MEDICAL NECESSITY GUIDELINES

CareAllies

Subject: **Biofeedback** **Effective Date: 8/15/2006**
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Biofeedback is considered medically necessary for all of the following conditions:

- constipation in adults
- fecal incontinence in adults
- urinary incontinence in children and adults
- migraine in children and adults
- cancer pain in adults

Biofeedback is considered experimental, investigational or unproven and thus not medically necessary for any other condition.

General Background

According to the National Center for Complementary and Alternative Medicine (NCCAM), biofeedback is considered an alternative medicine technique under the mind-body category of complementary and alternative medicine (CAM) practices. CAM is a group of diverse medical and health care systems, practices and products that are not presently considered to be part of conventional medicine. Mind-body techniques such as biofeedback, relaxation, meditation and hypnosis have been proposed as methods to strengthen the communication between mind and body (NCCAM, 2005).

Biofeedback is a therapeutic process that electronically monitors bodily functions such as breathing, heart rate, blood pressure, skin temperature and muscle tension, which is then fed back to the individual by means of sounds, lights or electronic gauges. Biofeedback 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 (Payne, 2002; Karmody, 2003; Kiresuk, et al., 2005). Biofeedback technologies commonly use electromyography (EMG), electroencephalography (EEG, also known as neurofeedback), thermal hand warming, photoplethysmography and galvanometry (electrodermal biofeedback) (National Institutes of Health [NIH], 1995; Holroyd, et al., 2003).

Although the scientific rationale for biofeedback is unclear, biofeedback has been used to treat various medical conditions including: constipation, fecal and urinary incontinence, migraine headaches and cancer pain. Other proposed uses have been suggested; however, the scientific literature remains scant and the evidence lacking for use in other conditions.

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, 2005). There are numerous biofeedback devices available from multiple manufacturers.

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

The AGA also has a medical position statement titled “Anorectal Testing Techniques” which states that “Neurogenic fecal incontinence associated with weakness of the external anal sphincter and/or decreased ability to perceive rectal distention because of nerve injury can be treated with biofeedback training. Anorectal dysfunction in patients with associated pelvic floor dyssynergia has been treated with biofeedback techniques, with an overall improvement rate of 84%” (AGA, 1998).

The Agency for Healthcare Research and Quality (AHRQ) conducted a systematic review of the literature on the use of mind-body therapies for the treatment of health conditions and found sufficient studies (n=53) to issue a technology report titled “Mind-Body Interventions for Gastrointestinal Conditions.” The report notes that there is no evidence to support the efficacy of biofeedback in children and the results are mixed for adults.

Norton et al. (2002) conducted a systematic review of the literature (1966-January 2002) to determine the effectiveness of biofeedback, anal sphincter exercises, and pelvic floor muscle training in the treatment of fecal incontinence in adults. The investigators reviewed randomized or quasi-randomized trials and found five studies of 109 participants which met the inclusion criteria. The investigators reported all but one trial had methodological bias. They reported a wide variation in participant selection, types of interventions, use of outcome measures, duration of treatment and length of follow-up. Most of the trials were small and of probable insufficient power to permit statistical analysis. These combined factors made a meta-analysis impossible. The investigators concluded that there is not enough evidence from randomized controlled trials to evaluate the effectiveness of sphincter exercises or biofeedback therapy for the management of fecal incontinence in adults.

Wang et al. (2003) conducted a prospective study on 50 consecutive patients with chronic idiopathic constipation identified as slow transit constipation (n=8), anorectum outlet obstruction (n=36), and mixed constipation (n=6).Two modes of biofeedback were used; EMG-based biofeedback (n=30) and manometry-based biofeedback (n=20). The mean follow-up was 18 months. Seventy percent of patients felt that biofeedback was helpful and 62.5% of patients with constipation reported relief in clinical

manifestations (straining, abdominal pain, bloating) and reduced use of oral laxatives. There was significant improvement in spontaneous bowel frequency and psychological state.

Heymen et al. (2003) conducted a comprehensive review on biofeedback and pelvic floor dyssynergia constipation. Only prospective studies including five or more subjects that described the treatment protocol were included. A meta-analysis of the studies was performed to compare the outcome of different biofeedback protocols for treating constipation. Thirty-eight studies were reviewed with 10 studies using a parallel treatment design. Seven studies randomized subjects to treatment groups. Most studies reported positive results (range 69-78%) using biofeedback to treat this form of constipation. The mean success rate of studies using pressure biofeedback (78%) was superior (p=0.018) to the mean success rate for studies using EMG biofeedback (70%). The mean success rates of studies using intra-anal EMG sensors compared to studies using perianal EMG sensors were 69% and 72%, respectfully, indicating no advantage of one type of EMG biofeedback protocol over the other (p=0.428). The reviewers concluded that quality research is lacking and noted inconsistencies in the literature regarding the severity and etiology of symptoms, patient selection criteria, inadequate sample size, lack of clearly defined outcome measures and lack of long-term follow-up data.

Norton et al. (2003) conducted a randomized controlled trial of biofeedback for 171 patients with fecal incontinence. The study compared those treated with standard care (advice); advice plus instruction on sphincter exercises; facility-based, computer-assisted biofeedback; and facility-based, computer assisted biofeedback, plus the use of a home EMG biofeedback device. Outcome measures included diary, symptom questionnaire, continence score, patient's rating of change, quality of life, psycho logic status and anal manometry. The authors concluded that neither pelvic floor exercises nor biofeedback was superior to standard care supplemented by advice and education.

Mahony et al. (2004) compared the use of intra-anal EMG biofeedback alone with intra-anal biofeedback augmented with electrical stimulation in 60 women with postpartum fecal incontinence randomized to treatment. The primary outcome measures were continence score, anal manometry and endoanal ultrasound scanning. After 12 weekly treatments, both groups demonstrated significant improvement in continence score (p< 0.001) and in squeeze anal pressures (p< 0.04). There was no significant change in resting anal pressures. The authors concluded that the intra-anal EMG biofeedback therapy was associated with improved continence and quality of life; however, the addition of electrical stimulation of the anal sphincter did not improve the outcome results. The study was limited by the lack of a control group.

Brazzelli et al. (2004) reported on a systematic review of the literature (conducted between 1980-March 2001) of 16 randomized trials to assess the effects of behavioral and cognitive interventions for the management of defecation disorders in children (n=843). Children with anismus receiving biofeedback are more likely to achieve normal defecation in the short-term but there is no long-term maintenance. The authors reported that biofeedback training does not provide any additional benefit to conventional treatment (e.g., laxative, toilet training, dietary advice) for the management of children with constipation or encopresis (defined as repeated expulsion of feces whether involuntary or intentional, in inappropriate places in a child at least four years old).

