFIT VARIATIONS

TOP

The existence of this medical policy does not mean that this service is a covered benefit under the member's health benefit plan. Benefit determinations should be based in all cases on the applicable health benefit plan language. Medical policies do not constitute a description of benefits. A member’s health benefit plan governs which services are covered, which are excluded, which are subject to benefit limits and which require preauthorization. There are different benefit plan designs in each product administered by Capital Blue Cross. Members and providers should consult the member’s health benefit plan for information or contact Capital Blue Cross for benefit information.

VII. DISCLAIMER

TOP

Capital Blue Cross’s medical policies are developed to assist in administering a member’s benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member’s benefit information, the benefit information will govern. If a provider or a member has a question concerning the application of this medical policy to a specific member’s plan of benefits, please contact Capital Blue Cross’ Provider Services or Member Services. Capital Blue Cross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

TOP

Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Investigational; therefore, not covered: EMG controlled neuromuscular electrical stimulation:

Procedure codes
E0746

Covered when medically necessary for a diagnosis in Table 1 below as a standard benefit

Procedure Codes								
90901								

Covered when medically necessary for a diagnosis in Table 1 below as a standard benefit when BOTH psychotherapy & biofeedback are provided

Procedure Codes								
90875	90876							

Table 1

ICD-10-CM Diagnosis Codes	Description
G40.C01	Lafora progressive myoclonus epilepsy, not intractable, with status epilepticus
G40.C09	Lafora progressive myoclonus epilepsy, not intractable without status epilepticus
G40.C11	Lafora progressive myoclonus epilepsy, intractable, with status epilepticus
G40.C19	Lafora progressive myoclonsus epilepsy, intractable, without status epilepticus
G43.009	Migraine without aura, not intractable, without status migrainosus
G43.019	Migraine without aura, intractable, without status migrainosus
G43.109	Migraine with aura, not intractable, without status migrainosus
G43.119	Migraine with aura, intractable, without status migrainosus
G43.509	Persistent migraine aura without cerebral infarction, not intractable, without status migrainosus
G43.519	Persistent migraine aura without cerebral infarction, intractable, without status migrainosus
G43.709	Chronic migraine without aura, not intractable, without status migrainosus
G43.719	Chronic migraine without aura, intractable, without status migrainosus
G43.809	Other migraine, not intractable, without status migrainosus

G43.819	Other migraine, intractable, without status migrainosus
G43.829	Menstrual migraine, not intractable, without status migrainosus
G43.839	Menstrual migraine, intractable, without status migrainosus
G43.909	Migraine, unspecified, not intractable, without status migrainosus
G43.919	Migraine, unspecified, intractable, without status migrainosus
G43.B0	Ophthalmoplegic migraine, not intractable
G43.B1	Ophthalmoplegic migraine, intractable
G43.C0	Periodic headache syndromes in child or adult, not intractable
G43.C1	Periodic headache syndromes in child or adult, intractable
G43.E01	Chronic migraine with aura, not intractable, with status migrainosus
G43.E09	Chronic migraine, with aura, not intractable, without status migrainosus
G43.E11	Chronic migraine with aura, intractable, with status migrainosus
G43.E19	Chronic migrain with aura, intractable, without status migrainosus
G44.201	Tension-type headache, unspecified, intractable
G44.209	Tension-type headache, unspecified, not intractable
G44.211	Episodic tension-type headache, intractable
G44.219	Episodic tension-type headache, not intractable
G44.221	Chronic tension-type headache, intractable
G44.229	Chronic tension-type headache, not intractable
G89.3	Neoplasm related pain (acute) (chronic)
M54.2	Cervicalgia
M54.5	Low back pain
M54.50	Low back pain, unspecified
M54.51	Vertebrogenic low back pain
M54.59	Other low back pain

Covered when medically necessary for a diagnosis in Table 2 when member has a non-standard benefit

Procedure Codes								
90901	90912	90913						

Table 2

ICD-10-CM Diagnosis Codes	Description
F98.0	Enuresis not due to a substance or known physiological condition
K59.00	Constipation, unspecified
K59.01	Slow transit constipation
K59.02	Outlet dysfunction constipation
K59.09	Other constipation
K59.4	Anal spasm
N39.3	Stress incontinence (female) (male)
N39.41	Urge incontinence
N39.46	Mixed incontinence
N39.8	Other specified disorders of urinary system [when used in children for non-neurogenic dysfunctional voiding (i.e. abnormal contraction of the sphincter and/or pelvic floor musculature during voiding)]
R15.0	Incomplete defecation
R15.1	Fecal smearing
R15.2	Fecal urgency
R15.9	Full incontinence of feces

