

# Cigna Medical Coverage Policy



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Subject **Biofeedback**

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## INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna companies. Coverage Policies are intended to provide guidance in interpreting certain **standard** Cigna benefit plans. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document **always supersedes** the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations. Proprietary information of Cigna. Copyright ©2014 Cigna

## 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 by a licensed healthcare professional as medically necessary for ANY of the following conditions:

- constipation (adults only)

- stress, urgency, mixed, or overflow urinary incontinence when there is failure of other nonpharmacologic treatment (e.g., bladder training and/or pelvic floor muscle training [PFMT]) (children and adults)
- migraine and tension headaches (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 (NCCAM, 2012).

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.

Another form of biofeedback is electroencephalogram (EEG) biofeedback, also called neurofeedback, brainwave biofeedback 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/intellectual disability, fibromyalgia, dyslexia. However, the evidence in the published peer-reviewed scientific literature does not support the efficacy of EEG biofeedback. (For ADHD refer to the Attention-Deficit/Hyperactivity Disorder (ADHD): Assessment and Treatment Coverage Policy).

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 devices; 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.

Evidence in the published peer-reviewed literature and professional societies supports biofeedback for the treatment of constipation in adults and urinary incontinence and migraine and tension headaches in adults and children.

## **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, 2013). There are numerous biofeedback devices available from multiple manufacturers.

### **Constipation**

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.

The evidence in the published peer-reviewed scientific literature supports the use of biofeedback for the treatment of constipation in adults. Significant improvements in constipation with biofeedback have been reported in systematic reviews, meta-analysis and randomized controlled trials (Enck, et al., 2009; Koh, et al., 2008; Heyman, et al., 2007; Rao, et al., 2007; Chiarioni, et al., 2006; Heyman, et al., 2003).

Biofeedback for the treatment of constipation 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).

The 2013 American Gastroenterological Association's (AGA) position statement on constipation for adults stated that biofeedback improves symptoms in more than 70% of patients with defecatory disorders. Biofeedback can be used to train patients to relax their pelvic floor muscles during straining and to correlate relaxation and pushing to achieve defecation. The success of the therapy depends on the motivation of the patient and therapist, frequency and intensity of the retraining, and involvement of behavioral psychologist and dieticians. AGA “strongly recommends” “based on high quality evidence” that biofeedback be used rather than laxatives for defecatory disorders which are primarily characterized by impaired rectal evacuation from inadequate rectal propulsive forces and/or increased resistance to evacuation.

In practice guidelines on the management of constipation, the American Society of Colon and Rectal Surgeons (ASCRS) (2007) recommended biofeedback as a treatment option for patients with slow-transit constipation associated with symptomatic pelvic floor dyssynergia. Success rates range from 35–90% with sustained results reported for up to 24 months.

### **Urinary Incontinence (UI)**

UI is the involuntary leakage of urine caused by a variety of conditions that directly or indirectly affect bladder control. Incontinence may manifest as near-constant dribbling or as intermittent voiding with or without awareness of the need to void. Post-void dribbling is common. The amount of leakage varies with the type of incontinence and may be small to large amounts. 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). Pelvic floor muscle training is an established treatment modality for urinary incontinence. Bladder training, changes in fluid intake, pharmacotherapy and surgical intervention may also be indicated based on the type of incontinence. Biofeedback is an established treatment modality for children and adults with stress, urge, mixed or overflow urinary incontinence that is unresponsive to other nonpharmacologic modalities such as bladder training and/or pelvic floor muscle training. Biofeedback may enhance awareness of body functions and assist the individual in learning muscle strengthening pelvic floor exercises. 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 (Holroyd-Leduc, et al., 2008; Shamliyan, et al., 2008; Payne, 2007).

