

MEDICAL POLICY

POLICY TITLE	BIOFEEDBACK AND NEUROFEEDBACK THERAPY
POLICY NUMBER	MP 2.064

CLINICAL BENEFIT	<input type="checkbox"/> MINIMIZE SAFETY RISK OR CONCERN. <input type="checkbox"/> MINIMIZE HARMFUL OR INEFFECTIVE INTERVENTIONS. <input checked="" type="checkbox"/> ASSURE APPROPRIATE LEVEL OF CARE. <input type="checkbox"/> ASSURE APPROPRIATE DURATION OF SERVICE FOR INTERVENTIONS. <input type="checkbox"/> ASSURE THAT RECOMMENDED MEDICAL PREREQUISITES HAVE BEEN MET. <input type="checkbox"/> ASSURE APPROPRIATE SITE OF TREATMENT OR SERVICE.
Effective Date:	5/1/2025

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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 individuals 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 individuals 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 individuals who have failed a documented trial of pelvic muscle exercise (PME) training.

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Failure is defined as no clinically significant improvement in urinary continence after completing 4 weeks of an ordered regimen of PME.

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

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- 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 general conclusion 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 **investigational**, as there is insufficient evidence to support a general 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 These criteria are defined by age- and sex-appropriate normal values for the technique.

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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

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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

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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, non-arousing 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,

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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 (e.g., 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 (e.g., 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

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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 (e.g., fiber), bowel and toilet scheduling, and medications (e.g., 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 (i.e., 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 (i.e., 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

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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, non-arousing 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, cardiovascular diseases, childhood

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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 (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 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

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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

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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 (e.g., 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

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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

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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.

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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.

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For individuals who are susceptible to preterm birth who receive biofeedback, the evidence includes 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-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

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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 PTSD) 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

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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

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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 are based on the applicable health benefit plan language. Medical policies do not constitute a description of benefits. Members and providers should consult the member's health benefit plan for information or contact Capital Blue Cross for benefit information.

VII. DISCLAIMER

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Capital Blue Cross' medical policies are developed to assist in administering a member's benefits. These medical policies do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of

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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

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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 myoclonus epilepsy, intractable, without status epilepticus
G43.009	Migraine without aura, not intractable, without status migrainosus
G43.019	Migraine without aura, intractable, without status migrainosus

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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 migraine 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						

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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

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MP 2.064	06/19/2020 Consensus Review. No changes to policy statement. Product Variation updated. FEP statement updated. Coding reviewed with no changes. References reviewed and updated.
	04/27/2021 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 indications.
	05/12/2021: Per discussion at preconcept, changing stance from INV to “not medically necessary” for other types of constipation in adults and children.
	09/07/2021 Administrative Update. New code G44.86, M54.50-51, and M54.59 added. Effective 10/01/2021
	02/02/2022 Consensus Review. No policy statement changes. References, background, and rationale updated. G44.86 removed.
	09/07/2023 Consensus Review. No policy statement changes. Updated references. New ICD10 codes.
	10/18/2024 Consensus Review. No change to policy statement. Updated references.

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