According to Ilnyckyj et al. (2005), biofeedback is an accepted treatment modality for fecal incontinence despite the lack of supporting data. The authors conducted a study to determine if biofeedback had any benefit to offer above and beyond an educational intervention. Subjects included women ≥ age 18, with chronic and regular episodes of fecal incontinence, nonresponsive to treatment of a primary cause. Patients were randomized to the education and exercise instruction (n=11) group, or to the education and biofeedback exercise instruction (n=7) group. There was no significant difference in treatment success between the two groups. The biofeedback group demonstrated a significant improvement in resting and squeeze pressure, while both groups improved in squeeze duration. The authors concluded that the effect of biofeedback was questionable since both groups demonstrated treatment effect. Limitations to the study included small size and exclusion of patients with irritable bowel syndrome.

In a review article, Bassotti et al. (2004) reported on six studies of children with fecal incontinence that compared biofeedback to the use of mineral oil or some type of laxative. The studies demonstrated that even if biofeedback caused some improvement, the differences were not significant nor were the benefits

long term. Another review article by Catto-Smith (2005) discussing constipation and toileting in children stated that biofeedback compared with controls, does not have a lasting effect for children with anismus (i.e., pelvic floor dyssynergia). There is no evidence that biofeedback has any benefit over behavioral therapy and laxative use. In their article on evaluating and treating constipation in infants and children, Biggs and Dery (2006), based upon inconsistent and limited-quality evidence, stated that biofeedback was not recommended for the treatment of constipation. It does not improve outcomes when used as an adjuvant therapy with standard medical therapy.

A parallel group, randomized controlled trial by Chiarioni et al. (2006) was conducted to "(1) to compare biofeedback with laxative treatment of pelvic flood dyssynergia (PFD) (polyethylene glycol [PEG] 14.6 g/day) with respect to satisfaction with treatment (the primary outcome variable), stool frequency, laxative use (other than PEG), straining frequency, sense of incomplete evacuation, and feeling of blocked defecation; (2) to identify physiologic mechanisms for biofeedback training effects; and (3) to identify clinical and physiologic characteristics of patients that predict response to treatment." Patients were treated with fiber plus enemas or suppositories the first week. If the patients had an unsatisfactory response, they were randomized to the fiber group (n=55) or the biofeedback group (n=54) which entailed five 30-minute sessions in one week. Patient response to a questionnaire and symptoms reported in the patient diary were the outcome measures. Six- and 12-month follow-up visits occurred. Biofeedback patients reported improved sensation of evacuation, greater reduction in straining, and less abdominal pain and laxative use in 80% of cases. Improvement was maintained for at least two years by biofeedback. In comparison, the PEG patients had poor response, increased their laxative use, and poorly tolerated the increased dose. The authors concluded that the study demonstrated a "clear superiority" for the use of biofeedback for the treatment of constipation compared to daily doses of PEG. Limitations of the study included: patient's awareness of the treatments; the dose of PEG may have been too small; enrollment was restricted to patients with normal whole gut transit times; all patients were trained by the same, highly skilled biofeedback therapist.

In a 2006 Cochrane systematic review, Brazzelli et al. reviewed randomized and quasi-randomized trials of behavioral and cognitive intervention for the treatment of constipation in children. Eighteen trials including 1168 children met inclusion criteria, but the studies were small with variable interventions and outcomes. Success rates varied as well. The authors concluded that there was no evidence to support that biofeedback added any benefit to conventional treatment in children with functional fecal incontinence, nor was the evidence to assess the effects of biofeedback for the treatment of organic fecal incontinence. There was some evidence that behavioral interventions plus laxative were more effective than laxative alone for functional incontinence associated with constipation.

Urinary Incontinence (UI)
UI is a symptom that can be caused by a variety of conditions that directly or indirectly affect bladder control. Nonsurgical treatment options may include pharmacological treatment and behavioral therapy such as pelvic muscle exercises (PME), bladder training exercises and vaginal cones (for women). Kegel exercises can be performed to improve the strength of the pelvic floor muscles. Some individuals have difficulty in identifying the pelvic floor muscles to perform the exercises. Biofeedback has been proposed as a modality that may be helpful for these individuals to learn the muscle strengthening pelvic floor exercises.

There are several proposed methods of biofeedback which may be employed for the treatment of urinary incontinence:

- Vaginal cones are a simple method of providing biofeedback for females in the home setting. The cone is inserted into the vagina above the levator muscles, and biofeedback is produced when the patient feels the cone slipping down as the pelvic muscles must be tightened to retain the cone. When the patient is able to easily hold the lightest cone, a succession of heavier cones is used. Vaginal cones have some limitations: some patients will not use any vaginal device; some patients cannot retain the cone and some patients retain the cones with the use of thigh adductor muscles rather than proper levator contraction.

- Perineometers are devices which can be used in the home setting. They measure vaginal or anal squeeze pressure and may be more effective in teaching a patient to identify the proper muscles than vaginal cones. Perineometers have some limitations as abdominal pressure is also transmitted to the probe. A patient may perform a Valsalva maneuver (which is counterproductive) and believe that the pelvic muscles are contracting.

- Electromyographic (EMG) systems with vaginal and rectal sensors and perineal patches reduce the problem with Valsalva maneuvers; however, proper muscle isolation may still be impaired as they register activity of only one muscle group (Payne, 2002).

According to the FDA, the intended use of perineometers is “to provide feedback to a patient performing muscle strengthening exercises (Kegel exercises) for the treatment of certain types of urinary incontinence. There are two types of perineometers: those which measure pressure, and those which measure electrical activity (EMG) from muscles. Each device consists of a probe that is placed into either the vagina or the rectum, and a monitoring unit. The pressure devices use an air-filled probe connected to the monitoring unit by a piece of plastic tubing. When the patient performs the exercise, the probe is compressed, and the monitoring unit reports the change in pressure. The electrical devices use an electrode to measure the electrical activity of the target muscles during the exercises, and this information is reported by the monitoring unit. An operator training simulator (OTS) system, such as Disk Operating System (DOS) or Windows, may be used to record and display the data collected by the monitoring unit. Perineometers represent no threat of direct injury to the patient, since no energy is applied by the medical device to the patient. The risk of indirect injury due to inaccurate feedback during the exercise session is expected to be small, as these medical devices are only used as an adjunct to exercise therapy, and they are used under clinical supervision” (FDA,1999).

