I. POLICY

Biofeedback for migraine and tension-type headache
Biofeedback may be considered medically necessary as part of the overall treatment plan for migraine and tension-type headache. For the treatment of migraine and tension-type headaches, biofeedback may require 10 to 20 office-based sessions of 30 to 60 minutes each.

Biofeedback for chronic pain
Biofeedback as a treatment of chronic pain including, but not limited to, low back pain is considered investigational, as there is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

Biofeedback for constipation
Biofeedback for constipation in adults may be considered medically necessary for patients with dyssynergia-type constipation as demonstrated by meeting all 3 of the following criteria:

1. Symptoms of functional constipation that meet ROME III criteria (see Policy Guidelines).
2. Objective physiologic evidence of pelvic floor dyssynergia (see Policy Guidelines) demonstrated by inappropriate contraction of the pelvic floor muscles or less than 20% relaxation of basal resting sphincter pressure by manometry, imaging or EMG;
3. Failed a 3-month trial of standard treatments for constipation including laxatives, dietary changes, and exercises (as many of the previous as are tolerated).

Biofeedback is considered investigational as a treatment of constipation in adults and children in all other situations, as there is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.
Biofeedback for miscellaneous conditions.
Biofeedback is considered investigational as a treatment of the following miscellaneous conditions:

- asthma
- anxiety disorders
- autism
- insomnia
- sleep bruxism
- tinnitus
- movement disorders
- Bell’s palsy
- motor function after stroke, injury, or lower-limb surgery
- Raynaud’s disease
- orthostatic hypotension in patients with spinal cord injury
- hypertension
- cluster headaches
- fecal incontinence in adults and children
- urinary incontinence in adults
- constipation in children
- constipation in adults not due to pelvic dyssynergia
- pain management during labor

There is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure for the above indications.

**Home use of biofeedback**
Unsupervised home use of biofeedback is not medically necessary.

**Policy Guidelines**

Rome III Diagnostic Criteria for Functional Gastrointestinal Disorders

Rome III diagnostic criteria for functional constipation*

1. Must include two or more of the following:
   a. Straining during at least 25% of defecations
   b. Lumpy or hard stools in at least 25% of defecations
   c. Sensation of incomplete evacuation for at least 25% of defecations
   d. Sensation of anorectal obstruction/blockage for at least 25% of defecations

* Rome III diagnostic criteria for functional constipation
e. Manual maneuvers to facilitate at least 25% of defecations (e.g., digital evacuation, support of the pelvic floor)
f. Fewer than three defecations per week
2. Loose stools are rarely present without the use of laxatives
3. Insufficient criteria for irritable bowel syndrome

* Criteria fulfilled for the last 3 months with symptom onset at least 6 months prior to diagnosis.

Rome III diagnostic criterion for dyssynergic defecation:
Inappropriate contraction of the pelvic floor or less than 20% relaxation of basal resting sphincter pressure with adequate propulsive forces during attempted defecation

Guidance on biofeedback protocol
The recommended treatment course for patients with constipation who meet criteria is up to 6 biofeedback sessions over 3 months. This is consistent with the protocol used in key randomized trials showing benefit of biofeedback for selected patients

Neurofeedback

Neurofeedback, and EMG controlled neuromuscular electrical stimulation (e.g., the Care EMG™), are considered investigational, as there is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

Cross-reference:

MP-1.033 Sacral Nerve Neuromodulation/Stimulation and Pelvic Floor Stimulation Devices
MP-2.062 Temporomandibular Joint Dysfunction (TMJ)
MP-4.012 Urinary Incontinence Treatment (Including Periurethral Bulking Agents)
MP-6.020 Electrical Stimulation Modalities
MP-2.304 Pervasive Developmental Disorders
II. PRODUCT VARIATIONS

[N] = No product variation, policy applies as stated
[Y] = Standard product coverage varies from application of this policy, see below

[N] Capital Cares 4 Kids
[N] PPO
[N] HMO
[Y] SeniorBlue HMO**
[Y] SeniorBlue PPO**

*Biofeedback is a non-covered service. www.fepblue.org

**Refer to Centers for Medicare and Medicaid (CMS) National Coverage Determination (NCD) 30.1 Biofeedback Therapy and 30.1.1 Biofeedback Therapy for the Treatment of Urinary Incontinence. Also refer to Novitas Solutions Local Coverage Determination (LCD) L32943 Anorectal Manometry, Anal Electromyography, and Biofeedback Training for Perineal Muscles and Anorectal or Urethral Sphincters

III. DESCRIPTION/BACKGROUND

Biofeedback
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.

Background
Biofeedback involves the feedback of a variety of types of 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 physiological 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 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 individual attempts to control, and the information that is fed back to the individual. Biofeedback techniques include peripheral skin temperature feedback, blood-volume-pulse feedback (vasoconstriction and dilation), vasoconstriction training (temporalsis artery), and electromyographic (EMG) biofeedback; these may be used alone or in conjunction with other therapies (e.g., relaxation, behavioral management, medication).

Regulatory Status
A variety of biofeedback devices are cleared for marketing through the U. S. Food and Drug Administration (FDA) 510(k) process. These devices are designated by the FDA as class II with special controls and are exempt from the 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, etc.) so that the patient can control voluntarily these physiological parameters.”

Biofeedback as a Treatment of Headaches
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 individual, 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.

Biofeedback as a Treatment of Chronic Pain
Treatment for chronic pain is often multimodal and typically includes psychological therapy. Psychological techniques vary but may include cognitive therapy, which teaches subjects the ability to cope with stressful stimuli by attempting to alter negative thought and dysfunctional attitudes, and behavioral approaches to reduce muscle tension and break the pain cycle. Relaxation, using any of a variety of techniques including meditation or mental imagery, is considered a behavioral therapy that may be used alone or as a component of a cognitive-behavioral therapy (CBT) program. Electromyography (EMG) biofeedback has also been used
for the treatment of chronic pain, with the assumption that the ability to reduce muscle tension will be improved through feedback of data to the subject regarding degree of muscle tension. While some consider EMG biofeedback to be a method to obtain relaxation, others consider biofeedback to be distinct from other relaxation procedures.

**Biofeedback as a Treatment of Fecal Incontinence and Constipation**

Biofeedback, a technique intended to teach patients self-regulation of certain physiologic processes not normally considered to be under voluntary control, is used to treat a variety of conditions and is proposed as a treatment of fecal incontinence and constipation.

Fecal incontinence in adults is the recurrent uncontrolled passage of fecal material. Pathophysiology of the disorder ranges from abnormalities in intestinal motility (diarrhea or constipation), to poor rectal compliance, impaired rectal sensation, or weak or damaged pelvic floor muscles. There is no increase in mortality attributable to fecal incontinence. Morbidity includes skin breakdown and urinary tract infections. Fecal incontinence may affect quality of life through restricting work, recreation, and activities related to “getting out of the house,” impaired social role function, diminished sexual activity, and increase of social isolation due to embarrassment. Fecal incontinence can bring about loss of independence and mobility. It is the second most common reason for elderly institutionalization. The most common causes of fecal incontinence in adults are obstetric trauma coupled with age-related degeneration, previous anorectal surgery, rectal prolapse, and perineal trauma. In many individuals, the condition is multifactorial, involving a combination of structural, physiological, and psychosocial factors. Conventional interventions to treat fecal incontinence include dietary recommendations (e.g., fiber), bowel and toilet scheduling, and medications (e.g., bulking or antidiarrheal agents).

Constipation refers to infrequent bowel movements and difficulty expelling stool during defecation. Primary constipation is generally categorized into 3 groups. The most common type is normal-transit constipation in which there is a normal rate of stool movement, but patients feel constipated and may complain of abdominal pain and/or bloating. In the second type, slow-transit constipation, stool moves more slowly through the colon and individuals often experience a limited urge to defecate. The third type, dyssynergic defecation, refers to a loss of ability to coordinate contractions of the pelvic floor muscles and to relax the anal sphincter during defecation. Patients often report an inability to defecate despite the urge to do so. There are also secondary causes of constipation such as the use of certain medications, including opioids and psychoactive drugs; neurologic, endocrine, or metabolic disorders; structural abnormalities; and lifestyle factors. Conventional treatment includes dietary changes (i.e., adequate fiber and fluid intake), use of supplemental bulking substances, exercises, and medications.

In children, most cases of fecal incontinence and constipation are functional, in which structural, endocrine, or metabolic diseases have been ruled out. Factors contributing to functional incontinence and constipation are fear and/or pain associated with large, hard stools. This leads to retentive posturing in approximately half the children with chronic constipation (i.e., the avoidance of defecation by purposefully contracting the external anal sphincter, also termed
anismus or paradoxical sphincter contraction). Customary or conventional medical intervention includes dietary changes, bowel and toilet scheduling, softening agents, and education. Behavioral interventions aim at restoring normal bowel habits through toilet training, reward and incentive contingency management programs, desensitization of phobia and fear, or skill-building and goal-setting techniques with home practice. Counseling and psychotherapy provide support to the child and address social and psychological problems.

Biofeedback training for fecal incontinence focuses on improving the ability to voluntarily contract the external anal sphincter and puborectalis muscles in response to rectal filling and to decrease delay in response to a sensation of distension. For constipation, the aim of biofeedback is to teach patients how to tighten and relax their external anal sphincter in order to pass bowel movements.

Biofeedback attempts to improve rectal sensory perception, strength, coordination, or some combination of these three components. Sensory training involves inducing intrarectal pressure using a balloon feedback device. A manometric balloon probe is inserted into the rectum, and the balloon is filled with air to produce a sensation of rectal filling. Strength training uses either anal canal pressure (manometric) or intra-anal electromyography (EMG) feedback of pelvic floor muscles (PFM). The purpose is to strengthen the force of the PFM contraction without including rectal distention. Some training increases endurance (duration of external anal sphincter contraction), as well as peak strength. Coordination training uses pressure feedback of intrarectal balloon distention using a water-perfused catheter or Schuster-type balloon probe and PFM contractions in a simultaneous feedback display. The purpose of coordination training is to synchronize the contraction of the external anal sphincter with relaxation of the internal anal sphincter.

Biofeedback techniques convert the physiologic measures from an intra-anal EMG sensor, anal manometric probe (measuring intra-anal pressure), or perianal surface EMG electrodes to either visual or audio display for feedback. Ultrasound has also been used to show patients’ contraction of the anal sphincter on a screen. Biofeedback training is done alone, or in combination with other behavioral therapies designed to teach relaxation. Training sessions are performed in a quiet, non-arousing environment.

Biofeedback as a Treatment of Urinary Incontinence in Adults

Urinary Incontinence (UI) is a common condition defined as an involuntary leakage of urine. Women are twice as likely to be affected as men, and prevalence increases with age. The severity of incontinence affects quality of life and treatment decisions. The types of urinary incontinence include stress, urge, overflow, functional, and post-prostatectomy incontinence. Nonsurgical treatment options may include pharmacologic treatment, pelvic muscle exercises, bladder training exercises, electrical stimulation, and neuromodulation.
Biofeedback, in conjunction with pelvic floor muscle training (PFMT), is a possible treatment modality for stress, urge, mixed, and overflow urinary incontinence because it may enhance awareness of body functions and the learning of exercises to train pelvic muscles. There are several proposed methods of biofeedback that may be employed for the treatment of urinary incontinence (UI), including vaginal cones or weights, perineometers, and electromyographic (EMG) systems with vaginal and rectal sensors.

The various forms of biofeedback mainly differ in the nature of the disease or disorder under treatment, the biologic variable that the individual attempts to control, and the information that is fed back to the individual. Biofeedback techniques include peripheral skin temperature feedback, blood-volume-pulse feedback (vasoconstriction and dilation), vasoconstriction training (temporalis artery), and EMG biofeedback; these may be used alone or in conjunction with other therapies (e.g., relaxation, behavioral management, medication).

Biofeedback for Miscellaneous Indications

Biofeedback has been proposed as a treatment for a variety of diseases and disorders including anxiety, headaches, hypertension, movement disorders, incontinence, pain, asthma, Raynaud’s disease, and insomnia. The type of feedback used in an intervention e.g., visual, auditory, etc. depends on the nature of the disease or disorder under treatment.

Neurofeedback

Neurofeedback describes techniques of providing feedback about neuronal activity, as measured by electroencephalogram (EEG) biofeedback or functional magnetic resonance imaging (fMRI), in order to teach patients to self-regulate brain activity. Neurofeedback may utilize several techniques in an attempt to normalize unusual patterns of brain function in patients with central nervous system (CNS) disorders, such as attention deficit/hyperactivity disorder (ADHD), autism spectrum disorder, substance abuse, epilepsy, and insomnia.

Neurofeedback may be conceptualized as a type of biofeedback that has traditionally used the electroencephalogram (EEG) as a source of feedback data. Neurofeedback differs from traditional forms of biofeedback in that the information fed back to the patient (via EEG tracings or fMRI) is a direct measure of global neuronal activity, or brain state, compared to feedback of the centrally regulated physiologic processes, such as tension of specific muscle groups or skin temperature. The patient may be trained to either increase or decrease the prevalence, amplitude, or frequency of specified EEG waveforms (e.g., alpha, beta, theta waves), depending on the changes in brain function associated with the particular disorder. It has been proposed that training of slow cortical potentials (SCPs) can regulate cortical excitability and that using the EEG as a measure of CNS functioning can help train patients to modify or control their abnormal brain activity. Upregulating or downregulating neural activity with real-time feedback of fMRI signals is also being explored.

Neurofeedback is being investigated for the treatment of a variety of disorders including attention deficit/hyperactivity disorder (ADHD), learning disabilities, Tourette syndrome,
autism spectrum disorder traumatic brain injury, seizure disorders, menopausal hot flashes, panic and anxiety disorders, fibromyalgia, tinnitus, substance abuse disorders, depression, stress management, migraine headaches, Parkinson’s disease and sleep disorders. Two EEG training protocols, training of SCPs and theta/beta training, are typically used in children with ADHD. For training of SCPs, surface-negative SCPs and surface-positive SCPs are generated over the sensorimotor cortex. Negative SCPs reflect increased excitation and occur during states of behavioral or cognitive preparation, while positive SCPs are thought to indicate reduction of cortical excitation of the underlying neural networks and appear during behavioral inhibition. In theta/beta training, the goal is to decrease activity in the EEG theta band (4-8 hertz [Hz]) and increase activity in the EEG beta band (13-20 Hz), corresponding to an alert and focused but relaxed state. Alpha-theta neurofeedback is typically used in studies on substance abuse. Neurofeedback protocols for depression focus on alpha interhemispheric asymmetry and theta/beta ratio within the left prefrontal cortex. Neurofeedback for epilepsy has focused on sensorimotor rhythm up-training (increasing 12-15 Hz activity at motor strip) or altering SCPs. It has been proposed that learned alterations in EEG patterns in epilepsy are a result of operant conditioning and are not conscious or voluntary. A variety of protocols have been described for treatment of migraine headaches.

