Biofeedback is a technique intended to teach patients self-regulation of certain physiologic processes not normally considered to be under voluntary control. Biofeedback is frequently used in conjunction with other therapies (e.g., relaxation, behavioral management, medication) to reduce the severity and/or frequency of headaches.

Related Policies

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

Policy

Biofeedback may be considered medically necessary as part of the overall treatment plan for migraine and tension-type headache.

Biofeedback for the treatment of cluster headache is considered investigational.

Unsupervised home use of biofeedback for treatment of headache is considered not medically necessary.

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.

Biofeedback may require 10 to 20 office-based sessions of 30 to 60 minutes each.
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

Biofeedback 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 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 to 60 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 the physiologic parameter. This feedback may be signals such as lights or tone, verbal praise, or other auditory or visual stimuli.

The various forms of biofeedback differ mainly in the nature of the disease or disorder under treatment, the biologic variable that the subject attempts to control, and the information that is fed back to the subject. Biofeedback techniques include peripheral skin temperature feedback, blood-volume-pulse feedback (vasoconstriction and dilation), vasoconstriction training (temporalis artery), and electromyographic (EMG) biofeedback; these may be used alone or in conjunction with other therapies (e.g., relaxation, behavioral management, medication). In general, EMG biofeedback is used to treat tension headaches. With this procedure, electrodes are attached to the temporal muscles, and the patient attempts to reduce muscle tension. Feedback on achievement of a decrease in muscle tension is provided to the subject, reinforcing those activities (behaviors or thoughts) that are effective. Thermal biofeedback, in which patients learn to increase the temperature of their fingertips through the use of imagery and relaxation, is a commonly employed technique for migraine headaches. In this technique, a temperature sensor is placed on the finger, and the subject is taught to increase peripheral vasodilation by providing feedback on skin temperature, an effect that is mediated through sympathetic activity. The combination of thermal biofeedback and relaxation training has also been used to improve migraine symptoms. The pulse amplitude recorded from the superficial temporal artery has also been used to provide feedback. Temporal pulse amplitude (TPA) biofeedback has been used to treat both chronic tension type headaches and migraine headaches.

Regulatory Status

A variety of biofeedback devices are cleared for marketing through the U. S. Food and Drug Administration (FDA) 510(k) process. These devices are designated by FDA as class II with special controls and are exempt from the premarket notification requirements. FDA
defines a biofeedback device as “an instrument that provides a visual or auditory signal corresponding to the status of one or more of a patient's physiological parameters (e.g., brain alpha wave activity, muscle activity, skin temperature, etc.) so that the patient can control voluntarily these physiological parameters.”

**Adults**

A 2007 book chapter on integrative medicine states that biofeedback as part of a stress management program can provide significant benefit for patients with migraine and tension-type headache without adverse effects.(2) Meta-analysis of 25 controlled studies suggested that biofeedback is comparable with preventive pharmacotherapy. Another meta-analysis of 5 studies revealed a 37% improvement in headache symptoms associated with thermal biofeedback. There are no established criteria for predicting benefit, and the training requires a significant time commitment (e.g., 10 to 15 one-hour-long sessions plus home practice). Pharmacotherapy combined with biofeedback has not been studied for synergy. This is an important point because vascular reactivity (a major target in biofeedback training) may be modified by medications used for prevention (e.g., beta blockers), potentially limiting the effects of training.

In 2007 and 2008, Nestoriuc et al published systematic reviews of biofeedback for migraine and tension-type headaches.(3,4) The meta-analysis for treatment of migraine 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.(3) 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 3 months, and at least 4 patients per treatment group.(4) 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 2 therapies. Although these meta-analyses are limited by the inclusion of studies of poor methodologic quality, the authors did not find evidence of an influence of study quality or publication bias in their findings.

Verhagen et al published a systematic review of behavioral treatments for chronic tension-type headache in adults in 2009.(5) Eleven studies, including 2 studies with low risk of bias, compared biofeedback with waiting-list conditions. Results were found to be inconsistent due to low power, leading the authors to conclude that larger and more methodologically robust studies should be performed.

