Biofeedback is a technique to teach patients self-regulation of physiological processes not generally considered to be under voluntary control; a variety of approaches and devices are available. Among other possible indications, biofeedback is proposed as a treatment of fecal incontinence and constipation.

**Related Policies**
- Sacral Nerve Neuromodulation/Stimulation
- Transanal Radiofrequency Treatment of Fecal Incontinence
- Urinary Incontinence Outpatient Treatment

**Policy**
Biofeedback for constipation in adults may be considered **medically necessary** for patients with dyssynergia-type constipation as demonstrated by meeting all of the following criteria:
- Symptoms of functional constipation that meet ROME III criteria (See Policy Guidelines section)
- Objective physiologic evidence of pelvic floor dyssynergia (See Policy Guidelines) demonstrated by inappropriate contraction of the pelvic floor muscles or less than 20% relaxation of basal resting sphincter pressure by manometry, imaging, or EMG
- Failed a 3-month trial of standard treatments for constipation including laxatives, dietary changes, and exercises (as many of the previous as are tolerated)

Biofeedback is considered **investigational** as a treatment of either of the following conditions:
- Constipation in adults and children in all other situations not mentioned above
- Fecal incontinence in adults and children

**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.

**Rome III Diagnostic Criteria**


**Rome III Diagnostic Criteria for Functional Constipation**

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

**All** of the following (1, 2, and 3):

1. Must include 2 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 3 defecations per week

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

3. Insufficient criteria for irritable bowel syndrome

**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.

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**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.
Biofeedback, a technique intended to teach patients self-regulation of certain physiologic processes not normally considered to be under voluntary control, is used to treat a variety of conditions and is proposed as a treatment of fecal incontinence and constipation.

Fecal incontinence in adults is the recurrent uncontrolled passage of fecal material. Pathophysiology of the disorder ranges from abnormalities in intestinal motility (diarrhea or constipation) to poor rectal compliance, impaired rectal sensation, or weak or damaged pelvic floor muscles. There is no increase in mortality attributable to fecal incontinence. Morbidity includes skin breakdown and urinary tract infections. Fecal incontinence can affect quality of life through restricting work, recreation, and activities related to “getting out of the house,” impaired social role function, diminished sexual activity, and increase of social isolation due to embarrassment. Fecal incontinence can bring about loss of independence and mobility. It is the second most common reason for elderly institutionalization. The most common causes of fecal incontinence in adults are obstetric trauma coupled with age-related degeneration, previous anorectal surgery, rectal prolapse, and perineal trauma. In many individuals, the condition is multifactorial, involving a combination of structural, physiological, and psychosocial factors. Conventional interventions to treat fecal incontinence include dietary recommendations (e.g., fiber), bowel and toilet scheduling, and medications (e.g., bulking or antidiarrheal agents).

Constipation refers to infrequent bowel movements and difficulty expelling stool during defecation. Primary constipation is generally categorized into 3 groups. The most common type is normal-transit constipation in which there is a normal rate of stool movement, but patients feel constipated and may complain of abdominal pain and/or bloating. In the second type, slow-transit constipation, stool moves more slowly through the colon and individuals often experience a limited urge to defecate. The third type, dyssynergic defecation, refers to a loss of ability to coordinate contractions of the pelvic floor muscles and to relax the anal sphincter during defecation. Patients often report an inability to defecate despite the urge to do so. There are also secondary causes of constipation such as the use of certain medications, including opioids and psychoactive drugs; neurologic, endocrine, or metabolic disorders; structural abnormalities; and lifestyle factors. Conventional treatment includes dietary changes (i.e., adequate fiber and fluid intake), use of supplemental bulking substances, exercises, and medications.

In children, most cases of fecal incontinence and constipation are functional, in which structural, endocrine, or metabolic diseases have been ruled out. Factors contributing to functional incontinence and constipation are fear and/or pain associated with large, hard stools. This leads to retentive posturing in approximately half the children with chronic constipation (i.e., the avoidance of defecation by purposely contracting the external anal sphincter, also termed anismus or paradoxical sphincter contraction). Custodial or conventional medical intervention includes dietary changes, bowel and toilet scheduling, softening agents, and education. Behavioral interventions aim at restoring normal bowel habits through toilet training, reward and incentive contingency management programs, desensitization of phobia and fear, or skill-building and goal-setting techniques with home practice. Counseling and psychotherapy provide support to the child and address social and psychological problems.

Biofeedback training for fecal incontinence focuses on improving the ability to voluntarily contract the external anal sphincter and puborectalis muscles in response to rectal filling.
and to decrease delay in response to a sensation of distension. For constipation, the aim of biofeedback is to teach patients how to tighten and relax their external anal sphincter in order to pass bowel movements.

