Clinical Review Criteria
Biofeedback

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Criteria
For Medicare Members

<table>
<thead>
<tr>
<th>Source</th>
<th>Policy</th>
</tr>
</thead>
<tbody>
<tr>
<td>CMS Coverage Manuals</td>
<td>None</td>
</tr>
<tr>
<td>National Coverage Determinations (NCD)</td>
<td>Biofeedback Therapy (30.1).</td>
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<td></td>
<td>Biofeedback Therapy for the Treatment of Urinary Incontinence (30.1.1)</td>
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<tr>
<td>Local Coverage Determinations (LCD)</td>
<td>None</td>
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<tr>
<td>Local Coverage Article</td>
<td>None</td>
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</tbody>
</table>

For Non-Medicare Members

I. Biofeedback is covered for 1 of the following:
   A. Fecal Incontinence
   B. Tension or migraine headache if pharmacologic treatment inadequate or not indicated, by 1 or more of the following:
      ▪ Breast-feeding patient
      ▪ History of long-term, frequent, or excessive use of analgesic or medications that can aggravate headache
      ▪ Insufficient or no response to multiple pharmacologic treatment attempts
      ▪ Intolerance of multiple pharmacologic treatment attempts
      ▪ Patient attempting to become pregnant
      ▪ Pregnant patient

II. The following indications for biofeedback are not medically necessary. There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.
   • Abdominal pain, recurrent
   • Anxiety disorders
   • Arthritis
   • Asthma
   • Autism
   • Back pain
   • Bell's palsy
   • Bruxism and sleep bruxism
   • Cardiovascular disorders
   • Chronic fatigue
   • Chronic pain
   • Chronic obstructive pulmonary disease (COPD)
   • Depression
   • Epilepsy
   • Facial palsy
   • Fibromyalgia
• Hand hemiplegia
• Insomnia
• Knee pain
• Low back pain
• Low vision
• Lupus [systemic lupus erythematosus (SLE)]
• Motor function after stroke, injury, or lower limb surgery
• Movement disorders
• Myalgia or muscle pain
• Neck pain
• Orthostatic hypotension in patients with a spinal cord injury
• Post-traumatic stress disorder (PTSD)
• Raynaud’s disease
• Side effects of cancer chemotherapy
• Temporomandibular joint disorders
• Tinnitus
• Urinary disorders
• Post-prostatectomy urinary dysfunction
• Urinary incontinence in adults
• Urinary retention
• Vesicoureteral reflux
• Voiding dysfunction
• Vestibulodynia, vulvodynia, vulvar vestibulitis

**Biofeedback for the Treatment of Urinary Incontinence**
See the [Treatment of Urinary Incontinence criteria document](#)

**Neurofeedback for ADHD (EEG Biofeedback)**
See the [Neurofeedback criteria document](#)

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**Background**
Biofeedback is a technique designed to help individuals self-regulate certain physiological processes that are not normally considered to be under voluntary control or responses that are ordinarily easily regulated, but for which regulation has broken down due to trauma or disease. This is achieved through conveying audio and visual information about physiological processes such as blood pressure, heart rate, skin temperature, galvanic skin response (sweating), or muscle tension in real-time to raise awareness of physiological activities and train patients to control them. The goal of biofeedback is that eventually the patient will learn to control physiologic response without the aid of monitors (Kaiser 2011, Roditi 2011).

Different types of biofeedback include (Kaiser 2011, Magnusson 2008, Kapitza 2010):
• Electroencephalography (EEG) biofeedback, which monitors the activity of brain waves linked to different mental states.
• Electrocardiography (EKG) biofeedback, which tracks the patient’s heart rate.
• Electromyography (EMG) biofeedback, which uses sensors to measure tension in specific muscles.
• Galvanic skin response biofeedback, which uses sensors to signal anxiety based on the activity of a person’s sweat glands and the amount of perspiration on the skin.
• Skin temperature biofeedback, which involves attaching sensors to the fingers or feet to indicate stress when the temperature is low.
• Respiratory biofeedback, which uses sensors to measure breathing.
• Postural biofeedback, which uses sensors to measure body motion.

Biofeedback has been used to treat a variety of medical conditions such as urinary incontinence, ADHD, headaches, anxiety, and back pain.

**Evidence and Source Documents**
[Biofeedback for Anxiety Disorders](#)

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Biofeedback for Anxiety Disorders

02/13/2012: MTAC REVIEW

Evidence Conclusion: There is insufficient evidence to determine the safety and efficacy of biofeedback for the treatment of generalized anxiety disorders.

Articles: The literature search revealed several studies evaluating biofeedback for the treatment of generalized anxiety disorder. All of the studies had small sample sizes and the majority were published more than 20 years ago. The newest study was a randomized controlled trial that evaluated the efficacy of a biofeedback enhanced virtual reality system. This study was not selected for review as the treatment group contained only 4 subjects (Gorini 2010). Conclusion: There is insufficient evidence to determine the safety and efficacy of biofeedback for the treatment of generalized anxiety disorders.

The use of biofeedback for anxiety disorders does not meet the Kaiser Permanente Medical Technology Assessment Criteria.

