Biofeedback is a technique intended to teach patients self-regulation of certain physiologic processes not normally considered to be under voluntary control. This policy focuses on the use of biofeedback for treating miscellaneous indications not addressed in separate policies; these include, among others, hypertension, anxiety, insomnia, asthma, and movement disorders.

### Related Policies

- Biofeedback as a Treatment of Chronic Pain
- Biofeedback as a Treatment of Fecal Incontinence or Constipation
- Biofeedback as a Treatment of Headache
- Neurofeedback
- Temporomandibular Joint Dysfunction
- Urinary Incontinence Outpatient Treatment

### Policy

Biofeedback is considered *investigational* as a treatment of any of the following miscellaneous conditions:

- Anxiety disorders
- Asthma
- Autism
- Bell palsy
- Hypertension
- Insomnia
- Motor function after stroke, injury, or lower-limb surgery
- Movement disorders
- Orthostatic hypotension in patients with spinal cord injury
- Pain management during labor
- Prevention of preterm birth
- Raynaud disease
- Sleep bruxism
- Tinnitus

**Policy Guidelines**

**Note:** Some Blue Shield of California (BSC) plans exclude coverage of biofeedback. Please check benefit plan descriptions for details.

**Biofeedback devices:** Unsupervised home use of a biofeedback device has not been well studied, and further is excluded from coverage per Blue Shield Evidence of Coverage (EOC) General Exclusions and Limitations.

**Benefit Application**

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program (FEP)) prohibit Plans from denying Food and Drug Administration (FDA) - approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

**Rationale**

**Background**

Biofeedback is a technique intended to teach patients self-regulation of certain unconscious or involuntary physiologic processes. The technique involves the feedback of a variety of types of information not usually available to the patient, followed by a concerted effort on the part of the patient to use this feedback to help alter the physiologic process in a 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 type of feedback used in an intervention (e.g., visual, auditory, etc.) depends on the nature of the disease or disorder under treatment. This policy focuses on the use of biofeedback for the treatment of hypertension, anxiety, insomnia, asthma, movement disorders, and other miscellaneous applications (i.e., conditions not addressed in other policies on biofeedback).

Several methodologic difficulties exist in assessing biofeedback. For example, most interventions that include biofeedback are multimodal and include relaxation and behavioral instruction, which may have effects separate from those that may occur due to biofeedback. While studies may report a beneficial effect of multimodality treatment, without appropriate control conditions, it is impossible to isolate the specific contribution of biofeedback to the overall treatment effect. For example, relaxation, attention, or suggestion may account for the successful results that have been attributed to
biofeedback. These are nonspecific therapeutic factors, some of which can be considered placebo effects. Moreover, it is important that studies demonstrate that biofeedback improves disease-related health outcomes, as opposed to potentially affecting only physiologic, intermediate outcomes, and that they address the durability of effects beyond the initial, short-term biofeedback training period.

**Literature Review**

The 1995 TEC Assessment, on which the policy was based, concluded that there was insufficient evidence to support the use of biofeedback in the treatment of 9 different conditions: anxiety disorders, headaches, hypertension, movement disorders, incontinence, pain, asthma, Raynaud disease, and insomnia.(1) Following is a summary of key literature identified in policy updates, focusing on evidence from randomized controlled trials (RCTs) and meta-analyses.

**Autism**

In 2013, Kouijzer et al published an RCT evaluating electroencephalography (EEG) biofeedback as a treatment for autism spectrum disorders (ASD).(2) The trial included 35 teenagers between 12 and 18 years with confirmed diagnoses of ASD. Participants were randomly assigned to receive EEG biofeedback (n=13), skin conductance (n=12) biofeedback, or a waiting-list control group (n=13). The biofeedback interventions included 40 sessions provided twice a week. Patients and parents in the biofeedback groups, but not on the waiting-list, were blinded to treatment allocation. The primary outcome measure was change in symptoms at 3 months, as measured by the total score on the Social Communication Questionnaire (SCQ); scores have a potential range of 0 to 36. In the primary analysis, the investigators only included participants who successfully influenced their EEG activity (called “EEG-regulators”) in the primary analysis. The justification for this was to be able to identify the specific effects of biofeedback on symptoms. Among the 19 of 35 (54%) regulators, there was not a statistically significant difference in the SCQ scores between participants treated with EEG- or skin conductance biofeedback. The investigators evaluated nonspecific effects of EEG biofeedback by examining the SCQ scores among EEG-non-regulators as rated by the parents. There was not a statistically significant difference in scores among participants in the EEG biofeedback group, the skin conductance biofeedback group, and the control group.