IV. RATIONALE

Biofeedback as Treatment of Headache

This policy was originally based on a 1995 TEC Assessment, (1) and has since been updated periodically using the MEDLINE database. The most recent literature search was performed through March 26, 2013.

Adults

A 2007 book chapter on integrative medicine states that biofeedback as part of a stress management program can provide significant benefit for patients with migraine and tension-type headache without side effects. (2) Meta-analysis of 25 controlled studies suggested that biofeedback is comparable to preventive pharmacotherapy. Another meta-analysis of 5 studies revealed a 37% improvement in headache symptoms associated with thermal biofeedback. There are no established criteria for predicting benefit, and the training requires a significant time commitment (e.g., 10 to 15 one-hour-long sessions plus home practice). Pharmacotherapy combined with biofeedback has not been studied for synergy. This is an important point because vascular reactivity (a major target in biofeedback training) may be modified by medications used for prevention (e.g., beta blockers), potentially limiting the effects of training.

In 2007 and 2008, Nestoriuc and colleagues published systematic reviews of biofeedback for migraine and tension-type headaches. (3, 4) The meta-analysis for treatment of migraine included 55 studies (randomized, pre-post, and uncontrolled) and 39 controlled trials, reporting
a medium effect size of 0.58 (pooled outcome of all available headache variables) for treatment of migraine. (3) Effect sizes were computed using Hedges g, which refers to the mean difference between the experimental and control groups divided by the pooled standard deviation. For treatment of tension-type headaches, 53 studies met criteria for analysis; these 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 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 two therapies. Although these meta-analyses are limited by the inclusion of studies of poor methodologic quality, the authors did not find evidence of an influence of study quality or publication bias in their findings.

Verhagen and colleagues published a systematic review of behavioral treatments for chronic tension-type headache in adults in 2009. (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 the authors to conclude that larger and more methodologically robust studies should be performed.

In one study, Martin et al. compared cognitive behavioral therapy (CBT) versus temporal pulse amplitude (TPA) biofeedback (8 weekly sessions plus homework) or waiting-list control among patients who volunteered for a study of psychological treatments. (6) Thirty patients with migraine and 21 with tension-type headaches were randomized to 1 of the 3 treatments; 51 completed the protocol (20% dropout) with no significant difference in loss to follow-up among the groups. Patient logs showed an average reduction in headaches of 68% for the CBT group, 56% for biofeedback, and 20% for the control condition. Clinically significant improvement, defined as at least 50% reduction in either headache rating or medication use, was observed in 78% of the CBT group, 63% of the biofeedback group, and 23% of the control group. The cognitive mediators (self-efficacy and locus of control) that had been hypothesized to underlie efficacy of both biofeedback and CBT were not found to be associated with improvement for either treatment. Statistical analysis was limited by the small group sizes.

Some studies indicate that the physiologic parameter "fed back" to the patient may not be related to the pathophysiology of headache. For example, Andrasik and Holroyd examined the correlation between success in controlling scalp muscle tension and the reduction in headache symptoms. (7) Thirty patients with tension headaches were taught to decrease, keep stable, or increase frontal muscle tension but were all led to believe that they were decreasing muscle tone. Despite changes in muscle tone in the intended direction, the degree of headache relief was the same in all groups. In another similar study, patients who were told that they were successful at decreasing muscle tension, regardless of the actual results, achieved greater reduction in symptoms. (8) Similar results were reported in patients with migraine undergoing thermal biofeedback.(9)
Children

A meta-analysis by Trautmann et al. in 2006 assessed psychological treatments of recurrent tension headache or migraine in children. (10) Three studies were included that compared relaxation combined with biofeedback versus relaxation training alone. In general, small standardized effect sizes (0, 0.5, and 0.25) were reported from the 3 studies for the addition of biofeedback on headache symptoms (frequency, intensity, and duration of headache). Small standardized effect sizes were also reported for clinically significant changes (i.e., greater than 50% reduction) in headache symptoms (0.20, 0.34, and 0). A 2006 systematic review of nonpharmacologic treatments for migraine concluded that the literature at that time did not show clear effectiveness of biofeedback for migraine in children. (11)

A 2009 Cochrane review evaluated psychological therapies for the management of chronic and recurrent pain in children and adolescents. (12, 13) Twenty-one randomized controlled trials (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. The authors concluded that psychological treatments (including biofeedback as part of a treatment regimen) are effective in pain control for children with headache, and the benefits appear to be maintained.

In 2010, Gerber et al. reported an RCT of a multi-modal behavioral training program (n=19) compared to the “benchmark” of biofeedback (n=15) in pediatric patients 7 to 16 years of age with recurrent migraine and/or tension-type headache. (14) Patients with chronic daily headache (>15 days per month) were excluded from the study. The multi-model behavioral educational group program included eight 90-minute sessions of training (diagnostic, educational, and behavioral) for the children and four 120-minute sessions for their parents. Children in the biofeedback group underwent electromyographic (EMG) and thermal biofeedback once per week for 20 sessions (total of 900 minutes of training). During treatment, 5 patients withdrew due to difficulty with adherence (4 from the biofeedback group). At 6 months, children’s diaries indicated a 47% decrease in the intensity of headaches after biofeedback but no significant difference in the frequency or duration of headaches. Diary results are limited by the low (40%) completion rate. Questionnaire results from parents and children indicated a decrease in headache duration, frequency, and intensity. Diaries of daily living activities and a pediatric quality-of-life questionnaire indicated that after treatment, the children were less disturbed by their headaches in the domains of school, homework, and leisure time. There were no significant differences between the treatments, although power analysis indicated that 50 patients per group would be needed to detect differences.

Earlier work includes a study by Kroner-Herwig et al. in 50 pediatric patients with either tension headaches or combined tension-migraine headaches. (15) Four treatment groups were created, based on combinations of the presence or absence of parental involvement in treatment and whether patients received either relaxation training or biofeedback. A waiting-list control group was also included. Several analytic approaches were used, one of which found biofeedback to have better effects on pain than relaxation. Another study by Bussone et al.
compared biofeedback-assisted relaxation training in adolescents versus a control group, finding better pain improvement in the former group. (16) Scharff et al. enrolled 36 children and adolescents and randomized them to hand-warming biofeedback, to hand-cooling biofeedback, or to a waiting list. (17) Patients treated with hand-warming biofeedback achieved greater degrees of clinical improvement than either of the other two groups. Hand-cooling biofeedback could be considered a placebo. Sartory et al. randomly assigned 43 children to either relaxation training plus stress management, biofeedback plus stress management, or drug therapy with a beta-adrenergic blocking agent. (18) Both the relaxation and biofeedback groups had better therapeutic outcomes than the drug therapy group.

Clinical Input Received through Physician Specialty Societies and Academic Medical Centers

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

Summary

Biofeedback is a technique intended to teach patients self-regulation of certain physiologic processes not normally considered to be under voluntary control and is frequently used in conjunction with other therapies (e.g., relaxation, behavioral management, medication) to reduce the severity and/or frequency of headaches. Based on clinical input, physician specialty society recommendations, and the evidence available at this time, biofeedback may be considered medically necessary 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 psychological 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.

Practice Guidelines and Position Statements

The National Institute of Neurologic Disorders and Stroke (2013) states that when headaches occur 3 or more times a month, preventive treatment is usually recommended.(19) “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. Regular exercise, such as swimming or vigorous walking, can also reduce the frequency and severity of migraine headaches. Drug therapy for migraine is often combined with biofeedback and relaxation training.”

The American Academy of Family Physicians’ (AAFP) 2000 guidelines on preventive therapy for migraines, based on evidence review by the U.S. Headache Consortium, recommend
relaxation training, thermal biofeedback combined with relaxation training, EMG biofeedback, and cognitive-behavioral therapy as treatment options for prevention of migraine (Grade A recommendation). (20, 21) Relaxation techniques and biofeedback may be combined with preventative drug therapy to achieve additional clinical improvement (Grade B recommendation). According to the guidelines, nonpharmacologic therapy may be well-suited for patients who have exhibited a poor tolerance or poor response to drug therapy, who have a medical contraindication to drug therapy, and who have a history of long-term, frequent or excessive use of analgesics or other acute medications. Nonpharmacologic intervention may also be useful in patients with significant stress or in patients who are pregnant, are planning to become pregnant, or are nursing.

The American Academy of Neurology’s (AAN) recommendations for the evaluation and treatment of migraine headaches states that behavioral and physical interventions are used for preventing migraine episodes rather than for alleviating symptoms once an attack has begun. (22) Although these modalities may be effective as monotherapy, they are more commonly used in conjunction with pharmacologic management. Relaxation training, thermal biofeedback combined with relaxation training, electromyographic biofeedback, and cognitive-behavioral therapy may be considered treatment options for prevention of migraine. Specific recommendations regarding which of these to use for specific patients cannot be made.

In 2010, the European Federation of Neurological Societies (EFNS) gave an A-level recommendation for use of EMG biofeedback for the treatment of tension-type headache, based on the meta-analysis by Nestoriuc et al. (4, 23) The guidelines state that the aim of EMG biofeedback is to help the patient 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 the patient practices controlling muscle tension without the aid of feedback.

**Biofeedback as a Treatment of Chronic Pain**

Psychological treatments involve both nonspecific and specific therapeutic effects. Nonspecific effects, sometimes called placebo effects, occur as a result of therapist contact, positive expectancies on the part of the subject and the therapist, and other beneficial effects that occur as a result of being a patient in a therapeutic environment. Specific effects are those that occur only because of the active treatment, above any nonspecific effects that may be present. The literature review focuses on identifying evidence that biofeedback’s effects are not nonspecific placebo effects. Because an ideal placebo control is problematic with psychological treatments and because treatment of chronic pain is typically multimodal, isolating the specific contribution of biofeedback is difficult. An ideal study design would be a randomized controlled trial (RCT) comparing biofeedback to a sham intervention; an alternative design would be an RCT comparing an intervention such as exercise with and without the addition of biofeedback.
Literature Review

This policy was originally based on a 1995 TEC Assessment, which concluded that evidence was insufficient to demonstrate the effectiveness of biofeedback for treatment of chronic pain. (1) The policy was updated regularly with searches of the MEDLINE database. The most recent literature search was performed for the period January 2012 through January 28, 2013. Following is a summary of the key literature to date:

Several meta-analyses were identified that reviewed RCTs on psychological therapies for a variety of non-headache chronic pain conditions. One Cochrane review by Eccleston and colleagues focused on chronic pain in adults; this systematic review was last updated in 2009. (2) Two RCTs were identified that compared behavioral therapy against an active control designed to change behavior (e.g., exercise or instruction). Three RCTs had sufficient follow-up to be included in a comparison of behavioral therapy against usual treatment. The systematic review found that, although the quality of trial design had improved over time, there were too few studies to achieve a meaningful conclusion about the effects of behavioral therapy on pain, disability, or mood.

Another Cochrane review by Eccleston and colleagues focused on children and adolescents with chronic and recurrent pain. (3) Although psychological therapies were found to improve pain, only 1 of the 5 studies on non-headache pain evaluated biofeedback. Biofeedback was not found to improve abdominal pain more than cognitive-behavioral therapy (CBT) in this trial (which was conducted by Humphreys and Gevirtz and is discussed in greater detail below, reference (4)). An updated meta-analysis of studies on psychological therapies for management of chronic pain in children and adolescents was published by Palermo and colleagues in 2010. (5) The review did not identify any new randomized trials on biofeedback for managing non-headache pain.

RCTs and meta-analyses on biofeedback for specific chronic pain conditions

Lower Back Pain

A 2010 Cochrane review on behavioral treatments for chronic low back pain included a meta-analysis of 3 small randomized trials comparing electromyography (EMG) biofeedback to a waiting-list control group. (6) In the pooled analysis, there were a total of 34 patients in the intervention group and 30 patients in the control group. The standard mean difference in short-term pain was -0.80 (95% confidence interval [CI]: -1.32 to -0.28); this difference was statistically significant favoring the biofeedback group. The Cochrane review did not conduct meta-analyses of trials comparing biofeedback to sham biofeedback and therefore did not control for any non-specific effects of treatment.

Two randomized trials have compared biofeedback to a sham intervention for treatment of lower back pain; neither found a statistically significant benefit with real biofeedback. Bush and colleagues randomized 62 patients to either EMG biofeedback, sham biofeedback, or a no treatment control group for the treatment of lower back pain. (7) At the conclusion of the trial, all 3 groups showed significant improvement in multiple measures of pain. There were no significant effects found for treatment type, leading the authors to conclude that biofeedback is
not superior to placebo in controlling chronic pain. More recently, in 2010, Kapitza and colleagues compared the efficacy of respiratory biofeedback to sham biofeedback in 42 patients with lower back pain. (8) All participants were instructed to perform daily breathing exercises with a portable respiratory feedback machine; exercises were performed for 30 minutes on 15 consecutive days. Patients were randomized to an intervention group that received visual and auditory feedback of their breathing exercises or a control group that received a proxy signal imitating breathing biofeedback. Patients recorded pain levels in a diary 3 times a day, measuring pain on a visual analogue scale (VAS). Both groups showed reduction in pain levels at the end of the intervention period and at the 3 month follow-up, but there were no significant differences in pain between groups. For example, the mean change in pain with activity 3 months after the intervention was a reduction in 1.12 points on a 10-point VAS scale in the intervention group and 0.96 points in the sham control group; p>0.05. The mean change in pain at rest after 3 months was a reduction of 0.79 points in the intervention group and 0.49 points in the control group; p>0.05.

Another randomized trial, by Glombiewski and colleagues, assessed whether the addition of EMG biofeedback to CBT improved outcomes in 128 patients with lower back pain. (9) Patients with musculoskeletal pain of the low, mid, or upper back, with pain duration of at least 6 months on most days of the week, were randomized to CBT, CBT plus biofeedback, or a waiting-list control; 116 patients began the 1-hour weekly sessions (17-25 treatments) and were included in the final analysis. CBT alone included breathing exercises and progressive muscle relaxation; biofeedback was used for 40% of the CBT treatment time in the combined treatment condition. Both treatments were found to improve outcomes including pain intensity compared to a waiting-list control (moderate effect size of 0.66 for pain intensity in the CBT plus biofeedback group). However, the addition of biofeedback did not improve outcomes over CBT alone.

