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Biofeedback as a Treatment of Chronic Pain

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Coverage

Biofeedback as a treatment of chronic pain, including but not limited to low back pain**, is considered experimental, investigational and/or unproven.**

Policy Guidelines

None.

Description

Biofeedback is a technique intended to teach patients self-regulation of certain physiologic processes not normally considered to be under voluntary control. Electromyography biofeedback has been evaluated as a method to reduce chronic or recurrent pain of musculoskeletal or psychosomatic origin.

Biofeedback for Chronic Pain

Biofeedback is a technique intended to teach patients the self-regulation of certain unconscious or involuntary physiologic processes. Biofeedback equipment converts physiological signals into outputs given to patients. The technique involves the feedback of a variety of types of information not usually available to the patient, followed by a concerted effort on the part of the patient to use this feedback to help alter the physiologic process in a specific way. Biofeedback has been proposed as a treatment for a variety of diseases and disorders including anxiety, headaches, hypertension, movement disorders, incontinence, pain, asthma, Raynaud disease, and insomnia. The type of feedback used in an intervention (e.g., visual, auditory) depends on the nature of the disease or disorder being treated.

Biofeedback may be administered, using different techniques and monitoring devices and sensors (e.g., electromyograph), in an outpatient setting by psychiatrists, psychologists, and general practitioners. Biofeedback training is done either in individual or group sessions, alone or in combination with other behavioral therapies designed to teach relaxation. A typical program consists of 10 to 20 training sessions of 30 minutes each. Sessions can take up to 90 minutes. Training sessions are performed in a quiet, nonstimulating environment. Patients are instructed to use mental imagery techniques to affect the physiologic variable being monitored, and feedback is provided for the successful alteration of that physiologic parameter in the form of lights or tone, verbal praise, or other auditory or visual stimuli. This medical policy focuses on the use of biofeedback for the treatment of chronic pain.

Treatment for chronic pain is often multimodal and typically includes psychological therapy. Psychological techniques vary but may include cognitive therapy, which teaches subjects the ability to cope with stressful stimuli by attempting to alter negative thought patterns and dysfunctional attitudes, and behavioral approaches to reduce muscle tension and break the pain cycle. Relaxation, using any of a variety of techniques including meditation or mental imagery, is considered a behavioral therapy that may be used alone or as a component of a cognitive-behavioral therapy program. Electromyography biofeedback has also been used for the treatment of chronic pain, on the assumption that the ability to reduce muscle tension will be improved through the feedback of data to the patient regarding the degree of muscle tension. While some consider electromyography biofeedback to be a method used to obtain relaxation, others consider biofeedback to be distinct from other relaxation techniques.

Regulatory Status
Since 1976, a large number of biofeedback devices have been cleared for marketing by the U.S. Food and Drug Administration through the 510(k) process. FDA product code: HCC.

Rationale

Medical policies assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are the length of life, quality of life, and ability to function including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition.

Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of technology, 2 domains are examined: the relevance and quality and credibility. To be relevant, studies must represent 1 or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. Randomized controlled trials are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Psychological treatments involve both nonspecific and specific therapeutic effects. Nonspecific effects (sometimes called placebo effects) occur as a result of contact with the therapist, positive expectations on the part of the patient and therapist, and other beneficial effects that occur as a result of the patient being in a therapeutic environment. Specific effects are those that occur only because of the active treatment, beyond any nonspecific effects that may be present. This literature review focuses on identifying evidence that the effects of biofeedback are distinct from nonspecific placebo effects. Because establishing an ideal placebo control is problematic with psychological treatments and because treatment of chronic pain is typically multimodal, isolating the specific contribution of biofeedback is challenging.

Biofeedback

Clinical Context and Therapy Purpose

The purpose of electromyography (EMG) biofeedback in individuals who have chronic pain is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following PICO was used to select literature to inform this policy.

Populations

The relevant population of interest is individuals with chronic pain, including low back, knee, neck and shoulder, orofacial, and abdominal pain as well as fibromyalgia, osteoarthritis, systemic lupus erythematosus, and vulvar vestibulitis.

Interventions

The therapy being considered is EMG biofeedback.

