**Biofeedback as a Treatment of Chronic Pain**

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**POLICY**

Biofeedback as a treatment of chronic pain, including but not limited to low back pain, is **investigational**.

**POLICY GUIDELINES**

See the Codes table for details.

**BENEFIT APPLICATION**

**BLUECARD/NATIONAL ACCOUNT ISSUES**

In many Plans, biofeedback is contractually excluded. If contractually excluded in the host Plan, but not in the home Plan, the host Plan may use this policy as the basis of coverage decisions for the home Plan.

Biofeedback may be offered as part of a comprehensive program in pain management as offered by pain management centers.

**BACKGROUND**

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
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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 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.

Biofeedback provides physiologic information not normally available to the patient, with a concerted effort employed by the patient to use this feedback to help alter the physiologic process in some specific way. 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. 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 successful alteration of that physiologic parameter in the form of lights or tone, verbal praise, or other auditory or visual stimuli.

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. Food and Drug Administration product code: HCC.

RATIONALE
The evidence review was created in April 1998 and has been updated regularly with searches of the MEDLINE database. The most recent literature update was performed through September 14, 2018.

This evidence review was informed by a TEC Assessment (1995), which concluded that evidence was insufficient to demonstrate the effectiveness of biofeedback for the treatment of chronic pain.¹

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are 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 a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one 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. RCTs 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 patients who have chronic pain is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The question addressed in this evidence review is: Does the use of EMG biofeedback improve the net health outcome in those who suffer from chronic pain?

The following PICOTS were used to select literature to inform this review.

Patients
The relevant population of interest is individuals who suffer from 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.

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

Timing
Biofeedback training is taught over a series of sessions, depending on the condition. Sessions can take up to 90 minutes.

Setting
Biofeedback may be administered, using different techniques and monitoring devices and sensors (eg, electromyograph), in an outpatient setting by psychiatrists, psychologists, and general practitioners.

General Chronic Pain
Several meta-analyses have reviewed RCTs assessing psychological therapies for a variety of nonheadache chronic pain conditions. A Cochrane review by Eccleston et al (2009) focused on chronic pain in adults. Two RCTs were identified that compared behavioral therapy with an active control designed to change behavior (ie, exercise or instruction). Three RCTs had sufficient follow-up to be included in a comparison of behavioral therapy and usual treatment. Reviewers found that although the quality of trial design had improved over time, there were too few studies to achieve a meaningful conclusion about the effects of behavioral therapy on pain, disability, or mood.

Another Cochrane review by Eccleston et al (2009) focused on children and adolescents with chronic and recurrent pain. Although psychological therapies were found to improve pain, only one of the 5
studies on nonheadache pain evaluated biofeedback. Biofeedback did not improve abdominal pain more than cognitive-behavioral therapy (CBT) in this trial (by Humphreys and Gevitz [2000]⁴; see section on Abdominal Pain). Palermo et al (2010) published an updated meta-analysis of studies on psychological therapies for the management of chronic pain in children and adolescents.⁵ They did not identify any new 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.⁶ 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**

At least 1 RCT has compared biofeedback with a sham intervention for 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.⁷ All participants were instructed to perform daily breathing exercises with a portable respiratory feedback machine; exercises were performed for 30 minutes on 15 consecutive days. Patients were randomized to an intervention group that received visual and auditory feedback of their breathing exercises or to a control group that received a proxy signal imitating breathing biofeedback. Patients recorded pain levels in a diary 3 times a day, measuring pain on a 10-point visual analog scale (VAS). Both groups showed a reduction in pain levels 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>0.05); mean change in pain at rest decreased by 0.79 points in the intervention group and 0.49 points in the control group (p>0.05).

Several trials with active comparison groups have not found that biofeedback is superior to alternative treatments. More recently, Tan et al (2015) evaluated 3 self-hypnosis interventions and included EMG biofeedback as a control intervention.⁸ 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=0.042).

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.⁹ Patients were randomized to one of 3 groups: CBT, CBT plus biofeedback, or a 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

Collins et al (2012) conducted a systematic review and meta-analysis of RCTs on nonsurgical interventions for anterior knee pain.¹⁰ 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 = -22; 95% CI, -0.65 to 0.20).
Chronic Neck and Shoulder Pain
Ma et al (2011) in Hong Kong published an RCT that included 72 patients with chronic (at least 3 months) computer work–related neck and shoulder pain. Patients were randomized to 1 of 4 of 6-week interventions: biofeedback, exercise, passive treatment (eg, hot packs), or a control group receiving only an educational pamphlet. Members of the biofeedback group were given a portable EMG biofeedback machine and were instructed to use it for 2 hours daily while performing computer work. The exercise group was given an active routine to perform on their own for no more than 20 minutes, 4 times a day. At the postintervention follow-up, 60 (83%) of 72 participants were available for assessment (n=15 per group). By the end of the intervention, the average VAS and Neck Disability Index scores were significantly lower (improved) in the biofeedback group than in the other 3 groups. The mean VAS score postintervention was 1.87 in the biofeedback group and 2.10 in the exercise group (p<0.05).

Although this trial found a short-term benefit of a biofeedback intervention, the magnitude of difference in the VAS and Neck Disability Index scores was small and of uncertain clinical significance. In addition, there were several methodologic limitations. The trial had a small sample size and had a substantial number of dropouts. The intensity of the interventions was unbalanced; eg, the biofeedback intervention was more intensive (2 h/d) than other interventions (eg, passive treatment), which received two 15-minute sessions per week. Long-term data were not available due to the low rate of follow-up; at 6 months, data were available on only 39 (54%) of 72 of participants, which was too small for meaningful analysis.