A 2010 article by Coben and Myers reviewed the literature on EEG biofeedback for autistic disorders.(3) The authors identified 2 published non-RCTs evaluating EEG biofeedback in the treatment of autistic disorders. As described in the review, a study published by Jarusiewicz et al in 2002 compared treatment with 20 to 69 sessions of biofeedback in 12 autistic children to a matched control group that did not receive biofeedback. Mean reduction in autistic symptoms, as measured by the Autism Treatment Evaluation Checklist, was 26% in the biofeedback group and 3% in the comparison group; this difference was statistically significant. The other study was published by Coben and Padolsky in 2007. It compared 20 sessions of EEG biofeedback in 37 patients with a waiting-list control group. After treatment, parents reported reduction in symptoms in 89% of the treatment group compared with 17% of the control group (p value not reported). Studies differed in their biofeedback protocols and number of sessions.
Section Summary

There is insufficient evidence from RCTs that biofeedback improves outcomes in individuals with ASDs. Only 1 RCT has been published, and this study did not find a benefit of biofeedback on autism-related symptoms.

Bell Palsy

In 2008, Cardoso et al published a systematic review of studies on the effects of facial exercises on symptoms of Bell palsy.(4) Studies including patients with unilateral idiopathic facial palsy treated with facial exercises associated with mirror and/or EMG biofeedback were included in this review. Four studies (n=132) met the eligibility criteria. The studies described mime therapy versus control (n=50), mirror biofeedback exercise versus control (n=27), “small” mirror movements versus conventional neuromuscular retraining (n=10), and EMG biofeedback plus mirror training versus mirror training alone. The treatment length varied from 1 to 12 months. The authors concluded that “…because of the small number of randomized controlled trials, it was not possible to analyze if the exercises, associated either with mirror or EMG biofeedback, were effective. In summary, the available evidence from randomized controlled trials is not yet strong enough to become integrated into clinical practice.”

Section Summary

There are a small number of RCTs evaluating biofeedback for treating Bell palsy, and the available trials have small sample sizes and variability in the biofeedback protocol and type of comparison intervention. These studies represent insufficient evidence to draw conclusions on health outcomes.

Hypertension

A systematic review of studies on biofeedback for hypertension was published by Greenhalgh et al in 2010.(5) The investigators searched for RCTs that included adults with essential hypertension (defined as at least 140/90 mm Hg) and that compared biofeedback interventions, alone or in combination with other therapies, to medication, sham biofeedback, no treatment, or another behavioral intervention. A total of 36 trials (n=1660) met inclusion criteria. Trials generally had small sample sizes; only 4 included more than 100 patients. All were single-center, and most were conducted in the United States. Trials used a variety of biofeedback techniques including thermal biofeedback, galvanized skin response, pulse wave velocity, and heart rate variability; some trials used more than 1 modality. Twenty studies evaluated biofeedback alone, 15 evaluated biofeedback combined with another intervention, and 1 had multiple arms and evaluated both types of interventions; only 4 trials included a sham biofeedback comparison group. The authors stated that they did not pool study findings due to differences in interventions and outcomes and the generally poor quality of the studies.

The investigators reported that trials comparing biofeedback alone versus no treatment or another behavioral intervention did not provide convincing evidence of the superiority of biofeedback. Only 1 of 5 trials that compared a biofeedback combination intervention (most commonly combined with relaxation) with a different behavioral treatment found the biofeedback intervention to be superior. Approximately half of the trials comparing a biofeedback combination with no treatment found a significant benefit to the biofeedback combination, but the specific effects of biofeedback cannot be determined from this analysis. Only 1 trial was identified that compared a biofeedback combination intervention with sham biofeedback, and this study did not find a significant
difference in the efficacy of the 2 interventions. Four studies on biofeedback alone and another 4 on a combined biofeedback intervention reported data beyond 6 months; most of these found no significant differences in efficacy between the biofeedback and control groups. Greenhalgh et al concluded, “…we found no convincing evidence that consistently demonstrates the effectiveness of the use of any particular biofeedback treatment in the control of essential hypertension when compared with pharmacotherapy, placebo, no intervention or other behavioral therapies.”