In 1 study, Martin et al compared cognitive behavioral therapy (CBT) versus temporal pulse amplitude (TPA) biofeedback (8 weekly sessions plus homework) or waiting-list control among patients who volunteered for a study of psychologic treatments.(6) Thirty patients with migraine and 21 with tension-type headaches were randomized to 1 of the 3 treatments; 51 completed the protocol (20% dropout) with no significant difference in loss to follow-up among the groups. Patient logs showed an average reduction in headaches of 68% for the CBT group, 56% for biofeedback, and 20% for the control condition. Clinically significant improvement, defined as at least 50% reduction in either headache rating or medication use, was observed in 78% of the CBT group, 63% of the biofeedback group, and 23% of the control group. The cognitive mediators (self-efficacy and locus of control) that had been hypothesized to underlie efficacy of both
biofeedback and CBT were not found to be associated with improvement for either treatment. Statistical analysis was limited by the small group sizes.

Some studies indicate that the physiologic parameter “fed back” to the patient may not be related to the pathophysiology of headache. For example, Andrasik and Holroyd examined the correlation between success in controlling scalp muscle tension and the reduction in headache symptoms. (7) Thirty patients with tension headaches were taught to decrease, keep stable, or increase frontal muscle tension but were all led to believe that they were decreasing muscle tone. Despite changes in muscle tone in the intended direction, the degree of headache relief was the same in all groups. In another similar study, patients who were told that they were successful at decreasing muscle tension, regardless of the actual results, achieved greater reduction in symptoms. (8) Similar results were reported in patients with migraine undergoing thermal biofeedback. (9)

**Children**

A meta-analysis by Trautmann et al in 2006 assessed psychologic treatments of recurrent tension headache or migraine in children. (10) Three studies were included that compared relaxation combined with biofeedback versus relaxation training alone. In general, small standardized effect sizes (0, 0.5, 0.25) were reported from the 3 studies for the addition of biofeedback on headache symptoms (frequency, intensity, duration of headache). Small standardized effect sizes were also reported for clinically significant changes (i.e., >50% reduction) in headache symptoms (0.20, 0.34, 0). A 2006 systematic review of nonpharmacologic treatments for migraine concluded that the literature at that time did not show clear effectiveness of biofeedback for migraine in children. (11)

A 2009 Cochrane review evaluated psychologic therapies for the management of chronic and recurrent pain in children and adolescents. (12,13) Twenty-one randomized controlled trials (RCTs) met inclusion criteria for the analysis on headache, including 3 trials with biofeedback and relaxation training and 3 trials with biofeedback and cognitive training. Clinically significant pain reduction was found with biofeedback (odds ratio, 23.34), but there was no significant effect on disability or emotional functioning. The authors concluded that psychologic treatments (including biofeedback as part of a treatment regimen) are effective in pain control for children with headache, and the benefits appear to be maintained.

In 2010, Gerber et al reported an RCT of a multimodal behavioral training program (n=19) compared with the “benchmark” of biofeedback (n=15) in pediatric patients 7 to 16 years of age with recurrent migraine and/or tension-type headache. (14) Patients with chronic daily headache (≥15 days per month) were excluded from the study. The multimodal behavioral educational group program included eight 90-minute sessions of training (diagnostic, educational, behavioral) for the children and four 120-minute sessions for their parents. Children in the biofeedback group underwent electromyographic (EMG) and thermal biofeedback once per week for 20 sessions (total of 900 minutes of training). During treatment, 5 patients withdrew because of difficulty with adherence (4 from the biofeedback group). At 6 months, children’s diaries indicated a 47% decrease in the intensity of headaches after biofeedback but no significant difference in the frequency or duration of headaches. Diary results are limited by the low (40%) completion rate. Questionnaire results from parents and children indicated a decrease in headache duration, frequency, and intensity. Diaries of daily living activities and a pediatric quality-of-life questionnaire indicated that after treatment, the children were less disturbed by their headaches in the domains of school, homework, and leisure time. There were no significant differences between the treatments, although power analysis indicated that 50 patients per group would be needed to detect differences.
Earlier work includes a study by Kroner-Herwig et al in 50 pediatric patients with either tension headaches or combined tension-migraine headaches. Four treatment groups were created, based on combinations of the presence or absence of parental involvement in treatment and whether patients received either relaxation training or biofeedback. A waiting-list control group was also included. Several analytic approaches were used, one of which found biofeedback to have better effects on pain than relaxation. Another study by Bussone et al compared biofeedback-assisted relaxation training in adolescents versus a control group, finding better pain improvement in the former group. Scharff et al enrolled 36 children and adolescents and randomized them to hand-warming biofeedback, to hand-cooling biofeedback, or to a waiting list. Patients treated with hand-warming biofeedback achieved greater degrees of clinical improvement than either of the other 2 groups. Hand-cooling biofeedback could be considered a placebo. Sartory et al randomly assigned 43 children to either relaxation training plus stress management, biofeedback plus stress management, or drug therapy with a beta-adrenergic blocking agent. Both the relaxation and biofeedback groups had better therapeutic outcomes than the drug therapy group.

