CIGNA MEDICAL COVERAGE POLICY

The following Coverage Policy applies to all plans administered by CIGNA Companies including plans administered by Great-West Healthcare, which is now a part of CIGNA.

Effective Date 8/15/2009
Next Review Date……..8/15/2010
Coverage Policy Number 0166

Subject Biofeedback

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INSTRUCTIONS FOR USE

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Coverage Policy

Biofeedback and biofeedback devices are specifically excluded under many benefit plans. In addition, biofeedback and biofeedback devices are considered behavioral training and education/training in nature, and such services are specifically excluded under many benefit plans. Please refer to the applicable benefit plan document to determine benefit availability and the terms, conditions and limitations of coverage.

If coverage is available for biofeedback, the following conditions of coverage apply.

CIGNA covers biofeedback as medically necessary for the following conditions:

- constipation in adults
- fecal incontinence in adults

- urinary incontinence (i.e., stress, urge, mixed, overflow) in children and adults
- migraine and tension headaches in children and adults
- cancer pain in children and adults

CIGNA does not cover biofeedback for any other indication because it is considered experimental, investigational or unproven.

CIGNA does not cover EITHER of the following because they are considered experimental, investigational or unproven.

- electroencephalography (EEG) biofeedback or neurofeedback
- in-home biofeedback devices

General Background

Biofeedback is a therapeutic process that electronically monitors bodily functions, such as breathing, heart rate, blood pressure, skin temperature and muscle tension, which are fed back to the individual by means of sounds, lights or electronic gauges. It emphasizes relaxation and stress-reducing techniques. Most proponents believe that by using these techniques, individuals can learn to control a variety of physiological responses formerly thought to be completely involuntary and thereby, help manage anxiety and pain commonly associated with stress reactions (Holroyd, et al., 2003; Karmody, 2003; Kiresuk, et al., 2005). According to the National Center for Complementary and Alternative Medicine (NCCAM), biofeedback is considered an alternative medicine technique under the mind-body category of complementary and alternative medicine (CAM) practices (NCCAM, 2007).

There are several different types of biofeedback. The biofeedback modality selected for therapy depends upon the condition to be treated. EMG biofeedback measures muscle tension and is proposed for the treatment of chronic muscle stiffness, injury and pain (e.g., neck and back pain); headaches, asthma, incontinence; and intestinal symptoms. Thermal or temperature biofeedback measures skin temperature and is proposed for the treatment of circulatory disorders, such as headaches, hypertension, and Raynaud's phenomenon. Galvanic skin response (GSR) biofeedback, also called electrodermal response (EDR), electrodermal activity (EDA), skin conductance response (SCR) or skin conductance level (SCL) biofeedback, measures electrical conductance in the skin associated with sweat gland activity and perspiration. GSR is proposed for the treatment of anxiety disorders and phobias (Allen, 2007; EEG Spectrum International, 2001).

Another form of biofeedback is electroencephalogram (EEG) biofeedback, also called neurofeedback or neurotherapy, which measures alpha (associated with relaxation and meditation) and theta (associated with focused attention) brainwave activity. It is proposed to counterbalance genetic and environmental tendencies by learning to alter brain wave patterns. EEG biofeedback has been proposed for the treatment of multiple conditions including insomnia, attention deficit hyperactivity disorder (ADHD), anxiety disorders, autism spectrum disorders, epilepsy, addictions, tinnitus, brain injury, depression, learning disabilities, pervasive developmental delay. However, the evidence in the peer-reviewed literature does not support the efficacy of EEG biofeedback.

Although there are numerous biofeedback devices available for home use, biofeedback should be performed by a trained professional in a clinical setting. Examples of home devices include: StressEraser® (Helicor, Inc., New York, NY) for mind and body relaxation; BrainMaster (BrainMaster Technologies, Inc., Oakwood Village, OH) EEG biofeedback device; GSR/Temp2X™ (Biofeedback Instrument Corp., New York, NY) temperature biofeedback system; and RESPeRate (Intercure Ltd., Lod, Israel) which uses therapeutic paced breathing to lower blood pressure.

Although the scientific rationale for biofeedback is unclear, biofeedback is supported by professional societies and the evidence in the peer-reviewed scientific literature for the treatment of constipation, fecal and urinary incontinence, migraine and tension headaches and cancer pain.

U.S. Food and Drug Administration (FDA)

The FDA classifies biofeedback medical devices as 510(k), Class II, special controls, medical devices, subject to certain limitations, and they 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” (FDA, 2007). There are numerous biofeedback devices available from multiple manufacturers.

Constipation/Fecal Incontinence
Constipation is defined as three or fewer bowel movements a week often accompanied by hard, dry stool and pain. Although constipation can be associated with more serious disease, many times it is a feature of a colorectal motility disorder such as pelvic floor dysfunction (also known as pelvic floor dyssynergia, anismus, or outlet obstruction) where there is a normal or slightly slowed colonic transit and a prolonged storage of residue in the rectum. Fecal incontinence is the inability to control bowel movements and may involve leakage of stool. It may be caused by muscle or nerve damage or weakness, or pelvic floor dysfunction.