In a previous meta-analysis, published in 2003, Nakao et al found that biofeedback was effective in lowering systolic and diastolic blood pressure but only when the biofeedback was combined with relaxation techniques.(6) The authors further noted that study is needed to determine whether biofeedback has any blood pressure lowering effect without relaxation techniques.

**Section Summary**

Although there are a large number of RCTs evaluating biofeedback for treating hypertension, evidence is insufficient due to the shortage of studies isolating the effect of biofeedback, the generally poor quality of the trials, and the variability among interventions.

**Motor Function After Stroke**

Numerous RCTs and several systematic reviews of RCTs have been published. Systematic reviews have noted that RCTs tended to have relatively small sample sizes and only small RCTs were identified in policy updates.(7) A 2011 systematic review and meta-analysis by Stanton et al evaluated the impact of biofeedback on improving activities involving lower limb function after stroke.(8) A total of 22 trials with 591 participants met inclusion criteria. The largest trial had 54 participants, and 15 trials had 30 or fewer participants. Most trials (n=17) compared biofeedback plus usual therapy with usual therapy alone. The specific interventions varied; the types of biofeedback included biofeedback of ground reaction force from a force platform with visual and/or auditory feedback (13 trials), muscle activity via visual and/or auditory feedback (5 trials), joint position from an electrogoniometer via visual and/or auditory feedback (3 trials), and limb position via auditory feedback (1 trial). The duration of interventions ranged from 2 to 8 weeks, and intensity ranged between 1 to 5 days per week.

A pooled analysis of data from 17 trials on short-term effect (i.e., 1 month or less) found that biofeedback significantly improved lower limb activities compared with usual care or placebo (standardized mean difference [SMD]=0.41; 95% confidence interval [CI], 0.21 to 0.62). Outcomes included activities such as directional control during standing, weight distribution between the lower limbs, and gait parameters such as stride length. There was heterogeneity among studies. Trials did not report functional outcomes such as ability to perform activities of daily living (ADL). A sensitivity analysis determined that the heterogeneity was best explained by study quality. When lower quality trials were excluded, biofeedback was still found to improve lower limb activity compared with control conditions (SMD=0.49, 95% CI, 0.22 to 0.75). A subgroup analysis was also done by type of activity. There was only 1 high-quality trial on standing up (n=40). A pooled analysis of 5 high-quality trials on short-term effect found that biofeedback significantly improved standing outcomes compared with control (SMD=0.42, 95% CI, 0.05 to 0.78). A pooled analysis of 4 short-term trials on walking also found better outcomes with biofeedback compared with control (SMD=0.57, 95% CI, 0.10 to 1.03). Five high-quality trials with a total sample size of 136 contributed data to an analysis of long-term term efficacy (i.e., 1-5 months after cessation of the intervention). In this pooled analysis,
biofeedback was found to improve outcomes compared with control (SMD=0.41, 95% CI, 0.06 to 0.75).

Previously, a 2007 Cochrane review that assessed electromyographic (EMG) biofeedback for the recovery of motor function after stroke included 13 RCTs with a total of 269 patients. (9) All of the trials compared EMG biofeedback plus standard physiotherapy with standard physiotherapy; in addition to standard physiotherapy, several studies also included a sham biofeedback group. The studies tended to be small and poorly designed. The authors did not find support for EMG biofeedback to improve motor power, functional recovery, or gait quality when compared with physiotherapy alone.

A systematic review by Zijlstra et al, published in 2010, focused on studies evaluating biofeedback-based training to improve mobility and balance in adults older than 60 years of age. (10) Although the review was not limited to studies on motor function after stroke, more than half of the studies included older adults poststroke. For inclusion in this review, studies needed to include a control group of patients who did not receive biofeedback and to assess at least 1 objective outcome measure. A total of 97 potentially relevant articles were identified, and 21 (22%) studies, including 17 RCTs, met the selection criteria. Twelve of the 21 (57%) studies included individuals poststroke, 3 included older adults who had lower limb surgery, and 6 included frail older adults without a specific medical condition. Individual studies were small; sample sizes ranged from 5 to 30 patients. The added benefit of using biofeedback could be evaluated in 13 of 21 (62%) studies. Nine of the 13 studies found a significantly greater benefit with interventions that used biofeedback compared with control interventions. However, the outcomes assessed were generally not clinical outcomes but were laboratory-based measures related to executing a task (e.g., moving from sitting to standing in a laboratory setting and platform-based measures of postural sway). Only 3 studies reported long-term outcomes, and none of these reported a significant effect of biofeedback.