Summary

Biofeedback is a technique intended to teach patients self-regulation of certain physiologic processes not normally considered to be under voluntary control and is frequently used in conjunction with other therapies (e.g., relaxation, behavioral management, medication) to reduce the severity and/or frequency of headaches. Based on clinical input, physician specialty society recommendations, and the evidence available at this time, biofeedback may be considered medically necessary to treat migraine and tension-type headaches when included in a comprehensive treatment program. Evidence is insufficient to evaluate the effect of biofeedback on cluster headaches. Biofeedback, along with other psychologic and behavioral techniques, such as relaxation training, may be particularly useful for children, pregnant women, and other adults who are not able to take medications.

Practice Guidelines and Position Statements

The National Institute of Neurologic Disorders and Stroke (2013) states that when headaches occur 3 or more times a month, preventive treatment is usually recommended. “Drug therapy, biofeedback training, stress reduction, and elimination of certain foods from the diet are the most common methods of preventing and controlling migraine and other vascular headaches. Regular exercise, such as swimming or vigorous walking, can also reduce the frequency and severity of migraine headaches. Drug therapy for migraine is often combined with biofeedback and relaxation training.”

The American Academy of Family Physicians’ 2000 guidelines on preventive therapy for migraines, based on evidence review by the U.S. Headache Consortium, recommend relaxation training, thermal biofeedback combined with relaxation training, EMG biofeedback, and cognitive-behavioral therapy as treatment options for prevention of migraine (Grade A recommendation). Relaxation techniques and biofeedback may be combined with preventative drug therapy to achieve additional clinical improvement (Grade B recommendation). According to the guidelines, nonpharmacologic therapy may be well-suited for patients who have exhibited a poor tolerance or poor response to drug therapy, who have a medical contraindication to drug therapy, and who have a history of long-term, frequent or excessive use of analgesics or other acute medications. Nonpharmacologic intervention may also be
useful in patients with significant stress or in patients who are pregnant, are planning to become pregnant, or are nursing.

The American Academy of Neurology’s recommendations for the evaluation and treatment of migraine headaches states that behavioral and physical interventions are used for preventing migraine episodes rather than for alleviating symptoms once an attack has begun.(22) Although these modalities may be effective as monotherapy, they are more commonly used in conjunction with pharmacologic management. Relaxation training, thermal biofeedback combined with relaxation training, electromyographic biofeedback, and cognitive-behavioral therapy may be considered treatment options for prevention of migraine. Specific recommendations regarding which of these to use for specific patients cannot be made.

In 2010, the European Federation of Neurological Societies gave an A-level recommendation for use of EMG biofeedback for the treatment of tension-type headache, based on the meta-analysis by Nestoriuc et al.(4,23) The guidelines state that the aim of EMG biofeedback is to help the patient to recognize and control muscle tension by providing continuous feedback about muscle activity. Sessions typically include an adaptation phase, baseline phase, training phase, during which feedback is provided, and a self-control phase, during which the patient practices controlling muscle tension without the aid of feedback.

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
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headache (an evidence-based review): report of the Quality Standards
23. Bendtsen L, Evers S, Linde M et al. EFNS guideline on the treatment of tension-type
(May 2014).
**Documentation Required for Clinical Review**

- History and physical and/or consultation notes including:
  - Type of headache requiring biofeedback
  - Treatment plan (including type of biofeedback and number of treatment sessions)

**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.*

**MN/IE**

*The following service/procedure may be considered medically necessary in certain instances and investigational in others. Services may be medically necessary when policy criteria are met. Services are considered investigational when the policy criteria are not met or when the code describes application of a product in the position statement that is investigational.*

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<th>Type</th>
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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.