Biofeedback

Biofeedback is a technique intended to teach patients self-regulation of certain physiologic processes not normally considered to be under voluntary control. Biofeedback equipment takes physiological signals and creates output that can be given to patients. The technique involves the feedback of a variety of types of information not normally available to the patient, followed by a concerted effort on the part of the patient to use this feedback to help alter the physiological process in some specific way. Biofeedback has been proposed as a treatment for a variety of diseases and disorders, including anxiety, headaches, hypertension, movement disorders, incontinence, pain, asthma, Raynaud disease, and insomnia.

The various forms of biofeedback mainly differ in the nature of the disease or disorder under treatment, the biologic variable that the subject attempts to control, and the information that is fed back to the subject. Biofeedback techniques include peripheral skin temperature feedback, blood-volume-pulse feedback (vasoconstriction and dilation), vasoconstriction training (temporalis artery), and EMG biofeedback; these may be used alone or in conjunction with other therapies (e.g., relaxation, behavioral management, medication).

Neurofeedback may be conceptualized as a type of biofeedback that has traditionally used the electroencephalogram (EEG) as a source of feedback data. Neurofeedback differs from traditional forms of biofeedback in that the information fed back to the patient (via EEG tracings, functional magnetic resonance imaging [fMRI], near-infrared spectroscopy) is a direct measure of global neuronal activity, or brain state, compared with feedback of the centrally regulated physiologic processes, such as tension of specific muscle groups or skin temperature. The patient may be trained to either increase or decrease the prevalence, amplitude, or frequency of specified EEG waveforms (e.g., alpha, beta, theta waves), depending on the changes in brain function associated with the particular disorder. It has been proposed that training of slow cortical potentials (SCPs) can regulate cortical excitability and that using the EEG as a measure of central nervous system functioning can help train patients to modify or control their abnormal brain activity. Upregulating or downregulating neural activity with real-time feedback of fMRI signals is also being explored.

Regulatory Status:
A variety of biofeedback devices are cleared for marketing though the U.S. Food and Drug Administration’s (FDA) 510(k) marketing clearance process. These devices are designated by the FDA as class II with special controls and 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.”

Related Policies:
Biofeedback as a Treatment of Pain
Biofeedback

Temporomandibular Joint Dysfunction (TMJD) Treatment
Rehabilitation Therapies
Sensory Integration Therapy

***Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.

Policy

BCBSNC will provide coverage for Biofeedback when it is determined to be medically necessary because the medical criteria and guidelines shown below are met.

BCBSNC will not provide coverage for Neurofeedback. It is considered investigational. BCBSNC does not cover investigational services.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

See Professional Services. See also Sensory Integration Therapy for limitations and exclusions for investigational services.

When Biofeedback is covered

Biofeedback is considered medically necessary for treatment of the following conditions:
1. Torticollis, including facial tics
2. Stress urinary incontinence
3. Dyssynergia-type constipation in adults as demonstrated by meeting all 3 of the following criteria:
   a. Symptoms of functional constipation that meet ROME IV criteria (see Appendix).
   b. Objective physiologic evidence of pelvic floor dyssynergia (see Appendix) demonstrated by inappropriate contraction of the pelvic floor muscles or less than 20% relaxation of basal resting sphincter pressure by manometry, imaging or EMG;
   c. Failed a 3-month trial of standard treatments for constipation including laxatives, dietary changes, and exercises (as many of the previous as are tolerated).

When Biofeedback is not covered

1. Biofeedback is considered investigational for treatment of any diagnosis other than those listed above, including, but not limited to:
   - anxiety disorders
   - asthma
   - Attention Deficit Disorder
   - autism
   - Bell’s palsy
   - constipation in children
   - depression
   - fecal incontinence in adults and children
   - hypertension
   - insomnia
   - movement disorders, such as motor function after stroke, injury, or lower-limb surgery
   - multiple sclerosis
   - muscle re-education or muscle tension
Biofeedback

- orthostatic hypotension in patients with spinal cord injury
- pain management during labor
- posttraumatic stress disorder
- prevention of preterm birth
- Raynaud’s disease
- sleep bruxism
- temporomandibular joint dysfunction (TMJD)
- tinnitus

