Medical Policy

Subject:	Biofeedback and Neurofeedback		
Document#:	MED.00125	**Publish Date:**	04/01/2024
Status:	Revised	**Last Review Date:**	11/09/2023

Description/Scope

This document addresses biofeedback, a treatment method where an individual is given information, via an electronic monitor, about physiological processes that are normally involuntary, such as blood pressure, muscle tension, heart rate, and other bodily functions. The individual then uses this information to gain voluntary control and modify those processes. Examples of biofeedback techniques include thermal biofeedback, where the individual is provided information on skin temperature, and electromyographic (EMG) biofeedback, where the individual is provided information on muscle tension.

Neurofeedback (also known as EEG biofeedback) is a type of biofeedback that uses electroencephalograms (EEGs) as the feedback source. EEG information is signaled to the individual, usually by video or sound, for the purpose of training the individual to self-regulate brain activity. Neurofeedback is being studied for a variety of medical and psychological conditions.

Note: Neurofeedback (EEG biofeedback) should not be confused with electroencephalograms (EEGs) used for the diagnosis of neurological disorders.

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Historical

Position Statement

Medically Necessary:

Biofeedback therapy is considered **medically necessary** when the following criteria are met:

1. Supervised by a physician or licensed practitioner; **and**
2. Used as treatment for at least one of the following conditions:
   a. Cancer pain; **or**
   b. Chronic back pain as part of a rehabilitation program; **or**
   c. Chronic constipation; **or**
   d. Fecal incontinence; **or**
   e. Levator ani syndrome, also known as anorectal pain syndrome; **or**
   f. Migraine or tension headaches; **or**
   g. Urinary incontinence.

Investigational and Not Medically Necessary:

Biofeedback therapy is considered **investigational and not medically necessary** when the criteria above are not met, and for all other indications.

Neurofeedback, also known as electroencephalogram (EEG) biofeedback, is considered **investigational and not medically necessary** for all indications including, but not limited to:

a. asthma;

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b. attention-deficit hyperactivity disorder;
c. autistic spectrum disorders;
d. cardiovascular conditions;
e. cluster headaches;
f. epilepsy;
g. post-traumatic stress disorder;
h. substance use disorders;
i. traumatic brain injury.

The use of home biofeedback devices is considered **investigational and not medically necessary** for all indications.

Rationale

Biofeedback

Biofeedback for Migraine and Tension Headaches

Randomized controlled trials (RCTs) and systematic reviews of studies on adults and children with migraine or tension headaches have shown that biofeedback is associated with a decrease in headache pain and less use of migraine medication compared with self-relaxation therapy alone (Nestoriuc and Martin, 2007; Nestoriuc, 2008; Palermo, 2010; Scharff, 2002; Stubberud, 2016; Trautmann, 2006; Vasudeva, 2003).

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The American Academy of Neurology (AAN) (Silberstein, 2009) recommendations for the evaluation and treatment of migraine headaches stated that relaxation training, thermal biofeedback combined with relaxation training, electromyographic biofeedback, and cognitive-behavioral therapy may be considered treatment options for prevention of migraine. Although these modalities may be effective as monotherapy, they are more commonly used in conjunction with pharmacologic management.

The National Institute of Neurologic Disorders and Stroke (NINDS, 2018) stated "drug therapy, biofeedback training, stress reduction, and elimination of certain foods from the diet are the most common methods of preventing and controlling migraine and other vascular headaches. Drug therapy for migraine is often combined with biofeedback and relaxation training."

Biofeedback for Urinary Incontinence

The evidence on using biofeedback therapy in the treatment of urinary incontinence for adults and children includes RCTs (Burgio, 2002; Burgio, 2006, Hagen, 2020a; Klijn, 2006; Sahin, 2022; Sam, 2022), and systematic reviews (Fitz, 2012; Herderschee, 2011; Hsu, 2016; Johnson, 2023; Moroni, 2016; Nunes 2019). Conclusions of individual RCTs were mixed, for example Hagen (2020a and 2020b) did not find a significant benefit of biofeedback plus pelvic floor muscle training (PFMT) at 24 months compared with PFMT alone. However, systematic reviews and clinical guidelines are generally supportive of offering biofeedback as an option in individuals with urinary incontinence.