IX. REFERENCES

TOP

Biofeedback as a Treatment of Headaches

1. *Association for Applied Psychphysiology and Biofeedback. Standards for Performing Biofeedback. 2013*
2. *Bendtsen L, Evers S, Linde M, et al. EFNS guideline on the treatment of tension-type headache - report of an EFNS task force. Eur J Neurol. Nov 2010;17(11):1318-1325. PMID 20482606*
3. *Blue Cross and Blue Shield Association Technology Evaluation Center. Biofeedback. Technology Assessment. 1995;Volume 10:Tab 25.*
4. *Centers for Medicare & Medicaid Services. National Coverage Determination (NCD) for Biofeedback Therapy (30.1).*
5. *Morey SS. Guidelines on migraine: part 4. General principles of preventive therapy. Am Fam Physician. Nov 15 2000;62(10):2359-2360, 2363. PMID 11126860*
6. *National Institute of Neurologic Disorders and Stroke. Headache information page. n.d.; 2020*
7. *Nestoriuc Y, Martin A. Efficacy of biofeedback for migraine: a meta-analysis. Pain. Mar 2007;128(1-2):111-127. PMID 17084028*
8. *Nestoriuc Y, Rief W, Martin A. Meta-analysis of biofeedback for tension-type headache: efficacy, specificity, and treatment moderators. J Consult Clin Psychol. Jun 2008;76(3):379-396. PMID 18540732*

9. *Silberstein SD. Practice parameter: evidence-based guidelines for migraine headache (an evidence-based review): report of the Quality Standards Subcommittee of the American Academy of Neurology. Neurology. Sep 26 2000;55(6):754-762. PMID 10993991*
10. *Stubberud A, Varkey E, McCrory DC, et al. Biofeedback as prophylaxis for pediatric migraine: a meta-analysis. Pediatrics. Aug 2016;138(2). PMID 27462067*
11. *Verhagen AP, Damen L, Berger MY, et al. Behavioral treatments of chronic tension-type headache in adults: are they beneficial? CNS Neurosci Ther. Summer 2009;15(2):183-205. PMID 19499626*
12. *Blue Cross Blue Shield Association Medical Policy Reference Manual. 2.01.29, Biofeedback as a Treatment of Headache. Decemeber 2022.*

Biofeedback for Cancer Pain

1. *National Cancer Institute. Pain Control.*
2. *NCCN Clinical Practice Guidelines in Oncology. Adult Cancer Pain. 2.2023 – July 31, 2023.*
3. *Sheinfeld Gorin S, Krebs P, Badr H, et al. Meta-analysis of psychosocial interventions to reduce pain in patients with cancer. J Clin Oncol. 2012; 30(5):539-547. PMID 22253460*

Biofeedback as a Treatment for Chronic Pain

1. *Agency for Healthcare research and Quality. Systematic Review Update -Noninvasive Nonpharmacologic Treatment for Chronic Pain*
2. *American Society of Anesthesiologists Task Force on Chronic Pain Management, American Society of Regional Anesthesia and Pain Medicine. Practice guidelines for chronic pain management: an updated report by the American Society of Anesthesiologists Task Force on Chronic Pain Management and the American Society of Regional Anesthesia and Pain Medicine. Anesthesiology. Apr 2010;112(4):810-833. PMID 20124882*
3. *Eccleston C, Palermo TM, Williams AC, et al. Psychological therapies for the management of chronic and recurrent pain in children and adolescents. Cochrane Database Syst Rev. Apr 15 2009(2):CD003968. PMID 19370592*
4. *Eccleston C, Williams AC, Morley S. Psychological therapies for the management of chronic pain (excluding headache) in adults. Cochrane Database Syst Rev. Apr 15 2009(2):CD007407. PMID 19370688*
5. *Gatchel RJ, Robinson RC, Pulliam C, et al. Biofeedback with pain patients: evidence for its effectiveness. Seminars in Pain Medicine. June 2003;1(2):55-66.*
6. *Pagé I, Marchand AA, Nougarou F, et al. Neuromechanical responses after biofeedback training in participants with chronic low back pain: an experimental cohort study. J Manipulative Physiol Ther. 2015 Sep;38(7):449-57. PMID 26413899*

