Cigna Medical Coverage Policy- Therapy Services
Biofeedback

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GUIDELINES

Coverage for biofeedback varies across plans. Refer to the customer’s benefit plan document for coverage details.

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

Medically Necessary

Biofeedback performed by a licensed healthcare professional is considered medically necessary for ANY of the following conditions*:

- Chronic constipation with dyssynergic defecation (adults only)

- Fecal incontinence for patients with:
  - some degree of rectal sensation, and
  - ability to contract the sphincter voluntarily, and
  - failure/intolerance/contraindication of treatment with dietary changes, devices or drugs
• Stress, urgency, mixed, or overflow urinary incontinence when there is failure/intolerance/contraindication 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) as part of a comprehensive treatment plan

• Muscle re-education of specific extremity muscle groups or for treating pathological muscle abnormalities of spasticity, incapacitating muscle spasm, or weakness when:
  a. Patient is diagnosed with stroke, and
  b. Failure/intolerance/contraindication of conventional treatments (e.g. modalities, massage, soft tissue mobilization, exercise)

• Refractory levator ani syndrome (e.g. proctalgia fugax, chronic anal pain syndrome, anal spasm) with dyssynergic defecation when:
  - Condition is not neurological or disease-based
  - Failure/intolerance/contraindication of conservative treatment including:
    o high-fiber diet
    o withdrawal of drugs that cause constipation (e.g., calcium channel blockers, narcotics) or diarrhea (e.g., antibiotics, quinidine, theophylline)
    o perineal strengthening exercises
    o rectal massage
    o warm baths, and
    o drug therapy (e.g., muscle relaxants, non-narcotic analgesics, and sedatives)

*NOTE:

• Patients must be cognitively intact and willing and motivated to learn and practice the specific tasks needed to correct/improve their problems.

• There should be a written treatment plan which must include all of the following information:
  o The specific diagnosis/conditions to be treated
  o Long- and short-term goals
  o Measurable objectives
  o The time frame and the frequency of treatment in which the goals and objectives will be achieved.

**Experimental, Investigational, Unproven**

Biofeedback for ANY other indication is considered experimental, investigational or unproven, including but not limited to:

• As a rehabilitation modality for spasmodic torticollis, spinal cord injury, or following knee surgeries
• Attention deficit hyperactivity disorder (ADHD)
• Autism
• Bell's palsy (idiopathic facial paralysis)
• Cardiovascular diseases (e.g., heart failure)
• Chemotherapy-induced peripheral neuropathy
• Childhood apraxia of speech
• Chronic fatigue syndrome
• Chronic pain (e.g., back pain, fibromyalgia, neck pain) other than migraine and tension headache
• Epilepsy
• Essential hypertension (e.g., by means of the RESPeRATE Device)
• Facial pain
• Functional dysphonia
• Home biofeedback (for any indication)
• Improvement of anorectal/bowel functions after sphincter-saving surgery for rectal cancer
• Neurogenic bladder
• Non-neuropathic voiding disorders
• Labor pain
• Prophylaxis of medication overuse headache and pediatric migraine
• Raynaud's disease/phenomenon
• Rheumatoid arthritis
• Sleep bruxism
• Spasticity secondary to cerebral palsy
• Temporomandibular joint (TMJ) syndrome
• Toe-out gait modification/retraining in people with knee osteoarthritis
• Vaginismus
• Vulvodynia.

EACH of the following is considered experimental, investigational or unproven:
• electroencephalography (EEG) biofeedback or neurofeedback
• in-home biofeedback devices

DESCRIPTION
This guideline includes various indications for biofeedback, electroencephalography (EEG) biofeedback or neurofeedback, and in-home biofeedback devices.

GENERAL BACKGROUND
Biofeedback therapy provides visual, auditory or other evidence of the status of certain body functions so that a person can exert voluntary control over the functions, and thereby alleviate an abnormal bodily condition. Biofeedback therapy often uses electrical devices to transform bodily signals indicative of such functions as heart rate, blood pressure, skin temperature, salivation, peripheral vasomotor activity, and gross muscle tone into a tone or light, the loudness or brightness of which shows the extent of activity in the function being measured. It emphasizes relaxation, enhancement of muscle contraction and/or stress-reduction. Biofeedback is considered an alternative medicine technique (National Center for Complementary and Alternative Medicine [NCCAM], 2017; Holroyd, et al., 2003; Karmody, 2003; Kiresuk, et al., 2005).

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. The three most commonly used forms of biofeedback therapy are: (1) electromyography (EMG), which measures muscle tension; (2) thermal biofeedback, which measures skin temperature; and (3) neurofeedback or electroencephalography (EEG), which measures brain wave activity. Various forms of biofeedback appear to be effective for a narrow range of health problems.

