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Subject: Biofeedback

THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS MEDICAL COVERAGE GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.

DESCRIPTION:

Biofeedback is a technique intended to teach self-regulation of certain physiologic processes not normally considered to be under voluntary control.

Electromyography biofeedback utilizes sensors to help the individual identify and contract the anal sphincter muscles and has been evaluated as a method to reduce chronic or recurrent pain of musculoskeletal or psychosomatic origin, urinary incontinence, fecal incontinence, constipation, headache, tinnitus, and other miscellaneous indications.

Neurofeedback (also known as EEG biofeedback) is a type of biofeedback that uses electroencephalograms (EEGs) as the feedback source. EEG information is signaled to the individual, usually by video or sound, for the purpose of training the individual to self-regulate brain activity. Neurofeedback is being studied for a variety of medical and psychological conditions.

Summary and Analysis of Evidence: Cho et al (2017) reviewed updated pharmacological, non-pharmacological, and neurostimulation treatment options for chronic migraine (CM). The authors stated, “several studies have revealed that behavioral interventions such as cognitive behavioral therapy, biofeedback, and relaxation techniques are associated with significant improvements in symptoms. Thus, these treatment options are recommended for patients with CM, especially for refractory cases.” UpToDate review “Chronic migraine” states, “(i)n agreement with guidelines for migraine headache (mainly based upon studies of episodic migraine) from the American Academy of Neurology (AAN) published in 2000, we suggest the use of behavioral therapy for migraine prevention. Options include relaxation training, thermal biofeedback combined with relaxation training, electromyographic biofeedback, or cognitive-behavioral therapy. The choice among these interventions should be individualized according to factors that include clinician familiarity, local availability and expertise, and patient preference.” UpToDate review “Tension-type headache in adults: Preventive treatment” (Taylor, 2024) states, “(w)e suggest treatment using biofeedback combined with relaxation

therapy rather than other behavioral therapy options for initial nonpharmacologic management of patients with frequent episodic TTH or chronic TTH. This recommendation is similar to the conclusions of the 2010 European guidelines for the treatment of TTH, which reported biofeedback for TTH can have a substantial effect that may be enhanced by added relaxation therapy …" "Pericranial muscle tenderness is often associated with TTH, but many patients are either not aware of the relationship or overly fixate on its importance. Biofeedback may be helpful in either circumstance. Patients are typically trained over several guided sessions to recognize focal muscle tension and then to practice controlling muscle activation. Electromyography feedback is the predominant method used in TTH treatment. Biofeedback methods are based upon the notion that an individual can learn to control involuntary and subconscious physiologic processes when information about these processes is fed back in the form of a visual or auditory signal (Rains et al, 2005)."

The National Comprehensive Cancer Network (NCCN) Clinical Practice Guideline "Adult Cancer Pain" (V.2.2024) recommended biofeedback as a cognitive modality in an integrative intervention to reduce pain (2A recommendation).

UpToDate review "Fecal incontinence in adults: Management" (Lembo, Spivak, 2024) states, "(w)e suggest biofeedback therapy (ie, pelvic floor rehabilitation) in patients with fecal incontinence if anorectal manometry demonstrates weakness of the external anal sphincter or decreased ability to perceive rectal distension because of nerve injury. Biofeedback is also useful when muscles are not coordinated, and rectal compliance is decreased for cognitive retraining of the pelvic floor and the abdominal wall musculature. <In addition, it is> useful in individuals with intact anal sphincters and urge incontinence or decreased rectal sensation, which often presents as urge incontinence or overflow incontinence symptoms. [Landefeld et al, 2008; Madoff et al, 2004; Rao et al, 2016].