Section Summary

The evidence base on biofeedback for improving motor function after stroke is limited by small studies that are mostly not of high-quality, and there is variability in the type, duration, and intensity of interventions. In addition, the outcome measures used were primarily assessments of motor activity that were based in a laboratory or research setting. The applicability of improvements in these types of measures to clinical outcomes, such as the ability to perform ADLs or the rate of falls, is unknown. In addition, few studies have reported long-term outcomes. Conclusions about the efficacy of biofeedback for improving mobility and balance in older adults cannot be drawn from the evidence published to date for the reasons previously discussed.

Motor Function After Injury or Lower-Limb Surgery

A 2010 systematic review by Silkman and McKeon evaluated the effectiveness of EMG biofeedback for improving muscle function during knee rehabilitation after injury. (11) Four RCTs that compared knee rehabilitation exercise programs with and without biofeedback were identified. Sample sizes in individual studies ranged from 26 to 60 patients. Two of the 4 studies found a statistically significantly greater benefit in the programs that included biofeedback, and the other 2 did not find a significant difference between groups. The positive studies assessed intermediate outcomes (e.g., contraction values of the quadriceps muscles). None of the studies were designed to assess functional outcomes.
Section Summary

There is insufficient evidence that biofeedback improves motor function after injury or lower limb surgery. There are a few small RCTs that had inconsistent findings of benefit.

Orthostatic Hypotension in Patients with a Spinal Cord Injury

Gillis et al conducted a systematic review to identify and describe the body of literature pertaining to nonpharmacologic management of orthostatic hypotension during the early rehabilitation of persons with a spinal cord injury.(12) Participants with any level or degree of completeness of spinal cord injury and any time elapsed since their injuries were included. Interventions must have measured at least systolic blood pressure and have induced orthostatic stress in a controlled manner and have attempted to control orthostatic hypotension during an orthostatic challenge. Four distinct nonpharmacologic interventions for orthostatic hypotension were identified: application of compression and pressure to the abdominal region and/or legs, upper body exercise, functional electrical stimulation applied to the legs, and biofeedback. Methodologic quality varied dramatically between studies. The authors concluded that “...The clinical usefulness of compression/pressure, upper body exercise and biofeedback for treating OH [orthostatic hypotension] has not been proven.”

Section Summary

There is insufficient evidence from high-quality controlled studies that biofeedback improves orthostatic hypotension in patients with a spinal cord injury.

Pain Management During Labor

In 2011 a Cochrane review was published that evaluated RCTs on biofeedback for managing pain during labor.(13) The review identified 4 RCTs published between 1982 and 2000 with a total of 186 women. The studies were highly variable in terms of intervention modalities and outcomes measured, and thus findings were not pooled. In addition, the Cochrane review authors judged the trials to be at high risk of bias (e.g., unclear description of blinding and randomization methods). Overall, the authors found little difference in reported outcomes (e.g., rates of Cesarean section, pharmacologic pain relief in women receiving biofeedback compared with control interventions). Due to the small number of studies and small overall sample size, the evidence is insufficient to draw conclusions about the effectiveness of biofeedback in labor pain control.

Section Summary

There is insufficient evidence from a small number of RCTs with methodologic limitations, a small overall number of patients and variability in biofeedback protocols that biofeedback is effective for managing pain during labor.

Prevention of Preterm Birth

One small RCT was identified. In 2014, Siepmann et al published data on 48 women who had experienced threatened preterm labor between the 24th and 32nd gestational week.(14) Twenty-four patients received 6 biofeedback sessions over 2 weeks, and the other 24 patients were in a usual care group. Preterm delivery occurred in 3 patients (13%) in the biofeedback group and 8 patients (33%) in the control group; the difference between groups was not statistically significant, p>0.05. Other gestational outcome data, such as the gestational duration and birthweight, also did not differ significantly between groups.
Medical Policy

Section Summary

There is insufficient evidence that biofeedback is effective in preventing preterm birth in pregnant women with a history of threatened preterm labor.