7. *Qaseem A, Wilt TJ, McLean RM, et al. Noninvasive treatments for acute, subacute, and chronic low back pain: a clinical practice guideline from the American college of physicians. Ann Intern Med. 2017; 166(7):514-530. PMID 28192789*
8. *Sella GE, Moss D. Chronic muscle pain, biofeedback, and the neurophysiology of pain. Biofeedback. Spring 2016; 44(1):19-23.*
9. *Sielski R, Rief W, Glombiewski JA. Efficacy of biofeedback in chronic back pain: a meta-analysis. Int J Behav Med. 2017; 24(1):25-41. PMID 27307013*
10. *Thomas DA, Maslin B, Legler A, et al. Role of alternative therapies for chronic pain Syndromes. Curr Pain Headache Rep. 2016 May;20(5):29. PMID 27038968*
11. *Wald A, Bharucha AE, Cosman BC, Whitehead WE. ACG clinical guideline: management of benign anorectal disorders. Am J Gastroenterol. 2014;109(8):1141-1058. doi:10.1038/ajg.2014.190*
12. *Blue Cross Blue Shield Association Medical Policy Reference Manual. 2.01.30, Biofeedback as a Treatment of Chronic Pain. December 2022.*

Biofeedback as a Treatment of Fecal Incontinence or Constipation

1. *American Gastroenterological Association, Bharucha AE, Dorn SD, et al. American Gastroenterological Association medical position statement on constipation. Gastroenterology. Jan 2013;144(1):211-217. PMID 23261064*
2. *Bartlett L, Sloots K, Nowak M, et al. Biofeedback for fecal incontinence: a randomized study comparing exercise regimens. Dis Colon Rectum. Jul 2011;54(7):846-856. PMID 21654252*
3. *Goldenberg JZ, Brignall M, Hamilton M, et al. Biofeedback for treatment of irritable bowel syndrome. Cochrane Database Syst Rev. 2019;2019(11):CD012530. Published 2019 Nov 12. doi:10.1002/14651858.CD012530.pub2*
4. *Heymen S, Scarlett Y, Jones K, et al. Randomized, controlled trial shows biofeedback to be superior to alternative treatments for patients with pelvic floor dyssynergia-type constipation. Dis Colon Rectum. Apr 2007;50(4):428-441. PMID 17294322*
5. *Jamshed N, Lee Z, and Olden K. Diagnostic Approach to Chronic Constipation in Adults. Am Fam Physician. Aug 2011;84(3):299-306.*
6. *Norton C, Chelvanayagam S, Wilson-Barnett J, et al. Randomized controlled trial of biofeedback for fecal incontinence. Gastroenterology. Nov 2003;125(5):1320-1329. PMID 14598248*
7. *Norton C, Cody JD. Biofeedback and/or sphincter exercises for the treatment of fecal incontinence in adults. Cochrane Database Syst Rev. Jul 11 2012;7(7):CD002111. PMID 22786479*
8. *Paquette IM, Varma M, Ternent C, et al. The American Society of Colon and Rectal Surgeons' clinical practice guideline for the evaluation and management of constipation. Dis Colon Rectum. Jun 2016;59(6):479-492. PMID 27145304*

