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Medical Benefit		Effective Date: 10/01/11	Next Review Date: 05/21
Preauthorization	No	Review Dates: 11/08, 09/09, 09/10, 07/11, 07/12, 05/13, 05/14, 05/15, 05/16, 05/17, 05/18, 05/19, 05/20	

Preauthorization is not required.

The following protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.

Populations	Interventions	Comparators	Outcomes
Individuals: • With migraine or tension type headache	Interventions of interest are: • Biofeedback	Comparators of interest are: • Standard therapy without biofeedback	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life
Individuals: • With cluster headache	Interventions of interest are: • Biofeedback	Comparators of interest are: • Standard therapy without biofeedback	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life

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.

SUMMARY OF EVIDENCE

For individuals who have migraines or tension-type headaches who receive biofeedback, the evidence includes randomized controlled trials and systematic reviews of these trials. The 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 a meaningful improvement in the net health outcome.

For individuals who have cluster headaches who receive biofeedback, the evidence includes small case series and case reports. The 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.

POLICY

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

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

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

POLICY GUIDELINES

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

MEDICARE ADVANTAGE

Biofeedback is **not medically necessary** for the treatment of migraine and tension-type headache.

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, non-arousing 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.

RELATED PROTOCOLS

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

Services that are the subject of a clinical trial do not meet our Technology Assessment and Medically Necessary Services Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment and Medically Necessary Services Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

REFERENCES

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

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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 March 27, 2020.