Comparators

The following therapies are currently being used to treat chronic pain: pharmacologic and nonpharmacologic therapy. For chronic pain management, a multimodal, multidisciplinary approach that is individualized to the patient is recommended. (1) A multimodal approach to pain management consists of using treatments (i.e., nonpharmacologic and pharmacologic) from one or more clinical disciplines incorporated into an overall treatment plan. This allows for different avenues to address the pain condition, often enabling a synergistic approach that impacts various aspects of pain, including functionality. The efficacy of such a coordinated, integrated approach has been documented to reduce pain severity, improve mood and overall quality of life, and increase function.

Outcomes
The general outcomes of interest are reductions in symptoms and medication usage and improvements in functional outcomes.

The Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT) recommends that chronic pain trials should consider assessing outcomes representing 6 core domains: pain, physical functioning, emotional functioning, participant ratings of improvement and satisfaction with treatment, symptoms and adverse events, and participant disposition. (2) Table 1 summarizes provisional benchmarks for interpreting changes in chronic pain clinical trial outcome measures per IMMPACT. (3)

Table 1. Benchmarks for Interpreting Changes in Chronic Pain Outcome Measures

Outcome Domain and Measure	Type of Improvement	Change
Pain intensity 0 to 10 numeric rating scale	Minimally important Moderately important Substantial	10 to 20% decrease ≥30% decrease ≥50% decrease
Physical functioning Multidimensional Pain Inventory Interference Scale Brief Pain Inventory Interference Scale	 Clinically important Minimally important	 ≥0.6 point decrease 1 point decrease
Emotional functioning Beck Depression Inventory Profile of Mood States Total Mood Disturbance Specific Subscales	 Clinically important Clinically important Clinically important	 ≥5 point decrease ≥10 to 15 point decrease ≥2 to 12 point change
Global Rating of Improvement Patient Global Impression of Change	Minimally important Moderately important Substantial	Minimally improved Much improved Very much improved

Study Selection Criteria
Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

General Chronic Pain

Systematic Reviews

Several meta-analyses have reviewed RCTs assessing psychological therapies for a variety of nonheadache chronic pain conditions. A Cochrane review by Williams et al. (2020) focused on chronic pain in adults. (4) Two RCTs were identified that compared behavioral therapy with an active control designed to change behavior (i.e., exercise or instruction). Three RCTs had sufficient follow-up to be included in a comparison of behavioral therapy and usual treatment. Reviewers found no evidence that behavioral therapy had any effect on pain compared to active control or usual treatment. Additionally, there was no evidence of a difference between behavioral therapy and active control or usual treatment in terms of disability at the end of treatment.

Another Cochrane review by Fisher et al. (2018) focused on children and adolescents with chronic and recurrent pain. (5) Although psychological therapies were found to improve pain, only 1 study evaluated biofeedback in nonheadache pain. Biofeedback did not improve abdominal pain more than cognitive-behavioral therapy (CBT) in this trial (6); see the section on Abdominal Pain. Palermo et al. (2010) published a meta-analysis of studies on psychological therapies for the management of chronic pain in children and adolescents. (7) These authors did not identify any additional RCTs on biofeedback for managing nonheadache pain.

Low Back Pain

Systematic Reviews

A Cochrane review by Henschke et al. (2010) assessed behavioral treatments for chronic low back pain and conducted a meta-analysis of 3 small, randomized trials that compared EMG biofeedback with a waiting-list control group. (8) In the pooled analysis, there were a total of 34 patients in the intervention group and 30 patients in the control group. The standardized mean difference (SMD) in short-term pain was -0.80 (95% confidence interval [CI], -1.32 to -0.28); this difference was statistically significant favoring the biofeedback group. Reviewers did not conduct meta-analyses of trials comparing biofeedback with sham biofeedback and therefore were unable to control for any nonspecific effects of treatment.

Randomized Controlled Trials

Yelden et al. (2024) compared biofeedback to physiotherapist feedback in an RCT in 40 patients with chronic nonspecific low back pain. (9) All patients received 12 sessions of the designated therapy (3 sessions weekly for 4 weeks) and a core stabilization activity program. The primary outcome, disability as measured by the Revised Oswestry Disability Index scale was not

significantly different between groups at the end of treatment. Secondary measures of visual analogue scale pain scores, muscle activity, and quality of life were also not different between groups.