Raynaud Disease

A 2009 systematic review on complementary and alternative medicine in the treatment of Raynaud disease included an examination of the literature on biofeedback.(15) The authors identified 5 trials, and these reported a variety of outcomes. A pooled analysis of findings from 4 trials (total n=110) on the change in frequency of attacks favored the sham control group over the biofeedback group (weighted mean difference = -1.21; 95% CI, -1.68 to -0.73; p<0.000). Several trials had more than 2 arms; in the preceding analysis, only the arms comparing active and sham biofeedback were included.

The trial that was given the highest quality rating by the authors of the systematic review and had the largest sample size was the Raynaud's Treatment Study, published in 2000.(16) This was a randomized comparison of sustained-release nifedipine and thermal biofeedback in 313 patients with primary Raynaud disease. In addition to these 2 treatment groups, there were 2 control treatments: pill placebo and EMG biofeedback. EMG biofeedback was chosen as a control because it did not address the physiologic mechanism of Raynaud disease. The mean attack rate at 1 year, the primary study outcome, was 0.16 in the thermal biofeedback group, 0.23 in the EMG biofeedback group, 0.07 in the nifedipine group, and 0.21 in the placebo group. Nifedipine significantly reduced Raynaud attacks compared with placebo (p<0.002), but thermal feedback did not differ significantly from EMG biofeedback (0.37). There was not a significant difference in attack rates in the nifedipine and thermal biofeedback groups for the primary outcome (p=0.08). However, several secondary outcomes including all attacks and verified attacks at 2 months significantly favored nifedipine over thermal biofeedback.

Section Summary

There is insufficient evidence from a small number of RCTs that biofeedback is effective as a treatment of Raynaud disease. A meta-analysis of the available trials did not find that biofeedback was more effective than the control intervention.

Sleep Bruxism

In 2013, Wang et al published a systematic review of randomized and non-RCTs on biofeedback treatment for sleep bruxism.(17) The full text of 17 articles was reviewed and 7 studies with a total of 240 participants met the inclusion criteria. Studies were generally small; only 2 included more than 50 participants. Four studies used audio biofeedback, 2 used contingent electrical stimulation and 1 used visual biofeedback. Treatment duration ranged from 1 night to 6 weeks. In 4 of the studies, the duration of treatment was 2 weeks. Three of the studies were considered to be at moderate risk of bias and the other 4 were considered to be at high risk of bias. The primary outcome of the analysis was the number of sleep bruxism episodes per hour detected by EMG recording. Only 2 studies (total n=27) reported this outcome and had data suitable for meta-analysis. A pooled analysis did not find a statistically significant difference between the biofeedback and control groups; mean difference: -4.47 (95% CI, -12.33 to 3.38). Findings were not pooled for any other outcomes.

One of the larger RCTs (n=57) examined changes in sleep bruxism following treatment with a cognitive behavioral therapy program consisting of problem solving, progressive muscle relaxation, nocturnal biofeedback, and training of recreation and enjoyment.(18)
Similar improvements were observed for the occlusal splint group as for the multicomponent cognitive behavioral program. The effects of biofeedback were not isolated in this study, and thus conclusions cannot be drawn about its effectiveness compared with occlusal splinting.

**Section Summary**

The available RCTs represent insufficient evidence to draw conclusions on the impact of biofeedback on sleep bruxism because of the small number of patients studied, the relatively low-quality of the studies, the variability among interventions and the lack of a consistent finding of benefit.

**Tinnitus**

An RCT by Weise et al investigated the efficacy of a biofeedback-based cognitive-behavioral treatment for tinnitus in Germany.\(^{(19)}\) Tinnitus patients (n=130) were randomly assigned to an intervention or a waiting-list control group. Treatment consisted of 12 sessions of a biofeedback-based behavioral intervention over a 3-month period. The primary outcome measures were global tinnitus annoyance and a daily rating of tinnitus disturbance measured by a Tinnitus Questionnaire (TQ) and a daily diary using visual analog scale (VAS) scores. Patients in the waiting-list group participated in the treatment after the intervention group had completed the treatment. Results showed improvements regarding the following: tinnitus annoyance; diary ratings of loudness; feelings of controllability; changes in coping cognitions; changes in depressive symptoms; TQ: total score (range 0–84) preassessment mean 54.7, postassessment mean 32.52; TQ: emotional distress (range 0–24) preassessment mean 16.00, postassessment mean 8.15; and diary: loudness VAS (range 0–10) preassessment mean 5.68, postassessment mean 4.38. Improvements were maintained over a 6-month follow-up period in which variable effect sizes were observed.