In 2011, Herderschee and colleagues published a Cochrane review on biofeedback added to PFMT for urinary incontinence in women. The authors reviewed 24 trials (n=1583), 17 of which examined the primary outcome of interest. The authors found that women who received biofeedback reported better outcomes than those who

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received muscle training alone (risk ratio [RR] 0.75; 95% confidence interval [CI], 0.66 to 0.86). They noted that additional trials were needed to determine if biofeedback, or general feedback from a healthcare practitioner, was responsible for the superior outcomes.

Moroni and colleagues (2016) performed a systematic review and meta-analysis of RCTs to assess conservative management of stress urinary incontinence for adult women. The authors included trials that compared PFMT, with or without biofeedback, to no treatment (n=122) and PFMT versus PFMT plus biofeedback (n=250). The authors concluded that, although biofeedback during PFMT exercises did not seem to lead to systematically better results than PFMT alone, biofeedback may be an option in women who cannot adequately isolate and contract their pelvic floor muscles.

In a guideline on the nonsurgical management of urinary incontinence in women (Qaseem, 2014), the American College of Physicians (ACP) states that "pelvic floor muscle training alone and in combination with bladder training or biofeedback and weight loss with exercise for obese women were effective at achieving continence and improving UI [urinary incontinence]."

The American Urological Society (AUA) published a guideline (Kobashi, 2017) stating that pelvic floor muscle training, with or without biofeedback, should be offered to individuals with stress urinary incontinence or stress-predominant mixed urinary incontinence.

In a clinical guidelines practice bulletin on urinary incontinence in women (ACOG 2015; reaffirmed 2018), the American College of Obstetricians and Gynecologists (ACOG) states that "pelvic muscle exercises may be used alone or augmented with bladder training, biofeedback, or electrical stimulation. Pelvic floor muscle exercises can be effective as a first-line treatment for stress, urgency, or mixed urinary incontinence."

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Biofeedback for Chronic Constipation, Fecal Incontinence, and Anorectal Disorders

Several systematic reviews of RCTs have been published. In 2020, Moore and colleagues evaluated RCTs comparing any type of biofeedback to a different intervention in individuals who met the Rome criteria for dyssynergic defecation. A total of 11 trials with 725 participants met the inclusion criteria. The authors identified a large amount of heterogeneity among trials. In a pooled analysis of 6 RCTs, biofeedback had a significantly greater benefit on the primary outcome, global clinical improvement, compared with control interventions (OR [odds ratio] 3.63; 95% CI, 1.10 to 11.93; p=0.03).

Woodward and colleagues (2014) published a systematic review examining the effectiveness of biofeedback therapy for the treatment of chronic constipation in adults. The researchers included 17 RCTs (total n=931) that compared different biofeedback methods, compared biofeedback to sham treatment, or compared biofeedback to standard treatment. They found that supervised computer-assisted biofeedback was superior to sedatives, shams, laxatives, and lifestyle changes (diet and exercise). Some surgeries were found superior but had more side effects, whereas biofeedback was not found to cause any side effects or adverse events. However, due to the low quality of the studies, including the lack of a consistent protocol and the potential for bias, the researchers were not able to make a firm recommendation for biofeedback to treat constipation; further studies were recommended. Since then, additional studies have shown benefits of biofeedback for constipation (Ba-Bai-Ke-Re, 2014; Simón, 2019).

In a practice guideline (Wald 2021), the American College of Gastroenterology (ACG) made the following recommendations:

- We recommend that instrumented anorectal biofeedback therapy should be used to manage symptoms in DD (strong recommendation; minimal risk of harm; quality of evidence: moderate). Consensus score: 29.

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- We recommend biofeedback to teach pelvic floor muscle reconditioning for levator syndrome with abnormal ARM (strong recommendation; quality of evidence: very low). Consensus score: 26.
- We recommend that patients with FI [fecal incontinence] who do not respond to education and conservative measures should undergo biofeedback (i.e., pelvic floor rehabilitative techniques with visual or auditory feedback) (strong recommendation; quality of evidence: moderate). Consensus score: 30.

The ACG guideline addressing fecal incontinence (Wald, 2014) stated "pelvic floor rehabilitative techniques [including manometric or EMG-assisted biofeedback therapy] are effective and superior to pelvic floor exercises alone in patients with FI [fecal incontinence] who do not respond to conservative measures (strong recommendation, moderate quality of evidence)." However, ACG noted:

> Biofeedback is not indicated in patients with isolated internal anal sphincter weakness, overflow incontinence associated with behavioral or psychiatric disorders, neurological disorders associated with substantial loss of rectal sensation and/or the inability to contract the striated muscles, decreased rectal storage capacity from resection, inflammation or fibrosis, or major structural damage to continence mechanisms.