The Agency for Health Care Policy and Research (AHCPR), now known as the Agency for Healthcare Research and Quality (AHRQ), released a guideline on “Urinary Incontinence in Adults” in 1992 which has since become the standard of care for treatment of urinary incontinence. The guideline states that one of the recommended treatments for urinary incontinence is biofeedback used in conjunction with Kegel exercises, to help gain awareness and control of pelvic muscles (AHRQ, 1996).

The NIH issued a consensus statement titled “Urinary Incontinence in Adults” in 1988 which states “When used in patients with stress and/or urge incontinence, biofeedback has been shown to result in complete control of incontinence in approximately 20-25% of patients and to provide important improvement in another 30 percent. There are two caveats: the degree of improvement is variable, and long-term follow-up data are not available. It is important to recognize that biofeedback requires sophisticated equipment and training. The benefit of adding biofeedback to pelvic muscle exercise regimens has not been adequately evaluated” (NIH, 1988).

The Association of Women’s Health, Obstetric and Neonatal Nurses (AWHONN) supports the use of biofeedback as an “adjunct to correct performance of an effective program of pelvic floor muscle technique. Women who have difficulty isolating or contracting pelvic floor muscles may benefit from biofeedback” (AWHONN, 2000, 2002).

The American Urological Association (AUA) has issued a clinical practice guideline for the surgical management of female urinary stress incontinence. The guideline refers to other nonsurgical modalities which may be useful in the management of stress incontinence such as the use of biofeedback. Other behavioral therapies include timed voiding, pelvic muscle floor (PMF) exercises and vaginal insert devices (AUA, 1997).

The National Association for Continence (NAFC) notes that behavioral techniques for the treatment of incontinence include scheduled toileting, bladder retraining and pelvic muscle rehabilitation. The latter technique involves PMF exercises which can be used alone or in conjunction with biofeedback therapy, vaginal weight training, pelvic floor stimulation, and magnetic therapy (NAFC, 2004).

The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), a part of the NIH, notes that biofeedback can be used to help an individual learn to control the correct muscles to ensure that the

right muscles are being exercised. The method employs a therapist who places a patch over the muscles. A wire connects the patch to a TV screen where the individual can watch the screen to see if the right muscles are being exercised (NIDDK, 2003).

De Paepe et al. (1997) prospectively treated 42 girls, age 6-14, with recurrent urinary track infection and dysfunctional voiding for an 18-month period. Treatment included: voiding and drinking schedule, pelvic-floor relaxation biofeedback, instructions on toilet behavior, biofeedback uroflowmetry, and prophylactic antibiotics. Thirty-three girls with detrusor instability also received anticholinergics. Successful outcome was defined as infection-free for six months without the use of antibiotics. The training program was effective in treating recurrent UTI in 35 of 42 girls (83%). The authors concluded "Pelvic-floor therapy seems a reasonable and meaningful component in the treatment of recurrent UTIs in which detrusor-sphincter dyssynergia plays a role."

To "assess the efficacy of voiding and bladder biofeedback for achieving perineal synergy and curing symptoms in children with detrusor-sphincter dyssynergia", Porena et al. (2000) conducted a study which included 16 boys and 27 girls; age 4-14 with detrusor-sphincter dyssynergia. The children were treated with voiding biofeedback utilizing uroflowmeter with electromyography. Detrusor-sphincter dyssynergia was resolved in all children, with secondary enuresis resolving sooner than primary enuresis. The success rate was 87.18% at two years and 80% at four years. The authors concluded that "voiding and bladder biofeedback achieves perineal synergy and cures symptoms in children with detrusor-sphincter dyssynergia." They recommended, given the "excellent results" biofeedback should be the initial step in the treatment of detrusor-sphincter dyssynergia.

Burgio et al. (2002) conducted a randomized controlled trial of 222 women with urinary urge incontinence to compare the use of behavioral training with biofeedback (n=73) to behavioral training without biofeedback (n=74) and to a self-administered behavioral program (n=75). Outcome measurements included documentation in bladder diaries, patients' perceptions and satisfaction, and changes in quality of life. Patients were provided the anorectal biofeedback therapy to learn to correctly identify the pelvic floor muscles and to teach them how to contract and relax these muscles selectively. All biofeedback treatments were provided in the medical office setting by nurse practitioners. Treatment consisted of four visits during an eight week period. The reduction in incontinence was 63.1% with behavioral training with biofeedback, 69.4% with behavioral training without biofeedback and 58.6% with the self-help booklet. The authors concluded that all three behavioral interventions were effective in helping patients identify pelvic floor muscles and use them to decrease the episodes of urge incontinence. Patients' perceptions of treatment were significantly better with the two behavioral training interventions. The authors suggest that since all the treatment approaches appear to be clinically useful, a practical strategy would be to initiate training with an instruction booklet or verbal feedback initially and reserve biofeedback for patients who have difficulty learning or are unsuccessful in developing pelvic floor muscle control with these methods.

Hunter et al. (2004) conducted a systematic review of the literature (spanning from 1966-January 2004) to assess the effects of conservative management methods for urinary incontinence after prostatectomy. Conservative management methods included pelvic floor muscle training, biofeedback, electrical stimulation, compressions devices, lifestyle changes, extra-corporeal magnetic stimulation or a combination of methods. The investigators found 10 randomized controlled trials which met the inclusion criteria. Overall, the studies were of moderate quality and all involved men who had undergone radical prostatectomy for cancer. Five trials compared pelvic floor muscle training plus biofeedback with a no-treatment or placebo-treatment control group. The types of biofeedback utilized were different in each study (e.g., surface electrodes, perineal patch EMG, anal probe, digital or anal-probe) with no mention of biofeedback type in one study. One study mentioned the use of biofeedback in the home setting using the anal probe. The investigators concluded that, based on the results from one trial, there was some benefit of offering pelvic floor muscle training with biofeedback early in the postoperative period immediately following removal of the catheter as it may promote an earlier return to continence. The effectiveness of conservative measures in the longer term, or in those with persistent incontinence, remains inconclusive.

Herbison et al. (2004) conducted a systematic review of the literature (1966-May 2003) of randomized or quasi-randomized controlled trials to compare weighted vaginal cones with alternative treatments or no treatment in women with stress urinary incontinence. Fifteen studies were identified which involved 1126 women of whom 466 received vaginal cones. The investigators reported that all the trials were small and

their quality was difficult to ascertain. Outcome measures differed between studies and there were high drop-out rates with both cone and comparison treatments. The investigators concluded that there is some evidence that weighted vaginal cones are better than no active treatment in women with stress incontinence and may be as effective as pelvic floor muscle training (PFMT) and electrical stimulation.