2. Unsupervised home use of biofeedback for treatment of urinary incontinence is considered investigational.

3. Neurofeedback is considered investigational.

Policy Guidelines

**Urinary Incontinence**
For individuals who have urinary incontinence (women) who receive biofeedback with pelvic floor muscle training (PFMT), the evidence includes randomized controlled trials (RCTs) and systematic reviews. Relevant outcomes are symptoms, functional outcomes, and quality of life. A comparative effectiveness review did not find a statistically significant difference in continence rates when patients received PFMT with or without biofeedback. Other systematic reviews evaluating biofeedback and/or verbal feedback as part of treatment for urinary incontinence found improvement in some outcomes, but not others. There is a lack of consistent evidence from well-designed trials that biofeedback effectively treats urinary incontinence. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have post-prostatectomy urinary incontinence or who are scheduled for radical prostatectomy who receive biofeedback with PFMT, the evidence includes RCTs and systematic reviews. Relevant outcomes are symptoms, functional outcomes, and quality of life. Several RCTs have compared PFMT with or without biofeedback in men undergoing radical prostatectomy, and in men with post-prostatectomy urinary incontinence. These trials had mixed findings, but did not consistently report significantly improved outcomes when biofeedback was added to the intervention. The timing and delivery of the intervention were not well-defined. Additional well-designed trials are needed that demonstrate the superiority of biofeedback with PFMT over PFMT alone. The evidence is insufficient to determine the effects of the technology on health outcomes.

**Fecal Incontinence and Constipation**
For individuals who have fecal incontinence who receive biofeedback, the evidence includes randomized controlled trials (RCTs) and systematic reviews. Relevant outcomes are symptoms, functional outcomes, and quality of life. Whereas 1 RCT found that there was a significantly greater decrease in fecal incontinence symptoms with biofeedback plus exercise training than with exercise training alone, most trials did not show a significant benefit. Systematic reviews have not found that biofeedback provides additional benefit when offered in conjunction with conventional therapy compared with conventional therapy alone. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have dyssynergia-type constipation who receive biofeedback, the evidence includes RCTs and systematic reviews. Relevant outcomes are symptoms, functional outcomes, and quality of life. Several well-conducted RCTs focusing on patients with dyssynergia-type constipation have reported benefits in a subgroup of patients meeting well-defined criteria. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.
Biofeedback

For individuals who have constipation other than dyssynergia-type constipation who receive biofeedback, the evidence includes RCTs and systematic reviews. Relevant outcomes are symptoms, functional outcomes, and quality of life. A systematic review of RCTs found a benefit of biofeedback as a treatment for constipation in adults. Conclusions of the systematic review were limited by variability in patient populations, comparator groups, and outcome measures, and biofeedback was not clearly beneficial for any other type of constipation. The evidence is insufficient to determine the effects of the technology on health outcomes.

