

MEDICAL POLICY



MEDICAL POLICY DETAILS	
Medical Policy Title	Biofeedback
Policy Number	2.01.09
Category	Technology Assessment
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Committee Approval Date	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
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Product Disclaimer	<ul style="list-style-type: none"> • Services are contract dependent; if a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply. • If a commercial product (including an Essential Plan or Child Health Plus product), 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 STATEMENT

- I. Based upon our criteria and assessment of the peer-reviewed literature, biofeedback for migraine and tension-type headaches has been medically proven to be effective and, therefore, 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. Based upon our criteria and assessment of the peer-reviewed literature, biofeedback for dyssynergic-type constipation in adults has been medically proven to be effective and, therefore, 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. Based upon our criteria and assessment of the peer-reviewed literature, there is no consistent evidence that supervised or unsupervised biofeedback, alone or as an adjunct to other treatments, demonstrates improvement in patient outcomes. Therefore, 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, home biofeedback devices (e.g., Leva Pelvic Health System), preterm labor, tinnitus, urinary incontinence or retention.

Refer to Corporate Medical Policy #1.01.19 Pelvic Floor Electrical Stimulation as a Treatment for Urinary or Fecal Incontinence

Refer to Corporate Medical Policy #8.01.07 Treatment of Tinnitus

Refer to Corporate Medical Policy #11.01.03 Experimental or Investigational Services

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POLICY GUIDELINES

- 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 et al., 2018) consist of the following:

- I. Patient must satisfy the diagnostic criteria for functional constipation and/or constipation-predominant IBS; and
- II. During repeated attempts to defecate, there must be features of impaired evacuation as demonstrated by two of the following three tests:
 - A. Abnormal balloon expulsion test;
 - B. Abnormal anorectal evacuation pattern with manometry or anal surface EMG; and/or
 - C. Impaired rectal evacuation by imaging; and

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- III. Inappropriate contraction of the pelvic floor, as measured with anal surface EMG or manometry with adequate propulsive forces during attempted defecation; and
- IV. 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.

RATIONALE

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 et al., 1993; Heymen et al., 2007; Lee et al., 2010).

The 2016 American Society of Colon and Rectal Surgeons (ASCRS) practice guideline for the Evaluation and Management of Constipation, which 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).

There is a lack of evidence that addresses whether biofeedback is an effective treatment for constipation in children. As of 2024, there has been no update to 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 et al., 2014).

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.

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 et al., 2013 Jelovsek et al., 2019, Andy et al., 2020).

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Headache:

Two systematic reviews addressing biofeedback for migraine headaches and tension headaches were published in 2007 and 2008 (Nestoriuc, et al.). 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.

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 et al. (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 et al. (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.

EEG Biofeedback/Neurofeedback

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 et al., 2019; Aggensteiner et al., 2019; Arnold et al., 2020; Hasslinger et al., 2022; Purper-Ouakil et al., 2022) and systematic review with meta-analyses (Cortese et al., 2016; Van Doren et al., 2019; Yan et al., 2019; Lambez et al., 2020; Riesco-Matias et al., 2021, Lin et al., 2022, Rahmani et al., 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

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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 et al., 2019; chronic pain, Hesam-Shariati et al., 2022; post-traumatic stress disorder, Steingrimsson et al., 2020); randomized controlled trials (depression, Maynard et al., 2021 and Park et al., 2020; substance abuse, Gabrielsen et al., 2022; hypertension, Mengden et al., 2023; pediatric epilepsy, Morales-Quezada et al., 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 et al. (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 et al. (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 et al. (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 et al. (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.

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CODES

- Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.
- **CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.**
- Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.
- Code Key: Experimental/Investigational = (E/I), Not medically necessary/ appropriate = (NMN).

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)

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HCPCS Codes

Code	Description
E0746	Electromyography (EMG), biofeedback device
S9002 (E/I)	Intravaginal motion sensor system, provides biofeedback for pelvic floor muscle rehabilitation device (<i>effective 04/01/24</i>)

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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KEY WORDS

Biofeedback, EMG feedback, EEG biofeedback (also known as neurofeedback)

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

There are currently National Coverage Determinations (NCD) for biofeedback. Please refer to the following NCD websites for Medicare Members:

Biofeedback Therapy (NCD 30.1): [<https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?NCIDid=41>] accessed 03/29/24.

Biofeedback Therapy for the Treatment of Urinary Incontinence (NCD 30.1.1): [<https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=42&ncdver=1>] accessed 03/29/24.

There is currently a National Coverage Analysis (NCA) Decision Memo for home biofeedback for urinary incontinence. Please refer to the following NCA website for Medicare Members: [<https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=N&ncaid=34>] accessed 05/21/24.

There is currently a Local Coverage Determinations (LCD) for Psychiatry and Psychology Services (L33632). Please refer to the following LCD website for Medicare Members: [<https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?LCDId=33632&ContrId=275>] accessed 03/29/24.