The evidence in the peer-reviewed scientific literature supports the use of biofeedback for the treatment of constipation and fecal incontinence in adults. Positive results from biofeedback have been reported in systematic reviews, meta-analysis, randomized controlled trials and comparative studies (Heyman, et al., 2003; Norton, et al., 2003; Illnyckyj, et al., 2005; Brazelli, et al., 2006; Chiarioni, et al., 2006; Heyman, et al., 2007; Rao, et al., 2007; Koh, et al., 2008; Enck, et al., 2009; Lacima, et al., 2009). Outcomes included: relief of straining, abdominal pain, and bloating; reduced use of laxatives; improvement in spontaneous bowel movements; less straining and digital maneuvers; and improved quality of life and psychological state. In the treatment of incontinence, biofeedback subjects experienced improvement in continence scores, squeeze and anal pressures, squeeze duration, and improvement in vitality, social functioning and mental health.

The use of biofeedback for the treatment of constipation and fecal incontinence in children is not well established and has not been proven to add additional benefit to established conventional therapy (Brazzelli, et al. 2006; Brazzelli, et al. 2004; Agency for Healthcare Research and Quality [AHRQ], 2001).

In their guideline on the management of fecal incontinence, the National Institute for Health and Clinical Excellence (NICE) (United Kingdom), states that adults who have persistent fecal incontinence after initial management should consider special continence services including biofeedback (NICE, 2007).

The American Gastroenterological Association (2000) guidelines on the management of constipation note that “biofeedback and relaxation training have been quite successful and, importantly, free of morbidity. Biofeedback can be used to train patients to relax their pelvic floor muscles during straining and to facilitate relaxation and pushing to achieve defecation. By the relearning process, the non-relaxing pelvic floor is gradually suppressed and normal coordination restored. Biofeedback is also used in the treatment of fecal incontinence. There are, however, major differences between the approaches to fecal incontinence and constipation. The incontinent patient with intact neural pathways is able to appreciate a sensation of muscular contractile activity, whereas the constipated patient does not have a similar sensation of muscular relaxation. Nevertheless, biofeedback has been shown to reduce obstructive symptoms, with an increase in the frequency of bowel actions, the ability to develop a more obtuse anorectal angle at the time of defecation, and more dynamic pelvic floor movements when the anal sphincter is contracted.” The results of the use of biofeedback in intensive programs with adults are highly successful; however, its use in children has been disappointing.

Urinary Incontinence (UI)
UI is an involuntary leakage of urine caused by a variety of conditions that directly or indirectly affect bladder control. The types of urinary incontinence include stress, urge, mixed, overflow and functional. The inability of the badder to hold urine during activities that increase abdominal pressure (e.g., exercise, coughing, sneezing, laughing) is called stress incontinence; a sudden, involuntary loss of urine for no apparent reason accompanied by a strong sense to void is called urge incontinence; and a combination of stress and urge incontinence is called mixed incontinence. Overflow incontinence involves an over distention of the bladder causing the bladder to never empty completely, and functional, or environmental, incontinence is leakage of urine due to the individual’s inability to get to the bathroom in time due to mental or physical difficulties (e.g., Alzheimer’s disease, arthritis). Biofeedback has been proposed as a treatment modality for stress, urge, mixed and overflow urinary incontinence because it may enhance awareness of body functions and assist the individual in learning muscle strengthening pelvic floor exercises (Holroyd-Leduc, et al., 2008; Shamliyan, et al., 2008).

There are several proposed methods of biofeedback which may be employed for the treatment of urinary incontinence including: vaginal cones, perineometers, and electromyographic (EMG) systems (Payne, 2007).

Biofeedback is well established as a treatment alternative for urinary incontinence in children and adults. The peer-reviewed literature includes systematic reviews, randomized controlled trials, and case series have reported an improvement in incontinence for up to two years following the use of biofeedback (Porena, et al., 2000; Burgio, et al., 2002; Herbison, et al., 2002; Hunter, et al., 2004; Yabci, et al., 2005; Dannecker, et al., 2005; Burgio, et al., 2006; Klijn, et al., 2006). Improvements were reported in nocturnal enuresis, staccato voiding, detrusor-sphincter dyssynergia, enuresis, vesicoureteral reflux, and pelvic floor contraction strength. A decrease in high-grade stress incontinence, urine loss with activity, as well as infections were also reported.

In their guideline on the management of urinary incontinence in women, NICE (Oct 2006) 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".

Headaches
A migraine is a type of headache that is usually localized to one area of the head and may be accompanied by nausea, vomiting, light sensitivity and visual disturbances. A tension headache involves pain in the head, scalp, or neck, with muscle tightness in the affected area. A migraine may also be present with a tension headache (i.e., mixed tension migraine) and has features of both tension headache and migraine. In addition to migraine and tension headaches, chronic (i.e., occurring on more days than not for a three month period or longer) or recurrent headaches may occur secondary to multiple conditions, such as medication usage, infectious process, brain tumor, caffeine withdrawal, sleep deprivation, trauma and psychogenic disorders. In these conditions, the treatment is aimed at the underlying cause, and the use of biofeedback is typically not indicated (Huffman and Sakonju, 2005; Gladstein, 2006; McConaghy, 2007).