**Chronic Knee Pain**

In 2012, Collins and colleagues published a systematic review and meta-analysis of RCTs on nonsurgical interventions for anterior knee pain. (10) In a pooled analysis of data from 2 trials, there was no significant benefit of adding EMG biofeedback to an exercise-only intervention at 8 to 12 weeks (standard mean difference [SMD]: -22, 95% CI: -0.65 to 0.20).

**Chronic Neck and Shoulder Pain**

In 2011, Ma and colleagues in Hong Kong published an RCT that included 72 patients with chronic (at least 3 months) computer work-related neck and shoulder pain. (11) Patients were randomized to 1 of 4 6-week interventions: Biofeedback, exercise, passive treatment (e.g., hot packs), or a control group receiving only an educational pamphlet. Members of the biofeedback group were given a portable EMG biofeedback machine and were instructed to use it for 2 hours daily while performing computer work. The active exercise group was given an exercise routine to perform on their own for no longer than 20 minutes, 4 times a day. Sixty of 72 (83%) participants were available for the post-intervention follow-up assessment (n=15 per group). At the end of the intervention, the average VAS score and neck disability index (NDI) scores were significantly lower in the biofeedback group than in the other 3 groups. For example, the mean
VAS post-intervention was 1.87 (standard deviation [SD]: 0.74) in the biofeedback group and 2.10 (SD: 1.34) in the active exercise group, p<0.05. Data were available on only 39 of 72 (54%) of participants at 6 months.

This study found a short-term benefit of a biofeedback intervention, but the magnitude of difference in the VAS scores and the NDI index was small and of uncertain clinical significance. In addition, there were several methodologic limitations. The study was of small size and had a substantial number of dropouts. The interventions were not balanced in intensity, as the biofeedback intervention was more intensive (2 hours per day) than the other interventions, such as the passive treatment arm, which received two 15-minute sessions per week. Long-term data were not available due to the low follow-up rate, which at 6 months was too small for meaningful analysis.

Orofacial Pain

A 2011 Cochrane review identified 17 trials evaluating non-pharmacological psychological interventions for adults with chronic orofacial pain, e.g., temporomandibular joint (TMJ) disorder. (12) For the outcome short-term pain relief (3 months or less), there was a significantly greater reduction in pain with interventions that combined cognitive-behavioral therapy (CBT) and biofeedback compared to usual care (2 studies, SMD: 0.46, 95% CI: 0.02 to 0.90). However, there was not a significant benefit of a combined CBT/biofeedback on longer-term i.e., 6-month pain relief, and there were no studies that compared CBT alone to CBT combined with biofeedback. For biofeedback-only interventions, a pooled analysis of 2 studies on short-term pain relief did not find a significant benefit compared to usual care (SMD: -0.41, 95% CI: -1.06 to 0.25). There was only 1 study reporting long-term pain relief after a biofeedback-only intervention, so a pooled analysis could not be conducted. The authors concluded that there is weak evidence to support psychosocial interventions for managing chronic orofacial pain and the most promising evidence is for CBT, with or without biofeedback. They noted that the trials in the review were few in number and had a high risk of bias, and they recommended additional high-quality trials.

Conclusions of the Cochrane review are similar to previous systematic reviews on treatment of TMJ disorder. (13, 14) They also concluded that there is weak evidence that psychosocial/physical therapy interventions, including biofeedback among others, are beneficial for treating TMJ but that there were few studies and they tended to be of poor methodologic quality.

Fibromyalgia

Buckelew et al. assessed the use of biofeedback for fibromyalgia with a total of 119 patients who were randomly assigned to 1 of 4 treatment groups: 1) biofeedback/relaxation, 2) exercise training, 3) combination treatment, and 4) an educational/attention control program. (15) While the combination treatment group had better tender point index scores than other treatment groups, this study does not address placebo effects or the impact of adding biofeedback to relaxation therapy. In an RCT of 143 females with fibromyalgia, biofeedback and fitness training were compared to usual care by van Santen and colleagues. (16) The primary outcome
evaluated was pain using a VAS. The authors reported no clear improvements in objective or subjective patient outcomes with biofeedback (or fitness training) over usual care. A small double-blinded randomized trial from Asia compared actual and sham biofeedback on pain, fitness, function, and tender points in 30 patients with fibromyalgia. (17) Pain reduction as assessed on a VAS scale did not differ significantly between groups. The authors calculated that a sample size of 15 patients could detect a difference of 5 cm (10 cm max) on a VAS, suggesting that the study lacked adequate power.

**Abdominal Pain**

Humphreys and Gevirtz (4) randomly assigned 64 patients to groups treated with increased dietary fiber; fiber and biofeedback; fiber, biofeedback, and cognitive-behavioral therapy; or fiber, biofeedback, cognitive-behavioral therapy, and parental support. The 3 multicomponent treatment groups were similar and had better pain reduction than the fiber-only group. This study does not address placebo effects. In a systematic review of recurrent abdominal pain therapies in children, Weydert and colleagues concluded that behavioral interventions (cognitive-behavioral therapy and biofeedback) have a general positive effect on nonspecific recurrent abdominal pain and are safe. (18) The specific effects of biofeedback were not isolated in this systematic review and cannot be assessed.

**Arthritis**

A 2012 meta-analysis of RCTs evaluating practitioner-based complementary and alternative medicine treatments (defined as any treatment not taken orally or applied topically) for osteoarthritis identified 2 trials on biofeedback. (19) One was an RCT with 40 patients that assessed whether the addition of biofeedback to strengthening exercises improved outcomes in patients with osteoarthritis. (20) After a 3-week treatment period, no significant differences between the 2 treatment conditions in pain or quality of life were found. The other RCT, published in 2007, compared electrical stimulation to biofeedback-assisted exercise in 50 women with knee osteoarthritis. (21) After 4 weeks of treatment, there were no statistically significant differences between groups in pain and functioning scores.

**Systemic Lupus Erythematosus**

In an RCT of 92 patients with systemic lupus erythematosus (SLE), Greco and colleagues found patients treated with 6 sessions of biofeedback-assisted CBT for stress reduction had statistically significant greater improvements in pain post-treatment than a symptom-monitoring support group (p=0.044) and a usual care group (p=0.028). (22) However, these improvements in pain were not sustained at 9 months’ follow-up, and further studies are needed to determine the incremental benefits of biofeedback-assisted CBT over other interventions in patients with SLE.

**Vulvar Vestibulitis**

A randomized study by Bergeron and colleagues of 78 patients with vulvar vestibulitis compared biofeedback, surgery, and CBT. (23) Patients who underwent surgery had significantly better pain scores than patients who received biofeedback or cognitive-behavioral therapy. No placebo treatment was used.
Ongoing clinical trials

A Study to Investigate the Effect of a New Postural Biofeedback Device on Low Back Pain (NCT01572779) (24): This trial is randomizing 48 patients with moderate or severe low back pain to wear a back strain monitor with and without the addition of biofeedback. The biofeedback intervention involves cues to prompt the patient to alter their posture or position. Primary study outcomes are pain and disability scales.

Summary

Biofeedback, defined as patient self-regulation of certain physiological processes not normally considered to be under voluntary control, has been investigated for a variety of chronic pain conditions. Most of the published RCTs have not found a significantly greater benefit when biofeedback is offered instead of or in addition to other conservative interventions e.g. exercise. In addition, the available RCTs tended to have small sample sizes, were limited by high drop-out rates, and/or did not find that the benefits of biofeedback were sustained over time. Questions remain about the contribution of biofeedback beyond that of conservative treatments and about the specific effects of biofeedback beyond the non-specific effects of similar sham interventions. The scientific evidence available at this time does not permit conclusions regarding the effect of this technology on health outcomes. Therefore, biofeedback for treating chronic pain is considered investigational.

Practice Guidelines and Position Statements

A 2010 practice guideline by the American Society of Anesthesiologists Task Force on Chronic Pain Management and the American Society of Regional Anesthesia and Pain Medicine states that “cognitive behavioral therapy, biofeedback, or relaxation training: These interventions may be used as part of a multimodal strategy for patients with low back pain, as well as for other chronic pain conditions”. (25)

Biofeedback as a Treatment of Fecal Incontinence and Constipation

This policy is updated regularly with searches of the MEDLINE database. The most recent literature search was performed for the period July 2011 through November 2012. Following is a summary of the key literature to date:

Several methodologic difficulties exist in assessing biofeedback. For example, most interventions that include biofeedback are multimodal and include relaxation and behavioral instruction, which may have effects separate from those that may occur due to biofeedback. While studies may report a beneficial effect of multimodality treatment, without appropriate control conditions, it is impossible to isolate the specific contribution of biofeedback to the overall treatment effect. For example, relaxation, attention, or suggestion may account for the successful results that have been attributed to biofeedback. These are nonspecific therapeutic factors, some of which can be considered placebo effects. Moreover, it is important that studies demonstrate that biofeedback improves disease-related health outcomes, as opposed to potentially affecting only physiologic, intermediate outcomes, and that they address the durability of effects beyond the initial, short-term biofeedback training period.
The relevant clinical outcome for biofeedback as a treatment in incontinence should be an overall change in the patient’s symptoms. Reduction in episodes of fecal incontinence and increase in voluntary bowel movements are the primary clinical outcomes, and these are typically reported as the percentage of individuals cured or improved. Achieving normal defecation dynamics (e.g., anal pressure, squeeze pressure, sensory threshold, rectal inhibitory reflex, or defecation dynamics) does not correspond with symptom relief (i.e., clinical outcomes). Anorectal physiology measurements are a poor proxy for changes in clinical symptoms. Patient symptoms are usually assessed through diary, questionnaire, or interview (completed by the patient and, in the case of children, parents).

Fecal incontinence

*Does the addition of biofeedback to standard care reduce fecal incontinence, compared to standard care alone?*

**Adults**

Numerous randomized controlled trials (RCT) on biofeedback treatment for fecal incontinence in adults have been published. There are also several systematic reviews of RCTs. In 2009, Enck and colleagues identified 11 RCTs evaluating the efficacy of biofeedback therapy for fecal incontinence in adult populations. (1) Two RCTs were excluded, one because of the small sample size, and the other because it did not include an appropriate control group. The remaining 9 studies consisted of 5 comparisons of different modalities of biofeedback and 6 comparisons of electromyographic (EMG) biofeedback versus other types of therapy, mainly pelvic floor exercises (2 studies had multiple treatment groups and were included in both categories). The total number of patients included in the 9 studies was 540; sample sizes of individual studies ranged from 18 to 171. A meta-analysis of 5 studies did not find a significant difference in the efficacy of different types of biofeedback (pooled odds ratio [OR]: 1.23, 95% confidence interval [CI]: 0.74-2.20, p=0.38). Similarly, a meta-analysis of studies comparing biofeedback to other therapies did not find a significant difference in efficacy (pooled OR: 1.19, 95% CI: 0.69-2.05). The outcome measure used in the analysis was not specified and appears to vary from study to study.

A 2012 Cochrane review examined evidence on biofeedback and/or sphincter exercises for treating fecal incontinence in adults. (2) The authors identified 21 RCTs. Most studies used multi-faceted interventions e.g., biofeedback, education and sphincter exercise. In addition, a wide variety of control interventions were used. Three trials compared biofeedback plus sphincter exercises to sphincter exercises alone and 1 trial compared biofeedback plus 1 type of exercise to biofeedback to another type of exercise. The authors did not pool study findings due to heterogeneity among trials. This review demonstrated that while there is some evidence for benefit of biofeedback in specific situations, the overall body of evidence is insufficient to make definitive conclusions on the efficacy of biofeedback for fecal incontinence in adults.

**Representative RCTs are described below:**

In 2009, Heymen and colleagues randomly assigned 168 individuals with fecal incontinence to 3 months of biweekly pelvic floor exercise training alone (n=85) or exercise training with
manometric biofeedback (n=83). (3) Twenty-two patients in the exercise-only group and 38 in the biofeedback group improved during a 4-week run-in period and did not participate further, leaving 63 in the exercise group and 45 in the biofeedback group. The primary efficacy outcome was decrease in scores on the Fecal Incontinence Severity Instrument (FISI), a validated 4-item scale, from the end of the run-in to 3 months. The analysis included all patients who completed at least 1 treatment (a total of 15 patients dropped out). The authors reported that there was a greater reduction in FISI scores in the biofeedback group compared to the exercise-only group (p=0.01, exact scores were not reported). Complete continence (no staining) was reported by 13 of 63 (21%) in the exercise-only group and 20 of 45 (44%) in the biofeedback group; this difference was statistically significant (p=0.008). A study limitation was that only 108 of 168 randomized patients (64%) received the intervention, and therefore there may have been baseline differences in the treated groups that affected study outcomes. A stronger design is to randomize patients after, not before, a run-in period.

In 2011, Bartlett and colleagues in Australia published an RCT with 72 participants comparing 2 exercise regimens used with biofeedback for fecal incontinence. (4) The study did not find significant differences in outcomes with the 2 types of exercises. It is not possible to make conclusions about the efficacy of biofeedback from this study’s findings, since all participants received biofeedback.

Norton and colleagues reported in 2003 on the results of a trial that randomly assigned 171 patients with fecal incontinence to 1 of 4 groups: standard care (advice), advice plus instruction on sphincter exercises, hospital-based computer-assisted sphincter pressure biofeedback, and hospital biofeedback plus the use of a home EMG biofeedback device. (5) Outcomes included diary reports of incontinence, quality of life, and anal manometry measurements. The authors reported that biofeedback yielded no greater benefit than standard care.

In 2003, Solomon and colleagues reported on the results of a trial that randomly assigned 120 patients with mild to moderate fecal incontinence to 1 of 3 groups: biofeedback with anal manometry, biofeedback with transanal ultrasound, or pelvic floor exercises with feedback from digital examination alone. (6) There were no significant differences in outcomes among the treatment groups; all reported modest improvements.

