MEDICAL POLICY

MEDICAL POLICY DETAILS	
Medical Policy Title	**BIOFEEDBACK**
Policy Number	**2.01.09**
Category	**Technology Assessment**
Effective Date	**11/19/99**
Revised 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**
Product Disclaimer	• *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 product) or a Medicaid product covers a specific service, medical policy criteria apply to the benefit.* • *If a Medicare 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.*

POLICY STATEMENT

I. Based upon our criteria and review of the peer-reviewed literature, biofeedback is considered **medically appropriate** as part of the overall treatment plan for *migraine* and *tension-type headaches* only after other conventional methods of treatment have been attempted (e.g., medication management, relaxation) and not been successful in treating the patients headaches.

II. Based upon our criteria and review of the peer-reviewed literature, 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. Based upon our criteria and review 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 regarding Experimental or Investigational Services.

POLICY GUIDELINES

I. 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 three (3) months. Biofeedback sessions beyond six (6) sessions will require documentation of therapeutic effectiveness before further sessions will be considered for coverage.

II. The Federal Employee Health Benefit Program (FEHBP/FEP) requires that procedures, devices or laboratory tests approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational and thus these procedures, devices or laboratory tests may be assessed only on the basis of their medical necessity.

DESCRIPTION

Biofeedback is a technique, using electronic instrumentation, intended to teach patients self-regulation of certain physiologic processes not normally considered to be under voluntary control. The technique involves the feedback of a variety of types of information not normally available to the patient, followed by a concerted effort on the part of the patient to use this feedback to help alter the physiological process in some specific way.

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 (EEG biofeedback) and respiration. During biofeedback, sensors can be utilized to measure and

feedback the activity of the internal and external rectal sphincters, activity of the detrusor muscles of the urinary bladder, esophageal motility and stomach acidity.

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, epilepsy, pain, asthma, Raynaud's disease and insomnia.

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) consists of:

I. Patient must satisfy the diagnostic criteria for functional constipation and/or constipation-predominant irritable bowel syndrome (IBS); and
II. During repeated attempts to defecate, there must be features of impaired evacuation as demonstrated by two (2) of the following three (3) tests:
    A. Abnormal balloon expulsion test
    B. Abnormal anorectal evacuation pattern with manometry or anal surface EMG
    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 3 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 in order to pass bowel movements. Biofeedback attempts 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 in order to synchronize the contraction of the external anal sphincter with relaxation of the internal anal sphincter. 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.

In 2016, ASCRS published guidelines on the evaluation and management of constipation. In 2017, the guidelines state that biofeedback therapy is a first-line treatment for symptomatic pelvic floor dyssynergia (strong recommendation, moderate quality of evidence, 1B).

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.

Although several studies have recently been published the majority had limited experimental design (e.g., many contain a small sample size of less than 40 patients, randomized studies not blinded, performed at a single site).

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 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)

An American Society of Colon and Rectal Surgeons practice parameter addressing 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 of the North American Society for Pediatric Gastroenterology, Hepatology and Nutrition addressing the treatment of constipation states that biofeedback has been found to be efficacious in some open-label studies but recent controlled studies did not demonstrate long-term efficacy. 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 (2) 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 (3) months, and at least four (4) 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.

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.

In a Cochrane review (Stewart, et al 2016) of Incontinence Specialized Register Controlled Trials, journals and conference proceedings a review of electrical stimulation with non-implanted devices aimed to inhibit contractions of the detrusor muscle, potentially reducing urinary frequency and urgency was done. Included in this review of 63 eligible trials (4424 randomized patients) was a comparison with and without biofeedback. Low- or very low-quality evidence suggested no evidence of a difference in perception of improvement of UUI when ES was compared to PFMT with or without biofeedback. The low quality of the evidence base overall for these trials means that there cannot be a full

confidence in these conclusions until adequately powered trials is carried out, measuring subjective outcomes and adverse effects.

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.*

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
90911	Biofeedback training, perineal muscles, anorectal or urethral sphincter, including EMG and/or manometry *(deleted 1/1/2020)*
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 contract with the patient *(effective 1/1/2020)*
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) *(effective 1/1/2020)*

HCPCS Codes

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

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=gAAAABAAAAAA&

Biofeedback Therapy for the Treatment of Urinary Incontinence:
https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=42&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=gAAAABAAAAAA&

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=65&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=IAAAACAAAAAA&