Biofeedback is a standard treatment option for migraine and tension headaches. Systematic reviews and randomized controlled trials have reported that biofeedback is effective in reducing the severity and frequency of these headaches in adults and children (Vasudeva, et al., 2003; Eccleston, et al., 2004; Kaushik, et al., 2005; Nestoriuc and Martin 2007). After conducting a meta-analysis of 55 randomized controlled trials, including 1718 patients assigned to biofeedback and 511 patients assigned to controls, Nestoriuc and Martin (2007) stated that biofeedback "can be recommended as an evidence-based behavioral treatment option for the prevention of migraine".

The National Institute of Neurological Disorders and Stroke (2009) lists biofeedback as one form of stress management that may help limit discomfort and reduce the occurrence and severity of migraine attacks.

The American Academy of Neurology's (AAN) recommendations for the evaluation and treatment of migraine headaches states:

- "Relaxation training, thermal biofeedback combined with relaxation training, electromyographic biofeedback, and cognitive-behavioral therapy may be considered as treatment options for prevention of migraine. Specific recommendations regarding which of these to use for specific patients cannot be made.
- Behavioral therapy may be combined with preventive drug therapy to achieve additional clinical improvement for migraine relief" (Silberstein, 2000).

In their discussion of the treatment of chronic pain in the pediatric patient, the American Pain Society (APS) (2006) states that treatment should be based on underlying pain mechanisms and address symptom-focused management, and as an example, may include the use of biofeedback in conjunction with other appropriate therapies.

Guidelines by the National Headache Foundation (NHF) list biofeedback as a treatment option for evaluation and management of migraine headaches. The NHF states that non-pharmacologic adjuncts used for the treatment of migraine including biofeedback may be effective and eliminate the need for pharmacologic interventions (Landy, et al., 2004; Mauskop, 2004). Thermal and EMG biofeedback have been shown to be

effective in the prevention and relief of migraine headaches (Farmer, et. al., 2004). Biofeedback has also been proposed as a migraine treatment option for pregnant women, menstrually-related migraines and in children over age ten years ((Diamond, 2004; Pearlman, 2004).

Cancer Pain
Patients undergoing oncologic therapy frequently experience persistent pain. Additional modalities which can be utilized to manage pain include relaxation and biofeedback (Villaret, et al., 2001).

In their guidance on the treatment of breast cancer, NICE (2002) states that for cancer patients in general" there is very strong evidence that cognitive and behavioral interventions, including biofeedback, can reduce side effects of therapy and alleviate psychological and functional disturbances. Some forms of psychological and psychosocial counseling have been shown to increase life expectancy and improve a range of psychological, quality of life and other functional outcomes".

In reference to the management of cancer pain, the National Cancer Institute (NCI) (2008) states that alternative therapies (e.g., biofeedback) may be used in conjunction with pain medication in an effort to control pain. NCI states that even though some of these "methods have not been tested in cancer pain studies", they may help to relieve pain, stress, and anxiety therefore, improving the patient's quality of life.

Biofeedback is an established modality for the treatment of cancer pain, and the information discussed above does not indicate the use of biofeedback should be limited to adults.

Other Conditions
Biofeedback has been proposed as a treatment modality for numerous other conditions including: alcohol and drug abuse, anxiety disorders, asthma, attention deficit hyperactivity disorder (ADHD), autism spectrum disorders, cardiovascular disease, chronic back pain, epilepsy, fibromyalgia, functional dyspepsia, hypertension, pervasive developmental disorders, Raynaud's syndrome, rheumatoid arthritis, stroke, temporomandibular disorders, tinnitus and upper limb pain. However, the evidence in the scientific, peer-reviewed literature does not support the efficacy of biofeedback for the treatment of these conditions. Overall, there is a lack of randomized controlled trials using sufficient sample sizes, comparing biofeedback to established therapeutic modalities (e.g., pharmacotherapy, behavior therapy) with long-term follow-ups. Patient selection criteria for biofeedback for these conditions have not been established and reported sustained benefit past the treatment period are lacking.

The evidence in the clinical trials has not established clinical efficacy and effectiveness of EEG biofeedback (EEG Spectrum International, 2001b; Angelakis, et al., 2007; Dohrmann, et al., 2007; McDonough-Means and Cohen, 2007). A Hayes (2003) review of six studies that met inclusion criteria concluded that "there is insufficient evidence from the available peer-reviewed literature to conclude that EEG biofeedback therapy is effective for the treatment of disorders such as ADHD, epilepsy, insomnia, depression, mood disorders, posttraumatic stress disorder, alcoholism, drug addiction, or menopausal symptoms." Limitations of the studies included small patient populations, inadequate or no controls, lack of randomization or comparison to conventional therapies, and/or long-term follow-up, as well as inconsistent outcome measures and incomplete reporting of data. Because of these methodologic flaws, Hayes stated that "no definitive conclusions regarding the efficacy of EEG biofeedback can be drawn." In a subsequent literature search (2008), Hayes' conclusions have not changed.

