MEDICAL POLICY

Medical Policy Title	**Biofeedback**
Policy Number	**2.01.09**
Current Effective Date	June 26, 2025
Next Review Date	June 2026

Our medical policies are based on the assessment of evidence based, peer-reviewed literature, and professional guidelines. Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract. (Link to Product Disclaimer)

POLICY STATEMENT(S)

I. Biofeedback for migraine and tension-type headaches is considered **medically appropriate** as part of the overall treatment plan only after other conventional methods of treatment have been attempted (e.g., medication management, relaxation) and not been successful in treating a patient's headache.

II. Biofeedback for dyssynergic-type constipation in adults is considered **medically appropriate** for patients who have failed a three (3) month trial of standard treatments for constipation (e.g., laxatives, dietary changes, adequate fluids, exercise).

III. Biofeedback is considered **investigational** for **ALL** other indications, including but not limited to anxiety disorders, attention deficit hyperactivity disorder (ADHD), cluster headaches, epilepsy, fecal incontinence, in-home biofeedback devices (e.g., leva Pelvic Health System), preterm labor, tinnitus, urinary incontinence or retention.

RELATED POLICIES

Corporate Medical Policy

1.01.19 Pelvic Floor Electrical Stimulation as a Treatment for Urinary or Fecal Incontinence

11.01.03 Experimental or Investigational Services

POLICY GUIDELINE(S)

I. The recommended treatment course for patients with migraine and tension-type headaches, who meet the criteria stated in Policy Statement I above, is up to 20 biofeedback office-based sessions. Biofeedback sessions beyond 20 sessions will require documentation of therapeutic effectiveness before additional sessions will be considered for coverage.

II. The recommended treatment course for patients with dyssynergic-type constipation, who meet the criteria stated in policy statement II above, is up to six (6) biofeedback sessions over a three (3) month time. Biofeedback sessions beyond six (6) sessions will require documentation of therapeutic effectiveness before additional sessions will be considered for coverage.

DESCRIPTION

Biofeedback is a technique, using electronic instrumentation, intended to teach patients self-

regulation of certain physiologic processes not generally considered to be under voluntary control. The technique involves the feedback of a variety of types of information not generally available to the patient, followed by a concerted effort on the part of the patient to use this feedback to help alter the physiological process in some specific way. Over time, these changes can endure without continued use of an instrument. Biofeedback divides into two major groups, biomechanical and physiologic, based on the parameter of interest.

The most common types of biofeedback involve the measurement of muscle tension (electromyographic or EMG biofeedback), skin temperature (thermal biofeedback), electrical conductance or resistance of the skin (electrodermal biofeedback), and respiration. Electroencephalograph (EEG) biofeedback (also known as neurofeedback, neurotherapy) is a type of biofeedback training intended to enable people to alter their brain waves by using information from a video display or auditory signal of electroencephalograph (APA 2018).

Biofeedback has been proposed as a treatment for a variety of indications, including, but not limited to addictive behaviors, ADHD, temporomandibular joint dysfunction (TMJ), bruxism, asthma, cardiac arrhythmias, anxiety and panic disorders, headaches, hypertension, movement/neuromuscular disorders, urinary incontinence, fecal incontinence (encopresis), constipation, irritable bowel syndrome (IBS), epilepsy, pain, asthma, Raynaud's disease, and insomnia.

For frequent migraine sufferers, the treatment of choice is usually pharmacologic prophylaxis. Avoidance strategies (loud noises flashing lights, stress, and certain foods) also make up a very important first line approach in managing migraine. Biofeedback training with or without relaxation techniques have also been shown to be effective in treating migraine and tension headaches. In particular, thermal biofeedback training has been shown to be effective in treating migraine headache. For the management of tension headache, electromyogram (EMG) feedback has been primarily used. It has been identified that the combination of thermal and EMG biofeedback has been effective in the control of migraine, tension, and mixed migraine and tension headaches. Furthermore, it has been reported that relaxation techniques can produce improvements in headache. Patients should be examined by a physician to ensure that their headaches are not due to pathological conditions such as hematomas, aneurysm, brain tumors, brain edema, or diseases of the eye, ear, and sinus prior to participating in a biofeedback program.