Hay-Smith et al. (2005) performed a systematic review of the literature (spanning from1980-May 2000) to determine the effects of PFMT for women with stress, urge or mixed incontinence in comparison to no treatment or other treatment options. There were 10 trials which compared biofeedback-assisted PFMT to PFMT alone. Only three trials contributed data for the formal analyses. Biofeedback methods and protocols were varied. Four trials used clinic-based biofeedback and three used daily home biofeedback. Two trials used a combination of home and clinic biofeedback. Half of the trials used biofeedback from a vaginal probe with EMG electrode and the other half used a pressure sensitive intravaginal device. Three trials also used electrodes or rectal catheters to monitor muscle activity or abdominal pressure changes. The investigators concluded that formal comparisons of biofeedback PFMT versus PFMT alone consistently suggested that there is no added benefit of biofeedback in women with stress or mixed incontinence. Data from one trial suggested that the biofeedback group might experience more rapid improvement but this has not been confirmed by any other trial. The investigators noted that, anecdotally, many clinicians report that biofeedback is a useful addition to PFMT but from the results of this review, it was not clear what benefit biofeedback offers or if there is a difference in long-term outcomes.

Yabci et al. (2005) prospectively studied children, age 5-14, (n=188) to determine “the effects of biofeedback treatment on voiding and urodynamic parameters in children with voiding dysfunction.” Initially, biofeedback was performed with an urodynamics processor weekly, then every 3-4 weeks. Follow-up evaluations occurred at six months and at two years after completion of training. Of the 89.4% (168) of the patients who completed the therapy, improvement was seen in all patients. Maximum improvement occurred with flattened voiding and the least improvement occurred with daytime wetting. Improvements at the two-year follow-up ranged from 53.1% to 87.3%. The rate of improvement for nocturnal enuresis, staccato voiding, detrusor-sphincter dyssynergia, vesicoureteral reflux and urinary tract infection had increased at the two-year follow-up while the remaining improvements had decreased at the end of two-years. The authors concluded that biofeedback is an effective treatment option for multiple bladder dysfunctions. Motivation and willingness directly impact the success of the training.

PFMT is the most commonly used physical therapy modality for the treatment of urinary incontinence. Dannecker et al. (2005) wanted to determine the short- and long-term efficacy of EMG-biofeedback assisted PFMT for women with stress or mixed urinary incontinence. Their study subjects included all women in their pelvic floor reeducation (PFR) program from 1996-2003 (n=390). Prior to treatment over half of the women had high grade stress incontinence. At the completion of therapy, only 5% maintained high grade incontinence. The short-term training group included 263 women, whereas, long-term results included all 390 PFR participants. Clinical examination demonstrated improved pelvic floor contraction strength, and EMG-potential scores almost doubled. The results of patient questionnaires regarding self-improvement and satisfaction coincided with the results of the clinical examinations. The authors concluded that EMG-controlled biofeedback therapy is “very effective” and should be a treatment option for women prior to surgical intervention.

In a study to assess the effectiveness of “preoperative biofeedback assisted behavioral training for decreasing the duration and severity of incontinence, and improving quality of life in the six months following radical prostatectomy”, Burgio et al. (2006) conducted a prospective, randomized controlled trial comparing preoperative biofeedback training to standard of care. The biofeedback group received one preoperative training session and engaged in daily home exercise. The control group received the standard postoperative instruction regarding interruption of the urinary stream. Outcome measurements included: diaried duration of incontinence; incontinence severity; pad use; and the results of patient questionnaires. The subjects who received biofeedback training had significantly decreased time to continence and self-reported urine loss with activity (i.e., coughing, sneezing, and getting up from lying down). The authors concluded that preoperative biofeedback can enhance the recovery of urine control and decrease the severity of incontinence following radical prostatectomy.

Klijn et al. (2006) conducted a randomized controlled trial comparing “uroflowmetry for biofeedback training compared to added attention and standard therapy in a multicomponent behavioral training

program for voiding disorders in school-age children." The trial included 192 children, age 6-16 with recurrent urinary tract infection with or without urge incontinence. The subjects were randomly assigned to one of three groups. Group one (n=44) received eight weeks of "standard therapy" (i.e., outpatient behavioral therapy). Group two (n=46) received eight weeks of home video instructions plus standard therapy. Group three (n=53) received eight weeks of home uroflowmetry biofeedback plus standard therapy. At the end of the eight weeks, all subjects received standard therapy alone for 16 weeks. At the end of the 16 weeks of standard therapy, prophylactic antibiotics were discontinued and follow-up was continued for six months. Outcome measures included complete absence of urinary tract infections, and incontinence at the one-year follow-up visit. There was no difference in total relief between standard treatment and added video instruction. Total relief in the added home uroflowmetry group was higher than with standard therapy, but not statistically significant. The home uroflowmetry group demonstrated better total relief than group one and two. The authors concluded that "home uroflowmetry appeared to be a useful adjunctive treatment for the reduction of complaints in children with dysfunctional voiding due to nonneurogenic bladder-sphincter dyssynergia."

Migraine
Thermal biofeedback and EMG biofeedback have been proposed for use in migraine treatment. Thermal biofeedback, also known as temperature or hand warming feedback, utilizes feedback of skin temperature from a finger. It is frequently combined with EMG biofeedback (i.e., feedback of electrical activity from the muscles of the scalp or neck).

The American Academy of Neurology (AAN) issued a guideline "Practice Parameter: Evidence-based Guidelines for Migraine Headache", which contains major recommendations for the evaluation and treatment of migraine headache. The following is listed under the cognitive and behavioral treatment recommendations for migraine:

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

The American Academy of Family Physicians (AAFP) has issued guidelines on migraine preventive therapy which were developed by the U.S. Headache Consortium. The guidelines include recommendations for nonpharmacological therapy including the use of thermal biofeedback and EMG biofeedback as treatment options for prevention of migraine. Nonpharmacological therapies may be useful for patients who have failed or are intolerant to drug therapy; patients who have a history of long-term, frequent or excessive use of analgesics or other acute medications; patients with significant stress; or in patients who are pregnant, planning to become pregnant or are nursing.