Attention Deficit Hyperactivity Disorder (ADHD): Biofeedback is proposed for the treatment of ADHD under the hypothesis that EEG biofeedback can correct the abnormal brain wave activity associated with the condition. However, the effects of biofeedback remain controversial. In addition to the methodological flaws of the clinical trials, it is unclear if the positive outcomes following neurofeedback are due to the electrophysiological mechanisms or other factors such as parental intervention or properties of the therapeutic setting and content (Drechsler, et al., 2007; Heinrich, et al., 2007; Leins, et al., 2007; McDonough-Means and Cohen, 2007; Holtmann and Stadler, 2006).

ECRI (2007) conducted a systematic review and meta-analysis on the effectiveness of neurofeedback for the treatment of ADHD. Eight studies met inclusion criteria. Five studies (n=167) compared neurofeedback to a waitlist or placebo, and four studies (n=242) compared neurofeedback to stimulant medication. Most of the studies were nonrandomized, small and in some studies patients were also on medication. ECRI stated that

neurofeedback is comparable to standard medical care for improving attention in ADHD patients, but that the evidence was weak (based on four studies) and was insufficient to allow a precise, quantitative estimate of the effect of neurofeedback on this outcome. ECRI also stated that due to insufficient evidence, it could not be determined if neurofeedback was comparable to standard medical care for other ADHD symptoms (i.e., hyperactivity, impulsivity and aggression). The evidence was insufficient to determine if neurofeedback improved patient function and quality of life. No information was found on patient indications/contraindications for neurofeedback in professional medical organization guidelines. “Published studies have not yet established that training of EEG patterns is the active ingredient in neurofeedback. None of the controlled trials included a quantitative measure of changes in EEG”.

Monastra et al. (2005) summarized the results of five case studies (n=322) and five controlled-group studies (n=214) that used EEG biofeedback for the treatment of ADHD. The studies were reviewed by applying guidelines established by the AAPB and the International Society for Neuronal Regulation (ISNR). The authors determined that biofeedback was “probably” an efficacious treatment option for ADHD (i.e., 75% of patients demonstrated significant clinical improvement), but stated that randomized controlled trials were needed to demonstrated who will benefit from this treatment.

Fuchs et al. (2003) conducted a nonrandomized comparison study of children (n=34) diagnosed with ADHD. Their parents chose which treatment the child would receive, pharmaceutical management (n=12) or EEG biofeedback (n=22). The treatment was provided for 12 weeks, and both regimens were associated with improvements on all subscales of the Test of Variables of Attention and on the speed and accuracy measures of the d2 Attention Endurance Test. ADHD-related behaviors were noted to be significantly reduced in both groups when rated by both teachers and parents using the IOWA-Conners Behavior Rating Scale. In a randomized controlled trial, Leins et al. (2007) compared ADHD children treated with slow cortical potential (n=19) to theta/beta therapy (n=19). After three phases of ten sessions improvements were reported by parents and teachers and were maintained for six months.

The American Academy of Pediatrics (2001) clinical practice guideline on the treatment of the school-aged children with ADHD indicates the need for well-designed, rigorous studies of currently promoted but less well-established therapies such as occupational therapy, biofeedback, herbs, vitamins and food supplements. The guideline states that these interventions are not supported by evidence-based studies.

Chronic Back Pain: Biofeedback has been proposed as a treatment modality for chronic back pain to help relieve the tension in the back muscles and alleviate pain. Ostelo et al. (2005) conducted a systematic review of the literature to determine if behavioral treatments (including biofeedback) for nonspecific chronic low back pain (CLBP) were more effective than other treatments compared to waiting-list controls (WLC). Twenty-one randomized controlled trials met inclusion criteria. CLBP was defined as back pain that persisted for 12 weeks or more. Studies of individuals with CLBP caused by pathological entities including infection, neoplasm, fracture, osteoporosis and rheumatoid arthritis (RA) were excluded. The investigators reported that there is moderate evidence (three studies, n=88) that there is no significant difference between EMG biofeedback and WLC on behavioral outcomes in the short term. There is conflicting evidence (two studies, n=60) on the effectiveness of EMG biofeedback versus WLC on general functional status. There is limited evidence (one study, n=28) of EMG biofeedback for a small short-term positive effect on back-specific functional status. Cognitive behavioral treatment (CBT) was compared to EMG biofeedback in one study (n=28), which found no differences in the groups for pain or any behavioral outcome measures either in the short or long term. A combination of CBT and EMG biofeedback compared to WLC (four studies, n=134) found strong evidence for a short-term, positive effect on pain intensity, but no differences on behavioral outcomes or general functional status in the short term compared to WLC. The investigators concluded that combined CBT and EMG biofeedback and progressive relaxation therapy alone are effective for short-term pain reduction in patients with CLBP; however, more research is needed to determine what types of behavioral interventions are most effective for pain relief and which patients would benefit most from a specific type of behavioral treatment. The investigators stated no determination could be made from this review as to whether patients should be referred to behavioral treatment programs or to active conservative treatment programs.

The 2008 guidelines for acute and chronic low back pain published by the Work Loss Data Institute have biofeedback listed as a treatment modality that they do not recommend.