The published peer-reviewed scientific literature includes systematic reviews, randomized controlled trials, and case series that have reported an improvement in urinary incontinence for up to two years following biofeedback (Fitz, et al., 2012; Herderschee, et al., 2011; Desantis, et al., 2011; 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 Agency for Healthcare Research and Quality (AHRQ) (2013) conducted a systematic review on the diagnosis and nonsurgical treatment of urinary incontinence (UI) in adult women. The focus of the review was women with stress UI associated with sphincter function and urgency UI which is often associated with overactive bladder. The review included pharmacotherapy and nonsurgical management (e.g., pelvic floor muscle training, biofeedback, intravaginal electrical stimulation). Randomized controlled trials which included mostly mixed incontinence showed that nonpharmacological treatments were better than no active treatment. Regarding biofeedback, AHRQ's key findings stated that performing pelvic floor muscle training (PFMT) with biofeedback improved UI. AHRQ noted that women experienced improvement in UI with PFMT with and without biofeedback.

The 2010 American Urological Society's (AUS) 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 "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. A third type of headache is a chronic (i.e., occurring on more days than not for a three month period or longer) or recurrent headache which may occur secondary to multiple conditions, such as medication usage, infectious process, brain tumor, caffeine withdrawal, sleep deprivation, trauma and psychogenic disorders. The treatment of chronic headaches 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."

## **Other Conditions**

Biofeedback has been proposed as a treatment modality for numerous other conditions including: alcohol and drug abuse, anxiety disorders, asthma, autism spectrum disorders, cancer pain and symptoms, cardiovascular disease, cerebral palsy, chronic back pain, chronic prostatitis, cystic fibrosis, epilepsy, fecal incontinence, 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).

**Cancer:** Patients undergoing oncologic therapy experience persistent pain, fatigue, anxiety and side effects from chemotherapy. In addition to pharmacotherapy, biofeedback has been proposed as an adjunct treatment modality for this patient population. However, there is insufficient evidence in the published peer-reviewed literature to support biofeedback for the management of cancer. There have been a limited number of studies with small patient populations (n=12-81), short-term follow-ups (e.g., 3 months) and in some studies, lack of a control group. Most studies were conducted prior to 2000. Biofeedback has not been shown to be effective in reducing cancer pain or chemotherapy side effects.

In reference to the management of cancer pain, the National Cancer Institute (NCI) (2014) states that alternative therapies (e.g., biofeedback) may be used in conjunction with pain medication in an effort to control pain. NCI stated that even though non-medical therapies 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. NCI noted that if a patient was interested in trying biofeedback, they "must see a licensed biofeedback technician".

The American Cancer Society (2014) stated biofeedback under the supervision of a licensed biofeedback technician is a non-medical treatment that may be used for the treatment of cancer pain. Non-medical treatment are "widely used" to help manage cancer pain and is typically used with other pain-relief methods.

In the Cancer-Related Fatigue guideline, the National Comprehensive Cancer Network<sup>®</sup> (NCCN<sup>®</sup>) (2014) stated that behavioral techniques including biofeedback are beneficial in improving fatigue among breast cancer patients.

**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. 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".

**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, the evidence wasn't considered reliable.

### **Fecal Incontinence**

Fecal incontinence is the inability to control bowel movements and may involve leakage of stool. Causes of fecal incontinence include severe constipation, chronic diarrhea, overuse of laxatives, damage to the anal sphincter muscles or nerves, anal surgical procedures, spinal cord injury and stroke. Treatment includes changes in dietary habits, pelvic floor muscle exercises and pharmacotherapy. Biofeedback has been proposed for the treatment of fecal incontinence, but results from systematic reviews and randomized controlled trials reported that biofeedback does not improve this condition.

Norton and Cody (2012) conducted a systematic review of randomized and quasi-randomized controlled trial to evaluate biofeedback and/or anal sphincter exercises for the treatment of fecal incontinence in adults. Twenty-one studies (n=1525) met inclusion criteria. Two biofeedback studies reported follow-ups at nine months and five studies reported follow-ups at one year, but most studies reported no follow-up following cessation of treatment. The authors stated that they found no evidence that biofeedback provided any benefit over any other treatment (e.g., dietary modification, bulking agents, pelvic floor exercises). Evidence on patient selection criteria is lacking. Overall, the limited number of studies with methodological weaknesses, including incomplete outcome data, did not allow for definitive assessment of the role of biofeedback in the treatment of adults with fecal incontinence.