At least one RCT has compared biofeedback with a sham intervention for the treatment of low back pain. Kapitza et al. (2010) compared the efficacy of respiratory biofeedback with sham biofeedback in 42 patients with low back pain. (10) Both groups showed a reduction in pain levels on a 10-point visual analog scale (VAS) at the end of the intervention period and at 3-month follow-up. Between-group differences were not statistically significant. For example, 3 months after the intervention, mean change in pain with activity decreased by 1.12 points in the intervention group and 0.96 points in the sham control group ($p>.05$); mean change in pain at rest decreased by 0.79 points in the intervention group and 0.49 points in the control group ($p>.05$).

Lazaridou et al. (2023) conducted a prospective, single-center RCT to assess the impact of surface EMG biofeedback versus continued care (no intervention) on chronic lower back pain in adults. (11) Sixty-six patients were randomized 2:1 to receive EMG biofeedback or no additional intervention for 8 weeks and included in analysis. Compared to usual care, patients receiving EMG biofeedback reported lower pain intensity on the Brief Pain Inventory (BPI) questionnaire after 8 weeks (mean difference [MD], 0.9; 95% CI, -1.07 to -0.32; $p\leq.01$). Compared to baseline scores, individuals in the EMG biofeedback group demonstrated statistically significant reductions in pain interference (MD, 1.3; 95% CI, 0.42 to 2.1; $p\leq.01$), disability (MD, 4.32; 95% CI, 1.2 to 7.3; $p\leq.01$), and significant increases in low back pain thresholds (MD, 0.5; 95% CI, -0.87 to -0.05; $p\leq.01$). Significant changes were also observed in muscle tension for the lower back muscles in the EMG biofeedback group ($p<.001$).

Several trials with active comparison groups have not found that biofeedback is superior to alternative treatments. Tan et al. (2015) evaluated 3 self-hypnosis interventions and included EMG biofeedback as a control intervention. (12) This RCT enrolled 100 patients with chronic low back pain. After the 8-week intervention, reported reductions in pain intensity were significantly higher in the combined hypnosis groups than in the biofeedback group ($p=.042$).

A trial published by Glombiewski et al. (2010) assessed whether the addition of EMG biofeedback to CBT improved outcomes in 128 patients with low back pain. (13) Patients were randomized to one of 3 groups: CBT, CBT plus biofeedback, or waiting-list control. Both treatments improved outcomes including pain intensity compared with the waiting-list control (moderate effect size of 0.66 for pain intensity in the CBT plus biofeedback group). However, the addition of biofeedback did not improve outcomes over CBT alone.

Chronic Knee Pain

Systematic Reviews

Ananias et al. (2024) conducted a systematic review and meta-analysis of 8 RCTs that compared the efficacy of biofeedback and standard rehabilitation in patients undergoing anterior cruciate ligament reconstruction surgery. (14) Four of the RCTs were included in the meta-analysis. Two

RCTs showed a significant effect of biofeedback on quadriceps strength, 2 studies reported a significant difference in pain scores, 2 studies found a significant difference in knee extension deficit, and one study reported a significant difference in balance. The heterogeneity of outcomes assessed limits the interpretation of these results in this subset of studies.

Karaborklu Argut et al. (2022) conducted a systematic review of 8 RCTs of patients who had undergone orthopedic knee surgery. (15) Therapeutic EMG biofeedback during rehabilitation was more effective for improving muscle strength and activation compared to home exercise, standard rehabilitation, or electrical stimulation. There were no clear trends in the effect of EMG biofeedback on pain or knee range of motion.

Collins et al. (2012) conducted a systematic review and meta-analysis of RCTs on nonsurgical interventions for anterior knee pain. (16) In a pooled analysis of data from 2 trials, there was no significant benefit of adding EMG biofeedback to an exercise-only intervention at 8 to 12 weeks (SMD, -0.22; 95% CI, -0.65 to 0.20).