Miscellaneous Indications

For individuals with anxiety disorders who receive biofeedback, the evidence includes a systematic review and an RCT published after the review. Relevant outcomes are symptoms, functional outcomes, and quality of life. The systematic review on heart rate variability biofeedback and the RCT on diaphragmatic breathing relaxation reported the positive effects of these treatments on anxiety. However, the trials had small sample sizes (median, 14 participants) and study quality was generally poor. Additional limitations included improper randomization, allocation concealment, and inadequate descriptions of randomization or missing data. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with asthma who receive biofeedback, the evidence includes 3 RCTs. Relevant outcomes are symptoms, functional outcomes, and quality of life. Each RCTs used a different biofeedback technique, which provided patients with information on carbon dioxide, heart rate, and respiratory sinus arrhythmia. While the trials reported improvements in each parameter on which the patients received biofeedback, the improvements did not impact clinical outcomes such as medication use and forced expiratory volume. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with Bell palsy who receive biofeedback, the evidence includes 4 RCTs. Relevant outcomes are symptoms, functional outcomes, and quality of life. The RCTs evaluated the efficacy of adding mirror and/or electromyography biofeedback to facial exercises. Sample sizes were small, and there was heterogeneity across techniques used and length of treatments. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with depression who receive biofeedback, the evidence includes an RCT. Relevant outcomes are symptoms, functional outcomes, and quality of life. The RCT evaluated the effect of neurofeedback training on the ability of patients to control emotional responses. While patients undergoing treatment were better able to decrease their emotional responses compared with controls, the sample size was small and additional research with larger populations is needed. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with hypertension who receive biofeedback, the evidence includes a systematic review and an RCT published after the review. Relevant outcomes are symptoms, functional outcomes, and quality of life. The systematic review identified 36 RCTs, though sample sizes were small and overall study quality poor. Various biofeedback techniques were used: thermal, galvanized skin response, pulse wave velocity, and heart rate variability. Results across trials did not consistently show a benefit of biofeedback. Conclusions were limited due to the heterogeneity across interventions and the generally poor quality of the trials. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with motor dysfunction after stroke who receive biofeedback, the evidence includes systematic reviews and RCTs published after the systematic reviews. Relevant outcomes are symptoms, functional outcomes, and quality of life. A systematic review identified 18 high-quality trials using the following biofeedback techniques: weight distribution on a platform sensor, muscle activity from electromyography, linear gait parameters, and joint angle from a goniometer. Feedback was visual, auditory, or both. Outcome measures were primarily assessments of motor activity in research settings, rather than clinical outcomes such as rate of falls or ability to perform activities of daily living. Pooled effects showed improvements in motor function in the short term. The evidence is
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limited due to the variability in type, duration, and intensity of the interventions and lack of long-term outcomes. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with motor dysfunction after lower-limb injury or surgery who receive biofeedback, the evidence includes a systematic review. Relevant outcomes are symptoms, functional outcomes, and quality of life. The systematic review identified 4 RCTs evaluating the use of electromyography biofeedback. Sample sizes were small, with half of the trials reporting significant benefits of biofeedback and the other half reporting no difference between study groups. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with multiple sclerosis who receive biofeedback, the evidence includes 2 RCTs. Relevant outcomes are symptoms, functional outcomes, and quality of life. One trial used vibrotactile biofeedback and the other provided patients with heart rate and muscle tension biofeedback. Sample sizes were small, and trialists reported marginally significant differences between study groups. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with orthostatic hypotension due to spinal cord injury who receive biofeedback, the evidence includes a case report and a case series. Relevant outcomes are symptoms, functional outcomes, and quality of life. The case report and case series collectively provided information on 3 patients given visual and auditory feedback. Patients were able to raise their systolic blood pressure by an average of 39%. The evidence is insufficient to determine the effects of the technology on health outcomes. For individuals who need pain management during labor who receive biofeedback, the evidence includes 4 RCTs. Relevant outcomes are symptoms, functional outcomes, and quality of life. A Cochrane review assessed the four selected trials as having a high risk of bias due to unclear descriptions of blinding and randomization methods. Due to the heterogeneity in biofeedback methods and outcomes measured, pooled analyses could not be performed. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with posttraumatic stress disorder who receive biofeedback, the evidence includes an RCT, a nonrandomized study, and 2 case series. Relevant outcomes are symptoms, functional outcomes, and quality of life. The studies had small sample sizes and inconsistent results. A systematic review of the 4 studies rated the evidence a grade C for conflicting scientific evidence. The evidence is insufficient to determine the effects of the technology on health outcomes. For individuals who are susceptible to preterm birth who receive biofeedback, the evidence includes an RCT. Relevant outcomes are symptoms, functional outcomes, and quality of life. In the RCT, patients in the treatment group received heart rate variability biofeedback. Patients receiving the treatment experienced a decrease in perceived chronic stress, but there was no significant difference in the number of preterm births, gestational duration, or birthweight. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with Raynaud disease who receive biofeedback, the evidence includes a systematic review. Relevant outcomes are symptoms, functional outcomes, and quality of life. The systematic review identified 5 RCTs using biofeedback techniques. Pooled analysis was performed on four of these trials. Reduction in frequency of attacks was significantly lower in the sham-control group. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with sleep bruxism who receive biofeedback, the evidence includes a systematic review and an RCT published after the review. Relevant outcomes are symptoms, functional outcomes, and quality of life. The systematic review identified 7 randomized and nonrandomized studies using biofeedback techniques. Studies were generally small, used different techniques, measured different outcomes, and were assessed as having either moderate or high risk of bias. Two studies reported the number of bruxism episodes per hour and a pooled analysis of these studies showed no significant differences between biofeedback groups and control groups. The evidence is insufficient to determine the effects of the technology on health outcomes.
Biofeedback

For individuals with tinnitus who receive biofeedback, the evidence includes a single RCT. Relevant outcomes are symptoms, functional outcomes, and quality of life. Treatment consisted of a biofeedback based behavioral intervention over a 3-month period. The treatment group experienced improvements in tinnitus annoyance, loudness ratings, controllability, coping cognitions, and depressive symptoms. Additional studies are needed to confirm the results of this single trial. The evidence is insufficient to determine the effects of the technology on health outcomes.

