

MEDICAL POLICY

MEDICAL POLICY DETAILS	
Medical Policy Title	Biofeedback
Policy Number	2.01.09
Category	Technology Assessment
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Committee Approval Date	08/16/01, 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
Current Effective Date	06/22/23
Archived Date	N/A
Archive Review Date	N/A
Product Disclaimer	<ul style="list-style-type: none"> • 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 biofeedback, alone or as an adjunct to other treatments, demonstrates improvement in patient outcomes. Therefore, biofeedback is considered **investigational** for all other indications.

Refer to Corporate Medical Policy #11.01.03 Experimental or Investigational Services.

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 further 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 biofeedback sessions over a three (3) month time. Biofeedback sessions beyond six (6) sessions will require documentation of therapeutic effectiveness before further sessions will be considered for coverage.

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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. The most common forms 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), brain waves (Neurofeedback/EEG biofeedback), and respiration.

Biofeedback has been proposed as a treatment for a variety of diseases and disorders, including, but not limited to: addictive behaviors, ADHD/ADD, 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
- 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.

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.

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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.

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, several well-conducted, randomized, controlled trials have been published that focus on patients with dyssynergic-type constipation. Although the number of participants in each of the studies is generally small, the studies suggest benefits of biofeedback in this specific group of patients.

A systematic review of randomized, controlled trials found a benefit of biofeedback as a treatment of constipation in adults. The review was limited by the variability in patient populations, comparison groups, and outcomes measures. The authors concluded that, for constipation due to pelvic floor dyssynergia (anismus, spastic pelvic floor syndrome), the collected evidence underlines superiority of biofeedback over other management options and makes biofeedback the treatment of choice for this condition (Enck et al., 1993).

The 2016 American Society of Colon and Rectal Surgeons (ASCRS) practice guideline for the Evaluation and Management of Constipation recommends biofeedback therapy as the treatment of choice for patients with symptomatic pelvic floor dyssynergia (Level of Evidence: Class II; Grade of Recommendation: B).

There is a lack of evidence that addresses whether biofeedback is an effective treatment for constipation in children. A clinical practice guideline from the North American Society for Pediatric Gastroenterology, Hepatology and Nutrition (2014), addressing the treatment of constipation, states that evidence does not support the use of biofeedback in the treatment of childhood constipation. The National Institute for Health and Care Excellence (2017) updated its guidance on constipation in children and young people, indicating 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:

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.

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, reporting a medium effect size of 0.58 (pooled outcome of all available headache variables) for treatment of migraine. Effect sizes were computed using Hedges' g, which refers to the mean difference between the experimental and control groups divided by the pooled standard deviation. 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. Meta-analysis showed a medium-to-large effect size of 0.73 that appeared to be stable over 15 months of follow-up. 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 these meta-analyses are limited by the inclusion of studies of poor methodological quality, the authors did not find evidence of an influence of study quality or publication bias in their findings.

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Neurofeedback:

Neurofeedback (also known as EEG biofeedback) 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.

For individuals who have attention-deficit/hyperactivity disorder (ADHD) who receive neurofeedback, the evidence includes randomized controlled trials (RCTs) and meta-analyses (Van Doren et al., 2019; Lambez et al., 2020; Purper-Ouakil et al., 2022; Sampedro et al., 2021). For individuals who have disorders other than ADHD (e.g., chronic insomnia, epilepsy, substance abuse, pediatric brain tumors, and post-traumatic stress disorder) who receive neurofeedback, the evidence includes case reports, case series, comparative cohorts, small RCTs, and systematic reviews Jarusiewicz 2002; Morales-Quezada et al., 2019; Steingrimsson et al., 2020; Hesam-Shariati et al., 2022. Collectively, these studies found either small or no benefit of neurofeedback. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

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 trial ($n = 8975$ 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.

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

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Code	Description
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 (List separately in addition to code for primary procedure)

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Code	Description
E0746	Electromyography (EMG), biofeedback 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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*Key Article

KEY WORDS

Biofeedback, EMG feedback.

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

Based upon our review, there are currently two National Coverage Determinations (NCDs) addressing Biofeedback. Please refer to the following websites for Medicare Members:

Biofeedback Therapy:

[https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=41&ncdver=1&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=New+York++Upstate&KeyWord=biofeedback&KeyWordLookUp=Title&KeyWordSearchType=And&ncd_id=30.1&ncd_version=1&basket=ncd%25253A30%25252E1%25253A1%25253ABiofeedback+Therapy&bc=gAAAABAAAA&] accessed 5/1/23.

Biofeedback Therapy for the Treatment of Urinary Incontinence:

[<https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=42&ncdver=1&SearchType=Advanced&CoverageSelection=Both&NCSelection=NCA%7cCAL%7cNCD%7cMEDCAC%7cTA%7cMCD&ArticleType=SAD&PolicyType=Both&s=41&KeyWord=biofeedback&KeyWordLookUp=Title&KeyWordSearchType=Exact&kq=true&bc=MAAABAAAA&>] accessed 5/1/23.

Based upon our review, there is currently a Local Coverage Determination (LCD) for psychiatry and psychology services addressing psychophysiological therapy incorporating biofeedback training. Please refer to the following LCD website for Medicare Members: [<https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33632&ver=76&SearchType=Advanced&CoverageSelection=Both&NCSelection=NCA%7cCAL%7cNCD%7cMEDCAC%7cTA%7cMCD&ArticleType=SAD&PolicyType=Both&s=41&KeyWord=psychological+services&KeyWordLookUp=Doc&KeyWordSearchType=Exact&kq=true&bc=IAAAACAAGAAA&>] accessed 5/1/23.