Chronic Neck and Shoulder Pain

Systematic Reviews

Campo et al. (2021) published a systematic review and meta-analysis that evaluated the effectiveness of biofeedback for improving pain, disability, and work ability in adults with neck pain. (17) The review included 15 RCTs with 8 studies utilizing EMG biofeedback and 7 studies of pressure biofeedback (Table 2). There was no restriction on the control intervention (e.g., no treatment, placebo, active treatment) or co-intervention, provided the independent effects of biofeedback could be elucidated. An overview of the characteristics and results is presented in Tables 3 and 4. Results suggest that biofeedback has a moderate effect on reducing short-term disability and a small effect on reducing intermediate-term disability with no effect on pain or work ability in the short- and intermediate-term. Of note, there were a variety of control interventions across included studies (e.g., exercise, electroacupuncture, electrotherapy, education) with few studies directly comparing biofeedback to no treatment or placebo.

Kamonseki et al. (2021) completed a systematic review and meta-analysis of 5 RCTs that examined the effects of EMG biofeedback for shoulder pain and function. (18) Study characteristics and results are presented in Tables 3 and 4. Overall, the evidence did not support the use of EMG biofeedback for reducing shoulder pain and improving shoulder function.

Table 2. Comparison of Studies Included in Systematic Reviews and Meta-Analysis

Study	Campo et al. (2021) (17)	Kamonseki et al. (2021) (18)
Juul-Kristensen et al. (2019) (19)		•
Kosterink et al. (2010) (20)	•	•
Ma et al. (2011) (21)	•	•
Middaugh et al. (2013) (22)		•
Sandsjo et al. (2010) (23)	•	•

Arami et al. (2012) (24)	•	
Bissett et al. (1985) (25)	•	
Bobos et al. (2016) (26)	•	
Delive et al. (2011) (27)	•	
Ehrenborg et al. (2010) (28)	•	
Eslamain et al. (2020) (29)	•	
Iqbal et al. (2013) (30)	•	
Jull et al. (2002) (31)	•	
Jull et al. (2007) (32)	•	
Nezamuddin et al. (2013) (33)	•	
Voerman et al. (2007) (34)	•	
Wani et al. (2013) (35)	•	

Table 3. Systematic Review and Meta-Analysis Characteristics

Study	Dates	Trials	Participants	N (Range)	Design	Duration
Campo et al. (2021) (17)	To Sept 2020	15	Adults with neck pain including pain associated with radiculopathy, cervicogenic headaches, whiplash, shoulder pain, and work-related injuries administered biofeedback (EMG or pressure) on at least 2 occasions	990 (27 to 200)	RCT (8 studies EMG; 7 pressure)	8 days to 6 weeks (duration of interventions)
Kamonseki et al. (2021) (18)	To Dec 2020	5	Adults with shoulder pain	272 (15 to 72)	RCT (all EMG)	4 weeks to 6 months (follow-up period)

EMG: electromyography; RCT: randomized controlled trial.

Table 4. Systematic Review and Meta-Analysis Results

Study	Pain (short-term: 4 to 6 weeks)	Pain (inter-mediate-term: 8 to 12 weeks)	Disability (short-term: 4 to 6 weeks)	Disability (inter-mediate-term: 8 to 12 weeks)	Work ability (short-term: 4 to 6 weeks)	Work ability (intermediate-term: 8 to 12 weeks)
Campo et al. (2021) (17)						

Total N	602 (11 RCTs)	383 (6 RCTs)	627 (9 RCTs)	458 (5 RCTs)	190 (3 RCTs)	190 (3 RCTs)
Between-group difference in SMC (95% CI)	-0.26 (-0.77 to 0.24)	-0.15 (-0.34 to 0.05)	-0.42 (-0.59 to -0.26)	-0.30 (-0.53 to -0.06)	-0.01 (-0.26 to 0.28)	-0.03 (-0.26 to 0.31)
Certainty of Evidence[a]	Moderate	Low	Moderate	Moderate	Low	Low
Kamonseki et al. (2021) (18)						
	Shoulder pain intensity	**Shoulder function**				
Total N	250 (5 RCTs)	175 (3 RCTs)				
SMD (95% CI)	-0.21 (-0.67 to 0.34)	-0.11 (-0.41 to 0.19)				
p value (I^2)	.36 (65%)	.48 (0%)				
Quality of Evidence[a]	Very low	Very low				

CI: confidence interval; RCT: randomized controlled trial; SMC: standardized mean change; SMD: standardized mean difference.