The American Gastroenterological Association (AGA) published a medical position on constipation (Bharucha, 2013) that stated the following:

> Biofeedback therapy improves symptoms in more than 70% of patients with defecatory disorders. The motivation of the patient and therapist, the frequency and intensity of the retraining program, and the involvement of behavioral psychologists and dietitians as necessary all likely contribute

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> to the chances of success…Pelvic floor retraining by biofeedback therapy rather than laxatives is recommended for defecatory disorders (strong recommendation, high-quality evidence).

The American Neurogastroenterology and Motility Society (ANMS) and the European Society of Neurogastroenterology and Motility (ESNM) published guidelines (Rao, 2015) on the efficacy of biofeedback that concluded the following:

> Based on the strength of evidence, biofeedback therapy is recommended for the short term and long term treatment of constipation with dyssynergic defecation (Level I, Grade A), and for the treatment of fecal incontinence (Level II, Grade B). Biofeedback therapy may be useful in the short-term treatment of Levator Ani Syndrome with dyssynergic defecation (Level II, Grade B), and solitary rectal ulcer syndrome with dyssynergic defecation (Level III, Grade C), but the evidence is fair. Evidence does not support the use of biofeedback for the treatment of childhood constipation (Level 1, Grade D)…Treatment recommendations were based on grading recommended by the U.S. Preventive Services Task Force [https://www.uspreventive servicestaskforce.org].

In a clinical practice guideline for the evaluation and management of constipation (Paquette, 2016), the American Society of Colon and Rectal Surgeons (ASCRS) stated that biofeedback is helpful for constipation and dyssynergic defecation (strong recommendation based on moderate-quality evidence, 1B). Their guideline on treatment of fecal incontinence (Paquette, 2015) stated "biofeedback should be considered as an initial treatment for patients with incontinence and some preserved voluntary sphincter contraction. Grade of Recommendation: Strong recommendation based on moderate-quality evidence, 1B."

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Biofeedback for Chronic Back Pain

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.

In a clinical practice guideline on treatments for back pain (Qaseem, 2017), the ACP recommended that clinicians initially prescribe nonpharmacologic treatment for chronic low back pain, including electromyography biofeedback (Grade: strong recommendation).

The American College of Occupational and Environmental Medicine (ACOEM) 2016 guidelines on low back disorders recommended biofeedback "for highly select patients with chronic low back pain as part of a multi-disciplinary rehabilitation program" (Strength of evidence: recommended, insufficient evidence (I); level of confidence: low).

Biofeedback for Cancer Pain

In their guideline on adult cancer pain (V.3.2023), the National Comprehensive Cancer Network (NCCN) recommended biofeedback as an optional component of an integrative intervention to reduce pain (2A recommendation).

Biofeedback for Other Conditions

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There is insufficient or conflicting evidence in the peer-reviewed literature comparing biofeedback to established treatment modalities (for example, pharmacotherapy or behavior therapy) to conclude that biofeedback is an effective treatment for other conditions such as cardiovascular disease (Climov, 2014), chronic ankle instability (Koldenhoven, 2021), depression (Maynart, 2021), epilepsy (Nagai, 2018; Strehl, 2014), fibromyalgia (Babu, 2007; Theadom, 2015), hypertension (Greenhalgh, 2009; Nolan, 2010; Olsson, 2010;), panic disorder (Herhaus, 2022), Parkinson's disease (Yakşi, 2022), Raynaud's syndrome (Malenfant, 2009), rotator cuff tear (Tiryaki , 2023), subacromial pain syndrome (de Oliveira, 2022) and tinnitus (Weise, 2008).

Home use of Biofeedback Devices

In 2022, Keyser published results of a retrospective cohort study of real-world data from users of pelvic floor muscle training using a digital, motion-based, intravaginal wand-like device (LEVA® Pelvic Health System; Renovia, Inc., Boston, MA) The primary outcome was change in Urogenital Distress Inventory, Short Form (UDI-6) score. Enrolled participants were at least 18 years of age with a diagnosis of stress incontinence, urgency, or mixed urinary incontinence (n=265). At the end of the 8-week study period, the mean improvement in UDI-6 score was 13.90 ($p \leq 0.001$); 62% of study participants achieved a minimal clinically important difference (MCID) in symptoms. At week 4, device-use adherence (defined as, 14 uses/week) was 72% and at 8 weeks 66%. Study in the setting of a RCT is warranted.

