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Biofeedback as a Treatment of Headache

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Related Policies (if applicable)
None

Disclaimer

Carefully check state regulations and/or the member contract.
Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

Coverage

Biofeedback **may be considered medically necessary** as part of the overall treatment plan for migraine and tension-type headache. Initial coverage for these indications is limited to 20 office-based sessions. Requests for additional sessions are subject to medical necessity review.

Home use of biofeedback for treatment of headache **is considered not medically necessary**.

Biofeedback for the treatment of all other types of headache, including cluster headache, **is considered experimental, investigational and/or unproven**.

Policy Guidelines

None.

Description

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

Background

Headache Overview

Migraine, tension-type, and cluster headache are all primary headaches with distinct presentations. (1) Migraine is characterized by intense, often localized, pain or throbbing usually accompanied by nausea, vomiting, light and/or sound sensitivity. Tension headache pain tends to be less intense and may be bilateral or encircle the head. Both migraine and tension-type headache are relatively common conditions. Cluster headache occurs less frequently. Subjects with cluster headache have brief but intensely painful attacks that occur multiple times per day. Cluster attacks may last days, weeks, or months.

Biofeedback

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 the 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 the achievement of a decrease in muscle tension is provided to the subject, reinforcing those activities (behaviors or thoughts) that are effective. Thermal biofeedback is a commonly employed technique for migraine headache, in which patients learn to increase the temperature of their fingertips through the use of imagery and relaxation. 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.

Regulatory Status
A variety of biofeedback devices have been 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

Medical policies 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.

Migraine and Tension-Type Headache
Clinical Context and Therapy Purpose
The purpose of biofeedback for individuals who have migraines or tension-type headaches is to provide a treatment option that is an alternative to or an improvement on existing therapies.

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

Populations
The relevant population of interest is individuals with migraines or tension-type headaches.

Interventions
The therapy being considered is biofeedback.

Comparators
The following therapy is currently being used to treat migraines or tension-type headaches: standard therapy without biofeedback.

Outcomes
The general outcomes of interest are reductions on instances and intensity of migraines or tension-type headaches and reductions in medication usage. The intent of biofeedback use is for the prevention of migraine or tension-type headache. The American Headache Society (2) identified the following treatment goals of preventive biobehavioral therapy (including biofeedback):

- Reduced frequency and severity of headache;
- Reduced headache-related disability;
- Reduced reliance on poorly tolerated or unwanted pharmacotherapies;
- Enhanced personal control of migraine;
- Reduced headache-related distress and psychological symptoms.

Follow-up over the course of 10 to 20 sessions would be of interest to monitor for outcomes.

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

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

Adults
Systematic Reviews
Nestoriuc et al. (2007, 2008) published systematic reviews on biofeedback for migraines and tension-type headaches. (3, 4) Meta-analysis for the treatment of migraine included 55 studies (randomized, pre-post, uncontrolled) with 39 controlled trials, reporting a pooled medium effect size of 0.58 (95% confidence interval [CI], 0.52 to 0.65) for treatment of migraine. (3) Effect sizes were computed using Hedges' g, which quantifies between-group treatment outcome differences (mean difference [MD] between groups divided by the pooled standard deviation). For the treatment of tension-type headaches, 53 studies met criteria for analysis; they 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 (95% CI, 0.61 to 0.84) 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) conducted a systematic review of behavioral treatments for chronic tension-type headaches in adults. (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 reviewers to conclude that larger and more methodologically robust studies should be performed.

Martino Cinnera et al. (2023) conducted a systematic review and meta-analysis of electromyographic biofeedback for headache. A total of 29 RCTs were included in the systematic review, and 4 RCTs were included in the meta-analysis. (6) The headache types represented in the included studies were tension headache (69%), migraine (30%), and mixed types (1%). Risk of bias was generally low in the included studies, but about 60% of studies had concerns about potential deviations from the intended intervention. There was also high heterogeneity regarding patient demographics. The meta-analysis found no difference in headache frequency (p=.66), intensity (p=.99), or duration (p=.54) between electromyographic biofeedback and controls.

Children and Adolescents

Systematic Reviews

Stubberud et al. (2016) reported on a meta-analysis of biofeedback as prophylaxis for pediatric migraines. (7) They identified 5 RCTs (total n=137 children and adolescents) that met inclusion criteria. Mean age among the 5 included RCTs ranged from 10 to 13 years. Meta-analysis found that biofeedback reduced migraine frequency (MD in attacks per week, -1.97; 95% CI, -2.72 to -1.21; p<.001), attack duration (MD, -3.94; 95% CI, -5.57 to -2.31; p<.001), and headache intensity (MD, -1.77 out of 5; 95% CI, -2.42 to -1.11; p<.001) compared with wait-list controls. However, the identified studies had incomplete reporting and uncertain risk of bias, limiting confidence in the estimates.

