



CIGNA MEDICAL COVERAGE POLICY

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

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Subject Biofeedback

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- Autism Spectrum Disorders/Pervasive Developmental Disorders: Assessment and Treatment
- Complementary and Alternative Medicine Extracorporeal Electromagnetic Stimulation for Urinary Incontinence
- Hyperhidrosis Treatments
- Injectable Bulking Agents for Urinary Conditions
- Nocturnal Enuresis Treatment Services
- Physical Therapy
- Reflex Sympathetic Dystrophy/Complex Regional Pain Syndrome Treatment
- Surgical Interventions for Urinary Incontinence
- Tinnitus Treatment Services and Devices

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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 ANY of 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 each is 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, 2011).

There are several different types of biofeedback. The biofeedback modality selected for therapy depends on 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), dyslexia, anxiety disorders, autism spectrum disorders, epilepsy, addictions, tinnitus, brain injury, depression, learning disabilities, pervasive developmental delay//mental retardation, fibromyalgia, dyslexia. However, the evidence in the published peer-reviewed scientific 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 by the evidence in the published 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 published 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).

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).

In their 2010 guideline on the management of constipation in children and young adults, the National Institute for Health and Clinical Excellence (NICE) (United Kingdom), stated that biofeedback should not be used for ongoing treatment in children and young people with idiopathic constipation. Meta-analysis showed no improvement in outcomes when conventional treatment (e.g., use of laxatives, advice on a high-fiber diet, attempting defecation after meals) was compared to conventional treatment plus biofeedback.

In their guideline on the management of fecal incontinence, NICE, stated that adults who have persistent fecal incontinence after initial management should consider special continence services including biofeedback.

The American Gastroenterological Association (2008) guidelines on the management of constipation supported biofeedback for the management of constipation and fecal incontinence, and stated that the results of biofeedback in intensive programs with adults have been highly successful; however, its use in children has been disappointing.

The American Society of Colon and Rectal Surgeons (ASCRS) (2007) recommends biofeedback as an “initial treatment for motivated patients with voluntary sphincter contraction” any may be considered a first-line therapy for patient who have not responded to dietary modification and/or medication. ASCRS also noted that biofeedback was no more effective than advice and education (“standard care”) and that home training may be an alternative option for elderly individuals.

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 bladder 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 a well established treatment alternative for urinary incontinence in children and adults. The published peer-reviewed scientific literature includes systematic reviews, randomized controlled trials, and case series that have reported an improvement in incontinence for up to two years following 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).

The 2010 American Urological Society's guidelines on the management of children with vesicoureteral reflux and bladder/bowel dysfunction (BBD) stated that there was insufficient evidence to recommend a specific treatment but biofeedback is one possible treatment option for children more than age five years. AUS described BBD as abnormal lower urinary tract symptoms of storage and/or emptying which include lower urinary tract conditions such as overactive bladder and urge incontinence, voiding postponement, underactive bladder, and voiding dysfunction, and may also include abnormal bowel patterns including constipation and encopresis.

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

In their discussion of the treatment of chronic pain in the pediatric patient, the American Pain Society (APS) (2006) stated 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) listed biofeedback as a treatment option for the evaluation and management of migraine headaches. The NHF stated 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 children over age ten years (Pearlman, 2004).

Cancer Pain

Patients undergoing oncologic therapy frequently experience persistent pain. In addition to pharmacotherapy, modalities that can be utilized to manage pain include relaxation techniques and biofeedback (Villaret, et al., 2001).

In a guidance document on the treatment of breast cancer, NICE (2002) stated 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) (2010) stated 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 disorders (ADHD), autism spectrum disorders, cardiovascular disease, cerebral palsy, chronic back pain, chronic prostatitis, cystic fibrosis, epilepsy, fibromyalgia, functional dyspepsia, heart failure, hypertension, hyperhidrosis, knee osteoarthritis, labor pain, pervasive developmental disorders, posttraumatic stress disorder (PTSD), Raynaud’s syndrome, recurrent urinary tract infection, reflex sympathetic dystrophy or complex regional pain syndrome, rheumatoid arthritis, stroke, temporomandibular disorders, tinnitus, type 2 diabetes mellitus, upper limb pain, vulvodynia and whiplash. However, the evidence in the published peer-reviewed scientific 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 (McKee and Moravec, 2010; Yilmaz, et al., 2010; Glasscoe and Quittner, 2008; McGinnis, et al., 2005).

