Biofeedback as a Treatment of Headache

Policy
Blue Cross and Blue Shield of Kansas City (Blue KC) may provide coverage for biofeedback as a treatment of headache when it is determined to be medically necessary because the criteria shown below are met.

Biofeedback and biofeedback devices are specifically excluded under many benefit plans. In addition, biofeedback and biofeedback devices may be considered behavioral training and education/training in nature, and such services are specifically excluded under many benefit plans.

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

When Policy Topic is not covered
Biofeedback for the treatment of cluster headache is investigational.

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

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

Description of Procedure or Service

<table>
<thead>
<tr>
<th>Populations</th>
<th>Interventions of interest are:</th>
<th>Comparators of interest are:</th>
<th>Relevant outcomes include:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Individuals:</td>
<td>- With migraine or tension-type headache</td>
<td>- Biofeedback</td>
<td>- Standard therapy without biofeedback</td>
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<tr>
<td>Individuals:</td>
<td>- With cluster headache</td>
<td>- Biofeedback</td>
<td>- Functional outcomes</td>
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<table>
<thead>
<tr>
<th>Outcomes</th>
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<tr>
<td>Relevant outcomes include:</td>
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<tr>
<td>- Symptoms</td>
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<tr>
<td>- Functional outcomes</td>
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<tr>
<td>- Quality of life</td>
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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.

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.

Clinical input and physician specialty society recommendations have strongly supported the use of biofeedback to treat migraine and tension-type headaches when included in a comprehensive treatment program.

**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 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 FDA as class II with special controls and are exempt from 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 (eg, brain alpha wave activity, muscle activity, skin temperature) so that the patient can control voluntarily these physiological parameters.” FDA product code: HCC.

**Rationale**

This evidence review was created in April 1998 and has been updated regularly with searches of the MEDLINE database. The most recent literature update was performed through September 6, 2018. This review was informed by a TEC Assessment (1995).

Evidence reviews 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 patients 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 question addressed in this evidence review is: Does the use of biofeedback improve the net health outcome in individuals who suffer from migraines or tension-type headaches?

The following PICOTS were used to select literature to inform this review.

Patients
The relevant population of interest is individuals who suffer from 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.

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

Setting
Biofeedback would be administered by therapists in an outpatient setting and may require electromyographic monitoring.

Adults
Nestoriuc et al (2007, 2008) published systematic reviews on biofeedback for migraines and tension-type headaches. 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. 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; they included controlled studies with standardized treatment outcomes, follow-up of at least 3 months, and at least 4 patients per treatment group. 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) conducted a systematic review of behavioral treatments for chronic tension-type headaches in adults. 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**

Stubberud et al (2016) reported on a meta-analysis of biofeedback as prophylaxis for pediatric migraine. 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 estimates.

A meta-analysis by Palermo et al (2010) and a Cochrane review by Eccleston et al (2009) evaluated psychological therapies for the management of chronic and recurrent pain in children and adolescents. 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 psychological treatments (including biofeedback as part of a treatment regimen) are effective in pain control for children with headache, and the benefits appeared to be maintained.

**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**
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 migraine or tension-type headache who receive biofeedback, the evidence includes RCTs 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 migraines and tension-type headaches. Biofeedback, along with other psychologic and behavioral techniques (eg, 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 a meaningful 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 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, 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 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 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.

**National Institute of Neurologic Disorders and Stroke**
The National Institute of Neurologic Disorders and Stroke (2018) indicated 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. Drug therapy for migraine is often combined with biofeedback and relaxation training.”

**American Academy of Neurology et al**
In 2013, the American Academy of Neurology and American Headache Society updated their joint practice guidelines on migraine prevention in adults; the use of biofeedback was not mentioned in the recommendations.

**European Federation of Neurological Societies**
In 2010, the European Federation of Neurological Societies 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). The guidelines stated that the aim of electromyographic biofeedback is to help patients 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 patients practice controlling muscle tension without the aid of feedback.

**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.”

**Ongoing and Unpublished Clinical Trials**
A search of ClinicalTrials.gov in September 2018 did not identify any ongoing or unpublished trials that would likely influence this review.

**REFERENCES**

Billing Coding/Physician Documentation Information

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<th>Description</th>
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<td>90875</td>
<td>Individual psychophysiological therapy incorporating biofeedback training by any modality (face-to-face with the patient), with psychotherapy (eg, insight oriented, behavior modifying or supportive psychotherapy); approximately 20-30 minutes</td>
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<td>E0746</td>
<td>Electromyography (EMG), biofeedback device</td>
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ICD-10 Codes

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<tr>
<th>Code</th>
<th>Description</th>
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<tr>
<td>G44.201-</td>
<td>Tension headache code range</td>
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Additional Policy Key Words
N/A

Policy Implementation/Update Information
7/1/08 New policy; considered investigational.
7/1/09 Policy statement revised to remove the investigational status of this therapy and to include medically necessary indications. Unsupervised home therapy is considered not medically necessary. This remains a benefit exclusion on most plans.
7/1/10 Policy statement revised to indicate biofeedback for the treatment of cluster headaches is investigational.
7/1/11 No policy statement changes.
7/1/12 No policy statement changes.
7/1/13 No policy statement changes.
7/1/14 No policy statement changes.
7/1/15 No policy statement changes.
7/1/16 No policy statement changes.
7/1/17 No policy statement changes.
7/1/18 No policy statement changes.
7/1/19 No policy statement changes.

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