Yang et al (2023) analysed the specific exercise effects of pelvic floor muscle training (PFMT) with or without biofeedback or electrical stimulation on urinary incontinence rehabilitation after radical prostatectomy. A total of 18 studies with 29,925 patients were included, all of which were of critically low methodological quality. Biofeedback therapy seemed to show additional benefits compared to PFMT alone. The authors concluded "PFMT has a good effect on improving post-radical prostatectomy incontinence in men, and biofeedback can have an additional beneficial effect on patients, especially in the short-term and medium-term." The evidence on using biofeedback therapy in the treatment of urinary incontinence for adults and children includes RCTs (Sahin, 2022; Sam, 2022), and systematic reviews (Johnson, 2023; Nunes 2019). Conclusions of individual RCTs were mixed, but systematic reviews are generally supportive of offering biofeedback as an option in individuals with urinary incontinence. Moroni et al (2016) performed a systematic review and meta-analysis of randomized controlled trials that studied the conservative management of stress urinary incontinence (SUI). There were 1058 results after the initial searches, from which 37 studies were eligible according to previously determined inclusion criteria. For the primary outcomes, pelvic floor muscle training (PFMT) was more efficacious than no treatment in improving incontinence-specific quality of life (QoL) scales. However, its effect on pad tests was imprecise. Combining biofeedback with PFMT had an uncertain effect on QoL, but better results on the pad test. Both intravaginal and superficial electrical stimulation (IES and SES) were better than no treatment for QoL and pad test. The association of IES with PFMT may improve the efficacy of the latter for QoL and pad test, but the results of individual studies were not consistent. The authors concluded, (t)hus, there is evidence of the use of PFMT on the treatment of SUI, with and without biofeedback."

UpToDate review “Management of chronic constipation in adults” (Wald, 2024) states “Biofeedback is a behavioral approach that can be used to correct inappropriate contraction of the pelvic floor muscles and external anal sphincter during defecation in patients with defecatory dysfunction such as dyssynergic defecation. Clinical improvement has been reported in adults who have received EMG biofeedback for defecatory dysfunction. Two controlled trials in such patients found that biofeedback was more effective than laxatives. Approximately two-thirds of patients with dyssynergic defecation have coexisting slow transit constipation. In this group of patients, biofeedback improves bowel function, dyssynergia, and colonic transit by improving outlet dysfunction. Biofeedback is not widely available, has not been well standardized, and results may vary at different centers. However, where available, it is an attractive alternative for patients with pelvic floor dysfunction and severe constipation as it provides the potential for treatment without laxatives.”

Weinstein et al (2024) evaluated the impact of an 8-week PFMT program guided by a motion-based intravaginal device versus a standard home program over 24 months. Between October 2020 and March 2021, a total of 363 women with stress or stress-predominant mixed UI were randomized and completed an 8-week PFMT program using a motion-based intravaginal device (intervention group) or a home program following written/video instructions (control group). A total of 231 participants returned 24-month data. Reported improvement using PGI-I was greater in the intervention group than in the control group at 24 months (35% vs 22%). The authors concluded “(p)elvic floor muscle training guided by a motion-based prescription intravaginal device yielded durable and significantly greater UI symptom improvement than a standard home program, even in the absence of continued therapy.” Limitations of this study included a lack of bladder diaries, and the limitations inherent to a remotely conducted study, and the absence of a physical examination. Keyser et al (2023) studied the effectiveness of a prescription digital therapeutic (pDTx) in reducing urinary incontinence (UI) symptoms in real-world users. This retrospective cohort study of real-world data from 532 female users examined their use of a pDTx designed to guide pelvic floor muscle training (PFMT) between July 1, 2020-December 31, 2021. Most participants had stress UI (59%) followed by mixed UI (22%), urgency UI/OAB (11%), and unspecified UI (8%). Device-reported PFMT adherence was 72% at 4 weeks and 66% at 8 weeks (100% = 14 uses/week). Participants in each diagnosis category reported significant improvement on UDI-6 score from baseline to 8 weeks. Adverse events were reported by 4.5% of women. Study limitations included the challenges of real-world survey data and possible selection bias limiting interpretation and generalizability of results. Also, lower response rates to clinico-demographics such as parity, mode of delivery, and past or current UI interventions limited analysis of these parameters and their relationship to symptom improvement. It is possible that concurrent UI treatments, such as medications (e.g., anticholinergics, hormonal therapies) or pessaries also influenced outcomes. Rosenblatt et al (2019) assessed the effectiveness and patient satisfaction of pelvic floor muscle training (PFMT) guided by an intravaginal accelerometer-based system for the treatment of female urinary incontinence (UI) (the leva Pelvic Digital Health System (leva). The study was a prospective, single-center, open label study with 23 participants. Premenopausal women with mild-to-moderate stress or mixed UI were recruited to participate for 6 weeks with supervision. The author concluded that “pilot testing of this accelerometer-based system demonstrates improvements in objective PFM measures, patient-reported UI severity and condition-specific quality of life, with results evident after 1 week of use.” Limitations of this pilot, proof-of-concept study included a small sample of women with stress-dominant UI, lack of a comparison group, and regular interaction with the research assistant that may have increased the level of subjective

improvement. The authors stated "(t)his research serves as a foundation for future RCTs comparing this technology to other accepted interventions for UI."