[a] High certainty: we are very confident that the true effect lies close to that of the estimate of the effect; moderate certainty: we are moderately confident in the effect estimate.; low certainty: our confidence in the effect estimate is limited; very low certainty: we have very little confidence in the effect estimate.

Randomized Controlled Trials

de Oliveira et al. (2022) conducted an RCT in 24 patients with subacromial pain syndrome who received exercise or exercise plus EMG biofeedback for 8 weeks. (36) The primary outcomes were pain and shoulder function. At 8 weeks, pain was better in the exercise-only group (mean numeric pain rating, 0.5 vs. 2 with exercise plus biofeedback; p=.01); however, this outcome was not different between groups at other time points. The only other significant finding was forward rotation of the scapula, which was better in the biofeedback group at 12 weeks (p=.006). All other outcomes were similar between groups.

Ribeiro and Silva (2019) published an RCT assessing whether visual feedback improves range of motion in patients with chronic idiopathic neck pain. (37) Forty-two patients from a single Portuguese clinic were included in the study and randomly assigned to either the visual feedback group (n=21) or the control group (n=21). There was no effect of time and intervention on pain intensity (p=.729), but there was a significant interaction between time and intervention in neck flexion (p<.001). The study was limited by its small sample size, short duration of intervention, and by the researcher assessing patients not being blinded.

<u>Orofacial Pain</u>

Systematic Reviews

A Cochrane review by Aggarwal et al. (2011) identified 17 trials evaluating nonpharmacologic psychological interventions for adults with chronic orofacial pain (e.g., temporomandibular joint disorder). (38) For studies reporting on short-term pain relief (≤3 months), a significantly greater reduction in pain was found for interventions that combined CBT plus biofeedback compared with usual care (2 studies; SMD, 0.46; 95% CI, 0.02 to 0.90). However, when reviewers assessed results from studies reporting on long-term pain relief (≥6 months), no significant benefit was found with a combined intervention of CBT plus biofeedback, and there were no studies that compared CBT alone with CBT plus biofeedback. For studies reporting on biofeedback-only interventions, a pooled analysis of 2 studies on short-term pain relief did not find a significant benefit compared with usual care (SMD, -0.41; 95% CI, -1.06 to 0.25). Only 1 study reported long-term pain relief after a biofeedback-only intervention, so a pooled analysis could not be done. Reviewers concluded that there was weak evidence to support psychosocial interventions for managing chronic orofacial pain and the most promising evidence was for CBT, with or without biofeedback. The authors noted that the trials comprising the review were few in number and had a high-risk of bias.

The conclusions drawn from this Cochrane review are similar to those of earlier systematic reviews on the treatment of temporomandibular joint disorder. (39, 40) These older reviews also concluded that there was weak evidence that psychosocial/physical therapy interventions (including biofeedback) are beneficial for treating temporomandibular joint disorder and that, of the few studies available, they tended to be of poor methodologic quality.

Abdominal Pain

Systematic Review

In a systematic review of therapies for recurrent abdominal pain in children by Weydert et al. (2003), the behavioral interventions of CBT and biofeedback had a generally positive effect on nonspecific recurrent abdominal pain and were deemed safe. (41) The specific effects of biofeedback were not isolated in this systematic review and therefore cannot be assessed.

Randomized Controlled Trial

In a study by Humphreys and Gevirtz (2000), 64 children and teenagers diagnosed with recurrent abdominal pain were randomized to groups treated with increased dietary fiber; fiber and biofeedback; fiber, biofeedback, and CBT; or fiber, biofeedback, CBT, and parental support. (6) The similar nature of the 3 multicomponent treatment groups was associated with greater pain reduction than the fiber-only group. This trial did not address placebo effects.