9. *Paquette IM, Varma MG, Kaiser AM, et al. The American Society of Colon and Rectal Surgeons' clinical practice guideline for the treatment of fecal incontinence. Dis Colon Rectum. Jul 2015;58(7):623-636. doi:10.1097/DCR.0000000000000397*
10. *Robson K and Lembo A. Fecal incontinence in adults: Management. In: UpToDate Online Journal [serial online]. Waltham, MA: UpToDate; updated November 2, 2021. Literature review current through July 2023.*
11. *Sood M. Chronic functional constipation and fecal incontinence in infants, children, and adolescents: Treatment. In: UpToDate Online Journal [serial online]. Waltham, MA: UpToDate; updated June 23, 2023. Literature review current through July 2023.*
12. *Tabbers MM, DiLorenzo C, Berger MY, et al. Evaluation and treatment of functional constipation in infants and children: evidence-based recommendations from ESPGHAN and NASPGHAN. J Pediatr Gastroenterol Nutr. 2014;58(2):258-274. doi:10.1097/MPG.0000000000000266*
13. *Vonthein R, Heimerl T, Schwandner T, et al. Electrical stimulation and biofeedback for the treatment of fecal incontinence: a systematic review. Int J Colorectal Dis. Nov 2013;28(11):1567-1577. PMID 23900652*
14. *Wald A. Outlet Dysfunction Constipation. Curr Treat Options Gastroenterol. 2001;4(4):293-297. doi:10.1007/s11938-001-0054-y*
15. *Wald A, Bharucha AE, Cosman BC, Whitehead WE. ACG clinical guideline: management of benign anorectal disorders. Am J Gastroenterol. 2014;109(8):1141-1058. doi:10.1038/ajg.2014.190*
16. *Blue Cross Blue Shield Association Medical Policy Reference Manual. 2.01.64, Biofeedback as a Treatment of Fecal Incontinence or Constipation. December 2022.*

Biofeedback as a Treatment for Urinary Incontinence

1. *American Academy of Pediatrics. Standing letter to Medical Director regarding biofeedback and lower urinary tract dysfunction in children*
2. *Bettez M, Tu le M, Carlson K, et al. 2012 update: guidelines for adult urinary incontinence collaborative consensus document for the Canadian Urological Association. Can Urol Assoc J. Oct 2012;6(5):354-363. PMID 23093627*
3. *Burgio KL, Goode PS, Locher JL, et al. Behavioral training with and without biofeedback in the treatment of urge incontinence in older women: a randomized controlled trial. JAMA. Nov 13 2002;288(18):2293-2299. PMID 12425706*
4. *Herderschee R, Hay-Smith EJ, Herbison GP, et al. Feedback or biofeedback to augment pelvic floor muscle training for urinary incontinence in women. Cochrane Database Syst Rev. Jul 6 2011(7):CD009252. PMID 21735442*
5. *Hirakawa T, Suzuki S, Kato K, et al. Randomized controlled trial of pelvic floor muscle training with or without biofeedback for urinary incontinence. Int Urogynecol J. Aug 2013;24(8):1347-1354. PMID 23306768*
6. *Hsu LF, Liao YM, Lai FC, et al. Beneficial effects of biofeedback-assisted pelvic floor muscle training in patients with urinary incontinence after radical prostatectomy: A*

systematic review and metaanalysis. Int J Nurs Stud. Aug 2016;60:99-111. PMID 27297372

7. *MacDonald R, Fink HA, Huckabay C, et al. Pelvic floor muscle training to improve urinary incontinence after radical prostatectomy: a systematic review of effectiveness. BJU Int. Jul 2007;100(1):76-81. PMID 17433028*
8. *Moroni RM, Magnani PS, Haddad JM, et al. Conservative treatment of stress urinary incontinence: a systematic review with meta-analysis of randomized controlled trials. Rev Bras Ginecol Obstet. Feb 2016;38(2):97-111. PMID 26883864*
9. *Neeple KG and Cooper CS. Management of bladder dysfunction in children. In: UpToDate Online Journal [serial online]. Waltham, MA: UpToDate; updated February 28, 2023. Literature review current through July 2023.*
10. *Qaseem A, Dallas P, Forciea MA, et al. Nonsurgical management of urinary incontinence in women: a clinical practice guideline from the American College of Physicians. Ann Intern Med. Sep 16 2014;161(6):429-440. PMID 25222388*
11. *Shamilyan T, Wyman J, Bliss DZ, et al. Prevention of urinary and fecal incontinence in adults. Evidence Reports/Technology Assessments No. 161. Rockville, MD Agency for Healthcare Research and Quality; 2007.*
12. *Shamliyan T, Wyman J, Kane RL, et al. Nonsurgical Treatments for Urinary Incontinence in Adult Women: Diagnosis and Comparative Effectiveness. Comparative Effectiveness Review No. 36. Rockville, MD: Agency for Healthcare Research and Quality; 2012.*
13. *Blue Cross Blue Shield Association Medical Policy Reference Manual. 2.01.27, Biofeedback as a Treatment of Urinary Incontinence in Adults. September 2023.*