Although there are numerous biofeedback devices available for home use, biofeedback should be performed in a clinical setting with the continuous presence of the physician or by a qualified non-physician practitioner. Continuous presence requires one-on-one face-to-face involvement with the patient and practitioner during training. Qualified non-physician practitioners include physical and occupational therapists in independent practice, Nurse Practitioners, Physician Assistants, and Clinical Nurse Specialists. 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/Temp2XTM (Biofeedback Instrument Corp., New York, NY) temperature biofeedback system; and RESPeRate (Intercure Ltd., Lod, Israel) which uses therapeutic paced breathing to lower blood pressure.

**Urinary Incontinence**

Urinary incontinence (UI) affects people of all ages, especially elderly women. Among adults, there are 4 prevalent types of UI: (1) stress incontinence (closure problem), (2) urge incontinence (storage problem), (3) overflow incontinence, and (4) mixed stress and urge incontinence. In women, stress incontinence is generally caused by an incompetent urethral mechanism which arises from damage to the sphincter(s) or weakening of the bladder neck support that typically occurred during childbirth. In men, stress incontinence is usually a consequence of operations for benign prostatic hypertrophy (BPH) or prostate cancer. Urge incontinence is usually associated with an over-activity of the detrusor muscle. When the involuntary contraction of the detrusor muscle is associated with a neurological deficit, it is known as detrusor hyperreflexia. On the other hand, when detrusor over-activity is not associated with any neurological deficit, it is labeled as detrusor instability (unstable bladder). Overflow incontinence may be due to an underactive detrusor muscle or obstruction of the urethra. In men, overflow incontinence associated with obstruction is usually due to prostatic hyperplasia. Urethral obstruction in women may occur as a consequence of anti-incontinence operation or severe prolapse of the uterus or relaxation of the anterior vaginal wall with cystocele or cystourethrocele.

First line treatment of urinary incontinence (stress, urgency, mixed) consists of behavioral treatments with an emphasis on improving quality of life because of their relatively non-invasive and low risk nature. Initial treatment includes lifestyle modifications and pelvic floor muscle exercise (Kegel exercises). Biofeedback is used as an adjunct to pelvic floor muscle exercises. By providing individuals with concurrent feedback on muscle tone, biofeedback is intended to improve the patient’s ability to perform pelvic muscle exercises. Augmented versions also use abdominal and perineal EMG recordings to demonstrate improper contraction of abdominal and gluteal muscles. Pelvic muscle exercises can aid in strengthening the voluntary periurethral and pelvic muscles needed to maintain urinary continence since contractions of these muscles raise the urethral pressure. This form of exercise is indicated for women with stress incontinence, men with incontinence following prostatic surgery, and patients with urge incontinence. Depending on the type of UI, patients are taught to contract the pelvic floor muscles, relax the detrusor and the abdominal muscles, and/or contract the sphincters. Biofeedback has been suggested to be useful in teaching patients with UI pelvic muscle exercises because it relays to them whether they are contracting the right muscle(s) and provides positive reinforcements as they acquire the skill during training sessions.

**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. Fecal incontinence (FI) is fairly common in the elderly and children. Dysfunction/abnormality of one or more of many factors; such as mental function, stool volume and consistency, anorectal sensation and reflexes and anal sphincter function, can result in FI. There are various methods for the treatment of FI including behavioral therapies, drug therapies, and surgical intervention. Various biofeedback techniques have also been used in the management of FI. In particular, external anal sphincter (EAS) biofeedback training has been shown to be effective in treating FI. This technique teaches patients to increase the strength of contraction of their EAS in response to rectal distention. There is evidence that biofeedback techniques are safe and effective in the treatment of patients with fecal incontinence, especially those who have some degree of rectal sensation and ability to contract the sphincter voluntarily. Biofeedback training has been demonstrated to restore continence or reduce the frequency of incontinence in patients with fecal incontinence with satisfactory long term results.

**Levator Ani Syndrome**

Levator ani syndrome (LAS) is characterized by chronic or recurring episodes of rectal pain or aching in patients with normal structural examinations of the rectum and pelvic floor. Patients with these findings are considered “highly likely” to have LAS if they experience tenderness on palpation of the levator muscles or to have "possible" LAS if they do not experience tenderness. This pain is usually unrelated to a bowel movement, and there appear to be no structural abnormalities or underlying conditions responsible for the symptoms. Though the exact cause
is unknown, it is commonly believed that chronic tension of the pelvic floor muscles plays a role in levator ani syndrome. Another theory is that inflammation in the pelvic area is a contributing factor.

People may be at higher risk of levator ani syndrome after childbirth or following surgery on the pelvic area, anus, or spine.