Fibromyalgia

Systematic Review

Glombiewski et al. (2013) published a systemic review and meta-analysis of RCTs reporting data on the efficacy of EMG and electroencephalography (EEG) biofeedback (i.e., neurofeedback) for treating patients with fibromyalgia. (42) Reviewers identified 7 RCTs that compared biofeedback with a control method in patients with fibromyalgia. Studies in which biofeedback was evaluated only as part of multicomponent interventions were excluded. Three studies used EEG biofeedback and 4 used EMG biofeedback (N=321 patients). A sham intervention was used

as a control condition in 4 studies, 2 using EEG biofeedback and 2 using EMG biofeedback. In a pooled analysis of the studies using EMG biofeedback, a significant reduction in pain intensity was found compared with a different intervention (effect size, Hedges *g*=0.86; 95% CI, 0.11 to 0.62). A pooled analysis of studies on EEG biofeedback did not find a significant benefit in pain reduction compared with control methods. Pooled analyses of studies of EMG and EEG biofeedback did not find a significant benefit of either intervention on other outcomes such as sleep problems, depression, and health-related quality of life. None of the studies reviewed were of high quality, with the risk of bias assessed as unclear or high for all included studies. In addition, all studies reported short-term outcomes, resulting in a lack of evidence on whether longer-term outcomes improved with these interventions.

Randomized Controlled Trials

In a small, double-blind RCT from Asia, Babu et al. (2007) compared actual and sham biofeedback for effects on pain, fitness, function, and tender points in 30 patients with fibromyalgia. (43) Pain reduction, as assessed on a VAS, did not differ significantly between groups. The trialists calculated that a sample size of 15 patients could detect a difference of 5 cm (on a 10-cm scale) on a VAS, suggesting that the trial lacked adequate power.

A larger unblinded RCT by van Santen et al. (2002) evaluated 143 women with fibromyalgia and compared EMG biofeedback with fitness training and usual care. (44) The primary outcome was pain measured on a VAS. Compared with usual care, the investigators reported no clear improvements in objective or subjective patient outcomes with biofeedback (or fitness training).

Another RCT on EMG biofeedback for fibromyalgia was conducted by Buckelew et al. (1998), and enrolled 119 patients; however, the trial did not follow a double-blind design. (45) Patients were randomized to 1 of 4 treatment groups: 1) biofeedback/relaxation training, 2) exercise training, 3) combination treatment, and 4) an educational/attention control program. While the combination treatment group had better tender point index scores than other treatment groups, this trial did not address placebo effects or the impact of adding biofeedback to relaxation therapy.

<u>Osteoarthritis</u>

Systematic Review

A systematic review by Macfarlane et al. (2012) evaluated practitioner-based complementary and alternative medicine treatments (defined as any treatment not taken orally or applied topically) for osteoarthritis and identified 2 trials on biofeedback. (46) One was an RCT by Yilmaz et al. (2010) that assessed whether the addition of EMG biofeedback to strengthening exercises improved outcomes in 40 patients with knee osteoarthritis. (47) After a 3-week treatment period, no significant differences between the 2 treatments regarding pain or quality of life were found. The other RCT by Durmus et al. (2007) compared electrical stimulation with biofeedback-assisted exercise in 50 women with knee osteoarthritis. (48) After 4 weeks of treatment, there were no statistically significant differences between groups in pain and functioning scores.

Systemic Lupus Erythematosus

Randomized Controlled Trial

In an RCT by Greco et al. (2004), of 92 patients with systemic lupus erythematosus, those treated with 6 sessions of biofeedback-assisted CBT for stress reduction had statistically greater reductions in pain posttreatment than a symptom-monitoring support group (p=.044) and a group receiving usual care (p=.028). (49) However, these reductions in pain were not sustained at a 9-month follow-up.

Vulvar Vestibulitis

Randomized Controlled Trial

A randomized study by Bergeron et al. (2001) of 78 patients with dyspareunia resulting from vulvar vestibulitis compared treatment with EMG biofeedback, surgery, or CBT. (50) Patients who underwent surgery had significantly lower pain scores than patients who received biofeedback or CBT. No placebo treatment was used.