**Children**

A Cochrane review on behavioral and cognitive interventions for children with fecal incontinence was published in 2006 and updated in 2011. (7, 8) Of the 21 studies, 9 compared conventional treatment alone (i.e., laxatives, toilet training, dietary advice) to conventional treatment plus biofeedback. Eight trials included children with functional fecal incontinence, and the ninth included children with fecal incontinence due to myelomeningocele (n=12). In 4 trials, children were included who had fecal incontinence due to constipation, and in 3 other trials, children had fecal incontinence due to constipation and pelvic floor dyssynergia. When data from the 9 studies were combined, 133 of 260 (51.2%) in the conventional treatment plus biofeedback group were not cured or improved at follow-up compared to 121 of 250 (48.4%) patients in the conventional only group. In a meta-analysis (random effects), this difference was not statistically significant (pooled OR: 1.08, 95% CI: 0.63 to 1.84). The analysis combined 6-
and 12-month follow-up data; 12-month data were used when available. The authors concluded that findings from RCTs do not support the claim that biofeedback training provides additional benefit to conventional treatment in the management of fecal incontinence associated with constipation. They also stated that, due to a lack of sufficient trials, they were unable to evaluate the effects of biofeedback in children with organic fecal incontinence.

**Constipation**

*Does the addition of biofeedback to standard care improve refractory constipation, compared to standard care alone?*

**Adults**

The Enck et al. systematic review, described above in the section on fecal incontinence, also reviewed the literature on biofeedback for constipation. (1) Eight RCTs conducted in adults were identified. Four of these compared 2 types of biofeedback; a meta-analysis of these 4 studies did not find a significant benefit of one technique over another (pooled OR: 1.44, 95% CI: 0.69-3.09, p=0.32). The other 4 studies compared biofeedback to another treatment. Comparison treatments (1 study each) were botulinum toxin, laxatives, diazepam, and best supportive care (diet, exercise, and laxatives). Two studies also included a third arm, in which treatment was a sham or placebo intervention. Three of the 4 studies included patients with dyssynergia-type constipation and the fourth included patients with anismus. A meta-analysis of the 4 studies comparing one treatment to another (using the active intervention arm as the comparison in the 3-arm trials) found a significantly greater benefit of biofeedback in improving constipation symptoms (pooled OR: 3.23, 95% CI: 1.88-5.58, p<0.001). The results of this systematic review are limited by the heterogeneity in patient populations, comparison treatments, and outcome measures. The 2 three-arm studies and newer RCTs published after the Enck review, are described below:

Heymen and colleagues included adults who met Rome II diagnostic criteria for pelvic floor dyssynergia, had 2 or more symptoms of functional constipation for at least 12 weeks in the past year, and had manometry or electromyography findings consistent with chronic constipation (e.g., evidence of inadequate propulsive forces and incomplete evacuation). (9) Patients participated in a 4-week run-in period consisting of education on diet and exercise and provision of fiber and stool softeners. Those who still met eligibility criteria at the end of the run-in period (84 of 117, 72%) were randomly assigned to EMG biofeedback (n=30), diazepam 5 mg (n=30), or placebo medication (n=24). All participants were trained to perform pelvic floor exercises, and all received 6 biweekly visits over 3 months, each lasting approximately 50 minutes. Patients and investigators were blinded to which patients received active versus placebo medication but not to whether or not they received biofeedback. In an intention-to-treat (ITT) analysis after the 3-month intervention, the proportion of patients reporting adequate relief of constipation symptoms was 70% in the biofeedback group, 23% in the diazepam group, and 38% in the placebo group; biofeedback had a significantly greater benefit when compared either to diazepam (p<0.001) or placebo (p<0.017). A strength of this study was that it attempted to control for nonspecific effects of biofeedback e.g., increased contact with a healthcare provider and lifestyle modification advice, by including a run-in period and similar
follow-up visits for all groups. Moreover, randomization did not occur until after the run-in period, so treatment groups were more likely to be similar at the start of the treatment phase.

Rao and colleagues included patients who met Rome II diagnostic criteria for functional constipation, had dyssynergia-type constipation and, when expelling a simulated stool, had either prolonged difficulty (at least 1 minute) or prolonged delay (at least 20% marker retention in colonic transfer). (10) All participants had failed routine management of constipation. A total of 77 patients were randomly assigned to receive 3 months of standard therapy i.e., education, dietary advice (n=24), standard therapy and biofeedback therapy (n=28), or standard therapy and sham feedback (n=24). Patients receiving active biofeedback received up to 6 biweekly 1-hour sessions: training was performed using a rectal manometry probe and software for displaying the biofeedback data. In the sham treatment group, patients also used a rectal manometry probe but did not receive visual and verbal feedback. Patients were not blinded to treatment group, but the manometry reader was unaware of treatment assignment. In an ITT analysis, after the 3-month intervention, patients in the biofeedback group reported a significantly greater increase in complete spontaneous bowel movements than the sham feedback group (p<0.05) and the standard treatment group (p<0.062). In addition, a greater proportion of the patients in the biofeedback group reported improved global bowel satisfaction compared to the sham feedback group (p=0.04), but the comparison with the standard treatment group was not significantly different. (The authors did not report exact numbers for either of these preceding primary analyses). Of the primary physiologic parameters, the ITT analysis found that the dyssynergia pattern was corrected in 79% of those in the biofeedback group, 4% in the sham group, and 8% in the standard treatment group. This difference was statistically significant in favor of the biofeedback group compared to each of the other groups (p<0.001 for both analyses). Moreover, the balloon expulsion time during simulated defecation decreased significantly more in the biofeedback group compared to sham (p=0.003) or standard treatment (p=0.03) (exact times not reported for the ITT analysis).

A 2010 publication reported on 1-year findings of the Rao study in 13 of 21 (62%) patients in the biofeedback group and 13 of 23 (57%) in the standard treatment group. (11) Patients in the sham group were not included in this follow-up study. The extension study included visits at 3-month intervals, with additional advice provided as needed. Seven of the 13 (54%) biofeedback patients and all 13 patients in the standard treatment group completed the 1-year follow-up. Mean change in complete spontaneous bowel movements (the primary outcome) favored the biofeedback group (increase of 2.9) compared to the standard treatment group (decrease of 0.2). The follow-up study suggests longer-term effectiveness of biofeedback for this patient population. However, the small numbers of patients who completed the 1-year follow-up, along with the drop-out rate in the biofeedback group, limit the conclusions that can be reached.

A 2012 RCT by Hart and colleagues included 21 patients with constipation who failed to respond to dietary and medical therapies. (12) (The study was not limited to patients with dyssynergia-type constipation). The experimental arm consisted of biofeedback with an EMG rectal probe. Patients were taught to isolate the anal sphincter and receive feedback on the muscle activity of the external anal sphincter. In the control intervention, investigators attempted to control for the non-specific effects of biofeedback by using biofeedback but no
rectal probe. The comparison intervention involved biofeedback with bilateral EMGs in conjunction with surface electrodes placed on the trapezius or temporalis muscle and muscle tension reduction instruction. Both groups were given 6 treatment sessions (every other week for 12 weeks). A total of 15 of 21 patients (71%) completed the study and were included in the follow-up evaluation. The 2 primary outcome measures were the Constipation Severity Instrument (CSI) and the Irritable Bowel Syndrome Quality of Life Scale (IBS-QOL); both of these are multi-item self-report instruments. For the CSI, a lower score represents less severe symptoms and for the IBS-QOL, a higher score represents a higher quality of life. The authors did not report the possible maximum scores for either measure. The change in scores from baseline to follow-up assessments did not differ significantly between groups for either outcome measure. Mean scores on the CSI decreased from 46.5 to 30.0 in the anorectal biofeedback group and 41.2 to 34.9 in the biofeedback control group. Mean scores on IBS-QOL increased from 80.8 to 96.1 in the anorectal biofeedback group and from 90.6 to 96.7 in the biofeedback control group. The study had a small sample size and was likely underpowered to statistically significant difference between groups.

Children

No systematic reviews or meta-analyses on biofeedback for constipation in children, not associated with fecal incontinence, were identified. The literature search did identify the one RCT published since 2000. Van Ginkel and colleagues in the Netherlands included 212 children at least 5 years-old with constipation who met at least 2 of the following 4 criteria: 1) stool frequency fewer than 3 times per week; 2) 2 or more soiling and/or encopresis episodes per week; 3) periodic passage of very large amounts of stool every 7 to 30 days; or 4) a palpable abdominal or rectal fecal mass. Participants were randomly assigned to 6 weeks of standard treatment i.e., education, laxatives (n=111) or standard treatment plus 2 sessions of anorectal manometry (n=91). During the manometry sessions, the child was asked to squeeze the sphincter as tight as possible 5 times. Squeeze pressure data were converted to digital values and transmitted to a computer; the data could be viewed by the child and parent. The data were discussed after the sessions, and instructions were given on how to perform defection exercises at home. Ten of 212 (5%) randomly assigned patients did not receive treatment, and the remainder completed the intervention. Treatment success was defined as achievement of 3 or more bowel movements per week and fewer than 1 soiling and/or encopresis episodes per 2 weeks while not receiving laxatives. At 6 weeks, 4 of 111 (4%) in the standard treatment group and 6 of 91 (7%) in the biofeedback group were considered to have successful treatment; this difference was not significantly different. There was also no statistically significant difference between groups at any other follow-up point. At the final 104-week follow-up, 36 of 83 (43%) patients in the standard treatment group and 23 of 65 (35%) in the biofeedback group were considered treatment successes. Data on 30% of the randomized patients were missing at the final follow-up. This intervention did not control for the non-specific effects of biofeedback.

Summary

There is a relatively large body of literature (i.e., randomized controlled trials [RCTs] and systematic reviews) evaluating the efficacy of biofeedback for treating fecal incontinence and
constipation. For the treatment of fecal incontinence, systematic reviews have not found that biofeedback provides additional benefit when offered in conjunction with conventional therapy, compared to conventional therapy alone. While one recent RCT found that there was a significantly greater decrease in fecal incontinence symptoms with biofeedback plus exercise training than with exercise training alone, the majority of trials do not show a significant benefit. Overall, the evidence is insufficient to conclude that biofeedback improves the net health outcome for adults and children with fecal incontinence; therefore, this treatment is considered investigational.

For the treatment of constipation, a systematic review of RCTs found a benefit of biofeedback as a treatment of constipation in adults. Conclusions of the systematic review were limited by variability in patient populations, comparison groups and outcomes measures. However, detailed examination of several well-conducted RCTs focusing on patients with dyssynergia-type constipation suggests benefits in a sub-group of patients who meet criteria similar to trial participants. Thus, biofeedback may be considered medically necessary in adult patients with dyssynergia-type constipation who meet selection criteria and investigational for other patients with constipation.

Practice Guidelines and Position Statements

In May 2010, the National Institute for Clinical Excellence (NICE) issued a guideline on constipation in children and young people. The guideline states that biofeedback should not be used for ongoing treatment. (14) In June 2007, they issued a guideline on fecal incontinence in adults which states the following regarding biofeedback: “The evidence we found did not show biofeedback to be more effective than standard care, exercises alone, or other conservative therapies. The limited number of studies and the small number of participants in each group of the studies make it difficult to come to any definitive conclusion about its effectiveness.” (15)

In 2008, the National Institutes of Health issued a state-of-the-science statement on fecal and urinary incontinence based on a consensus conference held in December 2007. (16) Included in the conclusions was the following statement, “pelvic floor muscle training and biofeedback are effective in preventing and reversing fecal and urinary incontinence in women for the first year after giving birth…”

In December 2007, an Evidence Report/Technology Assessment, Prevention of Urinary and Fecal Incontinence in Adults, (17) based on research conducted by the Minnesota Evidence-based Practice Center under contract to the Agency for Healthcare Research and Quality (AHRQ), was issued. One of the research objectives was to review the effectiveness of clinical interventions to reduce the risk of incontinence. The authors identified one RCT that found twice the rate of control of fecal incontinence in women who had obstetric and sphincter trauma after biofeedback training with pelvic floor muscle (PFM) training compared to muscle training alone. The review concluded that limited evidence supports a reduction in fecal incontinence after complex behavioral interventions, which include exercises augmented with biofeedback.

In October 2007, the American Society of Colon and Rectal Surgeons released Practice Parameters for the Treatment of Fecal Incontinence. (18) The report stated that biofeedback
can be considered as a treatment option for patients who have not responded to dietary modification or medication (Level of Evidence: III; Grade of Recommendation: B). It also states that biofeedback may be considered in the early post-partum period for women with symptomatic sphincter weakness. Also, in 2007, they published Practice Parameters for the Evaluation and Management of Constipation. (19) They recommend biofeedback therapy for patients with symptomatic pelvic floor dyssynergia (Level of Evidence: Class II; Grade of Recommendation: B).

In 2004, the American College of Gastroenterology published a practice guideline on the diagnosis and treatment of fecal incontinence. (20) They recommended offering biofeedback, which they called a safe treatment that is relatively inexpensive and easy to administer, to all patients with fecal incontinence who failed supportive measures.

Biofeedback as a Treatment of Urinary Incontinence in Adults

This policy is updated regularly with searches of the MEDLINE database. The most recent literature search was performed for the period May 2012 through May 29, 2013. Following is a summary of the key literature to date:

As acknowledged in a 1995 TEC Assessment on biofeedback for various indications, there are several methodologic difficulties that arise in assessing biofeedback. (1) For example, most interventions that include biofeedback are multimodal and include relaxation and behavioral instruction, which may have effects separate from those that may occur due to biofeedback. While studies may report a beneficial effect of multimodality treatment, without appropriate control conditions, it is impossible to isolate the specific contribution of biofeedback to the overall treatment effect. For example, relaxation, attention, or suggestion may account for successful results that have been attributed to biofeedback. These effects are nonspecific therapeutic factors, some of which can be considered placebo effects. In order to demonstrate efficacy of biofeedback for treating incontinence, studies are therefore needed that isolate the effect of biofeedback and demonstrate an improvement in health outcomes compared to other interventions such as relaxation or behavioral therapy alone. In addition, although studies in the 1990s found that feedback on physiologic processes provided patients with an enhanced ability to control these processes, evidence is needed on the relationship between a patient’s ability to exert control over the targeted physiologic process and any health benefits of the intervention. The latter finding underscores the importance of seeking controlled studies showing whether use of biofeedback improves disease-related health outcomes, as opposed to physiologic, intermediate outcomes.