Epilepsy: In an effort to reduce abnormal brain waves and seizure frequency, biofeedback has been proposed for the treatment of epilepsy. Nagai et al. (2004) conducted a preliminary single-blind, randomized controlled study on 18 adults with drug-refractory epilepsy to evaluate the effect of galvanic skin response (GSR) biofeedback (n=10) as compared to sham (n=8) on seizure frequency. The primary outcome measure was change in seizure frequency after one month of biofeedback. The patients receiving biofeedback training significantly reduced the seizure frequency. There was no change in seizure activity in the sham group. Limitations of the study include the small patient population, lack of monitoring of medication compliance which could affect seizure activity, and short-term follow-up.

In a Cochrane review, Ramaratnam et al. (2005) conducted a meta-analysis of psychological treatments, including biofeedback, for epilepsy. Randomized and quasi-randomized studies were analyzed. Outcomes included quality of life and seizure frequency. Of the two trials including relaxation and behavioral therapy, one showed positive results by decreasing anxiety and enhancing adjustment. Another study of galvanic skin response reported reduction in seizure activity. A study using EEG biofeedback improved cognitive and motor functions in subjects with the greatest seizure reduction. The studies were deficient in methodology and, due to the limited number of studies, no reliable evidence was evident.

In their clinical guideline for diagnosing and managing epilepsy in children and adults, NICE (2004) states that psychological interventions, including biofeedback, may be used as an adjuvant therapy to anti-epileptic drugs (AED) to improve quality of life in adults who are not receiving optimal benefit from AED. They go on to state that psychological interventions have not proven to affect seizure frequency and are not an alternative to pharmacological treatment.

Fibromyalgia: Biofeedback has been proposed for the treatment of fibromyalgia in an effort to facilitate and train an individual in maintaining a state of relaxation and decreased pain. In a randomized controlled trial, Babu et al. (2007) compared the use of EMG biofeedback (n=15) to sham (n=15) and reported a significant decrease in pain and the number of tender points in the treatment group. However, there were no significant differences in the fibromyalgia impact questionnaire, or the six-minute walk test. Both groups experienced a significant decrease in FIQ and visual analogue scale but the decreases were greater in the biofeedback group.

Functional Dyspepsia (FD): Because low vagal tone may be a mediating mechanism by which psychological factors induce dyspepsia in FD, it has been hypothesized that biofeedback may be helpful in the treatment of FD by enhancing vagal tone, leading to improvement in parasympathetic activity and drinking capacity. In a randomized controlled trial (n=40) patients were allocated to investigation, information, and biofeedback with breathing exercises or to investigation and information only. Drinking capacity and quality of life significantly improved (p=0.02, p=0.01, respectively) following biofeedback, but an improvement in baseline vagal tone was not noted (Hjelland, et al., 2007).

Hypertension: Because of its potential to decrease stress and enhance relaxation, biofeedback has been proposed for the treatment of hypertension. Yucha et al. (2001) conducted a meta-analysis of 23 randomized controlled studies to determine the effectiveness of biofeedback in the treatment of stages I and II essential hypertension. Biofeedback therapy included different biofeedback modalities and elements of cognitive behavior therapy and relaxation training. The active control groups included treatments known to reduce blood pressure such as relaxation training, cognitive therapy and home blood pressure monitoring. The inactive control groups included waiting-list control, clinic blood pressure monitoring and sham biofeedback. The investigators concluded that both biofeedback and active control treatments resulted in a reduction in systolic blood pressure (SBP) and diastolic blood pressure (DBP), but only biofeedback showed a significantly greater reduction in both SBP (6.7 mm Hg) and DBP (4.8 mm Hg) when compared to inactive control treatments. The authors noted that statistical significance was achieved only in comparison with the inactive control groups. They also noted the difficulty in determining the effectiveness of specific biofeedback modalities because of the small number of studies using each modality. Some studies tested one treatment at a time, while others used combined treatments, and complete data were not reported in many studies. The authors concluded that biofeedback as a treatment for stage I and II hypertension in healthy adults should be considered before the initiation of pharmacological treatments and as adjunctive therapy to standard pharmacological treatment.

Nakao et al. (2003) conducted a meta-analysis of 22 randomized controlled studies of essential hypertensive patients (n=905). Biofeedback intervention resulted in blood pressure reductions that were greater by 7.3 millimeters (mm) of mercury (Hg) systolic and 5.8 mmHg diastolic compared to nonintervention controls (such

as clinical visits or self-monitoring of blood pressure). Compared to sham or nonspecific behavioral intervention controls, the net reductions in systolic and diastolic blood pressures by biofeedback intervention were 3.9 mmHg and 3.5 mmHg, respectively. Reviewers were unable to determine whether biofeedback itself has an antihypertensive effect beyond the general relaxation response because biofeedback was only found to be superior to sham or nonspecific behavioral intervention when combined with other relaxation techniques. The investigators concluded that large, randomized controlled trials are needed to determine whether biofeedback itself has an antihypertensive effect beyond the general relaxation response.

