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

### Related Policies

- Biofeedback as a Treatment of Fecal Incontinence or Constipation
- Biofeedback as a Treatment of Headache
- Biofeedback for Miscellaneous Indications
- Neurofeedback
- Urinary Incontinence Outpatient Treatment

### Policy

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

### Policy Guidelines

**Note:** Some Blue Shield of California (BSC) plans exclude coverage of biofeedback. Please check benefit plan descriptions for details.

**Biofeedback devices:** Unsupervised home use of a biofeedback device has not been well studied, and further is excluded from coverage per Blue Shield Evidence of Coverage (EOC) General Exclusions and Limitations.

### Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member’s contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program (FEP)) prohibit Plans from denying Food and Drug Administration (FDA) - approved technologies as
investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

**Rationale**

**Background**

Treatment for chronic pain is often multimodal and typically includes psychologic therapy. Psychologic techniques vary but may include cognitive therapy, which teaches subjects the ability to cope with stressful stimuli by attempting to alter negative thought 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 (CBT) program. Electromyography (EMG) biofeedback has also been used for the treatment of chronic pain, with the assumption that the ability to reduce muscle tension will be improved through feedback of data to the subject regarding degree of muscle tension. While some consider EMG biofeedback to be a method to obtain relaxation, others consider biofeedback to be distinct from other relaxation procedures.

Biofeedback provides physiologic information not normally available to the patient, with a concerted effort on the part of 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, nonarousing environment. Subjects are instructed to use mental techniques to affect the physiologic variable monitored, and feedback is provided for successful alteration of that physiologic parameter. The feedback may be in the form of lights or tone, verbal praise, or other auditory or visual stimuli.

Psychologic treatments involve both nonspecific and specific therapeutic effects. Nonspecific effects, sometimes called placebo effects, occur as a result of therapist contact, positive expectancies on the part of the subject and the therapist, and other beneficial effects that occur as a result of being a patient in a therapeutic environment. Specific effects are those that occur only because of the active treatment, above any nonspecific effects that may be present. The literature review focuses on identifying evidence that biofeedback's effects are not nonspecific placebo effects. Because an ideal placebo control is problematic with psychologic treatments and because treatment of chronic pain is typically multimodal, isolating the specific contribution of biofeedback is difficult. An ideal study design would be a randomized controlled trial (RCT) comparing biofeedback with a sham intervention; an alternative design would be an RCT comparing an intervention such as exercise with and without the addition of biofeedback.

**Literature Review**

This policy was originally based on a 1995 TEC Assessment, which concluded that evidence was insufficient to demonstrate the effectiveness of biofeedback for treatment of chronic pain. (1) The following is a summary of the key literature to date.

Several meta-analyses were identified that reviewed RCTs on psychologic therapies for a variety of nonheadache chronic pain conditions. A Cochrane review by Eccleston et al focused on chronic pain in adults; this systematic review was last updated in 2009. (2) Two
RCTs were identified that compared behavioral therapy against an active control designed to change behavior (e.g., exercise or instruction). Three RCTs had sufficient follow-up to be included in a comparison of behavioral therapy against usual treatment. The systematic review 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 focused on children and adolescents with chronic and recurrent pain. Although psychologic therapies were found to improve pain, only 1 of the 5 studies on nonheadache pain evaluated biofeedback. Biofeedback was not found to improve abdominal pain more than cognitive-behavioral therapy (CBT) in this trial (which was conducted by Humphreys and Gevirtz and is discussed in greater detail next, reference (4)). An updated meta-analysis of studies on psychologic therapies for management of chronic pain in children and adolescents was published by Palermo et al in 2010. The review did not identify any new randomized trials on biofeedback for managing nonheadache pain.

**RCTs and Meta-Analyses on Biofeedback for Specific Chronic Pain Conditions**

**Low Back Pain**

A 2010 Cochrane review on behavioral treatments for chronic low back pain included a meta-analysis of 3 small randomized trials comparing EMG biofeedback to a waiting-list control group. In the pooled analysis, there were a total of 34 patients in the intervention group and 30 patients in the control group. The standard mean difference 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. The Cochrane review did not conduct meta-analyses of trials comparing biofeedback with sham biofeedback and therefore did not control for any nonspecific effects of treatment.