Women with Urinary Incontinence

A number of randomized controlled trials (RCTs) addressing biofeedback for urinary incontinence have been published, and there are several systematic reviews of RCTs. In 2012, an Agency for Healthcare Research and Quality (AHRQ) comparative effectiveness review was published. (2) The review identified 6 RCTs with a total of 542 patients comparing pelvic floor muscle training (PFMT) with biofeedback to PFMT alone. A meta-analysis of these studies did not find a statistically significant difference between interventions in continence rates. When
findings of the studies were pooled, the relative risk (RR) was 1.27 and the 95% confidence interval (CI) was 0.88 to 1.85. The absolute risk difference was 0.08 (95% CI: -0.03 to 0.19).

A 2011 Cochrane systematic review of RCTs included studies on feedback or biofeedback in conjunction with pelvic PFMT for treating urinary incontinence in women. (3) To be included in the review, trials needed to study women with stress, urge or mixed incontinence and needed to have at least 2 arms with PFMT and at least 1 arm with feedback and/or biofeedback. Feedback was defined as verbal feedback by a clinician, whereas biofeedback involved use of an instrument or device. After examining 36 full-text articles, 24 trials were found to meet the review’s eligibility criteria and 17 contributed data to the analysis of at least one primary outcome measure. Sixteen of the 24 trials included a comparison of PFMT plus biofeedback to PFMT alone; 9 of these included the same PFMT programs in both groups. The primary outcomes of the review were quality of life and improvement or cure. Nine trials used one of several validated quality-of-life instruments; however, only 4 of these reported data in a form that could be used for meta-analysis. Thus, quality-of-life results were not pooled. Data were pooled for the other primary outcome, improvement or cure, but there were a sufficient number of studies only for the comparison between PFMT with and without biofeedback. In a pooled analysis of 7 studies, there was a significant reduction in the proportion of women reporting ‘no improvement or cure’ when biofeedback was added to muscle exercise (RR: 0.75, 95% CI: 0.66 to 0.86). The authors noted that there may have been other differences between groups, such as more frequent contact with a healthcare professional or a greater number of treatment sessions, which might partially explain the difference in the improvement or cure rate in women who did or did not receive biofeedback. Moreover, when only the outcome ‘no cure’ was examined, there was not a significant difference between groups that did and did not receive biofeedback (5 studies: RR: 0.92, 95% CI: 0.81-1.05). Among secondary outcomes, a pooled analysis of 7 trials did not find a significant difference in leakage episodes in a 24-hour period after treatment (mean difference: -0.01, 95% CI: -0.21 to 0.01). For the outcomes frequency and nocturia, data could not be combined but the review authors reported that the pattern was one of no difference between groups.

As noted in the description of the Cochrane review, above, studies evaluating biofeedback for treating urinary incontinence in women have used various combinations of interventions and a variety of comparison interventions. Selected larger RCTs that compared PFMT with and without biofeedback (i.e., attempted to isolate the effect of biofeedback) and that were published as full articles are described below:

Burgio and colleagues published a study in 2003 reporting on findings of a RCT with 222 women who had urge or mixed incontinence. (4) Interventions in this 3-armed trial were as follows: 1) n=74 patients who received behavioral training along with digital palpation instruction (no biofeedback) and 4 office visits in 8 weeks; 2) n=73 patients who received biofeedback-assisted behavioral training and 4 office visits in 8 weeks; and 3) n=75 patients who were given a self-help book with no office visits (control condition). Behavioral training in the 2 intervention groups included teaching pelvic floor exercises, as well as skills and strategies for reducing incontinence. Patients in all groups kept bladder diaries through the 8-week treatment period. In an intention-to-treat analysis, the mean reduction in incontinence
episodes was 69.4% in the behavioral training plus verbal feedback group, 63.1% in the behavioral training plus biofeedback group, and 58.6% in the control group. The 3 groups were not significantly different from one another (p=0.23). In addition, quality-of-life outcomes were similar in the 3 groups.

In 2006, Williams and colleagues in the U.K. published a study that included 238 women who had failed a primary behavioral therapy (e.g., advice on fluid intake, bladder re-education, and weight loss) for 3 months. (5) They were randomized to receive intensive PFMT (n=79), PFMT using vaginal cones (n=80) or continued behavioral therapy (n=79) for 3 months. Patients in all 3 groups were seen in the clinic every other week for 8 weeks and also at 12 weeks. At 12 weeks, all 3 groups had moderate reductions in incontinence episodes and some improvement in voiding frequency; there were no statistically significant differences in outcomes among the 3 groups. For example, mean reduction in incontinence episodes over 24 hours was -1.03 in the PFMT group, -0.28 in the vaginal cone group, and -0.59 in the control group (p=0.2).

Several RCTs comparing the efficacy of PFMT alone to PFMT with biofeedback were published in 2012 and 2013. (6, 7) These studies tended not to find statistically significant differences in outcomes between interventions; however, sample sizes were small (i.e., less than 25 per group) and thus the studies may have been underpowered.

Section summary: Numerous RCTs have evaluated biofeedback as a treatment of urinary incontinence in women. The methodology of the studies has varied, and many were not able to isolate the potential contribution of biofeedback. A comparative effectiveness review did not find a statistically significant difference in continence rates when patients were treated with PFMT with biofeedback and PFMT without biofeedback. Previously, a Cochrane review evaluating biofeedback and/or verbal feedback as part of treatment for urinary incontinence found improvement in some outcomes (e.g., improvement or cure) but not others (e.g., cure, leakage episodes). There is a lack of consistent evidence from well-designed trials that biofeedback is an effective treatment of urinary incontinence.

Men with Post-prostatectomy Urinary Incontinence

Several randomized controlled trials evaluating biofeedback to treat post-prostatectomy urinary incontinence have been published. In addition, there have been several systematic reviews of RCTs. In 2007, a systematic review of PFMT to improve urinary incontinence after radical prostatectomy was published by MacDonald and colleagues. (8) The review identified 3 studies (281 men) that compared biofeedback and PFMT to muscle training alone (written/verbal instructions provided). Study findings were not pooled; none of the individual trials found a statistically significant difference in outcomes between groups. In 2012, a Cochrane review was published on conservative treatments for post-prostatectomy urinary incontinence. (9) The review included a comparison of PFMT (with or without biofeedback) and sham or no treatment. It did not include an evaluation of the potential added value of biofeedback i.e., by comparing PFMT with biofeedback and PFMT without biofeedback.

Relevant RCTs are described below:
In 2012, Tienforti and colleagues in Italy compared biofeedback (a session before and after surgery) in combination with written/verbal instructions on performing pelvic floor muscle exercises to a control intervention of written/verbal instructions alone. (10) The study included 34 patients, 32 of whom (16 in each group) were available for the final 6-month analysis. By 6 months, 10 of 16 patients (62.5%) in the treatment group and 1 of 16 patients (6.3%) in the control group had achieved continence; this difference was statistically significant (p value not reported). The mean number of incontinence episodes per week was also significantly lower in the intervention group (2.7) than the control group (13.1) at 6 months.

Two trials have evaluated the combination of biofeedback and electrical stimulation in men with post-prostatectomy incontinence. (11, 12) (These studies are also discussed in policy 1.01.17 Pelvic Floor Stimulation as a Treatment of Urinary Incontinence). The trials had mixed findings. Mariotti et al. (2009) (11) found a beneficial effect of the combined intervention of biofeedback and electrical stimulation, whereas the Goode et al. (2011) (12) study did not find a benefit compared to behavioral therapy alone. Both studies were limited in that they did not isolate the effect of biofeedback, and thus the independent effect of biofeedback on outcomes cannot be determined. Trials are described briefly below:

In 2009, Mariotti and colleagues in Italy compared a program of pelvic floor electrical stimulation and electromyographic (EMG) biofeedback (2 sessions weekly for 6 weeks) to written/verbal instructions for pelvic floor muscle exercises. All 60 patients (30 per group) completed the study through the 6-month follow-up. The mean time to regain continence was significantly shorter in the treatment group (8.0 weeks) than the control group (13.9 weeks, p=0.003). The continence rate was significantly higher in the treatment group beginning at the 4-week visit and continuing through the 20-week visit at which time 29 of 30 (96.7%) in the treatment group and 18 of 30 (60%) in the control group were continent. The difference in the rate of continence was not statistically significantly different at the final, 6-month visit at which time 29 patients in the treatment group continued to be continent compared to 20 of 30 (66.7%) in the control group. In this study, the effect of biofeedback without electrical stimulation compared to written/verbal instructions to perform pelvic floor muscle exercises was not evaluated.

In 2011, Goode and colleagues published the results of a randomized trial comparing behavioral therapy alone to behavioral therapy in combination with biofeedback and pelvic floor electrical stimulation. The trial included 208 men with urinary incontinence persisting at least 1 year after radical prostatectomy. Men with pre-prostatectomy incontinence were excluded. Participants were randomized to 1 of 3 groups; 8 weeks of behavioral therapy (PFMT and bladder control exercises) (n=70), behavioral therapy plus biofeedback and electrical stimulation (n=70), and a delayed-treatment control group (n=68). The biofeedback and electrical stimulation intervention, called “behavior-plus,” consisted of in-office electrical stimulation with biofeedback using an anal probe and daily home pelvic floor electrical stimulation. After 8 weeks, patients in the 2 active treatment groups were given instructions for a maintenance program of pelvic floor exercises and fluid control and were followed up at 6 and 12 months. The primary efficacy outcome was reduction in the number of incontinent episodes at 8 weeks, as measured by a 7-day bladder diary. A total of 176 of 208 (85%) randomized men completed
the 8 weeks of treatment. In an intention-to-treat analysis of the primary outcome, the mean reduction in incontinent episodes was 55% (28 to 13 episodes per week) in the behavioral therapy group, 51% (26 to 12 episodes per week) in the behavior-plus group, and 24% (25 to 20 episodes per week) in the control group. The overall difference between groups was statistically significant (p=0.001), but the behavior-plus intervention did not result in a significantly better outcome than behavioral therapy alone. Findings were similar on other outcomes. For example, at the end of 8 weeks, there was a significantly higher rate of complete continence in the active treatment groups (11 of 70, 16% in the behavior group and 12 of 70, 17% in the behavior-plus group) than the control group (4 of 68, 6%), but the group receiving biofeedback and electrical stimulation did not have a significantly higher continence rate than the group receiving behavioral therapy alone.

Section summary: A few RCTs on biofeedback for post-prostatectomy incontinence have been completed, with mixed results. Some studies report a significant improvement in symptoms with biofeedback, but others do not. This evidence is insufficient to determine whether biofeedback improves health outcomes for patients with post-prostatectomy incontinence.

Clinical Input Received Through Physician Medical Societies and Academic Medical Centers

In response to requests, input was received through 4 Physician Specialty Societies and 2 Academic Medical Centers while this policy was under review in 2009. 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. The clinical input was variable. Several reviewers commented about the lack of data (e.g., those who cannot do pelvic exercises), as well as the inability to separate from the available literature the contribution of biofeedback to overall outcomes in many studies.

Summary

There is a lack of consistent evidence from RCTs that biofeedback improves incontinence outcomes in women, or in men after prostate surgery compared to pelvic floor muscle exercises alone. No published evidence supports the unsupervised home use of biofeedback for treatment of urinary incontinence. Thus, biofeedback for the treatment of urinary incontinence, whether as part of an outpatient program or unsupervised in the home, is considered investigational.

Practice Guidelines and Position Statements

In April 2012, the Agency for Healthcare Research and Quality (AHRQ) published a comparative effectiveness review on nonsurgical treatment of urinary incontinence in women. (2) (Evidence is discussed above). The review included the following conclusion on biofeedback:

“Women with stress UI (urinary incontinence) can achieve continence performing PFMT. Continence rates are similar between those who undergo PFMT with and without biofeedback.”
In 2007, the National Institutes of Health (NIH) convened a Consensus Development Conference, Prevention of Fecal and Urinary Incontinence and subsequently released a statement. (13) Included in this statement was the following regarding pelvic floor muscle training and biofeedback: “…"Pelvic floor muscle training and biofeedback are effective in preventing and reversing some pregnancy-related fecal and urinary incontinence for the first year after delivery. There is insufficient research on the sustained long-term benefits of pelvic floor muscle training or biofeedback on preventing fecal or urinary incontinence.”

In 2006, National Institute for Health and Clinical Excellence (NICE) issued a guideline on the management of urinary incontinence in women. NICE states that “perineometry or pelvic floor electromyography as biofeedback should not be used as a routine part of pelvic floor muscle training” but that “electrical stimulation and/or biofeedback should be considered in women who cannot actively contract pelvic floor muscles in order to aid motivation and adherence to therapy.” (13) The conclusion regarding use of biofeedback is based on expert opinion.

Biofeedback for Miscellaneous Indications

Several methodologic difficulties exist in assessing biofeedback. For example, most interventions that include biofeedback are multimodal and include relaxation and behavioral instruction, which may have effects separate from those that may occur due to biofeedback. While studies may report a beneficial effect of multimodality treatment, without appropriate control conditions, it is impossible to isolate the specific contribution of biofeedback to the overall treatment effect. For example, relaxation, attention, or suggestion may account for the successful results that have been attributed to biofeedback. These are nonspecific therapeutic factors, some of which can be considered placebo effects. Moreover, it is important that studies demonstrate that biofeedback improves disease-related health outcomes, as opposed to potentially affecting only physiologic, intermediate outcomes, and that they address the durability of effects beyond the initial, short-term biofeedback training period.

This policy was originally created in 1997 following a 1995 TEC Assessment. The TEC Assessment reviewed the literature on the use of biofeedback in the treatment of 9 different conditions: anxiety disorders, headaches, hypertension, movement disorders, incontinence, pain, asthma, Raynaud’s disease, and insomnia. (1) The Assessment concluded that, due to methodologic limitations of the literature, there was insufficient evidence to conclude that biofeedback provides benefit in treating any of the 9 conditions. While a substantial number of studies reported improvement in the biofeedback group relative to the no-treatment group, there were generally no differences when the isolated effect of biofeedback was compared with relaxation or behavioral therapy alone. In addition, although there was evidence that feedback on physiologic processes provides patients with an enhanced ability to control these processes, there was, nevertheless, no consistent evidence of any relationship between a patient’s ability to exert control over the targeted physiologic process and any health benefits of the intervention.

The policy has been updated regularly with searches of the MEDLINE database. The most recent literature search was performed for the period June 2012 through June 20, 2013.
Following is a summary of updated literature on topics covered in the TEC Assessment, as well as in new literature on biofeedback for any other miscellaneous conditions not considered in other reference policies. Updated literature searches have focused on identifying randomized controlled trials (RCTs) and meta-analyses.