**Chronic Constipation**

Constipation is one of the most common gastrointestinal complaints in the United States affecting at least 10 % of the general population, and 25 % of the elderly. It is not a disease, but a symptom of various diseases/disorders of mixed etiologies and mechanisms. Constipation is defined as the occurrence of 2 or more of the following symptoms in the previous 12 months (without the use of laxatives): (1) fewer than 3 bowel movements per week, (2) excessive straining during at least 25 % of bowel movements, (3) a feeling of incomplete evacuation after at least 25 % of bowel movements, and (4) passage of hard or pellet-like stool during at least 25 % of bowel movements (Whitehead et al, 1991). Causes for constipation may be colorectal (e.g., malignancy, diverticular disease, pelvic floor dysfunction, and anal fissure), drug-induced (e.g., opiate analgesics, calcium and aluminum-containing antacids, anti-diarrheal agents, anti-depressants, and anti-histamines), metabolic/endocrine (diabetes mellitus, hypothyroidism, hypercalcemia, and pregnancy), and neurogenic (multiple sclerosis, Parkinson's disease, cerebral tumors, and Hirschsprung's disease). Other possible causes include irritable bowel syndrome, inadequate dietary fiber, and psychosocial problems. Pelvic floor outlet obstruction is a functional disorder of evacuation involving the external anal sphincter and pelvic floor voluntary musculature in which the muscles contract, rather than relax. This results in the anal canal being kept tightly closed during straining at attempted defecation. Biofeedback has been used successfully to teach patients with this disorder to relax the sphincter and pelvic floor musculature.

**Migraine and Tension-type Headache**

It is estimated that 50 million Americans suffer from headache. It is now generally accepted that about 1 in 8 adults in the developed countries has migraine headaches. Women are affected 2 to 3 times more than men. This disorder predominantly affects young adults and the peak incidence is between the age of 25 and 34. There are 2 major types of migraine headaches: (1) migraine with aura (classical migraine) which accounts for 15 to 18 % of all migraine episodes, and (2) migraine without aura (common migraine) which accounts for 80 % of all migraine attacks. Some individuals suffer from both types of migraine at different times. The treatment of choice for frequent migraine sufferers is usually pharmacologic prophylaxis. Avoidance strategies (loud noises flashing lights, stress and certain foods) also constitute a very important first line approach in managing migraine. Biofeedback training with or without relaxation techniques have also been shown to be effective in treating migraine and tension headache. In particular, thermal biofeedback training has been shown to be effective in treating migraine headache. This technique teaches patients to increase the temperature of their fingers. Supposedly, dilatation of the peripheral blood vessels in the hand is associated with reduced blood flow in the regions of the supra-orbital and superficial temporal arteries, although the exact mechanism by which thermal biofeedback improves migraine headaches is still unclear. For the management of tension headache, EMG feedback has been employed primarily. Moreover, it has been shown that the combination of thermal and EMG biofeedback has been effective in the control of migraine, tension, and mixed migraine and tension headache. Furthermore, it has been reported that relaxation techniques can produce improvements in headache. Available evidence indicates that biofeedback techniques (thermal, EMG, and temporal blood volume pulse biofeedback), with or without other behavioral therapies (relaxation and cognitive training), are safe and effective methods for the treatment of migraine and tension headache. This therapeutic modality has no side effects and does not preclude other options. Unlike migraine and tension headache, there is a lack of published data concerning the safety and effectiveness of biofeedback in the management of cluster headache. Before participating in a biofeedback program, patients should be examined by a physician to ensure that their headaches are not due to pathological conditions such as hematomas, aneurysm, brain tumors, brain edema, or diseases of the eye, ear and sinus. First line approaches, including avoidance of precipitating stimuli and pharmacologic prophylaxis, should have been tried and failed.

**Neuromuscular Rehabilitation**

Typically stroke rehabilitation includes various combinations of range of motion and muscle strengthening exercises, gait and mobility training, and compensatory techniques. Other therapies include neurodevelopmental based methods in which the treatment incorporates neuromuscular re-education techniques where biofeedback may be employed. Among biofeedback techniques employed in neuromuscular rehabilitation, EMG biofeedback is the most common one. It is often utilized by stroke patients for facilitation of contraction (strength) and relaxation.
of spasticity (inhibition). Electromyographic biofeedback has also been used to treat patients with spasmodic torticollis and patients with muscular atrophy resulting from surgery. The goals of EMG biofeedback in neuromuscular rehabilitation include relaxation of muscles or recruitment of muscles. Relaxation of muscles is performed where muscles are either trained to relax as a consequence of hyperactivity that may be stress or work related or as a result of spasticity caused by central nervous system dysfunction. Recruitment of muscles is to facilitate increased motor unit output for movement generation or strength. This is most commonly used when muscles have been weakened or inhibited as a result of injury, immobilization or surgical procedure of a limb/joint.

The majority of biofeedback research has focused on the effects of biofeedback therapy in the treatment of upper limb and lower limb motor deficits in neurological disorders (e.g. stroke). Traditionally biofeedback is presented to the patient and the clinician via visual displays, acoustic or vibrotactile feedback. A recent development in rehabilitation is exercising in a gaming or virtual reality (VR) environment, thus providing a novel form of immersive biofeedback. With VR the measured patient activity is fed back via graphical or audiovisual animations providing a realistic impression to the patient.

