

2.01.29	Biofeedback as a Treatment of Headache		
Original Policy Date:	September 30, 2014	Effective Date:	January 1, 2018
Section:	2.0 Medicine	Page:	Page 1 of 7

Policy Statement

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

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

Description

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 as a Treatment of Urinary Incontinence in Adults
- Biofeedback for Miscellaneous Indications

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)] prohibits 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.

Regulatory Status

A variety of biofeedback devices are cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. These devices are designated by the FDA as class II with special controls and are exempt from premarket notification requirements. The 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) so that the patient can control voluntarily these physiological parameters." FDA product code: HCC.

Rationale

Background

Biofeedback involves the feedback of a variety of types of physiologic 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 biofeedback; these may be used alone or in conjunction with other therapies (e.g., relaxation, behavioral management, medication). In general, electromyographic 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 biofeedback has been used to treat both chronic tension-type headaches and migraine headaches.

Literature Review

This review was originally informed by a 1995 Blue Cross Blue Shield Association Technology Evaluation Center (TEC) Assessment.¹

Assessment of efficacy for therapeutic intervention involves a determination of whether an intervention improves health outcomes. The optimal study design for this purpose is a randomized controlled trial (RCT) that includes clinically relevant measures of health outcomes. Nonrandomized comparative studies and uncontrolled studies can sometimes provide useful information on health outcomes but are prone to biases such as noncomparability of treatment groups, placebo effect, and variable natural history of the condition.

Migraine and Tension-Type Headache

Adults

In 2007 and 2008, Nestoriuc et al in Germany published systematic reviews on biofeedback for migraine and tension-type headaches.^{2,3} Meta-analysis for the treatment of migraine included 55 studies (randomized, pre-post, uncontrolled) with 39 controlled trials, reporting a medium effect size of 0.58 (pooled outcome of all biofeedback interventions) for treatment of migraine.² Effect sizes were computed using Hedges' *g*, which quantifies between-group treatment outcome differences (mean difference between 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.³ 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 were limited by the inclusion of studies of poor methodologic quality, reviewers did not find evidence of an influence of study quality or publication bias in their findings.

Verhagen et al (2009) in The Netherlands published a systematic review of behavioral treatments for chronic tension-type headache in adults.⁴ 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 reviewers to conclude that larger and more methodologically robust studies should be performed.

Children

In 2016, Stubberud et al reported a meta-analysis of biofeedback as prophylaxis for pediatric migraine.⁵ They identified 5 RCTs (total N=137 children and adolescents) that met inclusion criteria. Meta-analysis found that biofeedback reduced migraine frequency (mean difference in attacks per week, -1.97, 95% confidence interval, -2.72 to -1.21; $p<0.001$), attack duration (mean difference, -3.94; 95% confidence interval, -5.57 to -2.31; $p<0.001$) and headache intensity (mean difference, -1.77 out of 5; 95% confidence interval, -2.42 to -1.11; $p<0.001$) compared with wait-list controls. However, the identified studies had incomplete reporting and uncertain risk of bias, limiting confidence in the estimate.

A 2009 Cochrane review and a 2010 meta-analysis evaluated psychologic therapies for the management of chronic and recurrent pain in children and adolescents.^{6,7} Twenty-one 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. Reviewers 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.

Section Summary: Migraine and Tension-Type Headache

The evidence on biofeedback for the treatment of migraine and tension-type headache includes meta-analyses of numerous RCTs. Systematic reviews have found significant effects of biofeedback on headache frequency and intensity in both children and adults. Biofeedback in combination with relaxation is more effective than relaxation alone, suggesting that these act independently.

Cluster Headache

Only case reports and small case series were identified on the treatment of cluster headache with biofeedback. No controlled trials were found.

Summary of Evidence

For individuals who have migraine or tension-type headache who receive biofeedback, the evidence includes randomized controlled trials and systematic reviews of these trials. Relevant outcomes are symptoms, functional outcomes, and quality of life. The literature, which includes meta-analyses of a large number of controlled and uncontrolled studies, has suggested that this treatment can reduce the frequency and/or severity of migraine and tension-type headaches. Biofeedback, along with other psychologic and behavioral techniques (e.g., relaxation training) may be particularly useful for children, pregnant women, and other adults who are not able to take medications. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have cluster headache who receive biofeedback, the evidence includes case reports and small case series. Relevant outcomes are symptoms, functional outcomes, and

quality of life. No controlled trials were identified on biofeedback for cluster headache. The evidence is insufficient to determine the effects of the technology on health outcomes.

Supplemental Information

Clinical Input from Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

In response to requests from Blue Cross Blue Shield Association, input was received through 3 physician specialty societies and 3 academic medical centers (4 inputs) in 2009. Input considered biofeedback to be a reliable and appropriate nonpharmacologic option for treatment of headaches.

Practice Guidelines and Position Statements

Association for Applied Psychophysiology and Biofeedback

In 2013, the Association for Applied Psychophysiology and Biofeedback issued standards for performing biofeedback.⁸ The standards stated that biofeedback for the treatment of migraine and tension headache has been validated as being safe and effective for these particular conditions and that biofeedback is not used alone as a diagnostic tool or treatment; rather, it is an adjunctive tool to be used in combination with other standard interventions.