Two randomized trials have compared biofeedback with a sham intervention for treatment of lower back pain; neither found a statistically significant benefit with real biofeedback. Bush et al randomized 62 patients to either EMG biofeedback, sham biofeedback, or a no treatment control group for the treatment of lower back pain. At the conclusion of the trial, all 3 groups showed significant improvement in multiple measures of pain. There were no significant effects found for treatment type, leading the authors to conclude that biofeedback is not superior to placebo in controlling chronic pain. More recently, in 2010, Kapitza et al compared the efficacy of respiratory biofeedback with sham biofeedback in 42 patients with lower back pain. 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 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 visual analog scale (VAS). Both groups showed reduction in pain levels at the end of the intervention period and at the 3-month follow-up, but there were no significant differences in pain between groups. For example, the mean change in pain with activity 3 months after the intervention was a reduction in 1.12 points on a 10-point VAS scale in the intervention group and 0.96 points in the sham control group (p > 0.05). The mean change in pain at rest after 3 months was a reduction of 0.79 points in the intervention group and 0.49 points in the control group (p > 0.05).

Another randomized trial, by Glombiewski et al, assessed whether the addition of EMG biofeedback to CBT improved outcomes in 128 patients with lower back pain. Patients
with musculoskeletal pain of the low, mid, or upper back, with pain duration of at least 6 months on most days of the week, were randomized to CBT, CBT plus biofeedback, or a waiting-list control; 116 patients began the 1-hour weekly sessions (17-25 treatments) and were included in the final analysis. CBT alone included breathing exercises and progressive muscle relaxation; biofeedback was used for 40% of the CBT treatment time in the combined treatment condition. Both treatments were found to improve outcomes including pain intensity compared with a 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

In 2012, Collins et al published a systematic review and meta-analysis of RCTs on nonsurgical interventions for anterior knee pain. 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 (standard mean difference [SMD] = -0.22; 95% CI, -0.65 to 0.20).

Chronic Neck and Shoulder Pain

In 2011, Ma et al 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 six-week interventions: Biofeedback, exercise, passive treatment (e.g., 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 active exercise group was given an exercise routine to perform on their own for no longer than 20 minutes, 4 times a day. Sixty of 72 (83%) participants were available for the postintervention follow-up assessment (n = 15 per group). At the end of the intervention, the average VAS score and Neck Disability Index (NDI) scores were significantly lower in the biofeedback group than in the other 3 groups. For example, the mean VAS postintervention was 1.87 (SD = 0.74) in the biofeedback group and 2.10 (SD = 1.34) in the active exercise group (p < 0.05). Data were available on only 39 of 72 (54%) of participants at 6 months.

This study found a short-term benefit of a biofeedback intervention, but the magnitude of difference in the VAS scores and the NDI was small and of uncertain clinical significance. In addition, there were several methodologic limitations. The study was of small size and had a substantial number of dropouts. The interventions were not balanced in intensity, as the biofeedback intervention was more intensive (2 hours per day) than the other interventions, such as the passive treatment arm, which received two 15-minute sessions per week. Long-term data were not available due to the low follow-up rate, which at 6 months was too small for meaningful analysis.

Orofacial Pain

A 2011 Cochrane review identified 17 trials evaluating nonpharmacologic psychologic interventions for adults with chronic orofacial pain (e.g., temporomandibular joint [TMJ] disorder). For the outcome short-term pain relief (≤3 months), there was a significantly greater reduction in pain with interventions that combined CBT and biofeedback compared with usual care (2 studies; SMD = 0.46; 95% CI, 0.02 to 0.90). However, there was not a significant benefit of a combined CBT/biofeedback on longer-term (i.e., 6-month pain relief), and there were no studies that compared CBT alone with CBT combined with biofeedback. For 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). There was only 1 study reporting long-term pain relief after a
biofeedback-only intervention, so a pooled analysis could not be conducted. The authors concluded that there is weak evidence to support psychosocial interventions for managing chronic orofacial pain and the most promising evidence is for CBT, with or without biofeedback. They noted that the trials in the review were few in number and had a high risk of bias, and they recommended additional high-quality trials.