LITERATURE REVIEW

Urinary Incontinence

Pelvic floor muscle training is an established treatment option 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., 2009; 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). In their guideline on the management of urinary incontinence in women, NICE (Sept 2015) stated that perineometry or pelvic floor electromyography as biofeedback should not be used as a routine part of pelvic floor muscle training, but biofeedback should be considered in women who cannot actively contract pelvic floor muscles in order to aid motivation and adherence to therapy. In their guideline on the management of urinary incontinence in women, NICE (Sept 2015) stated that perineometry or pelvic floor electromyography as biofeedback should not be used as a routine part of pelvic floor muscle training, but biofeedback should be considered in women who cannot actively contract pelvic floor muscles in order to aid motivation and adherence to therapy. The 2017 American Urological Society’s (AUS) guidelines on the management of surgical treatment of female stress urinary incontinence (SUI) recommends that physicians counsel patients with stress urinary incontinence or stress-predominant mixed urinary incontinence who wish to undergo treatment. Counseling should include available treatment options including pelvic muscle floor training with or without biofeedback.

Fecal Incontinence

Biofeedback has been proposed for the treatment of fecal incontinence, and overall, results from systematic reviews and randomized controlled trials reported that biofeedback may help improve this condition in certain patients. However, studies primarily include small heterogeneous patient populations and diagnosis; short-term follow-up, and various biofeedback regimens and methods. Patient selection criteria with appropriate types of biofeedback regimens have not been established. 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. 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. 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) for fecal incontinence. 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.

Vonthein et al. (2013) conducted a systematic review of randomized controlled trials to evaluate the effectiveness of biofeedback (BF) and electrical stimulation (ES) for the treatment of fecal incontinence. Included studies evaluated BF, ES, BF plus ES, and/or pelvic floor exercises as a second-line therapy in adults who had no obvious need for surgery. The included studies also had to report patient-related outcomes (i.e., remission, response, and/or disease-related quality of life). Thirteen trials met inclusion criteria. In 12 trials, at least one study group received biofeedback typically in combination with ES or another modality. One study compared BF alone vs. ES alone and reported no significant differences in FI in either group following treatment. Two studies reported a significant improvement in the FI severity index, number of days with FI, anal squeeze and/or quality of life. However, the majority of studies reported no significant difference with the addition of biofeedback. The authors noted that BF seemed to be better than no BF and concluded that ES plus BF seemed to be the most effective treatment. Limitations of the studies investigating biofeedback for fecal incontinence included: small patient populations; heterogeneous populations (e.g., obstetrical trauma, elderly women); short-term follow-ups, conflicting outcomes, and missing data. The Italian Society of Colorectal Surgery (SICCR) and the Italian Association of Hospital Gastroenterologists (AIGO) joint committee developed a 2015 consensus statement for the treatment of fecal incontinence (FI). In the discussion of rehabilitative treatment for functional FI, the Committee reported that randomized controlled studies sustain the use of biofeedback. According to SICCR, a few studies suggested that adding biofeedback does not enhance the outcome of conservative management while other studies suggested that biofeedback and pelvic floor exercises be considered as a first-line option for patients who fail treatment with dietary changes, devices or drugs. Since there are no side effects, failure of biofeedback would not affect decisions regarding future therapy. Biofeedback with kinesitherapy (movement therapy) may also be a useful treatment. One study suggested biofeedback can be helpful after sphincteroplasty. The authors noted that techniques used for biofeedback and other modalities vary greatly and results of studies are not comparable (SICCR, 2015). Limitations of the studies evaluating biofeedback for the treatment of FI included: small, heterogeneous patient populations; heterogeneity of diagnosis, biofeedback methods and outcome measures; inconsistent statistically improved outcomes (e.g., embarrassment score, severity of FI, number of FI occurrences) across studies; lack of a control group; and conflicting outcomes. In some studies outcomes were not generalizable due to the diagnosis (e.g., obstetrical trauma).