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. Henschke et al. (2010) conducted a systematic review of 30 randomized controlled trials (RCTs) that investigated behavioral treatment (e.g., biofeedback) for low back pain. There was low quality evidence (three RCTs; n=64) that EMG biofeedback was more effective than waiting list or progressive relaxation (one RCT; n=24).

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 American Society of Anesthesiologist Task Force on Chronic Pain Management and the American Society of Regional Anesthesia and Pain Medicine (2010) stated that psychological treatment including biofeedback “may be used as part of a multimodal strategy for low back pain and for other chronic pain conditions.”

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. Ramaratnam et al. (2008) 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 reported 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.

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 their clinical guideline for diagnosing and managing epilepsy in children and adults, NICE (2004) stated 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 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 a helpful treatment modality 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. Greenhalgh et al. (2009) conducted a systematic review to determine the clinical benefits and long-term effects of biofeedback for the treatment of essential hypertension in adults. Forty-one studies, including 36 randomized controlled trials (n=1660), met inclusion criteria. Twenty-one trials used biofeedback only and 15 trials used biofeedback with other treatment modalities. No meta-analysis was completed due to the poor reporting quality of the studies and the large degree of heterogeneity of treatments and comparators. Overall, the trials included small patient populations, no follow-up or follow-up less than 12 months. Other limitations of the studies included the variation in interventions, inconsistencies in measurement of outcomes, and the conflicting and variable results. No consistent short- or long-term benefits in the control of hypertension were seen when biofeedback was compared to pharmacotherapy, sham

biofeedback, no intervention or other behavioral therapies (e.g., relaxation, hypnosis, meditation, stress education).

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 had 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.

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.

In a guidance document on the management of hypertension, NICE (2006) stated 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.

Labor Pain: Barragán et al. (2011) conducted a systematic review of randomized controlled trials to evaluate the efficacy of biofeedback in the management of labor pain. Four trials (n=186) met inclusion criteria and primarily used EMG biofeedback. There were no significant differences between biofeedback and the control groups in terms of assisted vaginal birth, caesarean section, augmentation of labor and the use of pharmacological pain relief. Some studies reported that EMG biofeedback may have had some positive effects early in labor, but as labor progressed there was a need for additional pharmacological analgesia.

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. Malenfant et al. (2009) conducted a systematic review and meta-analysis of randomized controlled trials on complementary and alternative medicine, including biofeedback (n=5 studies), for the treatment of Raynaud's phenomenon. The outcomes of the biofeedback studies (n=15–155) favored sham therapy over biofeedback (p<0.02). There were no significant differences in frequency or duration or severity of Raynaud's attacks. The authors concluded that biofeedback is not an effective therapeutic intervention for the treatment of Raynaud's.

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 measure was 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) (2009) stated that while biofeedback is used for the treatment of a Raynaud's attack, formal studies have suggested that it is not helpful.

Recurrent Urinary Tract Infection: Minardi et al. (2010) conducted a randomized controlled trial to evaluate the efficacy of uroflowmetry biofeedback and pelvic floor relaxation biofeedback in women (n=86) with more than a three-year history of recurrent urinary tract infections (UTI) (i.e., three or more symptomatic episodes per year) and dysfunctional voiding. The authors defined dysfunctional voiding as an abnormally learned spectrum of voiding behavior in neurologically normal individuals. The women were randomized to one of four groups: group 1 (n=24), uroflowmetry biofeedback; group 2 (n=21), biofeedback training of the pelvic floor muscles; group 3 (n=20), uroflowmetry biofeedback combined with biofeedback training of the pelvic floor muscles; and group 4 (n=21), no treatment. Patients also received antibiotics during the study when indicated. At the three-, six- and 12-month follow-ups there were significant improvements ($p < 0.05$, each), which remained stable, in all of the following outcome measures: storage and emptying symptoms, mean flow rate, flow time, voiding and volume; overall voiding pattern; post-void residual urine; mean opening detrusor pressure and detrusor pressure at maximum flow; and the prevalence of UTI. No significant improvements were seen in the untreated group. At 24 months in the treated groups, the storage and emptying symptoms and voiding patterns were similar to baseline values in 55% of patients, and the incidence of UTIs was similar in 45% of patients. The authors noted that this was the first study of pelvic floor therapy for the treatment of recurrent UTIs in women. Limitations of the study include the small patient population, short-term follow-up and the number of patients lost to follow-up (142 were originally enrolled).