National Institute of Neurologic Disorders and Stroke

The National Institute of Neurologic Disorders and Stroke (2013) indicated that when headaches occur 3 or more times a month, preventive treatment is usually recommended⁹:

“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. Drug therapy for migraine is often combined with biofeedback and relaxation training.”

American Academy of Family Physicians

In 2000, the American Academy of Family Physicians published guidelines on preventive therapy for migraines.¹⁰ The guidelines recommended relaxation training, thermal biofeedback combined with relaxation training, electromyographic biofeedback, and cognitive-behavioral therapy as treatment options for prevention of migraine (grade A recommendation). Relaxation techniques and biofeedback may be combined with preventive 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 stressor in patients who are pregnant, are planning to become pregnant, or are nursing.

American Academy of Neurology

The American Academy of Neurology’s recommendations for the evaluation and treatment of migraine headaches, published in 2000, stated that behavioral and physical interventions are used for preventing migraine episodes rather than for alleviating symptoms once an attack has begun.¹¹ 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.

European Federation of Neurological Societies

In 2010, the European Federation of Neurological Societies¹² gave an A-level recommendation for the use of electromyographic biofeedback for the treatment of tension-type headache, based on the meta-analysis by Nestoriuc et al (2008).³ The guidelines stated that the aim of electromyographic 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.

U.S. Preventive Services Task Force Recommendations

Not applicable.

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.¹³ This therapy is not covered for treatment of ordinary muscle tension states or for psychosomatic conditions.

Ongoing and Unpublished Clinical Trials

A search of ClinicalTrials.gov in September 2017 did not identify any ongoing or unpublished trials that would likely influence this review.

References

1. Blue Cross and Blue Shield Association Technology Evaluation Center. Biofeedback. *Technology Assessment*. 1995;Volume 10:Tab 25.
2. Nestoriuc Y, Martin A. Efficacy of biofeedback for migraine: a meta-analysis. *Pain*. Mar 2007;128(1-2):111-127. PMID 17084028
3. Nestoriuc Y, Rief W, Martin A. Meta-analysis of biofeedback for tension-type headache: efficacy, specificity, and treatment moderators. *J Consult Clin Psychol*. Jun 2008;76(3):379-396. PMID 18540732
4. Verhagen AP, Damen L, Berger MY, et al. Behavioral treatments of chronic tension-type headache in adults: are they beneficial? *CNS Neurosci Ther*. Summer 2009;15(2):183-205. PMID 19499626
5. Stubberud A, Varkey E, McCrory DC, et al. Biofeedback as prophylaxis for pediatric migraine: a meta-analysis. *Pediatrics*. Aug 2016;138(2). PMID 27462067
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8. Association for Applied Psychophysiology and Biofeedback. Standards for Performing Biofeedback. 2013; <http://www.aapb.org/i4a/pages/index.cfm?pageid=3678#II>. Accessed September 21, 2017.
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10. Morey SS. Guidelines on migraine: part 4. General principles of preventive therapy. *Am Fam Physician*. Nov 15 2000;62(10):2359-2360, 2363. PMID 11126860
11. Silberstein SD. Practice parameter: evidence-based guidelines for migraine headache (an evidence-based review): report of the Quality Standards Subcommittee of the American Academy of Neurology. *Neurology*. Sep 26 2000;55(6):754-762. PMID 10993991

12. Bendtsen L, Evers S, Linde M, et al. EFNS guideline on the treatment of tension-type headache - report of an EFNS task force. *Eur J Neurol*. Nov 2010;17(11):1318-1325. PMID 20482606
13. Centers for Medicare & Medicaid Services. National Coverage Determination (NCD) for Biofeedback Therapy (30.1). n.d.; <https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=41&ncdver=1&bc=AgAAQAAAAAAAAAA%3d%3d&>. Accessed November 16, 2017.
14. Blue Cross Blue Shield Association. Medical Policy Reference Manual, No. 2.01.29 (November 2017).

Documentation for Clinical Review

Please provide the following documentation (if/when requested):

- 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 product 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 services may be considered medically necessary in certain instances and investigational in others. Services may be considered medically necessary when policy criteria are met. Services may be 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.

Type	Code	Description
CPT®	90875	Individual psychophysiological therapy incorporating biofeedback training by any modality (face-to-face with the patient), with psychotherapy (e.g., insight oriented, behavior modifying or supportive psychotherapy); 30 minutes
	90876	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
	90901	Biofeedback training by any modality
HCPCS	E0746	Electromyography (EMG), biofeedback device
ICD-10 Procedure	GZC9ZZZ	Biofeedback
ICD-10 Diagnosis	All Diagnoses	

Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

Effective Date	Action	Reason
09/30/2014	BCBSA Medical Policy adoption	Medical Policy Committee
01/01/2017	Policy Revision without position change	Medical Policy Committee
01/01/2018	Policy Revision without position change	Medical Policy Committee

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 (as applicable to your plan)

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 be directed to the Prior Authorization Department. Please call (800) 541-6652 or visit the provider portal at www.blueshieldca.com/provider.

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.