The American Society of Colon and Rectal Surgeons (ASCRS) (2015) stated that biofeedback should be considered as an initial treatment of fecal incontinence in motivated patients with some preserved voluntary sphincter contraction. ASCRS noted that the benefits are variable and standard care (e.g. advice and education) alone have been shown to be as effective as biofeedback therapy. The recommendation is based on moderate-quality evidence and ASCRS noted that larger, well-designed studies are needed to make any definitive conclusions. In their 2015 guidelines for the efficacy of biofeedback for anorectal disorders, the American Neurogastroenterology and Motility Society (ANMS) and the European Society of Neurogastroenterology and Motility (ESNM) recommended biofeedback for the short- and long-term treatment of fecal incontinence for patients who have not responded to conservative medical treatment (e.g., antidiarrheals, fiber supplements). The guideline noted that treatment success is best defined as a 50% reduction in episodes of fecal incontinence, which has not been used in clinical trials. Other publications support this (Patcharatrakul and Rao, 2018; Rao et al., 2016). The Societies recommendation was based on nonrandomized studies rated as fair evidence and they noted that further research is needed to standardize the treatment protocols and the training of biofeedback therapists (Rao, et al., 2015). Overall, studies investigating the effectiveness of biofeedback for fecal incontinence included small, heterogeneous patient populations and treatment regimens with short-term follow-ups. Biofeedback was used as an adjunctive therapy with various modalities. Outcomes were conflicting and several studies reported that no significant differences were seen with biofeedback. Because some studies included defined subpopulations (e.g., females with impaired fecal incontinence after obstetric anal sphincter injury) outcomes were not generalizable.
The Agency for Healthcare Research and Quality (AHRQ) conducted a 2016 comparative effectiveness review on treatments for fecal incontinence (FI) in adults. Thirteen randomized controlled trials examined pelvic floor muscle training (PFMT) and PFMT with biofeedback (PFMT-BF). Enrolled adults were mostly female with mixed FI etiologies. Meta-analysis was not possible due to the numerous outcomes that were used. PFMT-BF was the most frequently studied intervention. Outcomes included the frequency and severity of FI, quality of life and perceived improvement. AHRQ found that the evidence was insufficient to support PFMT-BF vs. standard care (e.g., dietary fiber, stool-modifying drugs, and/or advice). Low-strength evidence showed that PFMT-BF with electrostimulation was no more effective than PFMT-BF alone on FI severity and FI quality of life over two to three months. Although PFMT-BF showed improvement in FI outcomes, the improvements were not significantly different from the comparison groups. AHRQ noted that future studies should focus on longer term effects and attempt to identify subgroups of adults by FI etiology that might benefit from specific interventions.

**Levator Ani Syndrome**

In their 2015 guidelines for the efficacy of biofeedback for anorectal disorders, the American Neurogastroenterology and Motility Society (ANMS) and the European Society of Neurogastroenterology and Motility (ESNM) recommended biofeedback may be useful in the short-term treatment of Levator Ani Syndrome with dyssynergic defecation (Level II, Grade B) (Rao, et al., 2015). Reports of biofeedback treatment for chronic functional anorectal pain have shown inconsistent results, and most of these were small and uncontrolled (46). However, a RCT of 157 well-characterized patients with LAS compared three treatments: biofeedback to teach pelvic floor muscle relaxation, electrogalvanic stimulation (EGS) to relax the pelvic floor, and digital massage of the levator muscles (Chiarioni, et al., 2010). The primary outcome measure was the subjects’ report of adequate pain relief. Key to the interpretation of the study was an a priori decision to test for tenderness when traction was applied to the levator ani muscles during digital rectal examination, and patients were stratified into the three treatment arms based on the presence or absence of tenderness. Among patients with tenderness on physical examination, adequate relief was reported by 87% with biofeedback, 45% with EGS and 22% with digital massage. However, none of these three treatments were effective in patients who did not report tenderness on physical examination (Chiarioni, et al., 2010). The mixed results reported in previous biofeedback studies most likely were a consequence of failure to stratify patients based on the presence or absence of levator ani tenderness. Other publications also support this (Patcharatrakul and Rao, 2018; Rao et al., 2016). Biofeedback therapy has also been used to treat Solitary Rectal Ulcer Syndrome (SRUS) in open, short-term, small sized (less than 20 patients) studies. Inclusion criteria, physiological investigations and outcome parameters were variable. Biofeedback therapy was associated with symptom improvement in at least two thirds of patients with some histological improvement. Most notably, the highest successful outcome was reported when SRUS was associated with dyssynergic defecation (DD) (Rao et al., 2015). Narayanan et al. (2019) authored a review to update practitioners on recent advances and to identify practical obstacles to providing biofeedback therapy. Authors summarized recent findings: the efficacy and safety of biofeedback therapy evaluated in defecatory disorders, fecal incontinence, and levator ani syndrome. They note that based on literature, biofeedback therapy is effective for managing defecatory disorders, fecal incontinence, and levator ani syndrome. Biofeedback therapy is recommended for patients with fecal incontinence who do not respond to conservative management. A subset of patients with levator ani syndrome who have dyssynergic defecation are more likely to respond to biofeedback therapy.

**Chronic Constipation**

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 (Skardoon et al., 2017; Woodward et al., 2014; 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 2010 guideline (updated 2017) 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 a 2014 evidence-based guideline on the evaluation and treatment of functional constipation in infants and children, the North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition (NASPGHAN) and the European Society for Pediatric Gastroenterology, Hepatology, and Nutrition (ESPGHAN) concluded that the evidence did
not support the use of behavioral therapy or biofeedback in the treatment of childhood constipation (Tabbers, et al., 2014).

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 dieticans. 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) (2016) states that in general, biofeedback should be used to treat slow-transit constipation and pelvic floor dyssynergia before subtotal colectomy. ASCRS recommended biofeedback as a first-line treatment option for patients with constipation due to symptomatic pelvic floor dyssynergia.