Numerous systematic reviews with meta-analyses have compared neurofeedback versus other treatments for ADHD in children, adolescents, and adults [Riesco-Matías et al (2021); Lambez et al (2020); Van Doren et al (2019)]. Comparators included methylphenidate, biofeedback, cognitive behavioral therapy, cognitive training, or physical activity. The results of these analyses generally demonstrated either small to moderate or no benefit of neurofeedback versus other treatments for ADHD symptoms. Studies that used active controls have suggested that at least part of the effect of neurofeedback may be due to attention skills training, relaxation training, and/or other nonspecific effects. Also, the beneficial effects of neurofeedback are more likely to be reported by evaluators unblinded to treatment (parents) than by evaluators blinded to treatment (teachers), suggesting bias in the nonblinded evaluations. Additional research with blinded evaluation of outcomes is needed to demonstrate the effect of neurofeedback on ADHD.

For individuals who have disorders other than ADHD (eg, chronic insomnia, epilepsy, substance abuse, pediatric brain tumors, and post-traumatic stress disorder) who receive neurofeedback, the evidence includes case reports, case series, comparative cohorts, small RCTs, and systematic reviews. Relevant outcomes are symptoms, functional outcomes, and quality of life. A systematic review by Melo et al (2019) included 7 RCTs of biofeedback techniques, including neurofeedback, in the treatment of chronic insomnia. The authors identified conflicting results in comparisons of neurofeedback with other cognitive behavioral therapy techniques, placebo, and no treatment. A majority of outcomes demonstrated no significant differences between comparison groups. An RCT by Morales-Quezada et al (2019) randomized children with focal epilepsy to sensorimotor rhythm neurofeedback, SCP neurofeedback, or sham neurofeedback for 25 sessions over 5 weeks. At the end of the intervention period, only the sensorimotor rhythm neurofeedback group demonstrated significant improvement in the activity switching task and all groups demonstrated significant improvements in quality of life. Limitations included that patients were from a single site in Mexico, allocation concealment was unclear, and power calculations were not recorded. An RCT by Gabrielsen et al (2022) randomized adults with substance abuse disorders enrolled in outpatient abuse programs to either 20 sessions (30 minutes each) of infralow (ILF) neurofeedback plus standard of care, or standard of care alone, over a mean of 5 months. At the end of the intervention period, both groups demonstrated a significant improvement in quality of life scores from baseline, but there was no difference between groups. Restlessness was reportedly significantly lower in the ILF-neurofeedback group compared to standard of care post-treatment, but this was a secondary endpoint, meaning the study was not powered to find differences only in this endpoint. Individuals were not stratified based on drugs of abuse and there was a lack of sham neurofeedback, limiting results. De Ruiter et al (2016) reported on a multicenter, triple-blind RCT of neurofeedback in 80 pediatric brain tumor survivors who had cognitive impairments. The specific neurofeedback module was based on individual EEG, and participants, parents, trainers, and researchers handling the data were blinded to assignment to the active or sham neurofeedback module. At the end of training and 6-month follow-up, there were no significant differences between the neurofeedback and sham feedback groups on the primary outcome measures for cognitive performance, which included attention, processing speed, memory, executive functioning, visuomotor integration, and intelligence. Hong and Park (2022) conducted a meta-analysis of 7 RCTs of adults with PTSD treated with neurofeedback. Three studies used functional magnetic resonance imaging (fMRI) based neurofeedback

and 4 studies used EEG-based neurofeedback. The overall effect of all studies pooled together demonstrated a significant improvement in PTSD symptoms with neurofeedback compared to sham neurofeedback, no treatment, of other treatment. When analyzed by type of neurofeedback, the significant improvement in PTSD symptoms remained with EEG-based neurofeedback, but not with fMRI. Five studies overall assessed anxiety and depression with various validated scales. Overall, there was no significant impact on anxiety and depression with neurofeedback compared to control group. Two studies demonstrated a high risk of performance or detection bias, while all other studies demonstrated overall low risk of bias.