The National Headache Foundation (NHF) has issued numerous guidelines related to the evaluation and management of head pain. Biofeedback as a treatment modality is included in several of these guidelines as follows:

- The guideline titled "Treatment of primary headache: acute migraine treatment. Standards of care for headache diagnosis and treatment" states that non-pharmacologic adjuncts to migraine treatment may be effective and eliminate the need for pharmacologic interventions. Biofeedback is listed as one of the non-pharmacologic modalities (Landy, et al., 2004).

- The guideline titled "Special treatment situations: behavioral interventions for management of primary head pain. Standards of care for headache diagnosis and treatment" includes both thermal and EMG biofeedback. The guideline states that both types of biofeedback have been shown to be effective in preventive treatment of migraine and some patients may experience relief with an existing headache. Migraine sufferers have achieved a 55% reduction with EMG biofeedback and a 35% reduction with thermal biofeedback combined with relaxation training.

Tension-headache sufferers achieved a reduction of 50% with EMG biofeedback (Farmer, et. al., 2004).

- The guideline titled “Special treatment situations: alternative headache treatments. Standards of care for headache diagnosis and treatment” refers to biofeedback as being a beneficial adjunct to pharmacologic therapy for motivated patients (Mauskop, 2004).
- The guideline titled “Special treatment situations: menstrual migraine and menstrually-related migraine. Standards of care for headache diagnosis and treatment” states that biofeedback can provide a positive alternate method to treat migraine during pregnancy due to the potential risk of pharmacologic therapy during pregnancy (Diamond, 2004).

The AAN has a practice guideline for the evaluation of migraine in children and adolescents with recurrent headaches and a guideline for the pharmacological management of migraine in this population but neither guideline mentions the use of biofeedback as a treatment modality (Lewis, et al., 2002, 2004).

The NHF guideline “Special treatment situations: pediatric migraine. Standards of care for headache diagnosis and treatment” refers to the effective use of biofeedback for stress-reduction in children over the age of ten (Pearlman, 2004).

The American Pain Society mentions biofeedback in their guideline titled “Pediatric Chronic Pain - A Position Statement from the American Pain Society” which states that treatment techniques include cognitive-behavioral strategies such as hypnosis or biofeedback (APS, 2005).

In a review of CAM approaches for pain relief by Tsao et al. (2005), the use of CAM in the pediatric population has been increasing however, the research is limited. The authors report that thermal biofeedback for migraine may possibly be efficacious based on one study and thermal and EMG biofeedback for use in tension headaches appear promising. The authors stated more research was needed to obtain more definitive conclusions.

Vasudeva et al. (2003) prospectively studied 40 patients with migraine headaches to determine if migraine patients with an aura respond differently to biofeedback/relaxation than those without an aura. Twenty migraine patients received 12 sessions of biofeedback/relaxation therapy and 20 controls were told to relax on their own. Blood flow velocity which was measured bilaterally in the middle cerebral artery with transcranial Doppler, was used as a surrogate marker, while pain, depression and anxiety were used as endpoints. The biofeedback group showed significant reductions in pain, depression and anxiety compared to the control group. The authors concluded that the positive treatment response is not related to the presence of aura, or to changes in blood flow velocity but may be associated with reduction in anxiety and depression.

Bronford et al. (2004) conducted a systematic review of the literature (spanning from January 1966-November 2002) to compare the effects of non-invasive treatments in the treatment of headache. The investigators did not include biofeedback in this study.

Eccleston et al. (2004) conducted a systematic Cochrane review of the literature (spanning from 1966-December 1999) to assess the effectiveness of psychological therapies in treating chronic or recurrent pain (i.e., pain of at least three months’ duration) in children and adolescents (≤ age 21). Fifteen of the studies were on chronic or recurrent headache. Psychological therapy was defined as one or a combination of the following: biofeedback, relaxation, behavior therapy, CBT, coping skills training, hypnosis or family therapy. Eighteen randomized controlled trials (n=808) met the inclusion criteria. Intended outcome measures included pain, affect, coping, pain behavior, physical fitness, quality of life, social role performance; however, the final outcome measure utilized for analysis was the Pain Index. Results were not reported separately for the various types of psychological interventions. The investigators concluded that there is “very good evidence that psychological treatments, principally relaxation and cognitive behavior therapy are effective in reducing the severity and frequency of chronic headache in children and adolescents.” They also conclude that “there is no evidence for the effectiveness of psychological therapies in attenuating pain in conditions other than headache, and little evidence for the effectiveness of psychological therapies in improving non-pain outcomes.”

A randomized control trial was conducted by Kaushik et al. (2005) to "evaluate the utility of biofeedback assisted diaphragmatic breathing and systematic relaxation in migraine and to compare their efficacy with propranolol in long-term prophylaxis of migraine." Subjects were randomly assigned to the biofeedback group (n=96) or the propranolol group (n=96). The drug group received 80 milligrams (mg) propranolol per day for six months with gradual tapering off over a one-month period. The biofeedback group was treated with EMG and temperature biofeedback assisted diaphragmatic breathing, and systematic relaxation guided sessions with home practice. Significant response was seen in both groups at the end of six months. At the end of one year, significant decline of migraines was observed in the biofeedback group as compared to the propranolol group after cessation of treatment. The authors concluded that the biofeedback techniques observed in this study were "very useful" and had "significantly" better long-term effects than propranolol.

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

The National Cancer Institute (NCI) provides information on different types of cancer pain and the pharmacological and non-pharmacological management of pain. The non-pharmacological treatments include the use of relaxation techniques, biofeedback and imagery (NCI, 2000).

The National Comprehensive Cancer Network (NCCN) has issued a guideline titled "Cancer Pain Treatment Guidelines for Patients" which states that cancer pain can be treated in several ways including the use of medication and other therapies such as relaxation techniques or biofeedback, physical therapy, anesthesia procedures and surgical procedures (NCCN, 2001).

AHRQ has issued a technology assessment report on "Management of Cancer Pain" which mentions the use of non-invasive treatments which include cognitive behavior therapy (CBT) and hypnosis; however, there is no mention of biofeedback. The guideline notes the lack of studies and recommends further research (AHRQ, 2001).

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

Neither the peer-reviewed literature nor professional societies support the use of biofeedback as a treatment modality for children with cancer.

Other Conditions
Biofeedback has been proposed as a treatment modality for numerous other conditions including: chronic back pain, upper limb pain, rheumatoid arthritis, fibromyalgia, temporomandibular disorders, attention deficit hyperactivity disorder, epilepsy, Raynaud's Syndrome, stroke and anxiety. However, the scientific, peer-reviewed literature does not support the efficacy of biofeedback in these conditions.