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 flairs-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.

Stroke: The goal 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). Tate and Milner (2010) conducted a systematic review of randomized controlled trials (n=7) to evaluate the effectiveness of biofeedback in treating gait abnormalities. The types of biofeedback included real-time kinematic, temporospatial and kinetic. In five studies the patient population (n=105) was status-post stroke. One study included 42 patients with hip or knee replacement, hip fracture or amputation and one study included 28 patients status-post total hip replacement. There was a large range in the structure of the treatment protocol (e.g., treatment time, frequency, duration) and meta-analysis was not performed because of the wide variety of study designs, methodologies and outcome measures. Although some studies reported short-term improvement, long-term outcomes were not reported and whether or not improvements were maintained is unknown. The authors concluded that there was insufficient data to make a guideline recommendation for biofeedback for gait training.

Zijlstra et al. (2010) conducted a systematic review of randomized controlled trials (n=17) and comparative studies (n=4) to evaluate the effectiveness of biofeedback training for balance and/or mobility in older adults. Twelve studies included post-stroke patients, six included frail older adults in a care center and three studies included lower limb amputation and/or hip surgery. The biofeedback was visual and/or audio. The studies were determined to be of moderate quality with variations in analyses and outcomes. Due to the inability to perform quantitative analysis and the absence of large-scale randomized controlled trials, definitive conclusions could not be made. The addition of biofeedback during gait training did not seem to improve disability and mobility functioning.

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 did “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.

Pollock et al. (2003) conducted a systematic review on the 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. The review included randomized or quasi-randomized controlled trials with interventions of physiotherapies, including biofeedback. Outcomes measured the 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.

In their 2010 guidelines on stroke rehabilitation, the Department of Veterans Affairs, Department of Defense, American Heart Association and American Stroke Association recommended EMG biofeedback as a treatment modality for pain control when appropriate. However, “due to methodological flaws in current studies, further research is indicated to assess the efficacy of biofeedback as an adjunct to conventional therapy for post-stroke patients.”

In their discussion of rehabilitation for stroke patients, the 2010 National Stroke Foundation (NSF) clinical guidelines stated that EMG biofeedback is one modality that can be used in conjunction with conventional therapy in patients who have reduced strength and/or have difficulty using their upper limbs. Joint position biofeedback in conjunction with conventional walking training may be an option for patients having difficulty walking. Biofeedback may also be helpful in patient with dysarthria and persistent moderate to severe spasticity that interferes with activity or personal care. However, NSF noted that biofeedback should be used with caution in this patient population due to the limited number of studies supporting its efficacy.

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 following biofeedback would alleviate the pain of TMD. A systematic review by Medicott 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 systematic review, 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.

The 2010 guideline for the treatment of temporomandibular disorders by the American Association of Oral and Maxillofacial Surgeons does not include biofeedback as a treatment modality.

Tinnitus: Weise et al. (2008) conducted a randomized controlled trial to compare the effects of biofeedback (n=63) to a wait-list control group (WLG) (n=67) in patients with chronic tinnitus (i.e., more than six months duration). Patients underwent 12, one-hour EMG biofeedback sessions with tinnitus-specific cognitive-behavioral therapy (CBT) (e.g., directing attention away from tinnitus, relapse prevention) over a three-month period. Final follow-up occurred six months following cessation of treatment. Following treatment, intention-to-treat statistical analysis based on results of interviews and self-reported questionnaires showed significantly less

emotional and cognitive distress; less intrusive tinnitus, less auditory perceptual difficulties, less sleep disturbances and fewer somatic complaints in the biofeedback group ($p < 0.01$ for each). No significant differences were reported in the WLG. Compared to pretreatment and the WLG, patients in the biofeedback group reported fewer feelings of helplessness, increased feelings of resourcefulness, fewer catastrophizing self-statements, and more helpful coping self-statements. However, no significant effect was found for depressive and general psychopathological symptoms. Following a waiting period, 52 WTG patients received biofeedback and showed a significant improvement in outcomes. The authors noted that the study was limited by the WTG instead of an active treatment control group (CBT without biofeedback). Other limitations of the study are the short-term follow-up, and the drop out rate ($n=26$).