A 2006 Hayes report included three meta-analyses of 26, 21, and 22 randomized controlled trials and 11 prospective reports that investigated the effectiveness of biofeedback in the treatment of hypertension. Of the prospective reports, five studies compared biofeedback plus relaxation training or another cognitive behavioral health modality to no intervention or to clinic blood pressure monitoring or to home blood pressure training; four studies with no controls compared biofeedback effects in various patient populations; and two studies used placebo biofeedback as part of the control intervention. Hayes concluded that the evidence suggested that "biofeedback training programs including relaxation training may be beneficial for the management of hypertension, but the effects of biofeedback alone remain to be determined".

In their guidelines on the management of hypertension, NICE (2006) states that relaxation therapies, including biofeedback, can reduce blood pressure but "routine provision by primary care teams is not recommended". They stated individuals may want to pursue the use of relaxation therapies on their own.

Raynaud's Syndrome: Proponents of biofeedback for Raynaud's state that using thermal biofeedback to produce vasodilation may help relieve the severity and frequency of attacks. In 2000, a multicenter randomized clinical trial (i.e., The Raynaud's Treatment Study) included 313 patients with primary Raynaud's phenomenon. Patients were randomized into one of four treatment groups: sustained-release nifedipine, pill placebo, temperature biofeedback and EMG biofeedback (control). The primary outcome measures were self-reported Raynaud's attacks one year after initiation of treatment. The results revealed that temperature biofeedback was not better than its control treatment, and biofeedback was inferior to specific pharmaceutical therapy for treating primary Raynaud's (No author, 2000; Middaugh, et al., 2001).

The National Institute of Arthritis and Musculoskeletal Diseases (NIAMS) (2006) states that while biofeedback is used for the treatment of a Raynaud's attack, formal studies have suggested that it is not helpful.

The Raynaud's and Scleroderma Association (2005) states that "many people have tried self-hypnosis, biofeedback techniques and acupuncture with some success. Unfortunately, there have been very few clinical trials, but they do seem to show that although initially the patients claim some improvement, after about a year many patients stop the treatment because they feel no benefit or it takes up too much time".

Rheumatoid Arthritis (RA): Biofeedback has been proposed for the treatment of RA to help alleviate tension, stress, anxiety, insomnia and other symptoms that may cause acute flair-ups and/or enhance arthritic pain. Astin et al. (2002) conducted a systematic review of the literature to investigate the effect of psychological interventions (including biofeedback) on patients with RA. Outcome measures included functional ability, pain, tender joints, psychological status and coping ability. Twenty-five randomized controlled trials of 1676 patients met inclusion criteria. Because separate results by type of intervention (i.e., relaxation, biofeedback, CBT) were not identified, the authors could not report which psychological interventions or combinations of interventions were most effective and for which types of patients. Although the investigators noted some methodological flaws in the studies (e.g., inadequate description of controls, effect sizes not always consistent with signs of confidence intervals), they stated that psychological interventions may be more effective for patients who have had RA for shorter duration. The authors concluded that more research was needed to determine which treatments may be of benefit for patients with RA.

The American College of Rheumatology (2000) recommendations for the management of osteoarthritis of the hip and knee do not include biofeedback as a treatment modality in rheumatoid arthritis (RA) or osteoarthritis.

Stroke: The proposed indications for the treatment of stroke with biofeedback is to retrain the injured brain to replace the inattentive states of consciousness (theta wave) and/or excessive anxiety and tension (beta waves) with healthy waves needed for normal cognition, alertness and mental focus (Litvinas, 2007). Pollock et al. (2003) conducted a Cochrane review and reported the results of a literature search for recovery of postural

control and lower limb function following stroke. The objective was to determine if outcomes were different if the physiotherapy treatment was based on orthopedic, neurophysiology, motor learning principles, or a mixture of these modalities. They reviewed randomized or quasi-randomized controlled trials with interventions of physiotherapies, including biofeedback. Outcomes measured degree of disability and motor impairment. Eighteen studies were categorized as EMG biofeedback and fifteen studies as positional biofeedback. The authors concluded that there was insufficient evidence to determine if one method was more effective than the other.

Woodford and Price (2007) conducted a meta-analysis of 13 studies (n=269) on the use of electromyographic biofeedback (EMG-BFB) for the recovery of motor function following a stroke. The analysis included randomized controlled trials and quasi-randomized controlled trials that compared physiotherapy or exercises or physical therapy alone to these treatment modalities plus EMG/EMG-BFB. There were variations in the time from stroke to randomization (35 to 1140 days), and the length of the studies ranged from four to 16 weeks. Small sample sizes (n=10–40) were also a limitation of the studies. Outcome criteria included changes in motor strength, range of motion, stride length, gait speed, functional ability and gait quality score. Overall, the data did not demonstrate a positive effect on the outcomes. The authors concluded that EMG-BFB "does not appear to have a positive benefit for recovery after stroke," and it could not be recommended as a routine treatment modality. However, in view of the absence of reported adverse events, EMG-BFB could be considered as a cautious treatment for a select group of patients.

A 2006 Hayes report on neurological disorders included 22 studies on the use of biofeedback following stroke for the treatment of dysphagia, gait disturbances and upper and lower limb hemiplegia. They concluded that evidence in the literature did not support the safety and efficacy of biofeedback for the treatment of stroke patients.