Chronic Back Pain: The AHCPR (AHRQ) has issued a guideline "Acute Low-Back Problems in Adults which states that biofeedback is not recommended for treatment of patients with acute low-back problems (AHCPR, 1998).

The North American Spine Society's guideline for unremitting low back pain also does not mention the use of biofeedback as a treatment for this condition (NASS, 2000).

The NIH has issued a "Technology Assessment Conference Statement" titled "Integration of Behavioral and Relaxation Approaches into the Treatment of Chronic Pain and Insomnia" which states that "the evidence is moderate for the effectiveness of biofeedback in relieving chronic pain" (NIH, 1995).

The 2006 guidelines for acute and chronic low back pain published by the Work Loss Data Institute have biofeedback listed as a treatment modality that they do not recommend.

Morley et al. (1999) conducted a systematic review of the literature (spanning from 1974-1996) to determine if CBT (including behavior therapy and biofeedback) is an effective treatment for chronic pain. The investigators reviewed 25 controlled trials which included patients with chronic low-back pain (CLBP), rheumatoid arthritis (RA), osteoarthritis, upper limb pain and fibromyalgia but excluded patients with headache. The results were not reported separately for the various types of behavior interventions used, and the researchers did not report whether methodological flaws were assessed. The researchers concluded that active psychological treatments are effective for pain reduction, coping measures and behavioral expression; however, specific treatments were not identified nor the patients who would most benefit from these interventions.

Ostelo et al. (2005) conducted a systematic review of the literature (1966 through October 2003) to determine if behavioral treatments (including biofeedback) for non-specific CLBP were more effective than other treatments for non-specific CLBP as compared to waiting list control (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 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. 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 as compared to WLC. The investigators concluded that combined CBT and EMG biofeedback and progressive relaxation therapy alone are effective for short-term pain reduction in patients with CLBP; however, more research is needed to determine what types of behavioral interventions are most effective for pain relief and which patients would benefit most from a specific type of behavioral treatment. The investigators state 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.

Upper Limb Pain: Karjalainen et al. (2004) conducted a systematic review of the literature (1966 to April 2004) to determine the effectiveness of biopsychosocial rehabilitation for upper limb repetitive strain injuries among working age adults. The investigators found two prospective randomized studies and considered both studies to be of low quality due to methodological flaws. Studies which included EMG biofeedback as the only component of physiological rehabilitation were excluded. One study (n=32) compared the extra effect of hypnosis combined with biofeedback and autogenics (a form of autohypnosis using self-suggestion), given once a week for six weeks, compared with WLC. The investigators concluded that the evidence was limited due to the low quality of the studies, but they noted there was a positive effect of hypnosis combined with biofeedback and autogenics as compared to biofeedback and autogenics after six weeks of follow-up. The second study (n=48) compared three behavioral therapies: EMG biofeedback, applied relaxation with progressive muscular relaxation and imagery methods. The biopsychosocial intervention groups were given a combination of EMG biofeedback and applied relaxation, or applied relaxation only. One control group was given EMG-biofeedback and the other control group waited eight weeks before treatment. The drop out rate was reported to be 20.8% in this study. The investigators concluded that there were no differences in effect between applied relaxation, EMG biofeedback plus applied relaxation, and WLC after eight weeks and six months of follow-up.

Rheumatoid Arthritis: The American College of Rheumatology (ACR) has guidelines titled “Guidelines for the Management of Rheumatoid Arthritis” and “Recommendations for the Medical Management of Osteoarthritis of the Hip and Knee”. Neither guideline mentions the use of biofeedback as a treatment modality in rheumatoid arthritis (RA) or osteoarthritis (ARS, 2000; ARS, 2002).

Astin et al. (2002) conducted a systematic review of the literature (1966 through June 2001) to investigate the effect of psychological interventions (including biofeedback) on patients with RA. Outcome measures included functional ability, pain, tender joints, psychological status and coping ability. Twenty-five randomized, controlled trials of 1676 patients met inclusion criteria. Because separate results by type of intervention (i.e., relaxation, biofeedback, CBT) were not identified, the authors could not report which psychological interventions or combinations of interventions were most effective and for which types of patients Although the investigators noted some methodological flaws in the studies (e.g., inadequate description of controls, effect sizes not always consistent with signs of confidence intervals), they stated that psychological interventions may be more effective for patients who have had RA for shorter duration. The authors concluded that more research was needed to determine which treatments may be of benefit for patients with RA.

Fibromyalgia (FM): According to Goldenberg et al. (2004) the non-pharmacological therapies useful in the treatment of FM are exercise, CBT, patient education and multidisciplinary or combination therapies. The efficacy for the use of biofeedback in the treatment of FM is moderate.

The National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) provide information on the diagnosis and treatment of fibromyalgia which does not mention the use of biofeedback (NIAMS, 2005).

Karjalainen et al. (2004) conducted a systematic review of the literature (1966 to April 1998) to determine the effects of multidisciplinary rehabilitation treatment for patients with fibromyalgia or widespread musculoskeletal pain; however, EMG biofeedback was not included in this study.

Temporomandibular Disorders (TMD)/ Temporomandibular Joint (TMJ) Disorders: The NIH has issued a technology assessment conference consensus report titled “Management of temporomandibular Disorders” which provides the assessment and management approaches for TMD. The position refers to the use of CBT and relaxation but does not mention biofeedback (NIH, 1996).

The National Institute of Dental and Craniofacial Research (NIDCR), a part of the NIH, has information on TMD/TMJ diagnosis and treatment but does not mention the use of biofeedback as part of a treatment regimen (NIDCR, 2005). The NIH is sponsoring several clinical trials related to TMD treatment but none include biofeedback.

The American Association of Oral and Maxillofacial Surgeons (AAOMS) issued a statement concerning the “Management of Selected Clinical Conditions and Associated Clinical Procedures Temporomandibular Disorders” which does not mention the use of biofeedback (AAOMS, 2005).

Crider and Glaros (1999) performed a systematic review of literature to determine the efficacy of biofeedback-based treatments in patients with TMJ disorders. The evaluators found six controlled studies, four comparative studies and three uncontrolled studies of EMG biofeedback treatment for TMJ disorders. Outcome measurements included patient pain reports, clinical exam findings and ratings of global improvement. Five of the six controlled trials found EMG biofeedback treatments to be superior to no treatment or psychological placebo controls for at least one of the three outcome measures. Sixty-nine percent of patients, who received EMG biofeedback treatments were rated as symptom-free or significantly improved, compared to 35% of patients treated with a variety of placebo interventions. Though data appears to support the efficacy of EMG biofeedback treatments for TMJ disorders, study methodology is unclear or inconsistent, study sizes are small and results were not statistically significant.