In 2022, Weinstein and colleagues published results of a remotely conducted, open-label, 8-week, RCT evaluating the effect of pelvic floor muscle training using an intravaginal device (the LEVA® Pelvic Health System; n=143) compared to home pelvic floor muscle training (n=156) for the treatment of stress or stress-predominant mixed urinary incontinence. Enrolled participants were at least 18 years of age with a diagnosis of stress incontinence, urgency, or mixed urinary incontinence which had persisted for at least 3 months. The primary outcomes were

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Historical

change in UDI-6 score and stress urinary incontinence episodes captured via a 3-day bladder diary assessed 8 weeks after starting therapy. The mean change in UDI-6 score was greater for the intervention group compared with the control group (18.8 vs 14.7, p=0.01). The median number of stress urinary incontinence episodes captured via the 3-day bladder diary was reduced from 5 (interquartile range [IR], 3-8) episodes for both study arms to 1 (IR, 0-3) and 2 (IR, 1-4) (p=0.005) in the intervention arm compared to the control arm, respectively. A greater number of participants in the intervention group than in the control group reported feeling "much improved" or "very much improved" on self-report (OR=1.94; 95% CI, 1.21-3.15). There were no serious device-related adverse events, though 1 (0.55%) participant reported vaginal irritation in the control group and 5 (2.7%) in the intervention group. Despite statistical significance in the primary outcomes, the MCID for the UDI is 11 points, and only a difference of 4 points was demonstrated between groups in this study. Furthermore, while the mean difference in urinary incontinence episodes reached statistical significance, the range demonstrated 75% overlap raising uncertainty regarding the meaningfulness of this difference. Device-reported adherence was just 69% at study-end (84% by self-report), the control arm reported 89% adherence to the pelvic floor muscle training. Five additional symptom scales were presented as secondary measures, all demonstrated significant improvement, with no differences between study arms. Based on the findings from this RCT, compared to home pelvic floor muscle training, use of a digital, motion-based intravaginal device to treat urinary incontinence failed to demonstrate clinically meaningful short-term superiority and resulted in significantly more vaginal irritation.

In 2023, Weinstein and colleagues published results of the long-term efficacy of the LEVA® Pelvic Health System from the previously described RCT. In this planned secondary analysis, symptom and adherence data were collected at 6- and 12-months following baseline. From the 299 participants available for analysis in the initial 8-week study, 286 (95.7%) returned for this planned follow-up analysis (n=151 in the control arm and n=135 in the intervention arm). Mean change in UDI-6 score from at 6 and 12 months was marginally, but significantly greater in the intervention arm compared to the control arm (20.2 vs 14.8, p=0.03 and 22.7 vs 15.9, p=0.01, respectively).

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This difference between groups, still did not reach the MCID for changes in the UDI-6 score. While participants in the intervention group had more than twice the odds of reporting improvement on the Patient Global Impression of Improvement compared with the control group (OR 2.45, 95% CI 1.49-4.00), five additional, related self-report measures (Pelvic Floor Impact Questionnaire, Incontinence Impact Questionnaire, Pelvic Organ Prolapse Distress Inventory 6; Colorectal Anal Distress Inventory-8; and the Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire, IUGA-Revised) were not statistically different between the groups. For the intervention group, device-reported adherence was 69% at 8 weeks, this fell to 13% at 6 months, and was 17% at 12 months. Neither arm was instructed to continue intervention past 8 weeks, as such, adherence to the pelvic floor muscle training was not captured in this extended follow-up.

Biofeedback medical devices are classified by the U.S. Food and Drug Administration (FDA) as Class II, special controls, medical devices, participant to certain limitations and exempt from 510(k) pre-market notification. Despite the availability of numerous biofeedback devices for home use, biofeedback has not been adequately studied in home settings.