The American Neurogastroenterology and Motility Society (ANMS) and the European Society of Neurogastroenterology and Motility (ESNM) (Rao, et al., 2015) provided evidence-based recommendations on the efficacy of biofeedback for anorectal disorders. The Societies conducted a review of the literature and used the U.S. Preventive Services Task Force evidence criteria to grade the recommendations. The Societies’ recommendations included the following:

- Biofeedback is recommended for the short-term and long-term treatment of constipation with dyssynergic defecation (Level I, Grade A: evidence from at least one properly randomized controlled trial; good evidence; strongly recommends that clinicians routinely provide).
- Biofeedback may be useful for the short-term treatment of Levator Ani Syndrome with dyssynergic defecation (level II, Grade B: nonrandomized studies; fair evidence; recommends that clinicians routinely provide) and solitary rectal ulcer syndrome with dyssynergic defecation (level III, Grade C; opinions of authorities, based on clinical experience, descriptive studies and case reports or reports of expert committees; fair evidence; makes no recommendation).
- Biofeedback therapy is not recommended for the routine treatment of children with functional constipation, with or without overflow fecal incontinence. (Level 1, Grade D; evidence from at least one properly randomized controlled trial; recommends against its use).

**Migraine and Tension-type Headache**

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 could be recommended as an evidence-based behavioral treatment option for the prevention of migraine.

**Neuromuscular Rehabilitation**

There is sufficient evidence that EMG biofeedback is safe and effective for neuromuscular rehabilitation in patients who suffered from strokes (Giggins et al., 2013; Stanton et al., 2017). However, there is insufficient evidence that EMG biofeedback is effective as a rehabilitation modality for patients with spinal cord injury and in patients with spasmodic torticollis (Giggins et al., 2013). Additionally, although there is limited evidence that EMG biofeedback is effective in enhancing the return to full active knee extension and peak torque of the quadriceps femoris muscle following knee surgeries, there is little data on how these improvements translate clinically into improved functional outcomes (Giggins et al., 2013). For patients to potentially benefit from EMG biofeedback, they need to have some volitional muscle activity but remain disabled with no receptive aphasia. And biofeedback should be used when other standard forms of therapy have failed.

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
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. 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.”

Doğan-Aslan et al. (2012) evaluated the effect of electromyographic biofeedback (EMG-BF) treatment on wrist flexor muscle spasticity, upper extremity motor function, and ability to perform activities of daily living in patients with hemiplegia following stroke. A total of 40 patients were enrolled and were randomly assigned to two groups: a group treated with EMG-BF (study group) and a untreated (control) group. Both groups participated in a hemiplegia rehabilitation program consisting of neurodevelopmental and conventional methods. In addition, the study group received 3 weeks of EMG-BF treatment, 5 times a week, for 20 minutes per session at hemiplegic side wrist flexors. Clinical findings were assessed before and after rehabilitation using the Ashworth scale (AS), Brunstrom's stage (BS) of recovery for hemiplegic arm and hand, the upper extremity function test (UEFT), the wrist and hand portion of the Fugl-Meyer scale (FMS), goniometric measurements of wrist extension, surface EMG potentials, and the Barthel Index (BI). There was no statistically significant difference between the two groups in terms of baseline measures. There also was no statistically significant difference in the pretreatment values between two groups. Authors noted statistically significant improvements posttreatment in the AS, BS, UEFT, goniometric measurements of wrist extension, and surface EMG potentials in the study group. They also noted statistically significant differences in the wrist and hand portion of the FMS and the BI in both groups, but with significantly greater improvements in the study group. Authors concluded that findings indicate a positive effect of EMG-BF treatment in conjunction with neurodevelopmental and conventional methods in hemiplegia rehabilitation.

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. Stanton et al., (2017) completed on systematic review with meta-analysis to determine if biofeedback during the practice of lower limb activities after stroke is more effective than usual therapy in improving those activities. Outcome measures were activity measures congruent with the activity trained.

Eighteen trials including 429 participants met the inclusion criteria. The quality of the included trials was moderately high, with a mean PEDro score of 6.2 out of 10. Results demonstrated that biofeedback improved performance of activities more than usual therapy. Authors concluded that biofeedback is more effective than usual therapy in improving performance of activities. They also stated that further research is required to determine the long-term effect on learning and given that many biofeedback machines are relatively inexpensive, biofeedback could be utilised widely in clinical practice. Wattchow et al. (2018) investigated the therapeutic interventions reported in the research literature and synthesize their effectiveness in improving upper limb (UL) function in the first 4 weeks poststroke. A total of 104 trials (83 RCTs, 21 nonrandomized studies) were included (N=5225 participants). Evidence was found to support supplementary use of biofeedback and electrical stimulation. Authors concluded that use of mCIMT and task-specific training was supported, as was supplementary use of biofeedback and electrical simulation, within the acute phase poststroke.