Biofeedback for Miscellaneous Indications

1. *Barragan Loayza IM, Sola I, Juando Prats C. Biofeedback for pain management during labour. Cochrane Database Syst Rev. Jun 15 2011(6):CD006168. PMID 21678353*
2. *Brasileiro A, Gama G, Trigueiro L, et al. Influence of visual and auditory biofeedback on partial body weight support treadmill training of individuals with chronic hemiparesis: a randomized controlled clinical trial. Eur J Phys Rehabil Med. Feb 2015;51(1):49-58. PMID 25634107*
3. *Cardoso JR, Teixeira EC, Moreira MD, et al. Effects of exercises on Bell's palsy: systematic review of randomized controlled trials. Otol Neurotol. Jun 2008;29(4):557-560. PMID 18520590*
4. *Chen YF, Huang XY, Chien CH, et al. The effectiveness of diaphragmatic breathing relaxation training for reducing anxiety. Perspect Psychiatr Care. Aug 23 2016. PMID 27553981*
5. *Comparison of sustained-release nifedipine and temperature biofeedback for treatment of primary Raynaud phenomenon. Results from a randomized clinical trial with 1-year follow-up. Arch Intern Med. Apr 24 2000;160(8):1101-1108. PMID 10789602*
6. *Gelenberg A. Practice Guideline for the Treatment of Patients with Major Depressive Disorder. 2010*

7. *Ghomashchi H. Investigating the effects of visual biofeedback therapy on recovery of postural balance in stroke patients using a complexity measure. Top Stroke Rehabil. Jun 2016;23(3):178-183. PMID 27077976*
8. *Gillis DJ, Wouda M, Hjeltnes N. Non-pharmacological management of orthostatic hypotension after spinal cord injury: a critical review of the literature. Spinal Cord. Oct 2008;46(10):652-659. PMID 18542098*
9. *Goessl VC, Curtiss JE, Hofmann SG. The effect of heart rate variability biofeedback training on stress and anxiety: a meta-analysis. Psychol Med. May 08 2017:1-9. PMID 28478782*
10. *Greenhalgh J, Dickson R, Dundar Y. The effects of biofeedback for the treatment of essential hypertension: a systematic review. Health Technol Assess. Oct 2009;13(46):1-104. PMID 19822104*
11. *Kim JH. The effects of training using EMG biofeedback on stroke patients upper extremity functions. J Phys Ther Sci. Jun 2017;29(6):1085-1088. PMID 28626331*
12. *Lehrer P, Carr RE, Smetankine A, et al. Respiratory sinus arrhythmia versus neck/trapezius EMG and incentive inspirometry biofeedback for asthma: a pilot study. Appl Psychophysiol Biofeedback. Jun 1997;22(2):95-109. PMID 9341966*
13. *Lehrer PM, Vaschillo E, Vaschillo B, et al. Biofeedback treatment for asthma. Chest. Aug 2004;126(2):352-361. PMID 15302717*
14. *Mackay AM, Buckingham R, Schwartz RS, et al. The effect of biofeedback as a psychological intervention in multiple sclerosis: a randomized controlled study. Int J MS Care. May-Jun 2015;17(3):101-108. PMID 26052255*
15. *Malenfant D, Catton M, Pope JE. The efficacy of complementary and alternative medicine in the treatment of Raynaud's phenomenon: a literature review and meta-analysis. Rheumatology (Oxford). Jul 2009;48(7):791-795. PMID 19433434*
16. *Meuret AE, Ritz T, Wilhelm FH, et al. Targeting pCO(2) in asthma: pilot evaluation of a capnometry-assisted breathing training. Appl Psychophysiol Biofeedback. Jun 2007;32(2):99-109. PMID 17564826*
17. *Neurofeedback and Biofeedback for Mood and Anxiety Disorders: A Review of the Clinical Evidence and Guidelines - An Update. Ottawa, ON: Canadian Agency for Drugs and Technologies in Health; 2014.*
18. *Ommerborn MA, Schneider C, Giraki M, et al. Effects of an occlusal splint compared with cognitive-behavioral treatment on sleep bruxism activity. Eur J Oral Sci. Feb 2007;115(1):7-14. PMID 17305711*
19. *Rayegani SM, Raeissadat SA, Sedighipour L, et al. Effect of neurofeedback and electromyographic-biofeedback therapy on improving hand function in stroke patients. Top Stroke Rehabil. Mar-Apr 2014;21(2):137-151. PMID 24710974*
20. *Sato M, Iizuka T, Watanabe A, et al. Electromyogram biofeedback training for daytime clenching and its effect on sleep bruxism. J Oral Rehabil. Feb 2015;42(2):83-89. PMID 25256380*