Summary of Evidence

For individuals who have chronic pain (including low back, knee, neck and shoulder, orofacial, and abdominal pain as well as fibromyalgia, osteoarthritis, systemic lupus erythematosus, and vulvar vestibulitis) who receive biofeedback, the evidence includes multiple randomized controlled trials (RCTs) for different pain syndromes. Relevant outcomes are symptoms, functional outcomes, quality of life, and medication use. The results of these RCTs, some of which were sham-controlled, did not consistently report a benefit for biofeedback. Some RCTs reported improved outcomes with biofeedback, but these improvements were often of uncertain clinical significance or were not durable. Many other RCTs have found that biofeedback did not provide a significantly greater benefit in outcomes when it was used instead of or in addition to other conservative interventions such as exercise. Overall, the available RCTs were limited by small sample sizes and high dropout rates. This evidence base does not permit conclusions about the specific effects of biofeedback beyond the nonspecific effects of sham interventions, nor does it permit conclusions about the contribution of biofeedback beyond that of other conservative treatments for pain. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Practice Guidelines and Position Statements

American College of Occupational and Environmental Medicine

In 2020, the American College of Occupational and Environmental Medicine updated their guideline on noninvasive and minimally invasive management of low back disorders. (51) The role of biofeedback is not addressed in this updated guideline.

American Society of Anesthesiologists & American Society of Regional Anesthesia and Pain Medicine

In 2010, practice guidelines from the American Society of Anesthesiologists and the American Society of Regional Anesthesia and Pain Medicine suggested that "cognitive behavioral therapy,

biofeedback, or relaxation training.... may be used as part of a multimodal strategy for patients with low back pain, as well as for other chronic pain conditions." (52)

North American Spine Society

In 2020, the North American Spine Society published a guideline for the diagnosis and treatment of low back pain. (53) Although nonpharmacologic therapies are addressed in this guideline, the specific role of biofeedback for low back pain is not addressed.

U.S. Department of Veterans Affairs and U.S. Department of Defense

In 2022, the U.S. Department of Veterans Affairs and U.S. Department of Defense updated their guideline on the diagnosis and treatment of low back pain. (54) The guideline recommends several nonpharmacologic therapies for chronic low back pain (e.g., cognitive-behavioral therapy and/or mindfulness-based stress reduction, progressive relaxation, exercise including yoga, pilates, and tai chi) but does not address the role of biofeedback.

Ongoing and Unpublished Clinical Trials

Current ongoing and unpublished clinical trials that might influence this policy are listed in Table 5.

Table 5. Summary of Key Trials

NCT Number	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT04607460	Biofeedback EMG Alternative Therapy for Chronic Low Back Pain and Chronic Cancer Pain (BEAT-Pain): A Pilot Efficacy Study	330	Dec 2023 (recruiting)
Unpublished			
NCT05425121	Effects of Core Stability Exercises With Surface Electromyography Biofeedback on Postural Stability and Sensory Integration of Balance in Patients With Mechanical Low Back Pain	52	Dec 2024 (unknown status)

NCT: national clinical trial.

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	90875, 90876, 90901
HCPCS Codes	E0746

*Current Procedural Terminology (CPT®) ©2023 American Medical Association: Chicago, IL.

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Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been changed since this medical policy document was written. See Medicare's National Coverage at <https://www.cms.hhs.gov>.

Policy History/Revision

Date	Description of Change
01/01/2025	Document updated with literature review. Coverage unchanged. Added references 9, 11, 14, and 55.
01/01/2024	Reviewed. No changes.
01/15/2023	Document updated with literature review. Coverage unchanged. References 12, 14-17, 19-33, 50 and 51 added/updated; others removed.
02/01/2022	Reviewed. No changes.
10/01/2021	Document updated with literature review. Coverage unchanged. References 1-5, 29, 31, and 32 added; others removed.
01/15/2021	Reviewed. No changes.
05/15/2020	Document updated with literature review. Coverage unchanged. Reference 12 added; one reference removed.
02/15/2019	Reviewed. No changes.
06/15/2018	Document updated with literature review. Coverage unchanged. References 25, 26, and 29 added.
03/01/2017	Reviewed. No changes.
04/15/2016	Document updated with literature review. Coverage unchanged.
07/01/2015	Reviewed. No changes.
06/15/2014	Document updated with literature review. Coverage unchanged.
02/01/2013	New medical document. Biofeedback as a treatment of chronic pain, including but not limited to low back pain, is considered experimental, investigational and unproven. (Coverage is unchanged. This topic was previously addressed on PSY301.007 Biofeedback and Neurofeedback.)