Literature searches and a systematic review by Schoenberg et al (2014) assessing biofeedback for psychiatric and neurologic disorders have identified small studies (case reports, case series, comparative cohorts, small RCTs) of neurofeedback for anxiety and Asperger syndrome [Schoenberg et al (2014)], autism spectrum disorder (Sokhadze et al, 2014), cigarette cravings (Pandria et al, 2023), chronic pain (Hesam-Shariati et al, 2022), cognitive impairment (Lavy et al, 2019), depression (Lee et al, 2019), multiple sclerosis-related depression, pain, or fatigue in patients (Amatya et al, 2018), depression in alcohol addiction (Schoenberg et al, 2014), and dissociative identity disorder (Schoenberg et al, 2014). For these other disorders, the evidence is poor, and several questions concerning clinical efficacy remain unanswered. Larger RCTs that include either a sham or active control are needed to evaluate the effect of neurofeedback for these conditions.

POSITION STATEMENT:

Biofeedback **meets the definition of medical necessity** as part of the overall treatment plan for **migraine headache and tension-type headache**, when conservative treatment has failed (e.g., medications, stress management strategies), up to 20 biofeedback sessions.

Biofeedback **meets the definition of medical necessity** for treatment of **cancer pain**, up to 20 biofeedback sessions.

Biofeedback specific to the perineal muscles, and/or anorectal or urethral sphincter **meets the definition of medical necessity** for treatment of:

- **Fecal incontinence** when **ALL** of the following are met:
    - There is some degree of rectal sensation
    - The underlying cause is determined to be an ineffective anal sphincter squeeze function
    - Ability to contract the sphincter voluntarily
    - Conservative treatments (e.g., medication, diet changes) have failed
    - Treatment does not exceed 6 biofeedback sessions
- **Stress, urge, mixed, overflow** or **persistent post-prostatectomy urinary incontinence** when conservative treatments (e.g., medications, timed voiding, pelvic floor muscle exercises) have failed, up to 12 feedback sessions (one per week)
- ***Chronic constipation** when conservative treatments (e.g., dietary changes, enemas, laxatives, prescription drug therapy, suppositories) have failed, up to 6 biofeedback sessions.

Biofeedback is considered **experimental or investigational** for treatment of all other conditions, including but not limited to:

- Anxiety disorders
- Asthma
- Bell palsy
- Chronic pain (including but not limited to low back pain)
- Cluster headache
- Depression
- Functional urinary incontinence
- Hypertension
- Insomnia
- Mechanical urinary incontinence
- Movement disorders, such as motor function after stroke, injury, or lower-limb surgery
- Multiple sclerosis
- Orthostatic hypotension in patients with spinal cord injury
- Pain management during labor
- Post-traumatic stress disorder
- Prevention of preterm birth
- Psychosomatic conditions
- Raynaud's disease
- Sleep bruxism
- Tinnitus
- Vaginismus
- Vulvodynia

Data in published medical literature are inadequate to permit scientific conclusions on long-term and net health outcomes.

Home biofeedback (including the leva® Pelvic Health System) is considered **experimental or investigational** for all indications. There is insufficient published clinical evidence to support the safety and effectiveness of these devices.

Neurofeedback (EEG biofeedback) is considered **experimental or investigational** for all indications, as there is a lack of clinical scientific evidence published in peer-reviewed literature to permit conclusions on safety and net health outcomes.

BILLING/CODING INFORMATION:

CPT Coding:

90875	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
90876	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
90901	Biofeedback training by any modality
90912	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
90913	Biofeedback training, perineal muscles, anorectal or urethral sphincter, including EMG and/or manometry, when performed; each additional 15 minutes of one-on-one physician or other qualified health care professional contact with the patient (List separately in addition to code for primary procedure)

HCPCS Coding:

E0746	Electromyography (EMG), biofeedback device **(investigational)**
S9002	Intra-vaginal motion sensor system, provides biofeedback for pelvic floor muscle rehabilitation device (eg, leva® Pelvic Health System) **(investigational)**

ICD-10 Diagnosis Codes That Support Medical Necessity:

G44.201 – G44.229	Tension headache
G43.001 – G43.919	Migraine headache
G89.3	Neoplasm related pain (acute) (chronic)
K59.00 – K59.09	Chronic constipation
N39.3	Stress incontinence (female) (male)
N39.41	Urge incontinence
N39.46	Mixed incontinence
N39.490	Overflow incontinence
R15.0 – R15.9	Fecal incontinence

LOINC Codes:

The following information may be required documentation to support medical necessity: physician history and physical, physician progress notes, physical therapy assessment and progress notes, treatment plan, and diagnostic studies.

