2.01.29	Biofeedback as a Treatment of Headache		
Original Policy Date:	September 30, 2014	**Effective Date:**	February 1, 2024
Section:	2.0 Medicine	**Page:**	Page 1 of 10

Policy Statement

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

II. Biofeedback for the treatment of cluster headache is considered **investigational**.

III. Unsupervised home use of biofeedback for treatment of headache is considered **investigational**.

NOTE: Refer to Appendix A to see the policy statement changes (if any) from the previous version.

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 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

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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

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.

Literature Review

Evidence reviews assess the clinical evidence to determine whether the use of technology improves the net health outcome. Broadly defined, health outcomes are the length of life, quality of life, and ability to function¾including benefits and harms. Every clinical condition has specific outcomes that are important to patients and managing the course of that condition. Validated outcome measures

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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 technology, 2 domains are examined: the relevance and 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.

Promotion of greater diversity and inclusion in clinical research of historically marginalized groups (e.g., People of Color [African-American, Asian, Black, Latino and Native American]; LGBTQIA (Lesbian, Gay, Bisexual, Transgender, Queer, Intersex, Asexual); Women; and People with Disabilities [Physical and Invisible]) allows policy populations to be more reflective of and findings more applicable to our diverse members. While we also strive to use inclusive language related to these groups in our policies, use of gender-specific nouns (e.g., women, men, sisters, etc.) will continue when reflective of language used in publications describing study populations.

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 review.

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.

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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.

Review of Evidence

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.

Children and Adolescents

Systematic Reviews

Stubberud et al (2016) reported on a meta-analysis of biofeedback as prophylaxis for pediatric migraines.[6,] 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.

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Cluster Headache

Clinical Context and Therapy Purpose

The purpose of biofeedback for individuals 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 review.

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.

Review of Evidence

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

Supplemental Information

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

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.

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2009 Input
In response to requests, input was received from 3 physician specialty societies and 3 academic medical centers (4 inputs) while this policy was under review in 2009. Input considered biofeedback to be a reliable and appropriate nonpharmacologic option for the treatment of headaches.

Practice Guidelines and Position Statements
Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

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.[7,] 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.

U.S. Preventive Services Task Force Recommendations
Not applicable.

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." [8,]

Ongoing and Unpublished Clinical Trials
Some currently unpublished trials that might influence this review are listed in Table 1.

Table 1. Summary of Key Trials

NCT No.	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

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NCT No.	Trial Name	Planned Enrollment	Completion Date
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	Nov 2024

References

1. Baraness L, Baker AM. Acute Headache. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; Updated July 26, 2023. Accessed September 12, 2023.
2. Ailani J, Burch RC, Robbins MS. The American Headache Society Consensus Statement: Update on integrating new migraine treatments into clinical practice. Headache. Jul 2021; 61(7): 1021-1039. PMID 34160823
3. Nestoriuc Y, Martin A. Efficacy of biofeedback for migraine: a meta-analysis. Pain. Mar 2007; 128(1-2): 111-27. PMID 17084028
4. 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): 379-96. PMID 18540732
5. Verhagen AP, Damen L, Berger MY, et al. Behavioral treatments of chronic tension-type headache in adults: are they beneficial?. CNS Neurosci Ther. 2009; 15(2): 183-205. PMID 19499626
6. Stubberud A, Varkey E, McCrory DC, et al. Biofeedback as Prophylaxis for Pediatric Migraine: A Meta-analysis. Pediatrics. Aug 2016; 138(2). PMID 27462067
7. Association for Applied Psychphysiology and Biofeedback. Standards for Performing Biofeedback. 2013; https://aapb.org/Standards_for_Performing_Biofeedback. Accessed September 12, 2023.
8. Centers for Medicare & Medicaid Services. National Coverage Determination (NCD) for Biofeedback Therapy (30.1). n.d.; https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?NCDId=41&ncdver=1. Accessed September 12, 2023.

Documentation for Clinical Review

Please provide the following documentation:

- 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.

The following codes are included below for informational purposes. Inclusion or exclusion of a code(s) does not constitute or imply member coverage or provider reimbursement policy. Policy Statements are intended to provide member coverage information and may include the use of some codes for clarity. The Policy Guidelines section may also provide additional information for how to interpret the Policy Statements and to provide coding guidance in some cases.

Type	Code	Description
CPT®	90875	Individual psychophysiological therapy incorporating biofeedback training by any modality (face-to-face with the patient), with

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Type	Code	Description
		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 (egg, insight oriented, behavior modifying or supportive psychotherapy); 45 minutes
	90901	Biofeedback training by any modality
HCPCS	E0746	Electromyography (EMG), biofeedback device

Policy History

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

Effective Date	Action
09/30/2014	BCBSA Medical Policy adoption
01/01/2017	Policy Revision without position change
01/01/2018	Policy Revision without position change
02/01/2019	Policy Revision without position change
01/01/2020	Annual review. No change to policy statement. Literature review updated.
02/01/2024	Policy reactivated. Previously archived from 09/01/2020 to 01/31/2024.

Definitions of Decision Determinations

Medically Necessary: Services that are Medically Necessary include only those which have been established as safe and effective, are furnished under generally accepted professional standards to treat illness, injury or medical condition, and which, as determined by Blue Shield, are: (a) consistent with Blue Shield medical policy; (b) consistent with the symptoms or diagnosis; (c) not furnished primarily for the convenience of the patient, the attending Physician or other provider; (d) furnished at the most appropriate level which can be provided safely and effectively to the patient; and (e) not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the Member's illness, injury, or disease.

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 and Feedback (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

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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 at (800) 541-6652, or the Transplant Case Management Department at (800) 637-2066 ext. 3507708 or visit the provider portal at www.blueshieldca.com/provider.

We are interested in receiving feedback relative to developing, adopting, and reviewing criteria for medical policy. Any licensed practitioner who is contracted with Blue Shield of California or Blue Shield of California Promise Health Plan is welcome to provide comments, suggestions, or concerns. Our internal policy committees will receive and take your comments into consideration.

For utilization and medical policy feedback, please send comments to: MedPolicy@blueshieldca.com

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.

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Appendix A

POLICY STATEMENT	
BEFORE	**AFTER** Blue font: Verbiage Changes/Additions
Reactivated Policy **Policy Statement:** N/A	**Biofeedback as a Treatment of Headache 2.01.29** **Policy Statement:** I. Biofeedback may be considered **medically necessary** as part of the overall treatment plan for migraine and tension-type headache. II. Biofeedback for the treatment of cluster headache is considered **investigational**. III. Unsupervised home use of biofeedback for treatment of headache is considered **investigational**.

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