Biofeedback for Chronic Back Pain

02/13/2012: MTAC REVIEW

Evidence Conclusion: The Kaiser review included four randomized controlled trials that ranged in size from 42 to 128 patients. Findings from these trials suggest that pain and disability improved with biofeedback, cognitive behavioral therapy (CBT), biofeedback plus CBT, placebo biofeedback, and rehabilitation; however, no significant differences were found between biofeedback and the other treatments. The body of evidence was limited by heterogeneity in the patient population, biofeedback protocols, and comparator treatments. Additionally, the studies were small with short follow-up periods. Biofeedback vs. CBT alone vs. waitlisted controls (Newton-John 1995) • N=44 • Type of biofeedback: Electromyography biofeedback (EMG). • Both the biofeedback and the CBT groups showed improvement in pain intensity, pain belief, and depression; however, there no significant differences between the two groups. There was no improvement in the waitlisted control group. Biofeedback plus CBT vs. CBT alone vs. waitlisted controls (Glombiewski 2010) • N=128 • Type of biofeedback: EMG • Both the combined group and the CBT alone group showed improvement in pain intensity compared to waitlisted control; however, there no significant differences between the two groups. Active biofeedback vs. placebo biofeedback (Kapitza 2010) • N=42 • Type of biofeedback: Respiratory biofeedback. • There was no significant difference in pain reduction between the two groups. Biofeedback plus rehabilitation vs. rehabilitation alone (Magnusson 2008) • N=47 • Type of biofeedback: Postural biofeedback. • Although the combined group showed improvements in pain, range of motion, and quality of life, the study did not report if they were statistically significantly different from the rehabilitation alone group. Conclusion: There is insufficient evidence to determine the safety and efficacy of biofeedback for the treatment of chronic back pain.

Articles: The 2007 American College of Physicians and the American Pain Society (ACP/APS) guideline evaluated the evidence on biofeedback for chronic back pain. The studies evaluating this treatment were of poor quality and therefore they were unable to evaluate the net benefits of biofeedback. The conclusions of the ACP/APS guideline were supported by a 2009 BMJ clinical © Kaiser Permanente Cooperative. All Rights Reserved. evidence review (Chou 2009). In 2011, the Kaiser Permanente Medical Technology Assessment Team (MTAT) also reviewed biofeedback for the treatment of chronic back pain. No additional studies were identified after the Kaiser review. The following technology assessments were selected for review: Kaiser Permanente TPMG New Medical Technologies. Biofeedback for chronic neck and low back pain. May 2011.

The use of biofeedback for back pain does not meet the Kaiser Permanente Medical Technology Assessment Criteria.

Biofeedback for Migraine and Tension Type Headaches

02/13/2012: MTAC Review

Evidence Conclusion: A recent meta-analysis that included 94 RCTs and quasi-experimental studies evaluate the efficacy of different types of biofeedback for the treatment of migraine and tension-type headaches. Results from this analysis suggest that biofeedback was more effective than no treatment for headache reduction in patients with migraine headache (small effect size); however, there was no significant difference between biofeedback and placebo or relaxation. For patients with tension-type headache, biofeedback was significantly more effective than no treatment, placebo, and relaxation for headache reduction (small to medium effect size). There was no significant difference between biofeedback treatment modalities for the reduction of migraine
headache pain (Nestouric 2008). A meta-analysis is only as good as the studies that it includes. The studies included in the meta-analysis had several limitations. • The majority of the studies included in the meta-analysis were small. The mean number of subjects per study was 40 for migraine studies and 45 for tension-type headache studies. • The type and number of sessions of biofeedback varied. • Several studies failed to describe basic treatment and patient characteristics. • Several studies used unstructured diagnostic systems. Conclusion: Migraine • Results from a recent meta-analysis suggest that biofeedback may be more effective than no treatment, but not placebo or relaxation for headache reduction. Tension-type headaches • Results from a recent meta-analysis suggest that biofeedback may be more effective than no treatment, placebo, and relaxation for headache reduction. • Another recent BMJ Clinical Evidence review found insufficient evidence to determine whether EMG biofeedback is effective for treating chronic tension-type headaches (Krishnan 2009).

**Articles:** Several meta-analyses and randomized controlled trials (RCTs) were identified that evaluated the efficacy of biofeedback for the treatment of migraine and tension-type headaches. The most recent meta-analysis was selected for review. A RCT published after the meta-analysis was also identified that evaluated the efficacy of a pain program that included education and training in pain theory plus EMG and temperature biofeedback compared to the pain program alone. This study was not selected for review due to methodological limitations (i.e., small sample size, high loss to follow-up, power not addressed, and baseline characteristics were not presented) (Mullally 2009). The following study was selected for review: Nestoriuc Y, Martin A, Rief W, Andrasik F. Biofeedback treatment for headache disorders: a comprehensive efficacy review. Appl Psychophysiology Biofeedback. 2008;33:125-140. See Evidence Table.

The use of biofeedback for Migraine and Tension-type Headaches does not meet the Kaiser Permanente Medical Technology Assessment Criteria.