**Autism**

In 2013, Kouijzer and colleagues published an RCT evaluating electroencephalography (EEG) biofeedback as a treatment for autism spectrum disorders (ASD). (2) The trial included 35 teenagers between 12 and 18 years-old with confirmed diagnoses of ASD. Participants were randomly assigned to receive EEG biofeedback (n=13), skin conductance (n=12) biofeedback or a waiting-list control group (n=13). The biofeedback interventions included 40 sessions provided twice a week. Patients and parents in the biofeedback groups, but not on the waiting-list, were blinded to treatment allocation. The primary outcome measure was change in symptoms at 3 months, as measured by the total score on the Social Communication Questionnaire (SCQ); scores have a potential range of 0 to 36. In the primary analysis, the investigators only included participants who successfully influenced their EEG activity (called “EEG-regulators”) in the primary analysis. The justification for this was to be able to identify the specific effects of biofeedback on symptoms. Among the 19 of 35 (54%) regulators, there was not a statistically significant difference in the SCQ scores between participants treated with EEG- or skin conductance biofeedback. The investigators evaluated non-specific effects of EEG biofeedback by examining the SCQ scores among EEG-non-regulators as rated by the parents. There was not a statistically significant difference in scores among participants in the EEG biofeedback group, the skin conductance biofeedback group and the control group.

A 2010 article by Coben and Myers reviewed the literature on EEG biofeedback for autistic disorders. (3) The authors identified 2 published non-randomized controlled studies evaluating EEG biofeedback in the treatment of autistic disorders. As described in the review, a study published by Jarusiewicz and colleagues in 2002 compared treatment with 20 to 69 sessions of biofeedback in 12 autistic children to a matched control group that did not receive biofeedback. Mean reduction in autistic symptoms, as measured by the Autism Treatment Evaluation Checklist (ATEC), was 26% in the biofeedback group and 3% in the comparison group; this difference was statistically significant. The other study was published by Coben and Padolsky in 2007. It compared 20 sessions of EEG biofeedback in 37 patients to a waiting-list control group. After treatment, parents reported reduction in symptoms in 89% of the treatment group compared to 17% of the control group (p value not reported). Studies differed in their biofeedback protocols and number of sessions.

**Section summary:** There is insufficient evidence from RCTs that biofeedback improves outcomes in individuals with autism spectrum disorders. Only 1 RCT has been published, and this study did not find a benefit of biofeedback on autism-related symptoms.

**Bell's palsy**

In 2008, Cardoso and colleagues published a systematic review of studies on the effects of facial exercises on symptoms of Bell's palsy. (4) Studies including patients with unilateral
idiopathic facial palsy treated with facial exercises associated with mirror and/or EMG biofeedback were included in this review. Four studies (n=132) met the eligibility criteria. The studies described mime therapy versus control (n=50), mirror biofeedback exercise versus control (n=27), "small" mirror movements versus conventional neuromuscular retraining (n=10), and EMG biofeedback plus mirror training versus mirror training alone. The treatment length varied from 1 to 12 months. The authors concluded that “…because of the small number of randomized controlled trials, it was not possible to analyze if the exercises, associated either with mirror or EMG biofeedback, were effective. In summary, the available evidence from randomized controlled trials is not yet strong enough to become integrated into clinical practice.”

Section summary: There are a small number of RCTs evaluating biofeedback for treating Bell’s palsy, and the available trials have small sample sizes and variability in the biofeedback protocol and type of comparison intervention. These studies represent insufficient evidence to draw conclusions on health outcomes.

Hypertension
A systematic review of studies on biofeedback for hypertension was published by Greenhalgh and colleagues in 2010. (5) The investigators searched for RCTs that included adults with essential hypertension (defined as at least 140/90 mm Hg) and that compared biofeedback interventions, alone or in combination with other therapies, to medication, sham biofeedback, no treatment, or another behavioral intervention. A total of 36 trials (n=1,660) met inclusion criteria. Trials generally had small sample sizes; only 4 included more than 100 patients. All were single-center, and most were conducted in the United States. Trials used a variety of biofeedback techniques including thermal biofeedback, galvanized skin response, pulse wave velocity, and heart rate variability; some trials used more than 1 modality. Twenty studies evaluated biofeedback alone, 15 evaluated biofeedback combined with another intervention, and 1 had multiple arms and evaluated both types of interventions; only 4 trials included a sham biofeedback comparison group. The authors stated that they did not pool study findings due to differences in interventions and outcomes and the generally poor quality of the studies.

The investigators reported that trials comparing biofeedback alone versus no treatment or another behavioral intervention did not provide convincing evidence of the superiority of biofeedback. Only 1 of 5 trials that compared a biofeedback combination intervention (most commonly combined with relaxation) to a different behavioral treatment found the biofeedback intervention to be superior. Approximately half of the trials comparing a biofeedback combination to no treatment found a significant benefit to the biofeedback combination, but the specific effects of biofeedback cannot be determined from this analysis. Only 1 trial was identified that compared a biofeedback combination intervention to sham biofeedback, and this study did not find a significant difference in the efficacy of the 2 interventions. Four studies on biofeedback alone and another 4 on a combined biofeedback intervention reported data beyond 6 months; most of these found no significant differences in efficacy between the biofeedback and control groups. Greenhalgh and colleagues concluded, “…we found no convincing evidence that consistently demonstrates the effectiveness of the...
use of any particular biofeedback treatment in the control of essential hypertension when compared with pharmacotherapy, placebo, no intervention or other behavioral therapies.”

In a previous meta-analysis, published in 2003, Nakao and colleagues found that biofeedback was effective in lowering systolic and diastolic blood pressure but only when the biofeedback was combined with relaxation techniques. (6) The authors further noted that study is needed to determine whether biofeedback has any blood pressure lowering effect without relaxation techniques.

Section summary: Although there are a large number of RCTs evaluating biofeedback for treating hypertension, evidence is insufficient due to the shortage of studies isolating the effect of biofeedback, the generally poor quality of the trials and the variability among interventions.

Motor function after stroke

Numerous RCTs and several systematic reviews of RCTs have been published. In 2011, Stanton and colleagues conducted a systematic review and meta-analysis of RCTs evaluating biofeedback to improve activities involving lower limb function after stroke. (7) A total of 22 trials with 591 participants met inclusion criteria. All of the trials had relatively small sample sizes; the largest trial had 54 participants and 15 trials had 30 or fewer participants. The majority of trials (n=17) compared biofeedback plus usual therapy to usual therapy alone. The specific interventions varied; the types of biofeedback included biofeedback of ground reaction force from a force platform with visual and/or auditory feedback (13 trials), muscle activity via visual and/or auditory feedback (5 trials), joint position from an electrogoniometer via visual and/or auditory feedback (3 trials), and limb position via auditory feedback (1 trial). The duration of interventions ranged from 2 to 8 weeks, and intensity ranged between 1 to 5 days per week.

A pooled analysis of data from 17 trials on short-term effect (i.e. 1 month or less) found that biofeedback significantly improved lower limb activities compared to usual care or placebo (standardized mean difference [SMD]: 0.41; 95% confidence interval [CI]: 0.21 to 0.62). Outcomes included activities such as directional control during standing, weight distribution between the lower limbs, and gait parameters such as stride length. There was heterogeneity among studies. Trials did not report functional outcomes such as ability to perform activities of daily living (ADL). A sensitivity analysis determined that the heterogeneity was best explained by study quality. When lower quality trials were excluded, biofeedback was still found to improve lower limb activity compared to control conditions (SMD: 0.49, 95% CI: 0.22 to 0.75). A sub-group analysis was also done by type of activity. There was only 1 high-quality trial on standing up (n=40). A pooled analysis of 5 high-quality trials on short-term effect found that biofeedback significantly improved standing outcomes compared to control (SMD: 0.42, 95% CI: 0.05 to 0.78). A pooled analysis of 4 short-term trials on walking also found better outcomes with biofeedback compared to control (SMD: 0.57, 95% CI: 0.10 to 1.03). Five high-quality trials with a total sample size of 136 contributed data to an analysis of long-term term efficacy i.e., 1-5 months after cessation of the intervention. In this pooled analysis, biofeedback was found to improve outcomes compared to control (SMD: 0.41, 95% CI: 0.06 to 0.75).
A Cochrane review was published in 2007 that assessed electromyographic (EMG) biofeedback for the recovery of motor function after stroke. (8) It included 13 randomized or quasi-randomized studies with a total of 269 patients. All of the trials compared EMG biofeedback plus standard physiotherapy to standard physiotherapy; in addition to standard physiotherapy, several studies also included a sham biofeedback group. The studies tended to be small and poorly designed. The authors did not find support for EMG biofeedback to improve motor power, functional recovery, or gait quality when compared to physiotherapy alone.

A systematic review by Zijlstra and colleagues, published in 2010, searched for studies evaluating biofeedback-based training to improve mobility and balance in adults older than 60 years of age. (9) Although the review was not limited to studies on motor function after stroke, more than half of the studies included older adults post-stroke. For inclusion in this review, studies needed to include a control group of patients who did not receive biofeedback and to assess at least 1 objective outcome measure. A total of 97 potentially relevant articles were identified, and 21 (22%) studies, including 17 RCTs, met the selection criteria. Twelve of the 21 (57%) studies included individuals post-stroke, 3 included older adults who had lower-limb surgery, and 6 included frail older adults without a specific medical condition. Individual studies were small; sample sizes ranged from 5 to 30 patients. The added benefit of using biofeedback could be evaluated in 13 of 21 (62%) studies. Nine of the 13 studies found a significantly greater benefit with interventions that used biofeedback compared to control interventions. However, the outcomes assessed were generally not clinical outcomes but were laboratory-based measures related to executing a task, e.g., moving from sitting to standing in a laboratory setting and platform-based measures of postural sway. Only 3 studies reported long-term outcomes, and none of these reported a significant effect of biofeedback.

Section summary: The evidence base on biofeedback for improving motor function after stroke is limited by small studies that are mostly not of high-quality, and there is variability in the type, duration, and intensity of interventions. In addition, the outcome measures used were primarily assessments of motor activity that were based in a laboratory or research setting. The applicability of improvements in these types of measures to clinical outcomes, such as the ability to perform ADLs or the rate of falls, is unknown. In addition, few studies have reported long-term outcomes. Conclusions about the efficacy of biofeedback for improving mobility and balance in older adults cannot be drawn from the evidence published to date for the reasons discussed above.

Motor function after injury or lower-limb surgery

A 2010 systematic review by Silkman and McKeon evaluated the effectiveness of electromyography (EMG) biofeedback for improving muscle function during knee rehabilitation after injury. (10) Four RCTs that compared knee rehabilitation exercise programs with and without biofeedback were identified. Sample sizes in individual studies ranged from 26 to 60 patients. Two of the 4 studies found a statistically significantly greater benefit in the programs that included biofeedback, and the other 2 did not find a significant difference between groups. The positive studies assessed intermediate outcomes e.g.,
contraction values of the quadriceps muscles. None of the studies were designed to assess functional outcomes.

**Section summary:** There is insufficient evidence that biofeedback improves motor function after injury or lower-limb surgery. There are a few small RCTs that had inconsistent findings of benefit.

**Orthostatic hypotension in patients with a spinal cord injury**

Gillis and colleagues conducted a systematic review to identify and describe the body of literature pertaining to nonpharmacologic management of orthostatic hypotension during the early rehabilitation of persons with a spinal cord injury. (11) Participants with any level or degree of completeness of spinal cord injury and any time elapsed since their injuries were included. Interventions must have measured at least systolic blood pressure and have induced orthostatic stress in a controlled manner and have attempted to control orthostatic hypotension during an orthostatic challenge. Four distinct nonpharmacologic interventions for orthostatic hypotension were identified: application of compression and pressure to the abdominal region and/or legs, upper body exercise, functional electrical stimulation applied to the legs, and biofeedback. Methodologic quality varied dramatically between studies. The authors concluded that “The clinical usefulness of compression/pressure, upper body exercise and biofeedback for treating OH [orthostatic hypotension] has not been proven.”

**Section summary:** There is insufficient evidence from high-quality controlled studies that biofeedback improves orthostatic hypotension in patients with a spinal cord injury.

**Pain management during labor**

In 2011 a Cochrane review was published that evaluated RCTs on biofeedback for managing pain during labor. (12) The review identified 4 RCTs published between 1982 and 2000 with a total of 186 women. The studies were highly variable in terms of intervention modalities and outcomes measured, and thus findings were not pooled. In addition, the Cochrane review authors judged the trials to be at high risk of bias e.g., unclear description of blinding and randomization methods. Overall, the authors found little difference in reported outcomes e.g., rates of Cesarean section, pharmacologic pain relief in women receiving biofeedback compared to control interventions. Due to the small number of studies and small overall sample size, the evidence is insufficient to draw conclusions about the effectiveness of biofeedback in labor pain control.

**Section summary:** There is insufficient evidence from a small number of RCTs with methodological limitations, a small overall number of patients and variability in biofeedback protocols that biofeedback is effective for managing pain during labor.

**Raynaud’s disease**

A 2009 systematic review on complementary and alternative medicine in the treatment of Raynaud’s disease included an examination of the literature on biofeedback. (13) The authors identified 5 trials, and these reported a variety of outcomes. A pooled analysis of findings from 4 trials (total n=110) on the change in frequency of attacks favored the sham control
group over the biofeedback group (weighted mean difference [WMD]: -1.21; 95% CI: -1.68 to -0.73; p<0.00001). Several trials had more than 2 arms; in the preceding analysis, only the arms comparing active and sham biofeedback were included.

The trial that was given the highest quality rating by the authors of the systematic review and had the largest sample size was the Raynaud’s Treatment Study, published in 2000. (14) This was a randomized comparison of sustained-release nifedipine and thermal biofeedback in 313 patients with primary Raynaud’s disease. In addition to these 2 treatment groups, there were 2 control treatments: pill placebo and EMG biofeedback. EMG biofeedback was chosen as a control because it did not address the physiologic mechanism of Raynaud’s disease. The mean attack rate at 1 year, the primary study outcome, was 0.16 in the thermal biofeedback group, 0.23 in the EMG biofeedback group, 0.07 in the nifedipine group, and 0.21 in the placebo group. Nifedipine significantly reduced Raynaud’s attacks compared with placebo (p<0.002), but thermal feedback did not differ significantly from EMG biofeedback (0.37). There was not a significant difference in attack rates in the nifedipine and thermal biofeedback groups for the primary outcome (p=0.08). However, several secondary outcomes including all attacks and verified attacks at 2 months significantly favored nifedipine over thermal biofeedback.