**Section Summary**

There is insufficient evidence from 1 RCT that biofeedback is effective for treating tinnitus. The trial did not investigate the possible additive effect of biofeedback with cognitive-behavioral therapy and did not include an active treatment control group. In conclusion, these data are insufficient to draw clinical conclusions regarding the role of biofeedback for the treatment of tinnitus.

**Ongoing and Unpublished Clinical Trials**

No relevant trials were identified.

**Summary of Evidence**

There are a large number of RCTs evaluating biofeedback for certain miscellaneous conditions such as hypertension and motor function after stroke, a smaller number of RCTs on conditions such as Raynaud disease, tinnitus, and sleep bruxism, and no published RCTs on other conditions such as autism. Even in cases where there is a substantial body of published literature, 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 uncertain. Thus, biofeedback is considered investigational for the miscellaneous conditions listed in the policy statement.
Practice Guidelines and Position Statements

In 2008, an American Academy of Sleep Medicine special committee released a guideline on evaluation and management of chronic insomnia in adults. The guideline lists biofeedback as one of several behavioral or psychological therapies for chronic insomnia.

The 2010 Scottish Intercollegiate Guidelines Network guideline on management of patients with stroke states, “EMG biofeedback is not recommended as a routine treatment for gait, balance or mobility problems after stroke.”

U.S. Preventive Services Task Force Recommendations

No U.S. Preventive Services Task Force recommendations for the use of biofeedback have been identified.

Medicare National Coverage

National Coverage Determination for Biofeedback Therapy (30.1) stated “Biofeedback therapy is covered under Medicare only when it is reasonable and necessary for the individual patient for muscle re-education of specific muscle groups or for treating pathological muscle abnormalities of spasticity, incapacitating muscle spasm, or weakness, and more conventional treatments (heat, cold, massage, exercise, support) have not been successful. This therapy is not covered for treatment of ordinary muscle tension states or for psychosomatic conditions.”

References


**Documentation Required for Clinical Review**

- No records required

**Coding**

This Policy relates only to the services or supplies described herein. Benefits may vary according to benefit design; therefore, contract language should be reviewed before applying the terms of the Policy. Inclusion or exclusion of a procedure, diagnosis or
device code(s) does not constitute or imply member coverage or provider reimbursement.

IE

The following services are considered investigational and therefore not covered for any indication.

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<th>Code</th>
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<td>CPT®</td>
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<td>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); 30 minutes</td>
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**Policy History**

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

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<td>New policy Combined with the previously existing BSC Medical Policy: Neurofeedback</td>
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<tr>
<td>4/5/2013</td>
<td>Policy revision with position change</td>
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<tr>
<td>9/30/2014</td>
<td>Policy title change from Biofeedback Policy revision with position change</td>
<td>Medical Policy Committee</td>
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Definitions of Decision Determinations

**Medically Necessary:** A treatment, procedure or drug is medically necessary only when it has been established as safe and effective for the particular symptoms or diagnosis, is not investigational or experimental, is not being provided primarily for the convenience of the patient or the provider, and is provided at the most appropriate level to treat the condition.

**Investigational/Experimental:** A treatment, procedure or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

**Split Evaluation:** Blue Shield of California / Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a Split Evaluation, where a treatment, procedure or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

Prior Authorization Requirements

This service (or procedure) is considered medically necessary in certain instances and investigational in others (refer to policy for details).

For instances when the indication is medically necessary, clinical evidence is required to determine medical necessity.

For instances when the indication is investigational, you may submit additional information to the Prior Authorization Department.

Within five days before the actual date of service, the Provider MUST confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should also be directed to the Prior Authorization Department. Please call 1-800-541-6652 or visit the Provider Portal www.blueshieldca.com/provider.

The materials provided to you are guidelines used by this plan to authorize, modify, or deny care for persons with similar illness or conditions. Specific care and treatment may vary depending on individual need and the benefits covered under your contract. These Policies are subject to change as new information becomes available.