Brazzelli et al. (2011) conducted a systematic review of randomized and quasi-randomized controlled trials to assess the effectiveness of behavior and/or cognitive interventions, including biofeedback, for the treatment of children with fecal incontinence. Twenty-one trials (n=1371) met inclusion criteria. Follow-ups ranged from 4–24 months with two trials reporting no follow-up following cessation of treatment. Combined results of nine trials showed higher rates of persistent symptoms of fecal incontinence for up to 12 months when biofeedback was added to conventional treatment (e.g., laxatives, toilet training, dietary advice, behavior modification). Based on this data, the authors concluded that there was “no evidence” that biofeedback training added any benefit to conventional therapy for the management of functional fecal incontinence nor was there enough data to assess the effectiveness of biofeedback for the management of organic fecal incontinence in children.

The American Society of Colon and Rectal Surgeons (ASCRS) (2007) stated that biofeedback could be used as an initial treatment of fecal incontinence in motivated patients with some voluntary sphincter contraction. ASCRS noted that the benefits are variable and standard care (e.g. advice and education) alone has been shown to be as effective as biofeedback therapy.

**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.

An evidence-based statement by the American Heart Association (AHA) included the investigation of biofeedback as an alternative therapy for lowering blood pressure (BP). AHA noted that the mechanisms responsible for BP lowering by biofeedback are incompletely described. Some evidence favors alteration in the autonomic nervous system balance. Systematic reviews and meta-analysis that have investigated biofeedback for this indication have reported conflicting results. Studies have been limited by "short duration, small sample sizes, difficulties with blinding, and significant heterogeneity when trial data were combined". Also, some meta-analyses have combined multiple complementary medicine techniques in their analyses, making it difficult to assess the impact of biofeedback alone. Due to the paucity of data, recommendation for using a specific biofeedback method could not be made. Overall, no significant adverse effects were reported. Based on this review, AHA stated that biofeedback may be considered in clinical practice to lower BP. This is a Class IIB, Level of Evidence B, recommendation meaning that the usefulness/efficacy of biofeedback is less well established and there is greater conflicting evidence from randomized controlled trials or meta-analysis (Brooke, et al., 2013).

**Labor Pain:** In a systematic review, Jones, et al. (2012) summarized the evidence on the efficacy and safety of non-pharmacological and pharmacological interventions to manage labor pain. Fifteen Cochrane reviews (n=255 trials) and three non-Cochrane reviews (n=55 trials) met inclusion criteria. There was insufficient evidence from four randomized controlled trials (n=201) to determine if biofeedback was more effective than placebo or other interventions for labor pain management.

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.

**Knee Conditions:** Wasielewski et al. (2011) conducted a systematic review of eight randomized controlled trials (n=319 subjects) to evaluate the effectiveness of electromyographic biofeedback (EMGB) of the quadriceps femoris muscle for the treatment of knee conditions. Diagnosis included patellofemoral pain syndrome (two trials; n=86), anterior cruciate ligament reconstruction (two trials; n=52), arthroscopic surgery (two trials; n=91) or osteoarthritis (two trials; n=90). EMGB appeared to benefit short-term postsurgical pain or quadriceps strength in three out of the four postsurgical investigations but was reported ineffective for chronic knee conditions including patellofemoral pain and osteoarthritis. Limitations of the studies included small heterogeneous patient populations, variability in interventions and outcomes, and poor methodology. The authors stated that the results should be viewed with caution due to the limited data and poor studies.