**Section summary:** There is insufficient evidence from a small number of RCTs that biofeedback is effective as a treatment of Raynaud’s disease. A meta-analysis of the available trials did not find that biofeedback was more effective than the control intervention.

**Sleep bruxism**

In 2013, Wang and colleagues published a systematic review of randomized and non-randomized controlled trials on biofeedback treatment for sleep bruxism. (15) The full text of 17 articles was reviewed and 7 studies with a total of 240 participants met the inclusion criteria. Studies were generally small; only 2 included more than 50 participants. Four studies used audio biofeedback, 2 used contingent electrical stimulation and 1 used visual biofeedback. Treatment duration ranged from 1 night to 6 weeks. In 4 of the studies, the duration of treatment was 2 weeks. Three of the studies were considered to be at moderate risk of bias and the other 4 were considered to be at high-risk of bias. The primary outcome of the analysis was the number of sleep bruxism episodes per hour detected by EMG recording. Only 2 studies (total n=27) reported this outcome and had data suitable for meta-analysis. A pooled analysis did not find a statistically significant difference between the biofeedback and control groups; mean difference: -4.47 (95% CI: -12.33 to 3.38). Findings were not pooled for any other outcomes.

One of the larger RCTs (n=57) examined changes in sleep bruxism following treatment with a cognitive behavioral therapy program consisting of problem-solving, progressive muscle relaxation, nocturnal biofeedback, and training of recreation and enjoyment. (16) Similar improvements were observed for the occlusal splint group as for the multicomponent cognitive behavioral program. The effects of biofeedback were not isolated in this study, and thus conclusions cannot be drawn about its effectiveness compared to occlusal splinting.
Section summary: The available RCTs represent insufficient evidence to draw conclusions on the impact of biofeedback on sleep bruxism because of the small number of patients studied, the relatively low-quality of the studies, the variability among interventions and the lack of a consistent finding of benefit.

Tinnitus

An RCT by Weise and colleagues investigated the efficacy of a biofeedback-based cognitive-behavioral treatment for tinnitus in Germany. (17) Tinnitus patients (n=130) were randomly assigned to an intervention or a waiting-list control group. Treatment consisted of 12 sessions of a biofeedback-based behavioral intervention over a 3-month period. The primary outcome measures were global tinnitus annoyance and a daily rating of tinnitus disturbance measured by a Tinnitus Questionnaire (TQ) and a daily diary using visual analog scale (VAS) scores. Patients in the waiting-list group participated in the treatment after the intervention group had completed the treatment. Results showed improvements regarding the following: tinnitus annoyance; diary ratings of loudness; feelings of controllability; changes in coping cognitions; changes in depressive symptoms; TQ: total score (range 0–84) pre-assessment mean 54.7, post-assessment mean 32.52; TQ: emotional distress (range 0–24) pre-assessment mean 16.00, post-assessment mean 8.15; and diary: loudness VAS (range 0–10) pre-assessment mean 5.68, post-assessment mean 4.38. Improvements were maintained over a 6-month follow-up period in which variable effect sizes were observed.

Section summary: There is insufficient evidence from 1 RCT that biofeedback is effective for treating tinnitus. The trial did not investigate the possible additive effect of biofeedback with cognitive-behavioral therapy and did not include an active treatment control group. In conclusion, these data are insufficient to draw clinical conclusions regarding the role of biofeedback for the treatment of tinnitus.

Ongoing clinical trials

EEG Biofeedback Therapy as an Adjunct Treatment for PTSD (NCT01591408) (18): This RCT is evaluating the efficacy of EEG biofeedback to reduce anxiety symptoms in men with post-traumatic stress disorder (PTSD). Patients will be randomized to an active or sham biofeedback group and the primary outcome measure is change in symptom ratings. The expected enrollment is 80 patients.

Summary

There are a large number of randomized controlled trials (RCTs) evaluating biofeedback for certain miscellaneous conditions such as hypertension and motor function after stroke, a smaller number of RCTs on conditions such as Raynaud’s disease, tinnitus and sleep bruxism and no published RCTs on other conditions such as autism. Even in cases where there is a substantial body of published literature, the available RCTs either failed to show any beneficial impact of biofeedback or had design flaws that create uncertainty about the contribution of nonspecific factors such as attention or placebo effects versus the specific effect of biofeedback. Moreover, the trials are generally of short duration and the durability of
benefits reported is uncertain. Thus, biofeedback is considered investigational for the miscellaneous conditions listed in the policy statement.

**Practice Guidelines and Position Statements**

In 2008, an American Academy of Sleep Medicine special committee released a guideline on evaluation and management of chronic insomnia in adults. (19) The guideline lists biofeedback as one of several behavioral or psychological therapies for chronic insomnia.

The 2010 Scottish Intercollegiate Guidelines Network guideline on management of patients with stroke states, “EMG biofeedback is not recommended as a routine treatment for gait, balance or mobility problems after stroke.” (20)

**Neurofeedback**

This policy was originally based on a 1997 TEC Assessment and updated periodically with literature review using the MEDLINE database. The most recent update covers the period of June 2012 through May 24, 2013.

The 1997 TEC Assessment concluded that there were inadequate data to permit conclusions regarding the health outcome effects of neurofeedback for any indication. (1) Among the 19 studies reviewed in the TEC Assessment, few were randomized controlled trials (RCTs), and those that were did not support the efficacy of neurofeedback in improving health outcomes. In addition, even among the RCTs, only 2 studies used appropriate control conditions.

Literature published since the 1997 TEC Assessment consists of studies that evaluate neurofeedback for a variety of clinical indications, (2-6) with the greatest amount of scientific literature published on the treatment of ADHD. (7, 8) Relevant systematic reviews and key randomized or controlled trials of neurofeedback are described here.

**Attention Deficit Hyperactivity Disorder**

**Systematic Reviews.** A 2005 review/meta-analysis used criteria from the Association for Applied Psychophysiology and Biofeedback (AAPB) and the International Society for Neuronal Regulation (ISNR) to assess the clinical efficacy of neurofeedback for attention deficit/hyperactivity disorder (ADHD). (9) The authors concluded that neurofeedback for ADHD was ranked at level 3 or "probably efficacious" on a scale of 1 to 5 (1 being not empirically supported and 5 being efficacious and specific). The authors noted that benefits were reported in the 5 randomized group studies (totaling 214 patients) included in their analysis; however, the ranking for neurofeedback for ADHD was based on the need for further studies controlled for patient and therapist factors that could unduly influence outcomes.

In 2009, Arns and colleagues published a meta-analysis on neurofeedback and ADHD, concluding that neurofeedback could be considered “efficacious and specific” for ADHD based on level 5 evidence. (8) Fifteen studies met criteria (either between-subject or within-subject design) and were included in the analysis. Initial analysis indicated heterogeneity in study results, which typically would preclude meta-analysis. For this paper, studies were removed from the analysis until heterogeneity was achieved. The adjusted analysis indicated similar effect sizes between neurofeedback and stimulant medication; however, this result was
based on nonrandomized studies in which patients chose their treatment; this study design has a high potential for selection bias. (10) Four RCTs that utilized either a wait-list control or active control group were included in the meta-analysis. One of the studies is a German language report and another is an unpublished PhD thesis (total of 69 children); these have not been reviewed in this policy. The other 2 RCTs included in the systematic review are described below, including 20 and 94 children with ADHD, respectively. (11, 12) Overall, the literature included in this meta-analysis is characterized by small, poor quality studies with high potential for bias. The findings of the meta-analysis are also limited by significant heterogeneity in study results and exclusion of studies due to heterogeneity. Details of the English language RCTs are described below.

A 2011 review of complementary medicine for ADHD indicates that there is only one large randomized trial (Gevensleben et al., reviewed below) that found a significant benefit (i.e., with a moderate effect size of 0.6) of neurofeedback for children with ADHD. (13) In comparison, effect sizes in studies that used medication were around 0.8 for methylphenidate and around 1.2 for amphetamine. Three additional small RCTs have been identified which found no significant difference between neurofeedback and either attention skills training, placebo training, or biofeedback relaxation training. (14) Comparison with biofeedback relaxation training suggests that non-specific factors such as a structured learning environment may contribute to the effects of neurofeedback. (15)

Randomized Controlled Trials. A randomized study published in 2006 examined brain activity following neurofeedback in 15 children with ADHD. (11) The experimental subjects learned to inhibit the amplitude of theta waves (4–7 Hz) and increase amplitude of beta waves (15–18 Hz). Five children with ADHD were randomly assigned to a nontreatment control condition. Functional magnetic resonance imaging (fMRI) revealed increased activation of the right anterior cingulate cortex, an area related to selective attention that previously was shown to be altered in children with ADHD. However, it could not be determined whether the change in brain function was related to the specific neural training program (decreasing the amplitude of theta waves and increasing the amplitude of beta waves) or to the additional attentional training received by the experimental group. A 2007 report from Europe compared neurofeedback training of slow cortical potentials (SCPs) (n=17) with a control group (n=13) that participated in a group cognitive/behavior training program. (16) The report stated that randomization was incomplete because the age range in the group program was limited, parents had to be available for intense training during neurofeedback, and some parents had a preference for one type of training. Results showed that children in the neurofeedback group improved more than children who had participated in a group therapy program, particularly improved for attention and cognition. However, parental support was found to account for more of the improvement than neurofeedback training performance.

To control for nonspecific effects (attention training) and confounding variables (parental engagement), Gevensleben and colleagues compared neurofeedback with a control intervention of participation in a computerized attention skills training. (12) All children were drug-naïve or drug-free without concurring psychotherapy for at least 6 weeks before starting training. The 2 training conditions were designed to be as similar as possible, using computer
games, positive reinforcement by a trainer, homework, and parental encouragement in using the skills/strategies learned during training in real-life situations. Both groups participated in 2 blocks of 9 sessions (approximately 100 minutes per session plus a break), with 2–3 sessions per week, and parents were informed that both treatments were expected to be beneficial but were not informed as to which type of training their child had been assigned. A total of 102 children were randomly assigned in a 3:2 ratio; 8 children were excluded due to need for medical treatment or noncompliance with the study protocol by either the children or their parents, resulting in 59 children in neurofeedback and 35 in attention training (92% follow-up). Slow cortical potentials (SCPs) and theta/beta training were compared by starting with one type of training in the first block and then the other (counterbalanced order) in the second block. Investigator evaluations were performed by the teachers, and thus, the teachers were not blinded to the treatment. At the end of training/testing, there were no significant differences in parents’ attitude toward the 2 training conditions or in the perceived motivation of their children. Approximately 40% of the parents either did not know which training their child had participated in or guessed the wrong group. Both parents and teachers rated the neurofeedback group as more improved on the hyperactivity subcomponent of a Strength and Disabilities Questionnaire (e.g., SDQ, 19% vs. 3%, respectively, improved) and on a German ADHD scale (e.g., 26% vs. 9%, respectively, improved). Thirty children in the neurofeedback group (52%) and 10 children in the attention training group (29%) improved more than 25% in the German ADHD scale (odds ratio: 2.68), which was the primary outcome measure. Other components of the SDQ, including emotional symptoms; conduct problems; peer problems; and prosocial behavior, were not different between the 2 training conditions. No significant differences were noted between the 2 neurofeedback training protocols. Results of this randomized controlled study suggested that neurofeedback may have specific effects on attention and hyperactivity beyond those achieved by attention training and parental involvement. The authors noted that future studies should further address the specificity of effects and how to optimize the benefit of neurofeedback as a treatment module for ADHD.

Six-month follow-up from the RCT described above was reported in 2010. Of the 94 children who completed treatment, 17 started medication during the follow-up interval, and parents of 16 children did not return the questionnaires. Follow-up was obtained in 61 children (65%) of the original per-protocol 102 children. Although the percentage of dropouts did not differ between the 2 groups, dropouts tended to have higher scores on the German ADHD rating scale (FBB-HKS), particularly in the control group. The difference in dropouts between the groups limits the interpretation of the comparative data, as the scores in the 2 groups included in follow-up were not similar at baseline (e.g., baseline FBB-HKS of 1.50 for the neurofeedback group and 1.37 for the control group). The improvement observed in the neurofeedback group after treatment appeared to be preserved at 6-month follow-up. For example, the inattention subscore of the FBB-HKS improved from 2.02 to 1.51 after treatment and remained at 1.49 at 6-month follow-up (moderate effect size of 0.73). The hyperactivity/impulsivity subscore improved from 1.10 to 0.79 after treatment and remained at 0.76 at 6-month follow-up (small effect size of 0.35). The authors of this European study noted that the treatment effects appear to be limited but considered neurofeedback to be potentially effective as one component of a multimodal treatment approach.
In 2012, Duric et al. reported a comparative study of neurofeedback versus methylphenidate in 91 children with ADHD. (18) The children were randomized into 3 groups, consisting of 30 sessions of neurofeedback, methylphenidate, or a combination of neurofeedback and methylphenidate. The neurofeedback sessions focused on increasing cortical beta activity and decreasing theta activity. Parental evaluations found improvements in ADHD core symptoms for all 3 groups, with no significant differences between groups. Alternative reasons for improvement with neurofeedback include the amount of time spent with the therapist and cognitive-behavioral training introduced under neurofeedback.

Section Summary: There are a few small RCTs of neurofeedback for the treatment of ADHD, and systematic reviews of these studies have been performed. The available studies have methodologic limitations, and the results are not consistent in showing outcome benefits. One difficulty with this area of research is isolating the effect of neurofeedback from non-specific effects of a trial. Studies that have attempted to use active controls have suggested that at least part of the effect of neurofeedback may be due to attention skills training, relaxation training, and/or other non-specific effects. Larger sham-controlled studies are needed to evaluate whether neurofeedback (alone or in combination with other treatments) has beneficial effects for children with ADHD.

Autism Spectrum Disorder

In a 2009 systematic review of novel and emerging treatments for autism spectrum disorders, neurofeedback received a grade C recommendation, supported by one nonrandomized controlled trial. (19) The only controlled trial identified was a pilot study from 2002 that included 12 children with autism who received neurofeedback and an untreated control group of 12 children who were matched by sex, age, and disorder severity. (20) The study found a 26% reduction in autism symptoms based on the Autism Treatment Evaluation Checklists (ATEC), compared to 3% for the untreated controls. Parental assessments found improvements in all behavioral categories (socialization, vocalization, anxiety, schoolwork, tantrums, and sleep) in the group treated with neurofeedback, while minimal changes were reported in the control group. As discussed above, there is a need for sham controlled trials with neurofeedback training due to the possibility of nonspecific effects (e.g., attention training) and confounding variables (e.g., parental engagement and expectation). No randomized sham controlled trials on neurofeedback for autism spectrum disorders have been identified.