Conclusions of the Cochrane review are similar to previous systematic reviews on treatment of TMJ disorder.(13,14) They also concluded that there is weak evidence that psychosocial/physical therapy interventions, including biofeedback among others, are beneficial for treating TMJ but that there were few studies and they tended to be of poor methodologic quality.

Fibromyalgia

In 2013, Glombiewski et al published a meta-analysis of studies on the efficacy of EMG and EEG biofeedback (i.e., neurofeedback) for treating patients with fibromyalgia.(15) The authors identified 7 RCTs comparing biofeedback with a control condition in patients with fibromyalgia syndrome. Studies in which biofeedback was evaluated only as part of multicomponent interventions were excluded from the review. Three studies used EEG biofeedback and 4 used EMG biofeedback; there were a total of 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, biofeedback significantly reduced pain intensity compared with a comparison 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 compared with control conditions. Pooled analyses of studies of EMG and EEG biofeedback did not find a significant benefit of the intervention on other outcomes including sleep problems, depression, and health-related quality of life. None of the studies included in this review were high quality, with risk of bias assigned by the authors as either unclear or high for all included studies. In addition, all of the studies reported on short-term outcomes, resulting in a lack of evidence on whether longer-term outcomes are improved. (For more information on EEG-biofeedback, see Blue Shield of California Medical Policy: Neurofeedback)

Representative RCTs on EMG biofeedback include a trial by Buckelew et al, which was one of the larger trials, enrolling 119 patients with fibromyalgia, but which was not double-blinded.(16) Patients were randomly assigned to 1 of 4 treatment groups: (1) biofeedback/relaxation, (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 study did not address placebo effects or the impact of adding biofeedback to relaxation therapy. In another of the larger, unblinded RCTs, Van Santen et al included 143 women with fibromyalgia, and biofeedback combined with fitness training was compared with usual care.(17) The primary outcome evaluated was pain using a VAS. The authors reported no clear improvements in objective or subjective patient outcomes with biofeedback (or fitness training) over usual care. A small, double-blinded randomized trial from Asia compared actual and sham biofeedback on pain, fitness, function, and tender points in 30 patients with fibromyalgia.(18) Pain reduction as assessed on a VAS scale did not differ significantly between groups. The authors calculated that a sample size of 15 patients could detect a difference of 5 cm (10 cm max) on a VAS, suggesting that the study lacked adequate power.

Abdominal Pain

Humphreys and Gevirtz(4) randomly assigned 64 patients to groups treated with increased dietary fiber; fiber and biofeedback; fiber, biofeedback, and CBT; or fiber,
biofeedback, CBT, and parental support. The 3 multicomponent treatment groups were similar and had better pain reduction than the fiber-only group. This study does not address placebo effects. In a systematic review of recurrent abdominal pain therapies in children, Weydert et al concluded that behavioral interventions (CBT and biofeedback) have a general positive effect on nonspecific recurrent abdominal pain and are safe. The specific effects of biofeedback were not isolated in this systematic review and cannot be assessed.

Arthritis

A 2012 meta-analysis of RCTs evaluating practitioner-based complementary and alternative medicine treatments (defined as any treatment not taken orally or applied topically) for osteoarthritis identified 2 trials on biofeedback. One was an RCT with 40 patients that assessed whether the addition of biofeedback to strengthening exercises improved outcomes in patients with osteoarthritis. After a 3-week treatment period, no significant differences between the 2 treatment conditions in pain or quality of life were found. The other RCT, published in 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 of 92 patients with systemic lupus erythematosus (SLE), Greco et al found patients treated with 6 sessions of biofeedback-assisted CBT for stress reduction had statistically significant greater improvements in pain posttreatment than a symptom-monitoring support group (p=0.044) and a usual care group (p=0.028). However, these improvements in pain were not sustained at 9 months' follow-up, and further studies are needed to determine the incremental benefits of biofeedback-assisted CBT over other interventions in patients with SLE.