Temporomandibular Disorders (TMD)/Temporomandibular Joint (TMJ) Disorders: As in other chronic pain conditions, biofeedback has been investigated to determine if relaxation and relief of stress and tension from biofeedback will alleviate the pain of TMD. A systematic review by Medlicott and Harris (2006) included seven randomized controlled trials which evaluated the effectiveness of relaxation training or biofeedback in the management of TMD. From the review of these studies, the authors stated, "Programs involving relaxation techniques and biofeedback, EMG training, and proprioceptive reeducation may be more effective than placebo treatment or occlusal splints in decreasing pain and increasing total vertical opening in people with acute or chronic myofascial or muscular TMD in the short term and the long term." They stated that "these recommendations should be viewed cautiously."

In 2005, Crider et al. reported on six randomized controlled trials regarding the efficacy of biofeedback-based therapy for TMD. Two trials included surface electromyographic (SEMG) training of masticatory muscles; two combined SEMG with cognitive-behavioral therapy (CBT); and two involved biofeedback-assisted relaxation training (BART). The review determined the extent that each intervention met treatment efficacy criteria established by the Association for Applied Psychophysiology and Biofeedback (AAPB). Based upon the review of the studies, the authors stated that SEMG training and BART were "probably an efficacious treatment" and SEMG with CBT is an efficacious treatment. They recommended additional studies to identify specific treatment combinations.

In their 2009 guidelines for the treatment of temporomandibular disorders, the American Association of Oral and Maxillofacial Surgeons does not include biofeedback as a treatment modality.

Upper Limb Pain: A limited number of studies have been conducted to determine if the muscle relaxation effect of biofeedback could help alleviate the pain of repetitive strain in the upper limbs. Karjalainen et al. (2004) conducted a systematic review of the literature to determine the effectiveness of biopsychosocial rehabilitation for upper-limb repetitive strain injuries among working-age adults. The investigators found two prospective randomized studies and considered both studies to be of low quality due to methodological flaws. Studies which included EMG biofeedback as the only component of physiological rehabilitation were excluded. One study (n=32) compared the extra effect of hypnosis combined with biofeedback and autogenics (a form of autohypnosis using self-suggestion), given once a week for six weeks, compared to waiting-list controls (WLC). The investigators concluded that the evidence was limited due to the low quality of the studies, but they noted there was a positive effect of hypnosis combined with biofeedback and autogenics as compared to biofeedback and autogenics after six weeks of follow-up. The second study (n=48) compared three behavioral therapies:

EMG biofeedback, applied relaxation with progressive muscular relaxation and imagery methods. The biopsychosocial intervention groups were given a combination of EMG biofeedback and applied relaxation, or applied relaxation only. One control group was given EMG biofeedback, and the other control group waited eight weeks before treatment. The drop-out rate was reported to be 20.8% in this study. The investigators concluded that there were no differences in effect between applied relaxation, EMG biofeedback plus applied relaxation, and WLC after eight weeks and six months of follow-up.

Vulvodynia: Following the hypothesis that vulvodynia, or vulvar vestibulitis, and vulvar vestibulodynia may be due to an abnormality in pelvic floor muscle tone, biofeedback has been investigated as a treatment modality for muscle training. In a randomized controlled study, Bergeron et al. (2001) prospectively evaluated and compared EMG biofeedback (12-week trial), group cognitive-behavioral (12-week trial), and vestibulectomy in the treatment of dyspareunia resulting from vulvar vestibulodynia. Seventy-eight women were randomly assigned to one of the three treatment regimens. Following treatment, all groups reported statistically significant reductions on pain measures up to the six-month follow-up. The vestibulectomy group was significantly more successful than the other two groups, reporting a 70% mean reduction in pain and a greater quality of life improvement. The biofeedback participants experienced a higher six-month dropout rate, reflecting patient difficulty following through with the long-term and repetitive treatment protocols. The author stated, that the “results need to be interpreted with caution since there were significantly more participants in the vestibulectomy condition who refused to undergo the treatment they had been randomized to, as compared to participants in the two other treatment conditions.”

In a case series study, McKay et al. (2001) evaluated the effectiveness of EMG biofeedback of pelvic floor musculature in the management of patients with moderate to severe vulvar vestibulodynia syndrome. Fifteen of the 29 treated patients (51.7%) demonstrated a decrease in introital tenderness and 14 of the 15 were able to resume intercourse without discomfort. Following completion of treatment, 88.9% reported mild pain, and five of 29 women did not show any significant improvement and were unable to resume sexual activity. Within six months of starting therapy, 90% of the patients ultimately resuming sexual activity had done so. The authors noted that the open-ended evaluation of the severity of pain associated with intercourse, as well as sexual activity before, during, and after completion of a program of biofeedback was a limitation of the study.