Neurofeedback (EEG Biofeedback)

Anxiety and Panic Disorders

Menella and colleagues (2017) published an RCT exploring the use of neurofeedback on negative affect and anxiety. The participants were 32 healthy undergraduate women who were right-handed. (Asymmetrical alpha activity has been found to be influenced by handedness). Participants were randomized to receive EEG neurofeedback to increase frontal alpha symmetry (treatment group, n=16) or to increase mid-frontal alpha activity (active control group, n=16). The authors found that the intervention group had a greater increase in alpha

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Historical

asymmetry compared with the active control group. They also found a significant decrease in Beck Anxiety Inventory (BAI) scores pre- to post-intervention in the intervention group and no significant change in BAI scores in the active control group. Limitations of the study were the small sample size and the lack of inclusion of individuals diagnosed with anxiety disorders.

Attention-Deficit Hyperactivity Disorder (ADHD)

A number of RCTs and several systematic reviews and meta-analyses of these studies have been published (Micoulaud-Franchi, 2014; Roy, 2022; Van Doren, 2019; Yan 2019). Van Doren and colleagues (2019) included RCTs with at least 10 participants studying EEG neurofeedback to treat children with a primary diagnosis of ADHD. To be included in the review, studies needed to report follow-up data at 2 to 12 months and use DSM IV/V-based rating scales. A total of 10 studies with 506 participants met the review's inclusion criteria. Meta-analyses were stratified by use of active control groups, which were defined as medications and self-management training proven to have a clinical benefit, and non-active controls, defined as all other comparison interventions. In pooled analyses of study findings for the pre-treatment to follow-up time period, for the outcomes inattention and hyperactivity/impulsivity there was a significant benefit of neurofeedback compared with non-active controls but not compared with active controls. For both outcomes, the effective sizes compared with non-active controls were small and statistically significant. For the meta-analysis of change in inattention in the intervention and non-active control group, the standard mean difference (SMD)=0.38; 95% CI, 0.14 to 0.61. In the meta-analysis of change in hyperactivity/impulsivity, the SMD=0.25; 95% CI, 0.01 to 0.45.

The systematic review by Yan and colleagues (2019) included trials published in Chinese as well as in English. They identified 18 head-to-head RCTs on neurofeedback versus methylphenidate (MPH) for treatment of ADHD (13 in Chinese, 5 in English). The studies included a total of 778 participants in the neurofeedback group and 757 in

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Historical

the MPH group. A meta-analysis of teacher-reported outcomes at the 6-month follow-up found that MPH was significantly more effective than neurofeedback in decreasing the severity of inattention (SMD=-0.49; 95% CI, -0.83 to -0.14) and there was no significant difference between neurofeedback and MPH on hyperactivity/impulsivity. When parent-reported outcomes were evaluated, neurofeedback was found to be significantly more effective than MPH at decreasing inattention (SMD=0.45; 95% CI, 0.04 to 0.86) and hyperactivity/impulsivity (SMD=0.69; 95% CI, 0.40 to 0.97). However, in a sensitivity analysis removing Chinese studies and studies that received no outside funding, there were no statistically significant differences between neurofeedback and MPH.

A double-blind RCT published after the systematic reviews (Neurofeedback Collaborative Group, 2020) randomized 144 children aged 7 to 10 years with moderate-to-severe ADHD to a neurofeedback intervention or a control intervention of equal duration and appearance. After 13 months, there was no statistically significant difference between groups on the primary outcome, parent- and teacher-rated inattention. Study participants will continue to be followed for a total of 25 months.

In 2022, Hasslinger and colleagues evaluated the effects of neurocognitive training methods on a variety of cognitive functions in individuals (n=202) ages 9 to 17 diagnosed with ADHD. A four-arm RCT compared two types of neurofeedback with treatment as usual. Assessments were conducted at baseline, immediately posttreatment, and at 6 months. The effects of Working-memory training on spatial and verbal working-memory showed some improvements over neurofeedback and treatment as usual immediately posttreatment, but gains were largely lost by 6-month follow-up. No other consistent effects were demonstrated. Authors conclude, “The sustained effects of neurocognitive training on cognitive functioning in children and adolescents with ADHD may be limited.”

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In 2022, Roy and colleagues conducted a 3-arm, RCT in which they compared the efficacy of neurofeedback training, behavior management and medication in children (n=84), 6-12 years of age, diagnosed with ADHD. Conners 3-P Short Scale was assessed at baseline and again at 3-month follow-up. The medication group showed the greatest reduction of symptoms in inattention, hyperactivity, and executive functioning domain (core symptoms of ADHD). Although some improvement in core ADHD symptoms were demonstrated with all 3 intervention-types, medication conferred the most improvement.

