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
The literature on biofeedback, which includes systematic reviews of a large number of controlled and uncontrolled studies, suggests that this treatment may reduce the number and/or severity of migraine and tension-type headaches. In addition, clinical input and physician specialty society recommendations strongly support the use of biofeedback to treat migraine and tension-type headaches when included in a comprehensive treatment program. Evidence is insufficient to evaluate the effect of biofeedback on cluster headaches. Biofeedback, along with other psychologic and behavioral techniques, such as relaxation training, may be particularly useful for children, pregnant women, and other adults who are not able to take medications.

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, 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 (EMG) biofeedback; these may be used alone or in conjunction with other therapies (e.g., relaxation, behavioral management, medication). In general, EMG 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.

**Regulatory Status**

A variety of biofeedback devices are cleared for marketing through the FDA 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 (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 Protocol criteria and are considered investigational. For explanation of experimental and investigational, please refer to the Technology Assessment 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.


25. National Coverage Determination (NCD) for BIOFEEDBACK Therapy (30.1).