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, acute and 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, spastic torticollis, 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 (Hayes Inc., 2016; 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.

The American Cancer Society (2015) stated biofeedback under the supervision of a licensed biofeedback technician is a non-medical treatment that is sometimes used to help people relax and cope with pain and is typically used with other pain-relief methods.

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 College of Physicians (ACP) (2017) developed guidelines based on an evidentiary review of the literature to provide clinical recommendations on noninvasive treatment of low back pain. ACP recommended that select nonpharmacologic treatment be used initially. Low quality evidence reported that electromyography biofeedback reduced pain compared to wait list but there was no effect on function.

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. In their clinical guideline for diagnosing and managing epilepsy in children and adults, NICE (2016) 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.

**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).

**Irritable Bowel Syndrome (IBS):** The clinical guideline on the management of irritable bowel syndrome (IBS) published by NICE (2008; updated 2017) 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.

**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:** Richard et al. (2017) conducted a systematic review of the literature to evaluate the effectiveness of real-time biofeedback as a method for gait retraining to reduce knee adduction movement (KAM) in patients with knee osteoarthritis (KOA). Twelve uncontrolled studies met inclusion criteria. Seven studies used healthy subjects and five studies enrolled patients with KOA. Because of the lack of studies reporting between-group effects, this review focused on within-group effects. Within-group standardized mean differences (SMDs)
for reduction of KAM in healthy controls ranged from 0.44 to 2.47 and from 0.29 to 0.37 in patients with KOA. In patients with KOA, improvements were reported in pain and function, with SMDs ranging from 0.55 to 1.16. Limitations of the studies included: small number of studies that enrolled KOA patients; small patient populations; heterogeneity of study design, methods of feedback and number of training sessions (many studies only reported on one session); short-term follow-ups (e.g., one month); and lack of a comparator and control group. The authors noted that there was insufficient information to conclude the optimal method of feedback delivery or the optimal instructions for subjects to achieve KAM reductions. Additional studies with large patient populations and long-term follow-up are needed to support biofeedback for this indication.

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.

Nonneuropathic Voiding Disorders: Fazeli et al. (2014) conducted a systematic review and meta-analysis to evaluate biofeedback for the treatment of nonneuropathic daytime voiding disorders (NVD) in children. The hallmark of nonneuropathic voiding disorders is lower urinary tract symptoms with or without urinary incontinence. Five randomized controlled trials (n=487) met inclusion criteria and four studies (n=382) were included in the meta-analysis. At six months follow-up, there were no significant differences in the number of cases with resolved incontinence, mean maximum urinary flow rate or the likelihood of urinary tract infection with biofeedback vs. control group without biofeedback. The data does not support biofeedback for the treatment of this subpopulation.

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.

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 uroflowmetry biofeedback combined with biofeedback training of the pelvic floor muscles; and group 4 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 flair-ups and/or enhance arthritic pain. Astin et al. (2002) conducted a systematic review of the literature to investigate the effect of psychological interventions (including biofeedback) on patients with RA. Outcome measures included functional ability, pain, tender joints,
psychological status and coping ability. Twenty-five randomized controlled trials (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.

**Sleep Bruxism:** Biofeedback has been proposed as a treatment option for sleep bruxism, a sleep-related disorder characterized by teeth grinding or jaw clenching. In a systematic review of seven randomized controlled trials (n=240), Wang et al. (2014) concluded that the evidence did not support biofeedback for this condition. Meta-analysis showed no significant differences between biofeedback and controls (p=0.26). The studies were limited by the heterogeneity of the biofeedback modalities (i.e., auditory, electrical and visual feedback) and regimens, and the use of various control modalities (e.g., splint, occlusal adjustment) and outcome measures. The classification of risk of bias was moderate to high.

**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 Medlicott and Harris (2006) included seven randomized controlled trials which evaluated the effectiveness of relaxation training or biofeedback in the management of TMD. From the review of these studies, the authors stated 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.

**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 dropout 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.

Biofeedback (CPG 294)
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 a 2016 updated Committee Opinion on persistent vulvar pain, the American Congress of Obstetricians and Gynecologists (ACOG) and American Society for Colposcopy and Cervical Pathology (ASCCP) recommendations and conclusions stated that women with vulvodynia should be assessed for pelvic floor dysfunction. Biofeedback and/or physical therapy, including pelvic floor physical therapy can be used to treat localized and generalized vulvar pain especially if there is concomitant vaginismus.

EEG Biofeedback/Neurofeedback
The evidence in the clinical trials has not established clinical efficacy and effectiveness of EEG biofeedback for any indication. Studies include small patient populations and heterogeneous types of neurofeedback with short-term follow-ups (Lee, et al., 2015; Angelakis, et al., 2007; Dohrmann, et al., 2007; McDonough-Means and Cohen, 2007).