In 2005 Crider et al. reported on six randomized controlled trials regarding the efficacy of biofeedback-based therapy for TMD. Two trials included surface electromyographic (SEMG) training of masticatory muscles; two combined SEMG with congitive-behavioral therapy (CBT); and two involved biofeedback-assisted relaxation training (BART). The review determined the extent that each intervention met treatment efficacy criteria extablished 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 recommend additional studies to identify specific treatment combinations.

A systematic review by Medlicott and Harris (2006) included seven randomized controlled trials which evaluated the effectiveness of relaxation training or biofeedback in the management of TMD. From the review of these studies the authors stated “Programs involving relaxation techniques and biofeedback, EMG training, and proprioceptive reeducation may be more effective than placebo treatment or occlusal splints in decreasing pain and increasing total vertical opening (TVO) in people with acute or chronic myofascial or muscular TMD in the short term and the long term.” They stated that “these recommendations should be viewed cautiously.”

Attention Deficit Hyperactivity Disorder (ADHD): The NIH issued a statement titled “Consensus Development Conference Statement on Diagnosis and Treatment of Attention Deficit Hyperactivity Disorder” which states that the focus of studies has been primarily on the use of stimulant medications and psychosocial treatments. The evidence from studies on biofeedback and other interventions remain “uneven” (NIH, 1998).

The American Academy of Pediatrics (AAP) provides a clinical practice guideline titled “Treatment of the School-Aged Child with Attention-Deficit/Hyperactivity Disorder” which indicates the need for well-designed, rigorous studies of currently promoted but less well-established therapies such as occupational therapy, biofeedback, herbs, vitamins and food supplements. The guideline states these interventions are not supported by evidence-based studies at the present time. EEG biofeedback is unproven to work in the treatment of ADHD (AAP, 2001).

The AHRQ conducted a systematic review of the literature (spanning from 1966-1997) on the treatment of ADHD. There is no mention of the use of biofeedback as a treatment modality in the report (AHRQ, 1999).

Fuchs et al. (2003) conducted a nonrandomized, comparison study of children (n=34) diagnosed with ADHD. Their parents chose which treatment the child would receive; either pharmaceutical management (n=12) or an EEG biofeedback feedback program (n=22). The treatment was provided for 12 weeks and both regimens were associated with improvements on all subscales of the Test of Variables of Attention, and on the speed and accuracy measures of the d2 Attention Endurance Test. ADHD-related behaviors were noted to be significantly reduced in both groups when rated by both teachers and parents using the IOWA-Conners Behavior Rating Scale. The authors concluded that the findings suggest that neurofeedback was efficient in improving some of the behavioral concomitants of ADHD in children whose parents favored a non-pharmacological treatment. The study was limited by small size, lack of control and lack of long-term follow-up.

In a review article regarding EEG biofeedback in the treatment of ADHD, Monastra et al. (2005) summarized the results of five case studies (n=322) and five controlled-group studies (n=214) that occurred between 1976 and 2003. They reviewed the studies applying guidelines established by the AAPB and the International Society for Neuronal Regulation (ISNR). They determined that biofeedback was “probably” an efficacious treatment option for ADHD (i.e., 75% of patients demonstrated significant clinical improvement), but stated that randomized, controlled trials were needed to demonstrated who will benefit from this treatment.

In a narrative review of the literature, Holtmann and Stadler (2006) stated that EEG biofeedback for the treatment of ADHD has shown short-term effects comparable to the effects of medication at the behavioral and neuropsychological level. Nine studies were reviewed including 293 subjects. Studies involved the assessment of EEG-frequency training and training of slow cortical potentials. Decreases were seen in inattention, hyperactivity and impulsivity without side effects. The authors stated that although the results are encouraging, EEG biofeedback has not been an accepted treatment modality for ADHD and there is a “strong need for empirically and methodologically sound evaluation studies.”

Epilepsy: The AHRQ has two guidelines for the management of epilepsy: “Management of Newly Diagnosed Patients with Epilepsy: A systematic Review of the Literature (2001) and “Management of Treatment-Resistant Epilepsy (2003). Neither guideline refers to the use of biofeedback as a treatment modality for epilepsy (AHRQ, 2001, 2003).

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

Nagai et al. (2004) conducted a preliminary single-blind, randomized controlled study on 18 adults with drug-refractory epilepsy to evaluate the effect of galvanic skin response (GSR) biofeedback (n=10) as compared to sham (n=8) on seizure frequency. The primary outcome measure was change in seizure frequency after one month of biofeedback. Three patients in the control group dropped out before the end of the study. The patients receiving biofeedback training significantly reduced the seizure frequency. There was no change in seizure activity in the sham group. The authors noted a number of limitations of this study including small size, lack of investigator blinding and lack of monitoring of medication compliance which could affect seizure activity. The authors concluded that their findings suggested that GSR biofeedback has potential as an adjunct to pharmacological treatment to reduce the frequency of seizures in drug-resistant epilepsy.

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

Hypertension: The National Heart, Lung, and Blood Institute (NHLBI) issued a guideline titled “Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure” which does not mention biofeedback as a treatment modality for hypertension management (NHLBI, 2004).

The North of England Hypertension Guideline Development Group (2004) state in their guidelines on management of essential hypertension that relaxation therapies, including biofeedback, can reduce blood pressure, but “routine provision by primary care teams is not currently recommended.”

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

Nakao et al. (2003) conducted a meta-analysis of 22 randomized controlled studies of essential hypertensive patients (n=905). Biofeedback intervention resulted in blood pressure reductions that were greater by 7.3 mmHg systolic and 5.8 mmHg diastolic compared with nonintervention controls (such as clinical visits or self-monitoring of blood pressure). Compared with sham or non-specific behavioral intervention controls, the net reductions in systolic and diastolic blood pressures by biofeedback intervention were 3.9 mmHg and 3.5 mmHg, respectively. Reviewers were unable to determine whether biofeedback itself has an antihypertensive effect beyond the general relaxation response because

biofeedback was only found to be superior to sham or non-specific 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.