In dyssynergic-type constipation, there is a loss of the ability to coordinate contractions of the pelvic floor muscles and to relax the anal sphincter during defecation. Rome IV diagnostic criteria explain dyssynergic defecation as the inappropriate contraction of the pelvic floor with adequate propulsive forces during attempted defecation, as measured with anal surface EMG or manometry (Schmulson and Drossman, 2017). Rome IV criteria for dyssynergic defecation (Rezaie 2018) consist of the following:

- Patient must satisfy the diagnostic criteria for functional constipation and/or constipation-predominant IBS; and
    - During repeated attempts to defecate, there must be features of impaired evacuation as demonstrated by two of the following three tests:
    - Abnormal balloon expulsion test;

  - Abnormal anorectal evacuation pattern with manometry or anal surface EMG; and/or
- Impaired rectal evacuation by imaging; and
- Inappropriate contraction of the pelvic floor, as measured with anal surface EMG or manometry with adequate propulsive forces during attempted defecation; and
- Patient fulfills criteria for the last three months, with symptom onset at least six (6) months before diagnosis.

Biofeedback techniques convert the physiologic measures from an intra-anal EMG sensor, anal manometric probe (measuring intra-anal pressure), or perianal surface EMG electrodes to either visual or audio display for feedback. Biofeedback training is performed alone or in combination with other behavioral therapies designed to teach relaxation.

Patients often report an inability to defecate despite the urge to do so. The aim of biofeedback for constipation is to teach patients how to tighten and relax their external anal sphincter to pass bowel movements. Biofeedback is intended to improve rectal sensory perception, strength, and/or coordination. Sensory training involves inducing intrarectal pressure using a balloon feedback device in which 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 EMG feedback of pelvic floor muscles (PFM). The purpose is to strengthen the force of the PFM 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 intra-rectal balloon distention using a water-perfused catheter or Schuster-type balloon probe and PFM contractions in a simultaneous feedback display, to synchronize the contraction of the external anal sphincter with relaxation of the internal anal sphincter.

SUPPORTIVE LITERATURE

There are methodologic difficulties in assessing biofeedback. Most interventions that include biofeedback are multimodal and include relaxation and behavioral instruction, which may have an independent effect. While some studies may report a beneficial effect of multimodal treatments, without appropriate controls it is impossible to isolate the specific contribution of biofeedback to the overall treatment effect.

Constipation:

For the treatment of constipation, biofeedback can be used to correct inappropriate contraction of the pelvic floor muscles and external anal sphincter during defecation in patients with defecatory dysfunction such as dyssynergic defecation. Clinical improvement has been reported in adults who have received EMG biofeedback for defecatory dysfunction (Enck 1993; Heymen 2007; Lee 2010).

There is a lack of evidence or professional society guidelines/recommendations to determine that biofeedback is an effective treatment for constipation in children.

Fecal Incontinence:

Biofeedback has been investigated as a potential treatment for fecal incontinence. However,

literature addressing biofeedback for treating fecal incontinence in adults and children has not found that biofeedback provides additional benefit when offered in conjunction with conventional therapy, compared to conventional therapy alone. Overall, the evidence is insufficient to conclude that biofeedback improves the net health outcome for adults and children with fecal incontinence (Vonthein 2013 Jelovsek 2019, Andy 2020).

Migraine and Tension-Type Headaches

Two systematic reviews addressing biofeedback for migraine headaches and tension headaches were published in 2007 and 2008 by Nestoriuc and colleagues. The meta-analysis addressing treatment of migraine headaches included 55 studies (randomized, pre-post, and uncontrolled) and 39 controlled trials. For treatment of tension-type headaches, 53 studies met criteria for analysis; these included controlled studies with standardized treatment outcomes, follow-up of at least three months, and at least four patients per treatment group. Biofeedback was reported to be more effective than headache monitoring, placebo, and relaxation therapies. Biofeedback in combination with relaxation was more effective than biofeedback alone, and biofeedback alone was more effective than relaxation alone, suggesting different elements for the two therapies. Although the authors found that these meta-analyses are limited by the inclusion of studies of poor methodological quality, there was no evidence of an influence of study quality or publication bias in their findings. Authors concluded that biofeedback constitutes an evidence-based treatment option for tension-type headache.