In 2008, Hayes reviewed five studies (i.e., two randomized controlled trials, two case series, one retrospective review) (n=33–87) utilizing biofeedback for the treatment of vulvodynia and noted that the overall quality of the studies was limited by the “small number of well-designed studies and small samples sizes”. Duration of the studies ranged from two to three months, follow-up ranged from six months to over three years, compliance was unknown since biofeedback training was continued at home, and in some cases, drop-out rates were unknown or high. Hayes also noted that definitive patient selection criteria for biofeedback training for this indication have not been established.

The American Society for Colposcopy and Cervical Pathology’s (ASCCP) practice management guideline (2008) states that biofeedback may be used in the treatment of vulvodynia to relieve pain and discomfort.

In a patient education brochure, the American College of Obstetricians and Gynecologists (ACOG) (2007) states that physical therapy or biofeedback may be tried by women with vulvodynia to learn to control vaginal muscles which may help to reduce the pain.

In 2005, ACOG and ACOG issued a joint opinion on the diagnosis and treatment of vulvodynia. They stated that “There are very few randomized trials of vulvodynia treatments and most treatment information is based on clinical experience, descriptive studies, or reports of expert committees. Some treatments that have been used include medication, biofeedback training, physical therapy, dietary modifications, cognitive behavioral therapy, sex counseling, and surgery. Newer treatments include acupuncture, hypnotherapy, nitroglycerin, and botulinum toxin, according to the document”.

Home Biofeedback Devices
Biofeedback should be performed in a clinical setting by trained professionals. The evidence in the peer-reviewed literature does not support the effectiveness of home use of electronic biofeedback devices. In some instances the results of clinical trials were limited due to the inability to monitor the use of home biofeedback used by subjects in the trial. One randomized controlled trial compared the use of anorectal manometry EMG biofeedback performed in a laboratory (n=24) to EMG biofeedback performed in the home (n=12) for children

with chronic constipation who had failed conventional treatment. The outcomes indicated that no additional benefit was gained by the use of home biofeedback (Croffie, et al., 2005). In a randomized controlled trial, Aukee et al. (2004) reported that 11 of 16 women who received 12 weeks of home EMG-assisted biofeedback (FemiScanTM, MegaElectronics, Kuopio, Finland) avoided surgical intervention compared to ten of 19 control subjects who did not use home biofeedback. In a 2002 decision memo regarding the use of home biofeedback for urinary incontinence, the Centers for Medicare and Medicaid (2002), stated that "the scientific evidence is not adequate to conclude that the use of home biofeedback devices for the treatment of urinary incontinence is clinically effective, and, therefore, is not reasonable and necessary for treating urinary incontinence or to improve the functioning of a malformed body member".

Summary
The evidence in the published peer-reviewed literature and/or professional societies support the safety and efficacy of biofeedback for the treatment of constipation and fecal incontinence in adults and the treatment of stress, urge, mixed and overflow urinary incontinence, migraine and tension headaches and cancer pain in adults and children.

The evidence in the published peer-reviewed literature does not support the therapeutic effectiveness of biofeedback for any other diagnoses or conditions due to the small number of clinical trials and/or small patient populations, short-term follow-ups, lack of documentation of sustained benefits and lack of a comparison to established therapeutic modalities for the various conditions. In most cases, patient selection criteria for biofeedback have not been established. There is insufficient evidence in the published, peer-reviewed scientific literature to conclude that biofeedback is effective for any of the following indications (list is not all inclusive):

- alcohol and drug abuse
- anxiety disorders
- asthma
- attention deficit hyperactivity disorder
- autism spectrum disorders
- cardiovascular disease
- chronic back pain
- epilepsy
- fibromyalgia
- functional dyspepsia
- hypertension
- pervasive developmental disorders
- Raynaud's syndrome
- rheumatoid arthritis,
- stroke
- temporomandibular disorders
- tinnitus
- upper limb pain
- vulvodynia

Coding/Billing Information

Note: This list of codes may not be all-inclusive.

Covered when medically necessary, if coverage is available:

CPT®* Codes	Description
90875	Individual psychophysiological therapy incorporating biofeedback training by any modality (face-to-face with the patient), with psychotherapy (e.g., insight oriented, behavior modifying or supportive psychotherapy); approximately 20-30 minutes

90876	Individual psychophysiological therapy incorporating biofeedback training by any modality (face-to-face with the patient), with psychotherapy (e.g., insight oriented, behavior modifying or supportive psychotherapy); approximately 45-50 minutes
90901	Biofeedback training by any modality
90911	Biofeedback training, perineal muscles, anorectal or urethral sphincter, including EMG and/or manometry

ICD-9-CM Diagnosis Codes	**Description**
307.81	Tension headache
346.00-346.93	Migraine
338.3	Neoplasm related pain (acute) (chronic)
564.00-564.09	Constipation
787.6	Incontinence of feces
788.30-788.39	Urinary incontinence
	Multiple/varied

Experimental/Investigational/Unproven/Not Covered:

HCPCS Codes	**Description**
E0746	Electromyography (EMG), biofeedback device

ICD-9-CM Diagnosis Codes	**Description**
	Multiple/varied

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Policy History

Pre-Merger Organizations	Last Review Date	Policy Number	Title
CIGNA HealthCare	8/15/2008	0166	Biofeedback
Great-West Healthcare	12/20/07	00.241.04	Biofeedback