Neurofeedback:
The evidence for neurofeedback in individuals who have attention-deficit/hyperactivity disorder (ADHD) includes numerous uncontrolled studies along with some randomized controlled trials (RCTs). Relevant outcomes include symptoms and functional outcomes. Four moderate-sized RCTs have examined neurofeedback in comparison with methylphenidate, attention skills training, or cognitive therapy, and found either a small benefit or no benefit of neurofeedback. Studies that have attempted to use active controls suggest that at least part of the effect of neurofeedback may be due to attention skills training, relaxation training, and/or other nonspecific effects. Additional study, ideally RCTs with adequate power and sham controls, is needed to evaluate whether neurofeedback (alone or in combination with other treatments) has beneficial effects for children with ADHD and whether these effects are durable.

The evidence is insufficient to determine the effects of the technology on health outcomes. The evidence for neurofeedback in individuals who have various psychiatric and central nervous system disorders includes case reports, case series, comparative cohorts, and small RCTs. Relevant outcomes include symptoms and functional outcomes. For these disorders, the evidence is poor and a number of questions regarding clinical efficacy remain to be answered before applying neurofeedback techniques. The evidence is insufficient to determine the effects of the technology on health outcomes.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable service codes: 90901, 90911, 90875, 90876

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

Consultant Review (Attention Deficit Disorder) 11/94
Matrix
MPAG Review 3/99
Specialty Matched Consultant Advisory Panel, 5/01
BCBSA Medical Policy Reference Manual, 2.01.28; 5/15/02
BCBSA Medical Policy Reference Manual, 2.01.28, 7/12/02
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BCBSA TEC Assessment (December 1997). Neurofeedback. Vol 12, No. 21


BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.27, 10/10/06


BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.27, 2/14/08


BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.64, 2/14/08


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BCBSA Medical Policy Reference Manual [Electronic Version], 2.01.64, 10/4/11
BCBSA Medical Policy Reference Manual [Electronic Version], 2.01.29, 4/12/12
BCBSA Medical Policy Reference Manual [Electronic Version], 2.01.27, 7/12/12
BCBSA Medical Policy Reference Manual [Electronic Version], 2.01.64, 1/10/13
BCBSA Medical Policy Reference Manual [Electronic Version], 2.01.64, 1/9/14
BCBSA Medical Policy Reference Manual [Electronic Version], 2.01.28, 7/10/14
BCBSA Medical Policy Reference Manual [Electronic Version], 2.01.64, 1/15/15
BCBSA Medical Policy Reference Manual [Electronic Version], 2.01.27, 7/9/15
Medical Director review 8/2015
BCBSA Medical Policy Reference Manual [Electronic Version], 2.01.64, 11/12/15
BCBSA Medical Policy Reference Manual [Electronic Version], 2.01.27, 1/12/2017
## Biofeedback