Martino Cinnera and colleagues (2023) conducted a systematic review and meta-analysis of electromyographic biofeedback (EMG-BFB) for headache. A total of 29 randomized controlled trials (RCTs) (n=1342 participants) were included in the systematic review, and 4 RCTs were included in the meta-analysis. The headache types represented in the included studies were tension headache (69%), migraine (30%), and mixed types (1%). Risk of bias was generally low in the included studies; however, approximately 60% of studies had concerns about potential deviations from the intended intervention. Ten studies reported a significant improvement in the EMG-BFB group with respect to the control group. Meta-analyses showed a reduction in the intensity of attacks in patients subjected to EMG-BFB (p=0.07) based on 293 patients. Quantitative synthesis revealed a promising effect in the intensity of headache attacks. No significant effect was found about the effectiveness of EMG-BFB in the reduction of frequency (p=.66), intensity (p=.99), or duration (p=.54) between electromyographic biofeedback and controls. The authors conclude EMG-BFB represents a non-pharmacological approach to headache treatment as shown via qualitative synthesis, and despite unimpressive results, this technique can be particularly useful in pediatric or in adult patients who cannot undergo drug therapies. Future studies, with new multimodal technologic assessment and following RCT guidelines, can unmask the potentiality of EMG-BFB in the treatment of headache.

Urinary Incontinence:

There is insufficient evidence to determine the incremental effects of biofeedback on health outcomes in women with stress and/or urge incontinence and men with post-prostatectomy incontinence. Specifically, the value of adding biofeedback to a program of pelvic muscle exercises has not been demonstrated. Studies on combined electrical stimulation and biofeedback have shown mixed results but have not isolated the effect of biofeedback on outcomes.

Two Cochrane reviews provided findings on the use of biofeedback to manage urinary incontinence. Johnson and colleagues (2023) assessed the effects of conservative interventions, including biofeedback, for managing urinary incontinence after prostate surgery. Twenty-five studies including a total of 3079 participants were identified, finding that the certainty of evidence assessed using GRADE was mixed. The authors reported that the value of conservative interventions for urinary incontinence following prostate surgery alone, or in combination, remains uncertain. Existing trials are typically small with methodological flaws. Concluding that there is a need for large, high-quality, adequately powered, randomized control trials with robust methodology to address this subject.

Todhunter-Brown and colleagues (2022) summarized 29 relevant Cochrane Reviews, which included 112 unique trials (n = 8975 women) relating to the conservative management of urinary incontinence in women. The authors reportedly could not identify any Cochrane Reviews for some commonly used treatments (i.e., psychological therapies). There is moderate or high certainty evidence that pelvic floor muscle exercises work better if they are more intense, have more support from a health professional, and are combined with strategies to support continued use. However, long-term follow-up was lacking, and the use of multiple and diverse outcomes limited the possibility of combining results to give meaningful evidence. The authors concluded that there are many limitations with the current evidence for conservative treatment of urinary incontinence and often the evidence does not support clear clinical decisions.

<u>EEG Biofeedback/Neurofeedback</u>

EEG biofeedback (also known as neurofeedback) describes techniques for providing feedback about neuronal activity, to teach patients to self-regulate brain activity. Neurofeedback may use several techniques in an attempt to normalize unusual patterns of brain function in patients with various psychiatric and central nervous system disorders.

The evidence is insufficient to determine that EEG biofeedback/neurofeedback results in an improvement in the net health outcome for any indication.

For individuals who have attention-deficit/hyperactivity disorder (ADHD) who receive neurofeedback, the evidence includes randomized controlled trials (Lim 2019; Aggensteiner 2019; Arnold 2020; Hasslinger 2022; Purper-Ouakil 2022) and systematic review with meta-analyses (Cortese 2016; Van Doren 2019; Yan 2019; Lambez 2020; Riesco-Matias 2021, Lin 2022, Rahmani 2022).

The above-mentioned studies (N range = 144 to 202 patients) have compared neurofeedback with methylphenidate, biofeedback, cognitive behavioral therapy, cognitive training, or physical activity found either small to moderate or no benefit of neurofeedback, and sustained long-term benefit (e.g., at six (6) to 13 months) has not been consistently demonstrated. Studies using active controls have suggested that at least part of the effect of neurofeedback might be due to attention skills training, biofeedback, relaxation training, and/or other nonspecific effects. Two (2) of the RCTs indicated that any beneficial effects were more likely to be reported by evaluators unblinded to treatment (parents), than by evaluators blinded (teachers) to treatment, which would suggest bias in the nonblinded evaluations. One meta-analysis found no effect of neurofeedback on objective measures of attention and inhibition. Additional research with blinded evaluation of outcomes is needed to demonstrate the effect of neurofeedback on ADHD.