21. *Siepmann M, Hennig UD, Siepmann T, et al. The effects of heart rate variability biofeedback in patients with preterm labour. Appl Psychophysiol Biofeedback. Mar 2014;39(1):27-35. PMID 24271650*
22. *Silkman C, McKeon J. The effectiveness of electromyographic biofeedback supplementation during knee rehabilitation after injury. J Sport Rehabil. Aug 2010;19(3):343-351. PMID 20811082*
23. *Stanton R, Ada L, Dean CM, et al. Biofeedback improves activities of the lower limb after stroke: a systematic review. J Physiother. 2011;57(3):145-155. PMID 21843829*
24. *Stanton R, Ada L, Dean CM, et al. Biofeedback improves performance in lower limb activities more than usual therapy in people following stroke: a systematic review. J Physiother. Jan 2017;63(1):11-16. PMID 27989731*
25. *van der Logt RP, Findling O, Rust H, et al. The effect of vibrotactile biofeedback of trunk sway on balance control in multiple sclerosis. Mult Scler Relat Disord. Jul 2016;8:58-63. PMID 27456875*
26. *Wahbeh H, Senders A, Neuendorf R, et al. Complementary and alternative medicine for posttraumatic stress disorder symptoms: a systematic review. J Evid Based Complementary Altern Med. Mar 27 2014;19(3):161-175. PMID 24676593*
27. *Wang LF, Long H, Deng M, et al. Biofeedback treatment for sleep bruxism: a systematic review. Sleep Breath. May 2014;18(2):235-242. PMID 23756884*
28. *Wang MY, Chang NC, Hsieh MH, et al. Effect of feedback signal on blood pressure self-regulation capability in individuals with prehypertension or stage I hypertension: a randomized controlled study. J Cardiovasc Nurs. Mar-Apr 2016;31(2):166-172. PMID 25774838*
29. *Weise C, Heinecke K, Rief W. Biofeedback-based behavioral treatment for chronic tinnitus: results of a randomized controlled trial. J Consult Clin Psychol. Dec 2008;76(6):1046-1057. PMID 19045972*
30. *Yang DJ. Influence of biofeedback weight bearing training in sit to stand to sit and the limits of stability on stroke patients. J Phys Ther Sci. Nov 2016;28(11):3011-3014. PMID 27942111*
31. *Yorke J, Fleming S, Shuldham C, et al. Nonpharmacological interventions aimed at modifying health and behavioural outcomes for adults with asthma: a critical review. Clin Exp Allergy. Dec 2015;45(12):1750-1764. PMID 25675860*
32. *Zijlstra A, Mancini M, Chiari L, et al. Biofeedback for training balance and mobility tasks in older populations: a systematic review. J Neuroeng Rehabil. Dec 09 2010;7:58. PMID 21143921Alneyadi M, Drissi N, Almeqbaali M, Ouhbi S. Biofeedback-Based Connected Mental Health Interventions for Anxiety: Systematic Literature Review. JMIR Mhealth Uhealth. 2021;9(4):e26038. Published 2021 Apr 22. doi:10.2196/26038 PMID: 33792548*
33. *Schutte-Rodin S, Broch L, Buysse D, Dorsey C, Sateia M. Clinical guideline for the evaluation and management of chronic insomnia in adults. J Clin Sleep Med. 2008;4(5):487-504.- PMID 18853708Blue Cross Blue Shield Association Medical Policy Reference Manual. 2.01.53, Biofeedback for Miscellaneous Indications. December 2022.*

Neurofeedback

1. *Alegria AA, Wulff M, Brinson H, et al. Real-time fMRI neurofeedback in adolescents with attention deficit hyperactivity disorder. Hum Brain Mapp. Jun 2017;38(6):3190-3209. PMID 28342214*
2. *American Psychological Association. Getting in touch with your inner brainwaves through biofeedback. 2003*
3. *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*
4. *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*
5. *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*
6. *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*
7. *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*
8. *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*
9. *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*
10. *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*
11. *Dupaul DG, Power TJ, Anastopoulos AD, et al. ADHD Rating Scale-IV: Checklists, Norms, and Clinical Interpretations. New York, NY: Guilford; 1998.*
12. *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. Sep 2014;10:1645-1654. PMID 25214789*
13. *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. Aug 2012;12:107. PMID 22877086*