Renton et al. (2017) conducted a systematic review to evaluate the effectiveness of neurofeedback (NF) as a form of cognitive rehabilitation therapy for the treatment of stroke patients. Studies included subjects who were affected by a cognitive deficit following stroke (e.g., memory loss, loss of executive function, speech impairment). Seven studies met inclusion criteria including one randomized controlled trial, one non-randomized comparative trial, one case series and four case reports. Study designs and NF therapy and training protocols were heterogeneous. NF protocols were highly specific to each study (i.e. feedback location, number of sessions, training task involved, etc.). The majority of patients demonstrated moderate cognitive improvements in their respective pre-post NF outcome measures including reported improvements in memory, mood, concentration, energy, reading and speech abilities, and/or motivation. The authors noted that it was unlikely that NF alone was responsible for the improved results. Because of the heterogeneity of the studies, meta-analysis could not be performed. Limitations of the studies include: heterogeneous types of NF therapy; small patient populations; lack of a comparator; heterogeneity of the study designs; and poor quality of the studies. There is insufficient evidence to support NF therapy for cognitive rehabilitation of stroke patients.

Reiter et al. (2016) conducted a systematic review of the literature to assess the effectiveness of neurofeedback (NF) for the treatment of posttraumatic stress disorder (PTSD). Five studies including one randomized controlled trial met inclusion criteria. Three studies used neurofeedback for combat-related PTSD. One study focused on children with insecure attachment and trauma-related PTSD and one study included participants with PTSD related to childhood abuse. NF approach included alpha wave, alpha/theta training, sensorimotor rhythm, or combination NF. Training sessions varied from 30 minutes to one hour and ranged from one single session to 30 sessions. Three studies reported a statistically significant reduction in targeted symptomatology while some measures failed to show any improvement. Limitations of the studies include: limited number of studies; small patient populations (10–29); lack of female subjects; short-term follow-ups; lack of a comparator, and heterogeneity of treatment protocol and outcomes. Data are insufficient to support neurofeedback as an effective treatment option for PTSD. Additional research using well-designed randomized controlled trials with large patient populations is needed to establish which neurofeedback approach is clinically effective for PTSD.
Luctkar-Flude et al. (2015) conducted a systematic review of the literature to evaluate the safety and effectiveness of neurofeedback of the management of fatigue and cognitive impairment. Seven randomized, three quasi-randomized and four nonrandomized trials (case series and retrospective reviews) met inclusion criteria. A study was eligible for inclusion if it included adult cancer survivors, individuals with other chronic health conditions or nonclinical populations seeking to decrease fatigue and/or enhance cognitive abilities. Two studies included cancer patients. Most of these studies reported positive results for at least one fatigue or cognitive outcome in a variety of clinical populations (traumatic brain injury, fibromyalgia, CNS problems) and nonclinical (college students, adults, elderly). Limitations of the studies included: small patient populations; heterogeneity of the types of neurofeedback, comparators, number of training sessions, outcome measures and diagnosis; subjects lost to follow-up; and short-term follow-ups. Only four studies reported side effects or safety issues. Due to the limitations of the studies firm conclusions could not be made regarding the effectiveness of neurofeedback for fatigue and cognitive impairment including cancer patients.

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. This report has been archived.

The American Academy of Pediatrics (AAP) Task Force on Mental Health (2010) 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 (FemiScanTM, MegaElectronics, Kuopio, Finland) avoided surgical intervention compared to ten of 19 control subjects who did not use home biofeedback.
In a 2002 decision memo regarding the use of home biofeedback for urinary incontinence, the Centers for Medicare and Medicaid (2002), stated that “the scientific evidence is not adequate to conclude that the use of home biofeedback devices for the treatment of urinary incontinence is clinically effective, and, therefore, is not reasonable and necessary for treating urinary incontinence or to improve the functioning of a malformed body member”.

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.

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

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<tr>
<th>CPT® Codes</th>
<th>Description</th>
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<td>90875</td>
<td>Individual psychophysiological therapy incorporating biofeedback training by any modality (face-to-face with the patient), with psychotherapy (eg, insight oriented, behavior modifying or supportive psychotherapy); 30 minutes</td>
</tr>
<tr>
<td>90876</td>
<td>Individual psychophysiological therapy incorporating biofeedback training by any modality (face-to-face with the patient), with psychotherapy (eg, insight oriented, behavior modifying or supportive psychotherapy); 45 minutes</td>
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<tr>
<td>90901</td>
<td>Biofeedback training by any modality</td>
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<td>Biofeedback training, perineal muscles, anorectal or urethral sphincter, including EMG and/or manometry (Code deleted 12/31/2019)</td>
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<td>Biofeedback training, perineal muscles, anorectal or urethral sphincter, including EMG and/or manometry, when performed; initial 15 minutes of one-on-one physician or other qualified health care professional contact with the patient (Code effective 01/01/2020)</td>
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Considered Experimental, Investigational, Unproven:

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**Biofeedback Devices**

Considered Experimental/Investigational/Unproven:

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**References**