In 2022, Lam and colleagues conducted a double-blind, sham-controlled RCT to assess the efficacy of Functional MRI neurofeedback (fMRI-NF) of the inferior frontal cortex on symptoms and executive functions in 88 boys diagnosed with ADHD. Groups were assessed immediately posttreatment and at 6-month follow-up. The primary outcome measure was posttreatment score on the ADHD Rating Scale (ADHD-RS). No significant group differences were found on the ADHD-RS. Authors conclude, "the study findings do not suggest that fMRI-NF of the [right inferior frontal cortex] is effective in improving clinical symptoms or cognition in boys with ADHD."

The American Academy of Pediatrics (AAP) clinical practice guideline on ADHD/hyperactivity disorder in children and adolescents (Wolraich, 2019) listed EEG biofeedback among the interventions that have "too little evidence to recommend them or have been found to have little or no benefit."

Posttraumatic Stress Disorder (PTSD)

In 2020, Panisch and Hai published a systematic review of randomized and non-randomized studies on neurofeedback in the treatment of PTSD. The authors identified 10 studies, of which 3 were RCTs and 7 were pilot studies or used exploratory designs. The length of the intervention varied across studies, and range from 1 to 40 sessions. Eight studies used EEG neurofeedback and 2 used functional MRI. Eight of the 10 studies used

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standardized measures to assess PTSD symptoms but a variety of measurement instruments were used. Due to differences among studies, the authors did not pool study outcomes. The authors found that all studies had positive findings in at least one outcome, but that there was a relatively small number of trials, with variability among study designs.

Another systematic review, published in 2020, was limited to RCTs of neurofeedback for PTSD (Steingrimsson, 2020). The authors identified four RCTs comparing EEG neurofeedback to sham treatment or an alternative therapy in adults with PTSD. A pooled analysis was conducted for one of the primary outcomes of interest, self-reported PTSD symptoms. In a meta-analysis of three trials (total sample size=92), there was a significantly lower self-reported PTSD symptom score in the neurofeedback group compared with the comparison group (Mean difference, -2.30; 95% CI, -4.27 to -0.24). None of the studies in the pooled analysis used a sham control; one compared neurofeedback to standard care and there was a no treatment control group in the other two trials. The ability to draw conclusions from this meta-analysis is limited by the small number of trials and sample sizes, and the lack of sham interventions.

An RCT on neurofeedback for treating PTSD was published in 2016 by van der Kolk and colleagues. (This trial was included in the Steingrimsson meta-analysis, discussed above). Trial eligibility criteria included meeting DSM-IV criteria for PTSD and having had trauma-focused psychotherapy for at least 6 months. A total of 52 individuals were randomized to receive neurofeedback (n=26) or be placed in a wait-list control group (n=26). The neurofeedback intervention consisted of 24 training sessions up to 30 minutes each occurring twice weekly; sessions were intended to train individuals to enhance alpha activity. PTSD was assessed using the Clinicians Administered PTSD scale (CAPS), stated to be the gold standard measure. The CAPS can range from 0 to 136 points, with a score of at least 45 indicating a diagnosis of PTSD. A continuous CAPS measure was used as the primary efficacy endpoint. Several self-report instruments were also used to assess efficacy.

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Outcomes were measured at the end of treatment and 1 month afterwards. For the primary outcome, there was significantly greater improvement in CAPS scores in the neurofeedback group compared with the waitlist group ($p<0.001$ for treatment by time interaction). At baseline, all participants met past month criteria for PTSD; that is, they had a CAPS score of at least 45. In a completer analysis 1 month after the intervention, a significantly lower proportion of individuals in the neurofeedback group (8/19, 42%) met criteria for past month PTSD than in the control group (17/19, 90%), p=0.007. Some of the self-report measures, including the Davidson Trauma Scale (DTS) and several subscales of the Inventory of Altered Self-Capacities (IASC), also significantly favored the neurofeedback group. The van der Kolk study is one of the few published RCTs on neurofeedback for treating PTSD and is limited by a relatively small sample size, short duration of follow-up and lack of a sham control group. Additional controlled studies with a larger number of participants and longer follow-up are needed to confirm its findings and the efficacy of a particular treatment protocol.