In 2018, the National Institute for Health and Care Excellence (NICE) published an intervention evidence review on the efficacy of non-pharmacological treatment and the impact of adverse event associated with non-pharmacological treatments of ADHD. Specifically related to ADHD, the committee found that the current evidence was insufficient to make specific recommendation for the use of neurofeedback for children aged five (5) to 18 years and adults aged over 18 years. Although the committee found some clinically importance benefit from some outcomes, the final decision was based on small sample-sized studies and lower quality evidence.

For individuals who have disorders other than ADHD who receive any type of biofeedback, collectively the evidence from these studies found either small or no benefit from neurofeedback. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome. Evidence includes systematic review with meta-analysis (insomnia: Melo 2019; chronic pain: Hesam-Shariati 2022; post-traumatic stress disorder: Steingrimsson 2020). Randomized controlled trials (depression: Maynart 2021 and Park 2020; substance abuse: Gabrielsen 2022; hypertension: Mengden 2023; pediatric epilepsy: Morales-Quezada 2019). There is limited published evidence on the efficacy of biofeedback for cluster headaches, labor pain, back pain, or other indications not listed above.

Home Biofeedback Devices

Rosenblatt and colleagues (2019) conducted a pilot study to evaluate the effectiveness and usability of pelvic floor muscle training (PFMT) with the intravaginal accelerometer-based system leva Pelvic Digital Health System (leva) in woman with mild-to-moderate stress or mixed urinary incontinence (UI). With a small sample (N = 23) of woman, this single-center, open-label study performed PFM exercises guided by the accelerometer-based system twice daily for six (6) weeks. Based on the protocol included in the device and used for FDA clearance, each training session entailed five repetitions of 15-second PFM contraction followed by 15-second relaxation over a period of 2.5 minutes. The authors reported that early results indicate a significant, positive impact on UI-specific subjective outcomes and objective measures of PFM function. However, with study limitations, this research serves as a foundation for future RCTs comparing this technology to other accepted interventions for UI.

Keyser and colleagues (2022) reported findings of a retrospective cohort study aimed at determining the effectiveness of the prescription digital therapeutics (pDTx) in reducing urinary symptoms in real-world users. The analysis was conducted on 532 eligible women with UI, who completed baseline and 8-week Urogenital Distress Inventory Short Form (UDI-6) survey to assess presence and bother of UI symptoms. The pDTX, leva Pelvic Health System (Renovia, Inc) passively collected usage information and prompted symptoms survey completion to enable remote monitoring of adherence and symptoms. The authors concluded that the study finding demonstrates effectiveness of a pDTx in reduction UI symptoms among this cohort of users in a real-world setting, and the results can be used to inform additional research.

Weinstein and colleagues (2022) evaluated whether pelvic floor muscle training using a motion-based digital intravaginal device, the leva Pelvic Health System, is more effective than home pelvic floor muscle training for treatment of stress or stress-predominant mixed UI. In this 8-week prospective randomized controlled superiority trial, 363 women were randomized (1:1) and investigators were

masked to the group assignment. The two primary outcomes included change in UDI-6 score from baseline to eight (8) weeks and change in number of stress UI episodes on a 3-day bladder diary.

Weinstein and colleagues (2023) reported the planned secondary analysis, symptom, and adherence data at 6- and 12-months. Of the 363 study participants in the original study, 299 women were analyzed at eight (8) weeks and 286 women at 6- and 12-months.

Centers for Medicare Services (CMS) issued a decision summary in 2002, reaffirming that the medical literature is not sufficient to reliably conclude that the use of home biofeedback devices is reasonable and necessary to treat urinary incontinence.

PROFESSIONAL GUIDELINE(S)

Constipation, Fecal Incontinence, and Anorectal Disorders

The American Gastroenterological Association (AGA 2013) issued a medical position statement on constipation, recommending pelvic floor retraining by biofeedback therapy rather than laxatives for defecatory disorders (strong recommendation, high-quality evidence).