In addition to the Yucha and Nakao meta-analysis described above, a 2006 Hayes report also reviewed: a 1993 meta-analysis which included: five studies that compared biofeedback plus relaxation training or another cognitive behavioral health modality to no intervention or clinic blood pressure monitoring; four studies with no controls comparing biofeedback effects in various patient populations; and two studies that used placebo biofeedback as part of the control intervention. Hayes concluded that the evidence did not support the efficacy of biofeedback for the treatment of hypertension (Hayes, Feb 2006).

Raynaud's Syndrome: The National Institute of Arthritis and Musculoskeletal Diseases (NIAMS) states that biofeedback may be a useful modality in controlling the pain of acute attacks when combined with warming the hands or feet in water. Biofeedback may also be helpful in decreasing the number and severity of acute attacks (NIAMS, 2001).

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

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

Stroke: The Veterans Administration/Department of Defense (VA/DoD) issued a clinical practice guideline for the management of stroke rehabilitation in the primary care setting. The guidelines state that there can be no recommendation made either for or against routine use of biofeedback for post-stroke patients. The decision is deferred to the individual provider (VA/DoD, 2003).

There is an ongoing systematic review (Woodford, et. al., 2005) being conducted of the literature to determine the efficacy of EMG biofeedback used after a stroke to aid motor recovery. There currently is no published data from this review.

Pollock et al. (2003) conducted a Cochrane review and reported the results of a literature search for recovery of postural control and lower limb function following stroke. The objective was to determine if outcomes were different if the physiotherapy treatment was based on orthopedic, or neurophysiology, or motor learning principles, or a mixture of these modalities. They reviewed randomized or quasi-randomized controlled trials with interventions of physiotherapies, including biofeedback. Outcomes measured degree of disability and motor impairment. Eighteen studies were categorized as EMG biofeedback and fifteen studies as positional biofeedback. The authors concluded that there was insufficient evidence to determine if one method was more effective than the other.

In an article on recent developments of biofeedback for neuromotor rehabilitation, Huang et al. (2006) reviewed early biofeedback studies, recent development in technologies, and their role in treatment of neuromotor deficits. Early biofeedback to train single muscle activity or movement did not correlate well to improved motor function. Although some of the newer techniques are promising for task-oriented biofeedback, further studies are needed to prove their efficacy.

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

Anxiety: Neurofeedback, EEG biofeedback or brain wave training, has been proposed as a treatment modality in anxiety disorders. Electrodes are placed on the head at locations where EEG activity has been determined to be divergent from normal activity. A computer screen is used for visual display of brain activity. The brain wave patterns are thought to be modified through the use of operant conditioning. A therapist works with the individual to gradually modify the thresholds for inhibiting inappropriate activity and reinforcing healthier brain activity. Neurofeedback therapy for patients with anxiety is often done with eyes closed while listening to auditory feedback (Hammond, 2005).

Mamtani et al. (2002) reported on the relevance of complementary medicine modalities in the treatment of mental health problems. The author noted “Biofeedback is particularly effective to patients with migraine headache and chronic pain.” There is no mention of the use of biofeedback in anxiety disorders.

According to the National Institute of Mental Health (NIMH), generalized anxiety disorder (GAD) is characterized by six months or more of chronic, exaggerated worry and tension that is unfounded or much more severe than the normal anxiety most people experience; people with GAD worry excessively about finances, health, family, or work issues. These individuals are unable to relax and often suffer from insomnia and other physical symptoms such as fatigue, trembling, muscle tension, headaches, irritability or hot flashes. Treatments for this disorder include use of medications and CBT (NIH, 2004; NIMH, 2004). There is no mention of the use of biofeedback or neurofeedback as a treatment modality for GAD.

The American Academy of Child and Adolescent Psychiatry (AACAP) has issued a guideline titled “Summary of the Practice Parameters for the Assessment and Treatment of Children and Adolescents with Anxiety Disorder.” The guideline is based on literature review and reviews the evaluation and treatment of the following conditions: anxiety disorder, generalized anxiety disorder, social phobia, and panic disorder. Children and adolescents commonly experience anxiety disorders which can be manifested across a wide spectrum of symptomatology ranging from mild worry and distress to overwhelming, incapacitating anxiety that interferes with functioning. Treatment modalities include education about the disorder, consultation with school personnel and primary care physician, behavioral intervention with CBT, psychoanalysis, psychodynamic psychotherapy, family therapy, and pharmacotherapy (AACAP, 1997). There is no mention of the use of biofeedback or neurofeedback as a treatment modality for anxiety disorders.

The American Psychiatric Association (APA) provides information on the types of anxiety disorders and their treatment. The APA states “Although each anxiety disorder has its own unique characteristics, most respond well to two types of treatment: psychotherapy and medications. These treatments can be given alone or in combination. Treatment can give significant relief from symptoms, but not always a complete cure (APA, 2005). There is no mention of biofeedback or neurofeedback as treatment modalities for anxiety disorders.

The Anxiety Disorders Association of America (ADAA) notes that there are several treatment modalities which are effective for the treatment of anxiety disorders. These include: behavioral therapy, CBT, relaxation and medication therapy (ADAA, 2003). Biofeedback and neurofeedback are not included.

Summary

Biofeedback is a process in which an electronic device monitors an individual’s bodily functions and provides feedback of the body’s responses. Based upon this feedback, an individual can learn relaxation and stress-reducing behavior that can assist them in managing and controlling physiological responses and behaviors. The peer-reviewed, scientific literature and/or professional societies support the safety and efficacy of biofeedback for the treatment of constipation, fecal incontinence and cancer pain in adults and the treatment of urinary incontinence and migraine in adults and children.

The peer-reviewed literature does support the therapeutic effectiveness of biofeedback for any other diagnoses or conditions.

Coding/Billing Information

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

When medically necessary:

CPT®* Codes	Description
90875	Individual psychophysiological therapy incorporating biofeedback training by any modality (face-to-face with the patient), with psychotherapy (e.g., insight oriented, behavior modifying or supportive psychotherapy); approximately 20-30 minutes
90876	Individual psychophysiological therapy incorporating biofeedback training by any modality (face-to-face with the patient), with psychotherapy (e.g., insight oriented, behavior modifying or supportive psychotherapy); approximately 45-50 minutes
90901	Biofeedback training by any modality
90911	Biofeedback training, perineal muscles, anorectal or urethral sphincter, including EMG and/or manometry

HCPCS Codes	Description
E0746	Electromyography (EMG), biofeedback device

ICD-9-CM Diagnosis Codes	Description
	Multiple/varied

***Current Procedural Terminology (CPT®) ©2005 American Medical Association: Chicago, IL.**

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