Documentation Table	LOINC Codes	LOINC Timeframe Modifier Code	LOINC Time Frame Modifier Codes Narrative

Physician history and physical	28626-0	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim.
Physical therapy initial assessment	18735-1	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim.
Physical therapy progress note	11508-9	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim.
Attending physician visit note	18733-6	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim.
Treatment plan	18776-5	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim.
Diagnostic studies (non-lab)	27899-4	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim.

REIMBURSEMENT INFORMATION:

Refer to section entitled **POSITION STATEMENT**.

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Advantage products:

The following National Coverage Determinations (NCDs) were reviewed on the last guideline reviewed date: Biofeedback Therapy (30.1) and Biofeedback Therapy for the Treatment of Urinary Incontinence (30.1.10), located at cms.gov.

DEFINITIONS:

Chronic constipation: Defined by less frequent than normal or difficult bowel movements; while the frequency differs for each person, any length of time beyond three days is not typical and often leads to even more difficult bowel movements. Symptoms include reduction in frequency specific to the person's

normal schedule, feeling incompletely evacuated, abdominal pain, decreased amount of feces, and having to strain to produce a bowel movement.

Electromyography (EMG): An electrical recording of muscle activity that aids in the diagnosis of neuromuscular disease.

Fecal incontinence: The inability to control bowel movements which may involve leakage of stool.

Functional urinary incontinence: A physical or mental impairment that prevents making it to the toilet in time.

Migraine headache: A type of headache marked by severe head pain lasting for several hours or more.

Mixed urinary incontinence: Displays more than one form or urinary incontinence.

Overflow incontinence: May be due to an underactive detrusor muscle or obstruction of the urethra in women; in men, may be associated with obstruction such as prostatic hyperplasia.

Stress incontinence: Urine leaks when pressure is exerted on the bladder (e.g., coughing, sneezing, laughing, exercising, lifting something heavy).

Tension-type headache: A type of headache with generally mild to moderate pain that often occurs when neck and scalp muscles become tense or contract. Muscle contractions can be a result of stress, depression, head injury or anxiety.

Urge incontinence: Sudden, intense urge to urinate followed by involuntary loss of urine (examples of causes include infection, neurological disorders, and diabetes mellitus).

RELATED GUIDELINES:

Diagnosis and Treatment of Temporomandibular Joint Disorder, 02-20000-12

Treatment of Tinnitus, 01-92502-11

OTHER:

None applicable.

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5. Blue Cross Blue Shield Association Evidence Positioning System®. 2.01.29 - Biofeedback as a Treatment of Headache, 12/23.

6. Blue Cross Blue Shield Association Evidence Positioning System®. 2.01.30 - Biofeedback as a Treatment of Chronic Pain, 12/23.
7. Blue Cross Blue Shield Association Evidence Positioning System®. 2.01.53 - Biofeedback for Miscellaneous Indications, 12/2.
8. Blue Cross Blue Shield Association Evidence Positioning System®. 2.01.64 - Biofeedback as a Treatment of Fecal Incontinence or Constipation, 12/23.
9. Blue Cross Blue Shield Association Evidence Positioning System®. 8.01.39 - Treatment of Tinnitus, 03/24.
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COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy and Coverage Committee on 06/27/24.

GUIDELINE UPDATE INFORMATION:

09/15/01	Medical Coverage Guideline Revised and reformatted.
03/15/03	Annual review.
04/15/04	Scheduled review and revision of guideline; consisting of updated references and added to description section.
04/15/05	Scheduled review and revision of guideline; consisting of updated references and maintaining investigational status.
05/15/06	Medical Coverage Guideline archived.
01/01/23	Medical Coverage Guideline returned to active status.
07/15/23	Scheduled review. Maintained position statement and updated references.
04/01/24	Quarterly CPT/HCPCS coding update. Added S9002.
07/15/24	Scheduled review. Revised description. Maintained position statement and updated references.