Neurofeedback for Other Conditions

There is insufficient or conflicting evidence in the peer-reviewed literature comparing neurofeedback to established treatment modalities (for example, pharmacotherapy or behavior therapy) to conclude that neurofeedback is an effective treatments for other conditions, including, but not limited to: asthma, autism spectrum disorders (Kouijzer, 2013), cancer pain (Hetkamp, 2019), chronic pain (Roy, 2020), cluster headache, depression (Young, 2017), dyslexia (Breteler, 2010), fall prevention in older individuals (Shahrbanian, 2021); insomnia and sleep disorders (Schabus, 2017), obsessive-compulsive disorder (Deng, 2014), stroke (Dost Sürücü, 2021; Lirio-Romero, 2021; Liu, 2021; Mihara, 2021); Renton, 2017), traumatic brain injury (Elbogen, 2021), spinal cord injury (Guo, 2021), or substance abuse-related disorders (Gabrielsen, 2022; Gerchen, 2018; Scott, 2005; Sokhadze, 2008).

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Historical

Background/Overview

Biofeedback is a training program in which an individual is given information about physiological processes through electronic monitoring, with the goal of gaining conscious control and influencing those processes. Examples of such physiologic processes include heart rate, blood pressure, and muscle tension. The theory of biofeedback is that these processes are related to a disorder, and by controlling the physiologic process, an individual also controls the disorder. Different types of biofeedback modalities are utilized depending on the individual's symptoms or condition. Examples of different biofeedback methods include electromyography (EMG), thermal, heart variability, and galvanic skin response.

Neurofeedback (also known as EEG biofeedback) describes the feedback of neural information and has been investigated as a treatment for a variety of conditions including ADHD, anxiety disorders, panic disorders, post-traumatic stress disorder substance abuse disorders, and traumatic brain injury. Although related in concept to biofeedback, neurofeedback differs in that the information fed back to the individual is a direct measure of brain activity rather than of a specific physiological process. The individual may be trained to either increase or decrease the prevalence, amplitude, or frequency of specified EEG waveforms (alpha, beta, or theta waves), depending on the desired changes. The theory of neurofeedback is that certain medical and psychological disorders are associated with specific waveforms, and when an individual learns to control those waveforms, the disorder can be controlled.

Definitions

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Biofeedback: The use of sensory input, such as visual or auditory signals, to make unconscious or involuntary body processes perceptible. Conscious control of the processes is intended to diminish adverse signs and symptoms of a medical condition.

Electroencephalography (EEG) biofeedback (also called Neurofeedback): A biofeedback method intended to gain control of brain wave activity with the goal of improving a medical or psychological condition.

Electromyography (EMG) biofeedback: A biofeedback method intended to gain control of muscle tension.

Galvanic skin response biofeedback: A biofeedback method intended to gain control of body sweating.

Heart variability biofeedback: A biofeedback method intended to gain control of heart rate.

Thermal biofeedback: A biofeedback method intended to gain control of body temperature.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services are Medically Necessary for biofeedback techniques other than EEG biofeedback or neurofeedback:

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Historical

CPT	
90875	Individual psychophysiological therapy incorporating biofeedback training by any modality (face-to-face with the patient), with psychotherapy (eg, insight oriented, behavior modifying or supportive psychotherapy); 30 minutes
90876	Individual psychophysiological therapy incorporating biofeedback training by any modality (face-to-face with the patient), with psychotherapy (eg, insight oriented, behavior modifying or supportive psychotherapy); 45 minutes
90901	Biofeedback training by any modality
90912	Biofeedback training, perineal muscles, anorectal or urethral sphincter, including EMG and/or manometry, when performed; initial 15 minutes of one-on-one physician or other qualified health care professional contact with the patient
90913	Biofeedback training, perineal muscles, anorectal or urethral sphincter, including EMG and/or manometry, when performed; each additional 15 minutes of one-on-one physician or other qualified health care professional contact with the patient

ICD-10 Diagnosis	
G43.001-G43.E19	Migraine
G44.201-G44.229	Tension type headache
G89.3	Neoplasm related pain
K59.00-K59.09	Constipation
K59.4	Anal spasm
K62.89	Other specified diseases of anus and rectum
M54.00-M54.9	Dorsalgia

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Historical

N39.3-N39.498	Stress incontinence, other specified urinary incontinence
R15.0-R15.9	Fecal incontinence

When services are Investigational and Not Medically Necessary:
For the procedure codes listed above for all other diagnoses not listed, or when the code describes a procedure indicated in the Position Statement section as investigational and not medically necessary.