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. Two prospective randomized studies met inclusion criteria and both were considered 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 authors 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 authors 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, also called vulvar vestibulitis or 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 authors 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”.

The American Society for Colposcopy and Cervical Pathology’s (ASCCP) practice management recommendations (Haefner, et al., 2005) stated that biofeedback may be used in the treatment of vulvodynia to relieve pain and discomfort.

In 2006, ACOG and ASCCP 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.”

EEG Biofeedback/Neurofeedback

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 methodological flaws, Hayes stated that "no definitive conclusions regarding the efficacy of EEG biofeedback can be drawn." In a subsequent literature search (2008), Hayes' conclusions had not changed.

In a randomized controlled trial, Gevensleben et al. (2010) reported on the six-month follow-up of 61 of 94 children, ages 8–12 years, with ADHD who were treated with a computerized attention skills training (AST) (n=35) or neurofeedback (n=59). The neurofeedback system used was developed by the authors. Both treatments were divided into two blocks of 18 units consisting of 9 sessions, two to three times a week, for 50 minutes each. There was a two to three week break between the two blocks of treatment. Based on parental responses, there was a significant group overall effect ($P<0.005$) on the FBB-HKS ADHD rating scale and a significant group effect on the FBB-HKS inattention subscale ($p<0.005$), but no significant time effect following neurofeedback at the six-month follow-up. Compared to pre-training scores, reductions of inattention and hyperactivity/impulsivity at follow-up were 25–30% in the neurofeedback group compared to 10–15% in the AST control group. A significant group effect ($p<0.005$) was seen on the Strength and Difficulties Questionnaire hyperactivity subscale (SDQ) in the neurofeedback group. A significant group difference ($p<0.05$) was also seen in homework in the neurofeedback group. A total of 50% of children in the neurofeedback group showed a $\geq 25\%$ reduction in the primary outcome measure following post-training and at the six-month follow-up. In the control group, 26.1% were responders at post-training and 30.4% at six-months. Limitations of the study include the small patient population, short-term follow-up, number of patients lost to follow-up (n=33), neurofeedback system developed by the authors and outcomes reported by parents.

Home Biofeedback Devices

Biofeedback should be performed in a clinical setting by trained professionals. The evidence in the published peer-reviewed scientific literature does not support the effectiveness of home 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 (FemiScan™, 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 scientific 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 scientific 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. 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
- cerebral palsy
- chronic back pain
- chronic prostatitis
- cystic fibrosis
- epilepsy
- fibromyalgia
- functional dyspepsia
- heart failure
- hyperhidrosis
- hypertension
- knee osteoarthritis
- labor pain
- pervasive developmental disorders
- posttraumatic stress disorder (PTSD)
- Raynaud's syndrome
- recurrent urinary tract infections
- reflex sympathetic dystrophy/complex regional pain syndrome
- rheumatoid arthritis,
- stroke
- temporomandibular disorders
- tinnitus
- type 2 diabetes mellitus
- upper limb pain
- vulvodynia
- whiplash

Coding/Billing Information

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

Biofeedback

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

338.3	Neoplasm related pain (acute) (chronic)
339.1-339.12	Tension type headache
346.00- 346.93	Migraine
564.00- 564.09	Constipation
625.6	Stress incontinence, female
787.60- 787.63	Incontinence of feces
788.30- 788.39	Urinary incontinence

Experimental/Investigational/Unproven/Not Covered:

ICD-9-CM Diagnosis Codes	Description
088.0-088.9	Other arthropod-borne diseases
250.00	Diabetes mellitus without mention of complication, type II or unspecified type, not stated as uncontrolled
250.02	Diabetes mellitus without mention of complication, type II or unspecified type, uncontrolled
250.10	Diabetes with ketoacidosis, type II or unspecified type, not stated as uncontrolled
250.12	Diabetes with ketoacidosis, type II or unspecified type, uncontrolled
250.20	Diabetes with hyperosmolarity, type II or unspecified type, not stated as uncontrolled
250.22	Diabetes with hyperosmolarity, type II or unspecified type, uncontrolled
250.30	Diabetes with other coma, type II or unspecified type, not stated as uncontrolled
250.32	Diabetes with other coma, type II or unspecified type, uncontrolled
250.40	Diabetes with renal manifestations, type II or unspecified type, not stated as uncontrolled
250.42	Diabetes with renal manifestations, type II or unspecified type, uncontrolled
250.50	Diabetes with ophthalmic manifestations, type II or unspecified type, not stated as uncontrolled
250.52	Diabetes with ophthalmic manifestations, type II or unspecified type, uncontrolled
250.60	Diabetes with neurological manifestations, type II or unspecified type, not stated as uncontrolled
250.62	Diabetes with neurological manifestations, type II or unspecified type, uncontrolled
250.70	Diabetes with peripheral circulatory disorders, type II or unspecified type, not stated as uncontrolled
250.72	Diabetes with peripheral circulatory disorders, type II or unspecified type, uncontrolled
250.80	Diabetes with other specified manifestations, type II or unspecified type, not stated as uncontrolled
250.82	Diabetes with other specified manifestations, type II or unspecified type, uncontrolled
250.90	Diabetes with unspecified complication, type II or unspecified type, not stated as uncontrolled
250.92	Diabetes with unspecified complication, type II or unspecified type, uncontrolled
277.00- 277.09	Cystic fibrosis
296.00- 296.06	Bipolar I disorder, single manic episode, unspecified
296.30- 296.36	Major depressive disorder, recurrent episode

296.80- 296.89	Other and unspecified bipolar disorders
299.00- 299.91	Pervasive developmental disorders
300.00- 300.09	Anxiety states
300.10- 300.19	Dissociative, conversion and factitious disorders
303.00- 303.93	Alcohol dependence syndrome
304.00- 304.93	Drug dependence
307.20- 307.23	Tics
309.0-309.9	Adjustment reaction
309.81	Posttraumatic stress disorder
314.00- 314.01	Attention deficit disorder
327.00-327.8	Organic sleep disorders
337.20- 337.29	Reflex sympathetic dystrophy
343.0-343.9	Infantile cerebral palsy
345.00- 345.91	Epilepsy and recurrent seizures
348.30- 348.39	Encephalopathy, not elsewhere classified
388.30- 388.32	Tinnitus
401.0-401.9	Essential hypertension
428.0-428.9	Heart failure
434.91	Unspecified cerebral artery occlusion with cerebral infarction
443.0	Raynaud's syndrome
493.00- 493.92	Asthma
524.60	Temporomandibular joint disorders, unspecified
524.61	Temporomandibular joint disorders, adhesions and ankylosis (bony or fibrous)
524.62	Temporomandibular joint disorders, arthralgia of temporomandibular joint
524.63	Temporomandibular joint disorders, articular disc disorder (reducing or non-reducing)
524.69	Other specified temporomandibular joint disorders
536.8	Dyspepsia and other specified disorders of function of stomach
599.0	Urinary tract infection, site not specified
601.1	Chronic prostatitis
625.70- 625.79	Vulvodynia
705.21- 705.22	Focal hyperhidrosis
714.0	Rheumatoid arthritis
715.00- 715.98	Osteoarthritis
724.5	Backache, unspecified
728.81- 728.89	Other disorders of muscle, ligament, and fascia
729.1	Myalgia and myositis, unspecified
729.5	Pain in limb
780.8	Generalized hyperhidrosis

780.52	Insomnia, unspecified
847.0	Sprains and strains of neck
	All other codes

Biofeedback Devices

Experimental/Investigational/Unproven/Not Covered:

HCPCS Codes	Description
E0746	Electromyography (EMG), biofeedback device

ICD-9-CM Diagnosis Codes	Description
	All codes

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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

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