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.”
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 III 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

In 2015, the National Institute for Health and Clinical Excellence updated its 2006 guidance on the management of urinary incontinence in women. Recommendations on biofeedback included: “do not use perineometry or pelvic floor electromyography as biofeedback as a routine part of pelvic floor muscle training” and “electrical stimulation and/or biofeedback should be considered in women who cannot actively contract pelvic floor muscles in order to aid motivation and adherence to therapy”.

In their 2014 guidelines on diagnosis and treatment of overactive bladder (OAB), the American Urological Association and Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction did not make specific recommendations on biofeedback. The guidelines included the statement: “Clinicians should offer behavioral therapies (e.g., bladder training, bladder control strategies, pelvic floor muscle training, fluid management) as first line therapy to all patients with OAB”.

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.

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.

The evidence for the use of biofeedback in individuals with Bell palsy, hypertension, motor function after stroke, injury or lower-limb surgery, multiple sclerosis, prevention of preterm birth, postrumatic
Biofeedback

stress disorder, Raynaud disease, tinnitus, or sleep bruxism includes 1 or more randomized controlled trials (RCTs) on each indication. Relevant outcomes are symptoms, functional outcomes, and quality of life. The available RCTs either failed to show any beneficial impact of biofeedback or had design flaws that create uncertainty about the contribution of nonspecific factors such as attention or placebo effects versus the specific effect of biofeedback. Moreover, the trials are generally of short duration and the durability of benefits reported is unclear. The evidence is insufficient to determine the effects of the technology on health outcomes.

The evidence for the use of biofeedback in individuals with asthma, insomnia, movement disorders, or orthostatic hypotension associated with spinal cord injury includes a TEC Assessment or other systematic review of the literature. Relevant outcomes are symptoms, functional outcomes, and quality of life. The systematic reviews did not find sufficient evidence that biofeedback benefited these conditions. The evidence is insufficient to determine the effects of the technology on health outcomes.

The evidence for the use of biofeedback in individuals with anxiety or depression includes no published peer-reviewed studies. Relevant outcomes are symptoms, functional outcomes, and quality of life. The evidence is insufficient to determine the effects of the technology on health outcomes.

Coverage is 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).

There is a lack of consistent evidence from randomized controlled trials that biofeedback improves incontinence outcomes in women, or in men after prostate surgery compared to pelvic floor muscle exercises alone. No published evidence supports the unsupervised home use of biofeedback for treatment of urinary incontinence. The body of evidence consists of RCT’s that have conflicting results.

**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*
Biofeedback

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
- 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], 2.01.28, 7/20/06
- 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, 8/14/14


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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

Policy Implementation/Update Information

<table>
<thead>
<tr>
<th>Date</th>
<th>Change Description</th>
</tr>
</thead>
<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>
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<tr>
<td>7/99</td>
<td>Reformatted, Medical Term Definitions added.</td>
</tr>
<tr>
<td>2/00</td>
<td>Coding system change.</td>
</tr>
<tr>
<td>10/00</td>
<td>System coding change.</td>
</tr>
<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>2/2/06</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>
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</table>
Biofeedback

4/27/09  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 3/26/09. No change to policy statement.

6/22/10  Policy Number(s) removed. (amw)

4/12/11  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)

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)
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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)

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational 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 III Diagnostic Criteria for Functional Gastrointestinal Disorders
http://www.romecriteria.org/assets/pdf/19_RomeIII_apA_885-898.pdf:

Rome III 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 III 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.