When services are also Investigational and Not Medically Necessary:

CPT

	For the following CPT codes when specified as EEG biofeedback or neurofeedback:
90875	Individual psychophysiological therapy incorporating biofeedback training by any modality (face-to-face with the patient), with psychotherapy (eg, insight oriented, behavior modifying or supportive psychotherapy); 30 minutes *[when specified as EEG biofeedback or neurofeedback]*
90876	Individual psychophysiological therapy incorporating biofeedback training by any modality (face-to-face with the patient), with psychotherapy (eg, insight oriented, behavior modifying or supportive psychotherapy); 45 minutes *[when specified as EEG biofeedback or neurofeedback]*
90901	Biofeedback training by any modality *[when specified as EEG biofeedback or neurofeedback]*

HCPCS

E0746	Electromyography (EMG), biofeedback device

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Historical

S9002	Intra-vaginal motion sensor system, provides biofeedback for pelvic floor muscle rehabilitation device

ICD-10 Diagnosis

All diagnoses

References

Peer Reviewed Publications:

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7. Burgio KL, Goode PS, Urban DA, et al. Preoperative biofeedback assisted behavioral training to decrease post-prostatectomy incontinence: a randomized, controlled trial. J Urol. 2006; 175(1):196-201.
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Historical

Neurofeedback
Renovia leva®

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

Document History

Status	Date	Action
	04/01/2024	Updated Coding section with 04/01/2024 HCPCS changes; added S9002.
Revised	11/09/2023	MPTAC review. Reformatted MN, NMN and INV/NMN criteria. Updated Description/Scope, Rationale, References and Websites sections.
	09/27/2023	Updated Coding section with 10/01/2023 ICD-10-CM changes; added G43.E19 to end of range.
Reviewed	02/16/2023	MPTAC review. Updated Rationale, References and Websites sections.
	04/18/2022	Updated Index section to address new device.
Reviewed	02/17/2022	MPTAC review. Updated Rationale, References and Websites sections.
Revised	02/11/2021	MPTAC review. In INV/NMN statement, moved hyphen statement to state 'attention-deficit' hyperactivity disorder. Rationale, References and Websites sections updated.
Reviewed	02/20/2020	MPTAC review. Rationale, References and Websites sections updated.
	12/31/2019	Updated Coding section with 01/01/2020 CPT changes; added 90912, 90913 replacing 90911 deleted 12/31/2019.

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The requirements below are specific to the Florida Medicaid Managed Care Plan and are not a part of the Medical Policy or Clinical UM guideline approved by Elevance Health's Medical Policy and Technology Assessment Committee.

If the Florida Medicaid Managed Care Plan intends to deny coverage on the basis that a diagnostic test, therapeutic procedure, or medical device or technology is experimental or investigational, the Managed Care Plan shall submit a request for coverage determination to the Agency in accordance with rule 59G-1.035, F.A.C and Core SMMC Contract, Attachment II, Section VI.G.4.d.

Below is a list of the materials the plans are required to submit when they deny coverage as experimental/investigational:

- **A. Include the CPT or HCPCS code(s)**
- **B. Include a list of other state Medicaid agencies and private insurers who cover the service**
- **C. Include information about the health service from the U.S. Food and Drug Administration**
- **D. Include known risks of the service and health outcomes of others who have received it**
- **E. Include a list of covered alternative services, if any, that could be used to treat the condition**
- **F. Identify a specific recipient needing the service**
- **G. Include the recipient's health history**
- **H. Include the disease information necessitating the requested service**
- **I. Include a rationale for the immediacy of the review**

Additional required information

- **A. Submit the rationale used to preliminarily indicate the service is experimental/investigational**
  1. **Include peer-reviewed journal articles in PDF format with links to the online articles**
  2. **Include evidence-based clinical guidelines reviewed by the plan**
- **B. Submit direct contact information (name, phone number, & email address) for the Medical Director**

Historical

Revised	03/21/2019	MPTAC review. Updated formatting in Position Statement section. Rationale, Background, References and Websites sections updated.
Reviewed	11/08/2018	MPTAC review. Rationale, References, and Websites sections updated.
New	09/13/2018	MPTAC review. Initial document development.

Historical

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