Vulvar Vestibulitis

A randomized study by Bergeron et al of 78 patients with vulvar vestibulitis compared biofeedback, surgery, and CBT. Patients who underwent surgery had significantly better pain scores than patients who received biofeedback or CBT. No placebo treatment was used.

Ongoing Clinical Trials

A Study to Investigate the Effect of a New Postural Biofeedback Device on Low Back Pain (NCT01572779): This trial randomized 96 patients with moderate or severe low back pain to wear a back strain monitor with and without the addition of biofeedback. The biofeedback intervention involves cues to prompt patients to alter their posture or position. Primary study outcomes are pain and disability scales. As of February 2014, this study is active but is not recruiting patients.

Summary

Biofeedback, defined as patient self-regulation of certain physiologic processes not normally considered to be under voluntary control, has been investigated for a variety of chronic pain conditions. Most of the published randomized controlled trials have not found a significantly greater benefit when biofeedback is offered instead of or in addition to other conservative interventions (e.g., exercise). In addition, the available RCTs tended to have small sample sizes, were limited by high dropout rates, and/or did not find that the benefits of biofeedback were sustained over time. Questions remain
about the contribution of biofeedback beyond that of conservative treatments and about the specific effects of biofeedback beyond the nonspecific effects of similar sham interventions. The scientific evidence available at this time does not permit conclusions regarding the effect of this technology on health outcomes. Therefore, biofeedback for treating chronic pain is considered investigational.

**Practice Guidelines and Position Statements**

A 2011 guideline by the American College of Occupational and Environmental Medicine recommended biofeedback for “select patients with chronic low back pain as a component (not a separate procedure) of cognitive behavioral therapy (CBT) or as a procedure in the context of an interdisciplinary or functional rehabilitation program.” Biofeedback was not recommended for acute or subacute back pain.\(^{(26)}\)

A 2010 practice guideline by the American Society of Anesthesiologists Task Force on Chronic Pain Management and the American Society of Regional Anesthesia and Pain Medicine states that “cognitive behavioral therapy, biofeedback, or relaxation training: These interventions may be used as part of a multimodal strategy for patients with low back pain, as well as for other chronic pain conditions.”\(^{(27)}\)

**Medicare National Coverage**

Biofeedback therapy is covered under Medicare only when it is reasonable and necessary for the individual patient for muscle re-education 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.

**References**


**Documentation Required for Clinical Review**

- No records required

**Coding**

This Policy relates only to the services or supplies described herein. Benefits may vary according to benefit design; therefore, contract language should be reviewed before applying the terms of the Policy. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement.

**IE**

The following services are considered investigational and therefore not covered for any indication.

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<th>Type</th>
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<td><strong>CPT®</strong></td>
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<td>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</td>
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<td>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); 45 minutes</td>
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<td>Biofeedback training by any modality</td>
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Definitions of Decision Determinations

**Medically Necessary:** A treatment, procedure or drug is medically necessary only when it has been established as safe and effective for the particular symptoms or diagnosis, is not investigational or experimental, is not being provided primarily for the convenience of the patient or the provider, and is provided at the most appropriate level to treat the condition.

**Investigational/Experimental:** A treatment, procedure or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

**Split Evaluation:** Blue Shield of California / Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a Split Evaluation, where a treatment, procedure or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

Prior Authorization Requirements

This service (or procedure) is considered **medically necessary** in certain instances and **investigational** in others (refer to policy for details).

For instances when the indication is **medically necessary**, clinical evidence is required to determine **medical necessity**.

For instances when the indication is **investigational**, you may submit additional information to the Prior Authorization Department.

Within five days before the actual date of service, the Provider MUST confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should also be directed to the Prior Authorization Department. Please call 1-800-541-6652 or visit the Provider Portal www.blueshieldca.com/provider.
The materials provided to you are guidelines used by this plan to authorize, modify, or deny care for persons with similar illness or conditions. Specific care and treatment may vary depending on individual need and the benefits covered under your contract. These Policies are subject to change as new information becomes available.