**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.

The National Institute of Arthritis and Musculoskeletal Diseases (NIAMS) (2012) 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 flares 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 (n=1676) 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. Methodological flaws in the studies included: inadequate description of controls and the effect sizes were not always consistent with signs of confidence intervals. 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). Stanton et al. (2011) conducted a systematic review and meta-analysis of 22 randomized and quasi-randomized controlled trials to evaluate the effectiveness of biofeedback in enhancing lower-limb training for sitting, standing up, standing or walking following a stroke. Included clinical trials used various forms of biofeedback including any signal (position, EMG) via any sense (visual, auditor, tactile) during the practice of the whole activity. Based on pooled data from 17 trials (n=411) biofeedback improved lower limb activities compared to usual therapy or placebo in the short-term (i.e., one to five months following cessation of therapy). However, the authors noted that there was substantial heterogeneity of the low quality trials using any form of biofeedback; lack of blinding of subjects and therapists; possible small trial bias and selection bias based on intervention in the studies used for meta-analysis; and only half of the trials measured outcomes for any length of time following cessation of therapy. Well designed randomized controlled trials with long-term results are needed to support the effectiveness of biofeedback in stroke patients.

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.

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 that programs involving relaxation techniques and biofeedback, EMG training, and proprioceptive reeducation may be more effective than placebo or occlusal splints in decreasing pain and increasing total vertical opening in patients with

acute or chronic myofascial or muscular TMD. However, it was noted by the authors 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 (n=80) 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. The authors concluded that there were no differences in effect between applied relaxation, EMG biofeedback plus applied relaxation, and waiting-list controls 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 should be interpreted with caution because 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) vulvodynia guideline update (Stockdale, et al., 2013) stated that biofeedback may be used in the treatment of vulvodynia to aid patients in confronting and reducing pain.

In 2006 (reaffirmed 2008), the American College of Obstetricians and Gynecologists (ACOG) and American Society for Colposcopy and Cervical Pathology (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 (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 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.

The American Academy of Pediatrics (AAP) Task Force on Mental Health (2013) published a mental health tool kit for primary care clinicians as a guide for mental health care for pediatric practices. Included in the supplement is an “Evidence Based Child and Adolescents Psychosocial Interventions” document developed by using data from the PracticeWise Evidence-Based Services Database. The table lists primary problem areas and interventions based on the level of support. Biofeedback is listed as a level 4, minimal support, for anxious or avoidant behaviors and a level 5, no support for autism spectrum disorders. According to the authors the ratings are based on an ongoing review of randomized clinical psychosocial and combined treatment trials for children and adolescents with mental health needs.

### **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.

Peirce et al. (2013) conducted a randomized controlled trial (n=120) to determine if home biofeedback alone would have better anal manometry results at three months postpartum compared to pelvic floor exercises (PFEs) alone in women who sustained a primary third-degree postpartum tear. The secondary outcome criterion was improvement in continence scores. Subjects were randomized to home biofeedback (n=30) (CombiStim XP, Neurotech®, Galway, Ireland) or conventional PFEs (n=90). At the three month follow-up, there was no significant difference in anal resting (p=0.123), squeeze pressure (p=0.68), and the Cleveland Clinic continence scores (p=0.88) between the groups. There were no significant differences in the Rockwood fecal incontinence quality of life scale score including: lifestyle (p=0.29), coping (p=0.27), depression (p=0.89) and embarrassment (p=0.51). Seven of the 30 biofeedback subjects reported poor adherence. Home biofeedback did not improve the clinical outcomes of this subpopulation of women. Limitations of the study include the small patient population and short-term follow-up.

An earlier 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). A randomized controlled trial by 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”.

### **Use Outside of the US**

In their clinical guideline for diagnosing and managing epilepsy in children and adults, NICE (2013) 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. However, psychological interventions have not proven to affect seizure frequency and are not an alternative to pharmacological treatment.

The clinical guideline on the management of irritable bowel syndrome (IBS) published by NICE (2012) stated that reviews of biofeedback suggested a positive effect on the control of IBS symptoms, but “evidence was limited and not sufficient to make recommendations”. A systematic review of the literature identified four randomized controlled trials that met inclusion criteria. One study compared biofeedback to counseling and three studies evaluated multi-component therapy (a combination of educational information, progressive relaxation therapy, thermal biofeedback treatment and training in stress coping strategies) compared to symptom monitoring or attention placebo controls. There was limited, weak evidence to show a statistically significant improvement in global symptoms for biofeedback and reduction in diarrhea compared to symptom monitoring. No significant differences between biofeedback and attention placebo or between symptom monitoring and attention placebo were reported, but there was much uncertainty due to wide confidence intervals. There was insufficient evidence to determine the effects of biofeedback on pain, bloating and constipation.