Cognitive Performance

One small (n=6) quasi-randomized, double-blind pilot study was identified that examined whether increasing peak alpha frequency would improve cognitive performance in older adults (70–78 years of age). (21) Control subjects were trained to increase alpha amplitude or shown playback of one of the experimental subject’s sessions. Compared to controls, the experimental group showed improvements in speed of processing for 2 of 3 cognitive tasks (Stroop, Go/No-Go) and executive function in 2 tasks (Go/No-Go, n-back); other functional measures, such as memory, were decreased relative to controls.
Depression
Linden et al. reported a “proof-of-concept” study of neurofeedback with functional magnetic resonance imaging (fMRI) in 8 patients with major depressive disorder (MDD). (22) Four neurofeedback sessions resulted in the upregulation of brain areas that were shown to be involved in the generation of positive emotions (e.g., ventrolateral prefrontal cortex and insula). Testing immediately following the fourth session revealed a significant improvement in clinical symptoms (-4.13 points) on the Hamilton Rating Scale for Depression (HDRS). A subsequently recruited imagery control group underwent a training procedure with the same cognitive strategies (evoke positive memories) without neurofeedback and showed no clinical improvement (+1.0 point).

Epilepsy
A 2009 meta-analysis by Tan and colleagues identified 63 studies on neurofeedback for treatment of epilepsy. (23) Ten of the 63 studies met inclusion criteria; 9 of these studies included fewer than 10 subjects. The studies were published between 1974 and 2001 and utilized a pre-post design in patients with epilepsy refractory to medical treatment; only one controlled study was included. The meta-analysis showed a small effect size for treatment (-0.233), with a likelihood of publication bias based on funnel plot. Randomized placebo-controlled trials are needed to evaluate the effect of neurofeedback on seizure frequency in patients with epilepsy.

Fibromyalgia
In 2010, Kayiran and colleagues reported a randomized single blind study of neurofeedback versus escitalopram in 40 patients with fibromyalgia. (24) Patients in the neurofeedback group were instructed to widen a river on a computer monitor which corresponded to increasing sensory motor activity and decreasing theta activity. Patients received 5 sessions per week for 4 weeks. The control group received escitalopram for 8 weeks. Outcome measures at baseline and at weeks 2, 4, 8, 16, and 24 included visual analog scale (VAS) for pain, Hamilton and Beck Depression and Anxiety Inventory Scales, Fibromyalgia Impact Questionnaire and Short Form-36. Mean amplitudes of electroencephalogram (EEG) rhythms and the theta/sensory motor rhythm were also measured in the neurofeedback group. At baseline, the control group scored higher on the Hamilton and Beck Anxiety Scales and the Hamilton Depression Scale; all other baseline measures were similar between groups. Both groups showed improvements over time, with significantly better results in the neurofeedback group. There were no changes over time in mean amplitudes of EEG rhythms and essentially no change in the theta/sensory motor rhythm ratio (reduced only at week 4). This study is limited by the difference in intensity of treatment and contact with investigators between the neurofeedback and escitalopram groups. Sham controlled trials are needed when assessing the effect of neurofeedback on subjective outcome measures.

Insomnia
In 2010, Cortoos et al. published a small (n=17) randomized controlled trial (RCT) on the effect of neurofeedback training or biofeedback training (placebo control) on objective and...
subjective sleep in patients with primary insomnia. (25) Of 158 subjects with sleep complaints who were interested in participating, 131 (89%) were excluded due to study criteria or unwillingness to remain medication-free during the study period. Following polysomnograph (PSG) recorded sleep in the laboratory, all subjects received 20 sessions of therapist-controlled telefeedback training at home over a period of 8 weeks. The neurofeedback group was trained to increase the sensory-motor rhythm (12-15 Hz) and inhibit theta power (4-8 Hz) and high beta power (20-30 Hz). The biofeedback group was trained to decrease electromyographic (EMG) activity, which was equated with the reinforcement of relaxation (placebo control). Both treatments reduced sleep latency by 40% to 45% (22 minutes at baseline) on post-treatment PSG, measured 2 weeks after the end of training. Neurofeedback training reduced wake after sleep onset (54% vs. 13% decrease, respectively; however, no interaction was found on the 2-way analysis of variance [ANOVA]) and increased total sleep time (40 minutes vs. less than 5 minutes, respectively, p<0.05). This study is limited by the small number of subjects, differences in sleep parameters at baseline, and short follow-up. Additional studies are needed to evaluate this novel treatment approach.

Obsessive-Compulsive Disorder
In 2013, Koprivova et al. reported a double-blind randomized sham-controlled trial of independent component neurofeedback in 20 patients with obsessive-compulsive disorder. (26) Independent component neurofeedback is based on the individual diagnosis of pathological EEG sources and was directed at downtraining of abnormally high activity. All patients were hospitalized and participated in a 6-week standard treatment program that included cognitive-behavioral therapy and 25 neurofeedback or sham biofeedback sessions. The neurofeedback group showed greater reduction of compulsions compared to the sham group (56% vs. 21%). However, clinical improvement was not associated with a change in EEG.

Parkinson’s Disease
Subramanian et al. conducted a “proof of principle” study to determine whether fMRI-guided activity increase in the supplementary motor area (SMA) cortex complex would result in improved motor function in patients with early stage Parkinson’s disease. (27) Patients were instructed to practice the strategy/imagery that was used during the initial neurofeedback (n=5) or control imagery session (n=5) for 2-6 months at home. At follow-up, the patients in the fMRI neurofeedback group showed higher activation than imagery control patients in several brain regions and improved motor speed (finger tapping) and clinical ratings of motor symptoms. The imagery control patients showed no control of SMA activation and no motor improvement.

Substance Abuse
A 2008 systematic review of neurofeedback as a treatment for substance abuse disorders described difficulties in assessing the efficacy of this and other substance abuse treatments, including the lack of clearly established outcome measures, differing effects of the various drugs, presence of comorbid conditions, absence of a gold standard treatment, and use as an
add-on to other behavioral treatment regimens. (28) The authors concluded that alpha-theta training, when combined with an inpatient rehabilitation program for alcohol dependency or stimulant abuse, would be classified as level 3 or “probably efficacious.” This level is based on beneficial effects shown in multiple observational studies, clinical studies, wait-list control studies, or within-subject or between-subject replication studies. The authors also noted that few large-scale studies of neurofeedback in addictive disorders have been reported, and a shortcoming of the evidence for alpha-theta training is that it has not been shown to be superior to sham treatment.

Tourette Syndrome

A 2011 evidence review with clinical guidelines by the European Society for the Study of Tourette Syndrome identified a total of 2 case studies on neurofeedback for Tourette syndrome; this is considered investigational. (29)

Migraine Headaches

Walker reported quantitative EEG (QEEG) for the treatment of migraine headaches in 46 patients. (30) Results were compared with 25 patients who chose not to do neurofeedback and continued anti-migraine drug therapy. Since baseline QEEG assessment (all 71 patients) showed a greater amount of the high-frequency beta band (21-30 Hz); the 5 neurofeedback sessions focused on increasing 10-Hz activity and decreasing 21-30 Hz targeted individually to brain areas where high-frequency beta was abnormally increased. Patient diaries of headache frequency showed a reduction in migraines in a majority of patients in the QEEG group but not the drug-therapy group. Fifty-four percent reported complete cessation of migraines over 1 year, with an additional 39% reporting a greater than 50% reduction. In comparison, no patients in the drug-therapy group reported a cessation of headaches, and 8% had a reduction in headache frequency of greater than 50%. Randomized sham-controlled trials are needed to adequately evaluate this treatment approach.

Summary

The scientific evidence does not permit conclusions concerning the effect of the technology on health outcomes. The largest body of evidence is for treatment of attention deficit/hyperactivity disorder (ADHD), but the available RCTs in that area are not definitive in demonstrating health outcome benefits. For patients with insomnia, epilepsy, Tourette syndrome, autism spectrum disorder, fibromyalgia, migraine headache, substance abuse disorder, depression, Parkinson’s disease, or other neurologic disorders, the evidence is poor and a number of questions regarding clinical efficacy remain to be answered before applying neurofeedback techniques. As a result of the deficiencies in the evidence base, neurofeedback is considered investigational.

Practice Guidelines and Position Statements

The International Society for Neurofeedback & Research published a 2011 position paper on standards of practice for neurofeedback and neurotherapy. (31) Issues discussed include competency, qualifications of practitioners, scope of practice, informed consent, pretreatment assessment, standards for remote training, recordkeeping and billing, accountability, standards
for practitioner training and qualifications to be trained, adequate supervision and coaching of training sessions, ethical advertising, standards for professional societies, and standards for those who sell and manufacture neurofeedback equipment.

Clinical guidelines on behavioral and psychosocial interventions for Tourette syndrome and other tic disorders were published in 2011 by the European Society for the Study of Tourette Syndrome. The guidelines state that neurofeedback is still experimental. (29)

The American Psychological Association (APA) provides general information on biofeedback (including neurofeedback) on their website www.apaonline.org (APA Online), stating that “Biofeedback helps treat some illness, may boost performance, helps people relax, and is even used to help children with Attention Deficit-Hyperactivity Disorder.” (32)

The Association for Applied Psychophysiology & Biofeedback (AAPB) rates neurofeedback as efficacious (level 4 on a scale of 1–5 with 5 being the best) for ADHD, based on several small controlled and moderately large clinical studies showing that neurofeedback significantly helps children with ADHD who have problems with mathematics. (33)

No information on neurofeedback was identified from the American Academy of Child and Adolescent Psychiatry, the American Psychiatric Association, or the American Academy of Pediatrics.

V. Definitions

**Electroencephalograph (EEG)** is an instrument for recording the electrical activity of the brain.

**Electromyogram (EMG)** is the graphic record of resting and voluntary muscle activities as a result of electrical stimulation.

**Physiologic** pertains to normal functions of the human body as opposed to pathological.

VI. Benefit Variations

The existence of this medical policy does not mean that this service is a covered benefit under the member’s contract. Benefit determinations should be based in all cases on the applicable contract language. Medical policies do not constitute a description of benefits. A member’s individual or group customer benefits govern which services are covered, which are excluded, and which are subject to benefit limits and which require preauthorization. Members and providers should consult the member’s benefit information or contact Capital for benefit information.
VII. DISCLAIMER

Capital’s medical policies are developed to assist in administering a member’s benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member’s benefit information, the benefit information will govern. Capital considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Covered when medically necessary:

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<table>
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*If applicable, please see Medicare LCD or NCD for additional covered diagnoses.
Investigational; therefore not covered:

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<td>ELECTROMYOGRAPHY (EMG), BIOFEEDBACK DEVICE</td>
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The following ICD-10 diagnosis codes will be effective October 1, 2014:

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<td>Persistent migraine aura with cerebral infarction, intractable, without status migrainosus</td>
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<tr>
<td>G43.601</td>
<td>Persistent migraine aura with cerebral infarction, not intractable, with status migrainosus</td>
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<td>G43.611</td>
<td>Persistent migraine aura with cerebral infarction, intractable, with status migrainosus</td>
</tr>
<tr>
<td>G43.709</td>
<td>Chronic migraine without aura, not intractable, without status migrainosus</td>
</tr>
<tr>
<td>G43.719</td>
<td>Chronic migraine without aura, intractable, without status migrainosus</td>
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<td>G43.701</td>
<td>Chronic migraine without aura, not intractable, with status migrainosus</td>
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<td>G43.711</td>
<td>Chronic migraine without aura, intractable, with status migrainosus</td>
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<tr>
<td>G43.809</td>
<td>Other migraine, not intractable, without status migrainosus</td>
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<tr>
<td>G43.819</td>
<td>Other migraine, intractable, without status migrainosus</td>
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<td>G43.801</td>
<td>Other migraine, not intractable, with status migrainosus</td>
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<td>G43.811</td>
<td>Other migraine, intractable, with status migrainosus</td>
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<tr>
<td>G43.909</td>
<td>Migraine, unspecified, not intractable, without status migrainosus</td>
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<tr>
<td>G43.919</td>
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<td>G43.901</td>
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<tr>
<td>G43.911</td>
<td>Migraine, unspecified, intractable, with status migrainosus</td>
</tr>
</tbody>
</table>

*If applicable, please see Medicare LCD or NCD for additional covered diagnoses.*
IX. REFERENCES

Biofeedback as a Treatment of Headaches


Biofeedback as a Treatment for Chronic Pain


Biofeedback as a Treatment of Fecal Incontinence and Constipation


Biofeedback as a Treatment for Urinary Incontinence


**Biofeedback for Miscellaneous Indications**


Neurofeedback


Other sources


Neurofeedback


BCBSA 1997 TEC Assessment; tab 21


**MEDICAL POLICY**

<table>
<thead>
<tr>
<th>POLICY TITLE</th>
<th>BIOFEEDBACK AND NEUROFEEDBACK THERAPY</th>
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Taber’s Cyclopedic Medical Dictionary, 21stedition.


### X. POLICY HISTORY

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<td>CAC 7/28/09</td>
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<td>CAC 11/30/10 (BCBSA adopted)</td>
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C4/24/12 Minor Revision. Statement added that for the treatment of migraine and tension-type headaches, biofeedback may require 10 to 20 office –based sessions of 30 to 60 minutes each. In addition, two new investigational indications were added to include autism and after lower-limb surgery. References updated.

02/12/2013- Codes reviewed- skb

8/1/13 administrative change. Added reference to L32943 Anorectal Manometry, Anal Electromyography, and Biofeedback Training for Perineal Muscles and Anorectal or Urethral Sphincters in the Medicare variation and reference list.
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<tbody>
<tr>
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<td>MP- 2.064</td>
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</table>

CAC 3/26/13 policy to be effective 9/1/13 -- Minor revision. Added pain management during labor as an investigational indication. Changed treatment of adult dyssynergia-type constipation from investigational to medically necessary with criteria. References updated.

05/15/2013- Administrative code review completed.
01/28/2014- Consensus Review. No change to policy statements. References updated. Rationale section added. Codes reviewed.

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