Biofeedback attempts to improve rectal sensory perception, strength, coordination, or some combination of these 3 components. Sensory training involves inducing intrarectal pressure using a balloon feedback device. A manometric balloon probe is inserted into the rectum, and the balloon is filled with air to produce a sensation of rectal filling. Strength training uses either anal canal pressure (manometric) or intra-anal electromyography (EMG) feedback of pelvic floor muscles (PFM). The purpose is to strengthen the force of the PFM contraction without including rectal distention. Some training increases endurance (duration of external anal sphincter contraction), as well as peak strength. Coordination training uses pressure feedback of intra-rectal balloon distention using a water-perfused catheter or Schuster-type balloon probe and PFM contractions in a simultaneous feedback display. The purpose of coordination training is to synchronize the contraction of the external anal sphincter with relaxation of the internal anal sphincter.

Biofeedback techniques convert the physiologic measures from an intra-anal EMG sensor, anal manometric probe (measuring intra-anal pressure), or perianal surface EMG electrodes to either visual or audio display for feedback. Ultrasound has also been used to show patients’ contraction of the anal sphincter on a screen. Biofeedback training is done alone, or in combination with other behavioral therapies designed to teach relaxation. Training sessions are performed in a quiet, nonarousing environment.

**Regulatory Status**

A variety of biofeedback devices are cleared for marketing through the U.S. Food and Drug Administration's (FDA) 510(k) marketing clearance process. These devices are designated by FDA as class II with special controls and are exempt from the premarket notification requirements. FDA defines a biofeedback device as “an instrument that provides a visual or auditory signal corresponding to the status of 1 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.”

**Literature Review**

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.

The relevant clinical outcome for biofeedback as a treatment in incontinence should be an overall change in the patient’s symptoms. Reduction in episodes of fecal incontinence and increase in voluntary bowel movements are the primary clinical outcomes, and these are typically reported as the percentage of individuals cured or improved. Achieving normal defecation dynamics (e.g., anal pressure, squeeze pressure,
sensory threshold, rectal inhibitory reflex, or defecation dynamics) does not correspond with symptom relief (i.e., clinical outcomes). Anorectal physiology measurements are a poor proxy for changes in clinical symptoms. Patient symptoms are usually assessed through diary, questionnaire, or interview (completed by the patient and, in the case of children, parents).

**Fecal Incontinence**

Does the addition of biofeedback to standard care reduce fecal incontinence, compared with standard care alone?

**Adults**

Numerous randomized controlled trials (RCT) on biofeedback treatment for fecal incontinence in adults have been published. There are also several systematic reviews of RCTs. In 2009, Enck et al identified 11 RCTs evaluating the efficacy of biofeedback therapy for fecal incontinence in adult populations. Two RCTs were excluded, one because of the small sample size, and the other because it did not include an appropriate control group. The remaining 9 studies consisted of 5 comparisons of different modalities of biofeedback and 6 comparisons of electromyographic (EMG) biofeedback versus other types of therapy, mainly pelvic floor exercises (2 studies had multiple treatment groups and were included in both categories). The total number of patients included in the 9 studies was 540; sample sizes of individual studies ranged from 18 to 171. A meta-analysis of 5 studies did not find a significant difference in the efficacy of different types of biofeedback (pooled odds ratio [OR], 1.23; 95% confidence interval [CI], 0.74 to 2.20; p=0.38). Similarly, a meta-analysis of studies comparing biofeedback to other therapies did not find a significant difference in efficacy (pooled OR=1.19; 95% CI, 0.69 to 2.05). The outcome measure used in the analysis was not specified and appears to vary from study to study.

Other systematic reviews have addressed biofeedback alone and in combination with other interventions. A 2013 systematic review by Vonthein et al identified 13 RCTs on biofeedback, electrical stimulation or their combination for treatment of fecal incontinence. Ten trials included comparisons of biofeedback and an alternative treatment; some of the biofeedback interventions also involved other components such as sensory training and pelvic floor exercises. A meta-analysis of studies comparing biofeedback to a control intervention significantly favored biofeedback (relative risk, 2.12; 95% CI, 1.42 to 3.16). This study did not attempt to isolate the effect of biofeedback in multicomponent interventions that included pelvic floor exercise or other treatments. A 2012 Cochrane review identified 21 RCTs evaluating biofeedback and/or sphincter exercises for treating fecal incontinence in adults. Most studies used multifaceted interventions (e.g., biofeedback, education, and sphincter exercise). In addition, a wide variety of control interventions were used. Three trials compared biofeedback plus sphincter exercises to sphincter exercises alone and 1 trial compared biofeedback plus 1 type of exercise to biofeedback to another type of exercise. The authors did not pool study findings due to heterogeneity among trials.