The North American Society for Pediatric Gastroenterology, Hepatology and Nutrition clinical practice guideline, which addresses the treatment of constipation which states that evidence does not support the use of biofeedback in the treatment of childhood constipation (Tabbers 2014).

The American Society of Colon and Rectal Surgeons (ASCRS) practice guideline for the evaluation and management of constipation (Paquette 2016), recommends biofeedback therapy as a first-line treatment of choice for patients with symptomatic pelvic floor dyssynergia (strong recommendation based on moderate-quality evidence, 1B).

The National Institute for Health and Care Excellence (2017) guidance on constipation in children and young people, indicates that biofeedback should not be used for ongoing treatment. However, biofeedback may be beneficial in the short-term treatment of a small subgroup of patients with intractable constipation.

The American College of Gastroenterology (ACG) published updated clinical guidelines (Wald 2021) on the management of benign anorectal disorders, making the following recommendations:

- We recommend that instrumented anorectal biofeedback therapy should be used to manage symptoms in defecation disorders (DD). (strong recommendation; minimal risk of harm; quality of evidence: moderate).
- We recommend biofeedback to teach pelvic floor muscle reconditioning for levator syndrome with abnormal ARM (strong recommendation; quality of evidence: very low).
- We recommend that patients with fecal incontinence (FI) 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).

Headache

In 2021, the American Headache Society (Ailani 2021) released a consensus statement on integration of new migraine treatments into clinical practice, including biobehavioral therapies (cognitive behavioral therapy, biofeedback, and relaxation). (Grade A evidence).

EEG Biofeedback/Neurofeedback

In 2018, the National Institute for Health and Care Excellence (NICE) published an intervention evidence review on the efficacy of non-pharmacological treatment and the impact of adverse event associated with non-pharmacological treatments of ADHD. Specifically related to ADHD, the committee found that the current evidence was insufficient to make specific recommendation for the use of neurofeedback for children aged five (5) to 18 years and adults aged over 18 years. Although the committee found some clinically importance benefit from some outcomes, the final decision was based on small sample-sized studies and lower quality evidence.

REGULATORY STATUS

A variety of biofeedback devices have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. These devices are designated by the FDA as class II with special controls and are exempt from premarket notification requirements**.**

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
90875 (E/I)	Individual psychophysiological therapy incorporating biofeedback training by any modality (face-to-face with the patient), with psychotherapy (e.g., insight oriented, behavior modifying or supportive psychotherapy); 30 minutes
90876 (E/I)	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	each additional 15 minutes of one-on-one physician or other qualified health care professional contact with the patient (List separately in addition to code for primary procedure)

HCPCS Codes

Code	Description
E0746	Electromyography (EMG), biofeedback device
S9002 (E/I)	Intravaginal motion sensor system, provides biofeedback for pelvic floor muscle rehabilitation device

ICD10 Codes

Code	Description
G43.001-G43.919	Migraine (code range)
G44.201-G44.229	Tension-type headache (code range)
K59.02	Outlet dysfunction constipation

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SEARCH TERMS

Not Applicable

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Biofeedback Therapy (NCD 30.1) [accessed 2025 Mar 5]

Biofeedback Therapy for the Treatment of Urinary Incontinence (NCD 30.1.1) [accessed 2025 Mar 5]

Psychiatry and Psychology Services (LCD L33632) [accessed 2025 Mar 5]

Home Biofeedback For Urinary Incontinence (NCA CAG-00118N) [accessed 2025 Mar 5]

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.

- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product (including Medicare HMO-Dual Special Needs Program (DSNP) product) covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.
- If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.

POLICY HISTORY/REVISION	
Committee Approval Dates	
10/18/01, 05/16/02, 04/24/03, 04/15/04, 03/17/05, 03/16/06, 03/15/07, 04/17/08, 09/17/09, 09/16/10, 09/15/11, 09/20/12, 12/19/13, 11/20/14, 11/19/15, 10/20/16, 10/19/17, 10/18/18, 10/17/19, 10/22/20, 10/28/21, 06/16/22, 06/22/23, 06/20/24, 06/26/25	
Date	**Summary of Changes**
06/26/25	• Annual review, policy intent unchanged.
01/01/25	• Summary of changes tracking implemented.
10/18/01	• Original effective date