The 2010 guideline on the management of constipation in children and young adults by 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 the guideline on the management of fecal incontinence, NICE (2007) stated that adults who have persistent fecal incontinence after initial management should be considered for special continence services including biofeedback. Due to the limited evidence, biofeedback is not recommended as a first line therapy.

### **Summary**

The evidence in the published peer-reviewed scientific literature and professional societies support the safety and efficacy of biofeedback for the treatment of constipation in adults, and the treatment of stress, urge, mixed and overflow urinary incontinence, as well as, migraine and tension headaches in children and adults.

The evidence in the published peer-reviewed scientific literature does not support the therapeutic effectiveness of biofeedback for any other indication due to the small number of clinical trials and/or small heterogeneous 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 (this list is not all inclusive):

- alcohol and drug abuse
- anxiety disorders
- asthma
- autism spectrum disorders
- cancer
- cardiovascular disease
- cerebral palsy
- chronic back pain
- chronic prostatitis
- cystic fibrosis
- epilepsy
- fecal incontinence

- fibromyalgia
- functional dyspepsia
- heart failure
- hyperhidrosis
- hypertension
- irritable bowel syndrome
- 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

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## Coding/Billing Information

**Note:** 1) This list of codes may not be all-inclusive.

2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

3) ICD-10-CM Diagnosis Codes are for informational purposes only and are not effective until 10/01/2015.

## Biofeedback

**Covered when medically necessary, if coverage is available:**

<b>CPT<sup>®</sup> Codes</b>	<b>Description</b>
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); 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); 45 minutes
90901	Biofeedback training by any modality
90911	Biofeedback training, perineal muscles, anorectal or urethral sphincter, including EMG and/or manometry

<b>ICD-9-CM Diagnosis Codes</b>	<b>Description</b>
307.81	Tension headache
339.10-339.12	Tension type headache
346.00-346.93	Migraine
564.00-564.09	Constipation

625.6	Stress incontinence, female
788.31	Urge incontinence
788.32	Stress incontinence, male
788.33	Mixed incontinence (male) (female)
788.34	Incontinence without sensory awareness
788.35	Post-void dribbling
788.37	Continuous leakage
788.38	Overflow incontinence

<b>ICD-10-CM Diagnosis Codes (Effective 10/01/2015)</b>	<b>Description</b>
G43.001- G43.919	Migraine
G44.201- G44.209	Tension-type headache
G89.3	Neoplasm related pain (acute) (chronic)
K59.00- K59.09	Other functional intestinal disorders
N39.3	Stress incontinence (female) (male)
N39.41- N39.498	Other specified urinary incontinence
R15.0-R15.9	Fecal incontinence
R32	Unspecified urinary incontinence
R39.9	Unspecified symptoms and signs involving the genitourinary system

**Experimental/Investigational/Unproven/Not Covered:**

<b>ICD-9-CM Diagnosis Codes</b>	<b>Description</b>
	All other codes

<b>ICD-10-CM Diagnosis Codes (Effective 10/01/2015)</b>	<b>Description</b>
	All other codes

**Biofeedback Devices**

**Experimental/Investigational/Unproven/Not Covered:**

<b>HCPSC Codes</b>	<b>Description</b>
E0746	Electromyography (EMG), biofeedback device

<b>ICD-9-CM Diagnosis Codes</b>	<b>Description</b>
	All codes



<b>ICD-10-CM Diagnosis Codes (Effective 10/01/2015)</b>	<b>Description</b>
	All codes

**\*Current Procedural Terminology (CPT®) © 2013 American Medical Association: Chicago, IL.**

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