Section Summary: Migraine and Tension-Type Headache

The evidence on biofeedback for the treatment of migraines and tension-type headaches 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

Clinical Context and Therapy Purpose

The purpose of biofeedback for patients who have cluster headache is to provide a treatment option that is an alternative to or an improvement on existing therapies.

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

Populations
The relevant population of interest is individuals with cluster headache.

Interventions
The therapy being considered is biofeedback.

Comparators
The following therapy is currently being used to treat cluster headache: standard therapy without biofeedback.

Outcomes
The general outcomes of interest are reductions on instances and intensity of cluster headache and reduction in medication usage. The intent of biofeedback use is for the prevention of cluster headache. The American Headache Society (2) identified the following treatment goals of preventive biobehavioral therapy (including biofeedback):

- Reduced frequency and severity of headache;
- Reduced headache-related disability;
- Reduced reliance on poorly tolerated or unwanted pharmacotherapies;
- Enhanced personal control of migraine;
- Reduced headache-related distress and psychological symptoms.

Follow-up over the course of 10 to 20 sessions would be of interest to monitor for outcomes.

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

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

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

Summary of Evidence
For individuals who have migraines or tension-type headaches who receive biofeedback, the evidence includes systematic reviews. 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 migraines 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 unable to take certain medications. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have cluster headache who receive biofeedback, the evidence includes small case series and case reports. 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 that the technology results in an improvement in the net health outcome.

Practice Guidelines and Position Statements

American Headache Society

In 2021, the American Headache Society released a consensus statement on integration of new migraine treatments into clinical practice, including biobehavioral therapies (cognitive behavioral therapy, biofeedback, and relaxation). (2) According to the consensus statement, "biobehavioral therapies have Grade A evidence supporting their use as preventive treatments in patients with migraine." The statement notes that biobehavioral therapies are particularly suited for the following individuals:

- Prefer nonpharmacologic interventions
- Have inadequate response, poor tolerance, or medical contraindications to specific pharmacologic treatments
- Are pregnant, lactating, or planning to become pregnant
- Have a history of acute medication overuse or medication-overuse headache
- Exhibit significant stress or deficient stress-coping skills
- Have high migraine-related disability, and/or low health-related quality of life, and/or comorbidities.

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 conditions and that biofeedback is not used alone as a diagnostic tool or treatment; rather, it is an adjunctive tool used in combination with other standard interventions.

Medicare National Coverage

Medicare covers biofeedback therapy "only when it is reasonable and necessary for the individual patient for muscle re-education of specific muscle groups or for treating pathological 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." (9)

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this policy are listed in Table 1.

Table 1. Summary of Key Trials

NCT Number	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT04607460	Biofeedback EMG Alternative Therapy for Chronic Low Back Pain and Chronic Cancer Pain (BEAT-Pain): A Pilot Efficacy Study	330	Dec 2023 (recruiting)
NCT03472092	Distinct Mechanisms of Cognitive Behavioral Therapy Effects in Youth With Migraine & Dissecting Neural Mechanisms Supporting Mind and Body Approaches to Pain Reduction in Youth With Migraine	215	Jun 2025

NCT: National Clinical Trial.

Coding

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

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

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

CPT Codes	90875, 90876, 90901
HCPCS Codes	E0746

*Current Procedural Terminology (CPT®) ©2024 American Medical Association: Chicago, IL.

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Centers for Medicare and Medicaid Services (CMS)

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

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

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

Policy History/Revision

Date	Description of Change
03/15/2025	Document updated with literature review. Coverage unchanged. Added reference 6; others updated and/or removed.
10/15/2024	Reviewed. No changes.
09/15/2023	Document updated with literature review. Coverage unchanged. Added reference 2; others removed.
10/01/2022	Document updated with literature review. Coverage unchanged. Added reference 11.

02/01/2022	Reviewed. No changes.
07/15/2021	Document updated with literature review. Coverage unchanged. Added references 1 and 8.
01/15/2021	Reviewed. No changes.
08/15/2020	Document updated with literature review. Coverage unchanged. References 1 and 10 added; other references updated or deleted.
02/15/2019	Document updated with literature review. Coverage unchanged. References 4 and 9 added and reference 8 updated; other references deleted.
04/15/2018	Reviewed. No changes
04/01/2017	Document updated with literature review. Coverage unchanged.
04/01/2016	Reviewed. No changes
07/15/2015	Document updated with literature review. Coverage unchanged.
09/01/2014	Reviewed. No changes.
02/01/2013	New medical document. The following changes were made: Biofeedback may be considered medically necessary as part of the overall treatment plan for migraine and tension-type headache. Initial coverage for these indications is limited to 20 training sessions. Requests for additional sessions are subject to medical necessity review. Home use of biofeedback for treatment of headache is considered not medically necessary. Biofeedback for the treatment of all other types of headache, including cluster headache is considered experimental, investigational and unproven. (This topic was previously addressed on PSY301.007 Biofeedback and Neurofeedback.)