Orofacial Pain
A Cochrane review by Aggarwal et al (2011) identified 17 trials evaluating nonpharmacologic psychological interventions for adults with chronic orofacial pain (eg, temporomandibular joint disorder). 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. They 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 treatment of the temporomandibular joint disorder. These older reviews also concluded that there was weak evidence that psychosocial/physical therapy interventions (including biofeedback) are beneficial for treating the temporomandibular joint disorder and that, of the few studies available, they tended to be of poor methodologic quality.

Abdominal Pain

Systematic Reviews
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.\textsuperscript{15} The specific effects of biofeedback were not isolated in this systematic review and therefore cannot be assessed.

**Randomized Controlled Trials**

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.\textsuperscript{4} 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 Reviews**

Glombiewski et al (2013) published a systemic review and meta-analysis of RCTs reporting data on the efficacy of EMG and electroencephalography (EEG) biofeedback (ie, neurofeedback) for treating patients with fibromyalgia.\textsuperscript{16} Reviewers identified 7 RCTs that compared EEG 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 four used EMG biofeedback (total N=321 patients). A sham intervention was used as a control condition in 4 studies, two using EEG biofeedback and two 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 on short-term outcomes, resulting in a lack of evidence on whether longer term outcomes improved with these interventions. (For more information on EEG biofeedback, see evidence review 2.01.28.)

**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.\textsuperscript{17} 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 with usual care.\textsuperscript{18} 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).

In another large RCT on EMG biofeedback for fibromyalgia is that by Buckelew et al (1998), which enrolled 119 patients; however, the trial did not follow a double-blind design.\textsuperscript{19} Patients were randomized to one 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.
Osteoarthritis
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. 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. After a 3-week treatment period, no significant differences between the 2 treatment regimens were found. The other RCT, by Durmus et al (2007), compared electrical stimulation with biofeedback-assisted exercise in 50 women with knee osteoarthritis. After 4 weeks of treatment, there were no statistically significant differences between groups in pain and functioning scores.

Systemic Lupus Erythematosus
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=0.044) and a group receiving usual care (p=0.028). However, these reductions in pain were not sustained at 9-month follow-up.

Vulvar Vestibulitis
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. 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 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 the effects of the technology on health outcomes.

SUPPLEMENTAL INFORMATION

PRACTICE GUIDELINES AND POSITION STATEMENTS
American College of Physicians
The American College of Physicians (2017) issued practice guidelines on noninvasive treatments for acute, subacute, and chronic low back pain. For patients with chronic low back pain, the guidelines recommended that initial treatment should be nonpharmacologic, such as “exercise, multidisciplinary rehabilitation, acupuncture, mindfulness-based stress reduction, tai chi, yoga, motor control exercise, progressive relaxation, electromyography biofeedback, low-level laser therapy, operant therapy, cognitive behavior therapy or spinal manipulation” (strong recommendation).
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European League Against Rheumatism
The European League Against Rheumatism (2017) issued recommendations on the management of fibromyalgia based on systematic reviews published through May 2015. The multidisciplinary group used the 4-point scale of Grading of Recommendations Assessment, Development, and Evaluation system for making recommendations. The group rated biofeedback as “weak against,” which indicates that most people would, although a substantial minority would not, recommend biofeedback for the treatment of fibromyalgia.

American College of Occupational and Environmental Medicine
The guidelines by the American College of Occupational and Environmental Medicine (2016) recommended biofeedback for “highly select patients with chronic low back pain as part of a multidisciplinary rehabilitation program.” Biofeedback was not recommended for acute or subacute back pain.

American Society of Anesthesiologists et al
The practice guidelines from the American Society of Anesthesiologists and the American Society of Regional Anesthesia and Pain Medicine (2010) 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.”

U.S. PREVENTIVE SERVICES TASK FORCE RECOMMENDATIONS
Not applicable.

MEDICARE NATIONAL COVERAGE
Biofeedback therapy is covered by Medicare “only when it is reasonable and necessary for the individual patient for muscle reeducation of specific muscle groups or for treating pathologic muscle abnormalities of spasticity, incapacitating muscle spasm, or weakness, and more conventional treatments (heat, cold, massage, exercise, support) have not been successful. This therapy is not covered for treatment of ordinary muscle tension states or for psychosomatic conditions.”

ONGOING AND UNPUBLISHED CLINICAL TRIALS
Current ongoing clinical trials that might influence this review are listed in Table 1.

Table 1. Summary of Key Trials

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<td>NCT02426476</td>
<td>HRV Biofeedback in Pain Patients: Pilot Intervention for pain, Fatigue, and Sleep</td>
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<td>NCT03182556</td>
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NCT: national clinical trial.
ESSENTIAL HEALTH BENEFITS

The Affordable Care Act (ACA) requires fully insured non-grandfathered individual and small group benefit plans to provide coverage for ten categories of Essential Health Benefits (“EHBs”), whether the benefit plans are offered through an Exchange or not. States can define EHBs for their respective state.

States vary on how they define the term small group. In Idaho, a small group employer is defined as an employer with at least two but no more than fifty eligible employees on the first day of the plan or contract year, the majority of whom are employed in Idaho. Large group employers, whether they are self-funded or fully insured, are not required to offer EHBs, but may voluntary offer them.

The Affordable Care Act requires any benefit plan offering EHBs to remove all dollar limits for EHBs.

REFERENCES

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## CODES

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Original Policy Date: April 1998
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Policy updated with literature review through September 14, 2018; no references added; reference 27 updated. Policy statement unchanged.

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