14. *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*
15. *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*
16. *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*
17. *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*
18. *Jarusiewicz B. Efficacy of neurofeedback for children in the autism spectrum: a pilot study. J Neurother. Sep 8 2002;6(4):39-49. PMID*
19. *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*
20. *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*
21. *Linden DE, Habes I, Johnston SJ, et al. Real-time self-regulation of emotion networks in patients with depression. PLoS One. Jun 2012;7(6):e38115. PMID 22675513*
22. *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*
23. *National Institute for Health and Care Excellence. Efficacy of neurofeedback for children in the autism spectrum: a pilot study: management and support [CG170]. 2013*
24. *Schoenberg PL, David AS. Biofeedback for psychiatric disorders: a systematic review. Appl Psychophysiol Biofeedback. Jun 2014;39(2):109-135. PMID 24806535*
25. *Schönenberg M, Wiedemann E, Schneidt A, et al. Neurofeedback, sham neurofeedback, and cognitive-behavioural group therapy in adults with attention-deficit hyperactivity disorder: a triple-blind, randomised, controlled trial. Lancet Psychiatry. Sep 2017;4(9):673-684. PMID 28803030*
26. *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*
27. *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*

28. *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*
29. *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*
30. *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*
31. *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*
32. *van der Kolk BA, Hodgdon H, Gapen M, et al. A Randomized Controlled Study of Neurofeedback for Chronic PTSD. PLoS One. 2016;11(12):e0166752. PMID 27992435*
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. *Walker JE. QEEG-guided neurofeedback for recurrent migraine headaches. Clin EEG Neurosci. Jan 2011;42(1):59-61. PMID 21309444*
35. *Young KD, Siegle GJ, Zotev V, et al. Randomized Clinical Trial of Real-Time fMRI Amygdala Neurofeedback for Major Depressive Disorder: Effects on Symptoms and Autobiographical Memory Recall. Am J Psychiatry. Aug 1 2017;174(8):748-755. PMID 28407727*
36. *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*
37. *Zilverstand A, Sorger B, Slaats-Willemse D, et al. fMRI neurofeedback training for increasing anterior cingulate cortex activation in adult attention deficit hyperactivity disorder. an exploratory randomized, single-blinded study. PLoS One. Jan 26 2017;12(1):e0170795. PMID 28125735*
38. *Marzbani H, Marateb HR, Mansourian M. Neurofeedback: A Comprehensive Review on System Design, Methodology and Clinical Applications. Basic Clin Neurosci. 2016;7(2):143-158. doi:10.15412/J.BCN.03070208 PMID: 27303609*
39. *Fernández-Alvarez J, Grassi M, Colombo D, et al. Efficacy of bio- and neurofeedback for depression: a meta-analysis. Psychol Med. 2022;52(2):201-216. doi:10.1017/S0033291721004396 PMID: 34776024*
40. *Blue Cross Blue Shield Association Medical Policy Reference Manual. 2.01.28, Neurofeedback. July, 2023*

X. POLICY HISTORY

TOP

MP 2.064	**6/19/2020 Consensus Review.** No changes to policy statement. Product Variation updated. FEP statement updated. Coding reviewed with no changes. References reviewed and updated.
	4/27/2021 Minor review. Deleted number of sessions for tension type headache as the COC addresses number of sessions. Added chronic proctalgia, fecal incontinence in adults with some preserved voluntary sphincter contraction, and non-neurogenic dysfunctional voiding in children as MN indications. Deleted policy guidelines. Updated rationale and references. Added diagnosis codes K59.4; R15.0-R15.9; F98.0; and N39.8 for the new indictions. **5/12/2021**: Per discussion at preconcept, changing stance from INV to "not medically necessary" for other types of constipation in adults and children.
	9/7/2021 Administrative update. New code G44.86, M54.50-51, and M54.59 added. Effective 10/1/2021
	2/2/2022 Consensus review. No policy statement change. References, background and rationale updated. G44.86 removed.
	09/07/2023 Consensus review. No policy statement change. Updated references. New ICD10 codes.

Top