**BCBSA Medical Policy Reference Manual [Electronic Version], 2.01.64, 11/14/2017**

### Policy Implementation/Update Information

<table>
<thead>
<tr>
<th>Date</th>
<th>Update Information</th>
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<tbody>
<tr>
<td>11/94</td>
<td>Original policy issued</td>
</tr>
<tr>
<td>7/96</td>
<td>Reaffirmed</td>
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<tr>
<td>5/97</td>
<td>Codes deleted. See policy (L)90900.ARC.</td>
</tr>
<tr>
<td>7/99</td>
<td>Reformatted, Medical Term Definitions added.</td>
</tr>
<tr>
<td>2/00</td>
<td>Coding system change.</td>
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<tr>
<td>10/00</td>
<td>System coding change.</td>
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<tr>
<td>12/00</td>
<td>Revised. Added neurofeedback as investigational.</td>
</tr>
<tr>
<td>8/02</td>
<td>Reaffirmed. Source added to Scientific Reference Sources section.</td>
</tr>
<tr>
<td>5/03</td>
<td>Specialty Matched Consultant Advisory Panel review. Reference added. No change to policy.</td>
</tr>
<tr>
<td>12/03</td>
<td>Benefits Application and Billing/Coding sections updated for consistency.</td>
</tr>
<tr>
<td>2/06</td>
<td>Deleted statement regarding benefits limitation from Benefits Application section. Clarification of wording in Policy Guidelines section to indicate coverage limited to a total of 14 treatments in a 12 month period for any condition, or combination of conditions listed in this policy, except for torticollis (limit is 40 treatments).</td>
</tr>
<tr>
<td>4/27/09</td>
<td>Routine biennial review. Description section revised for clarity. Statement in the When Biofeedback is Not Covered section revised to read: Biofeedback is considered investigational for any diagnosis other than those listed above including the treatment of fecal incontinence in adults and children. References updated. Specialty Matched Consultant Advisory Panel review meeting 3/31/09. No change to policy statement.</td>
</tr>
<tr>
<td>6/22/10</td>
<td>Policy Number(s) removed. (amw)</td>
</tr>
<tr>
<td>4/12/11</td>
<td>Removed reference to Urinary Incontinence, Treatment policy since it was archived in 2007 and is not listed in the Medical Policy website. Under “When Covered section” changed the 1st bullet to Tension headaches from muscle contraction; also added statements “Biofeedback is considered investigational for the treatment of cluster headache and Unsupervised home use of biofeedback for treatment of headache is not medically necessary”; also added constipation to the investigational urinary incontinence statement under “when not covered”. Specialty Matched Consultant Advisory Panel review meeting 3/31/11. References added. (lpr)</td>
</tr>
</tbody>
</table>
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7/10/12 Under “When Not Covered” section added as investigational: autism, Raynaud’s disease, back pain, muscle re-education or muscle tension, hypertension, asthma, anxiety disorders, insomnia, sleep bruxism, tinnitus, movement disorders, Bell’s palsy, motor function after stroke, injury or lower limb surgery, orthostatic hypotension with spinal cord injury, and temporomandibular joint dysfunction (TMJD) for consistency with BCBSA. Policy guidelines extensively revised. Deleted the statement “Limitations and Exclusions for investigational services for use of Biofeedback with Attention Deficit Disorder” from Benefits Application section. Specialty Matched Consultant Advisory Panel review meeting 3/21/12. References added. Notification given 7/10/12 for effective date 10/16/12. Reviewed with medical director. Under “Not Covered” section: added pain management during labor as investigational; also added to the end of statement 1) “but not limited to” following “included”. These additions do not change the intent of the medical policy. Reference added. Reviewed with medical director. (lpr)


5/28/13 Reference added. No change to policy coverage criteria. (lpr)

8/13/13 Reference updated. No change to policy statement. (lpr)

9/10/13 Reference updated. No change to policy statement. (lpr)

3/11/14 Specialty Matched Consultant Advisory panel review meeting 2/25/2014. No change to policy statement. Reference added. (lpr)

7/29/14 Reference added. No change to policy statement. (lpr)

10/28/14 Under “When Not Covered” section: added “prevention of preterm birth” as investigational indication. References added. (lpr)

4/28/15 Specialty Matched Consultant Advisory panel review meeting 2/25/2015. No change to policy statement. Reference added. (lpr)

9/1/15 References added. No change to policy statement. (lpr)

10/1/15 Under “When Not Covered” section: multiple sclerosis, depression and posttraumatic stress disorder added to investigational statement. Medical Director review 8/2015. Reference added. (lpr)

1/26/16 References added. No change to policy statement. (lpr)

4/1/16 Specialty Matched Consultant Advisory Panel review 2/24/2016. No change to policy. (an)


9/29/17 Minor wording changes in Description and Coverage sections. No change to policy intent or coverage criteria. (an)

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purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.

Appendix: Diagnostic Criteria

Rome IV Diagnostic Criteria for Functional Gastrointestinal Disorders
http://www.romecriteria.org/assets/pdf/19_RomeIII_apA_885-898.pdf:

Rome IV diagnostic criteria for functional constipation*

1. Must include two or more of the following:
   a. Straining during at least 25% of defecations
   b. Lumpy or hard stools in at least 25% of defecations
   c. Sensation of incomplete evacuation for at least 25% of defecations
   d. Sensation of anorectal obstruction/blockage for at least 25% of defecations
   e. Manual maneuvers to facilitate at least 25% of defecations (e.g., digital evacuation, support of the pelvic floor)
   f. Fewer than three defecations per week

2. Loose stools are rarely present without the use of laxatives

3. Insufficient criteria for irritable bowel syndrome

* Criteria fulfilled for the last 3 months with symptom onset at least 6 months prior to diagnosis

Rome IV diagnostic criterion for dyssynergic defecation:

- Inappropriate contraction of the pelvic floor or less than 20% relaxation of basal resting sphincter pressure with adequate propulsive forces during attempted defecation

Guidance on biofeedback protocol

- The recommended treatment course for patients with constipation who meet criteria is up to 6 biofeedback sessions over 3 months. This is consistent with the protocol used in key randomized trials showing benefit of biofeedback for selected patients.