**Representative RCTs**

In 2009, Heymen et al randomly assigned 168 individuals with fecal incontinence to 3 months of biweekly pelvic floor exercise training alone (n=85) or exercise training with manometric biofeedback (n=83). Twenty-two patients in the exercise-only group and 38 in the biofeedback group improved during a 4-week run-in period and did not participate further, leaving 63 in the exercise group and 45 in the biofeedback group. The primary efficacy outcome was decrease in scores on the Fecal Incontinence
Severity Instrument (FISI), a validated 4-item scale, from the end of the run-in to 3 months. The analysis included all patients who completed at least 1 treatment (a total of 15 patients dropped out). The authors reported that there was a greater reduction in FISI scores in the biofeedback group compared to the exercise-only group (p=0.01, exact scores were not reported). Complete continence (no staining) was reported by 13 of 63 (21%) in the exercise-only group and 20 of 45 (44%) in the biofeedback group; this difference was statistically significant (p=0.008). A study limitation was that only 108 of 168 randomized patients (64%) received the intervention, and therefore there may have been baseline differences in the treated groups that affected study outcomes. A stronger design is to randomize patients after, not before, a run-in period.

In 2011, Bartlett et al in Australia published an RCT with 72 participants comparing 2 exercise regimens used with biofeedback for fecal incontinence. The study did not find significant differences in outcomes with the 2 types of exercises. It is not possible to make conclusions about the efficacy of biofeedback from this study’s findings because all participants received biofeedback.

Norton et al reported in 2003 on the results of a trial that randomly assigned 171 patients with fecal incontinence to 1 of 4 groups: standard care (advice), advice plus instruction on sphincter exercises, hospital-based computer-assisted sphincter pressure biofeedback, and hospital biofeedback plus the use of a home EMG biofeedback device. Outcomes included diary reports of incontinence, quality of life, and anal manometry measurements. The authors reported that biofeedback yielded no greater benefit than standard care.

In 2003, Solomon et al reported on the results of a trial that randomly assigned 120 patients with mild to moderate fecal incontinence to 1 of 3 groups: biofeedback with anal manometry, biofeedback with transanal ultrasound, or pelvic floor exercises with feedback from digital examination alone. There were no significant differences in outcomes among the treatment groups; all reported modest improvements.

Children

A Cochrane review on behavioral and cognitive interventions for children with fecal incontinence was published in 2006 and updated in 2011. Of the 21 studies, 9 compared conventional treatment alone (i.e., laxatives, toilet training, dietary advice) to conventional treatment plus biofeedback. Eight trials included children with functional fecal incontinence, and the ninth included children with fecal incontinence due to myelomeningocele (n=12). In 4 trials, children were included who had fecal incontinence due to constipation, and in 3 other trials, children had fecal incontinence due to constipation and pelvic floor dyssynergia. When data from the 9 studies were combined, 133 of 260 (51.2%) in the conventional treatment plus biofeedback group were not cured or improved at follow-up compared to 121 of 250 (48.4%) patients in the conventional only group. In a meta-analysis (random effects), this difference was not statistically significant (pooled OR=1.08, 95% CI, 0.63 to 1.84). The analysis combined 6- and 12-month follow-up data; 12-month data were used when available. The authors concluded that findings from RCTs do not support the claim that biofeedback training provides additional benefit to conventional treatment in the management of fecal incontinence associated with constipation. They also stated that, due to a lack of sufficient trials, they were unable to evaluate the effects of biofeedback in children with organic fecal incontinence.

Constipation

Does the addition of biofeedback to standard care improve refractory constipation, compared with standard care alone?
Adults

The Enck et al systematic review, described above in the section on fecal incontinence, also reviewed the literature on biofeedback for constipation. (1) Eight RCTs conducted in adults were identified. Four of these compared 2 types of biofeedback; a meta-analysis of these 4 studies did not find a significant benefit of 1 technique over another (pooled OR=1.44; 95% CI, 0.69 to 3.09; p=0.32). The other 4 studies compared biofeedback to another treatment. Comparison treatments (1 study each) were botulinum toxin, laxatives, diazepam, and best supportive care (diet, exercise, and laxatives). Two studies also included a third arm, in which treatment was a sham or placebo intervention. Three of the 4 studies included patients with dyssynergia-type constipation and the fourth included patients with anismus. A meta-analysis of the 4 studies comparing 1 treatment with another (using the active intervention arm as the comparison in the 3-arm trials) found a significantly greater benefit of biofeedback in improving constipation symptoms (pooled OR=3.23; 95% CI, 1.88 to 5.58; p<0.001). The results of this systematic review are limited by the heterogeneity in patient populations, comparison treatments, and outcome measures. The 2 three-arm studies and newer RCTs published after the Enck review are described below.

Heymen et al included adults who met Rome II diagnostic criteria for pelvic floor dyssynergia, had 2 or more symptoms of functional constipation for at least 12 weeks in the past year, and had manometry or electromyography findings consistent with chronic constipation (e.g., evidence of inadequate propulsive forces and incomplete evacuation). (10) Patients participated in a 4-week run-in period consisting of education on diet and exercise and provision of fiber and stool softeners. Those who still met eligibility criteria at the end of the run-in period (84 of 117, 72%) were randomly assigned to EMG biofeedback (n=30), diazepam 5 mg (n=30), or placebo medication (n=24). All participants were trained to perform pelvic floor exercises, and all received 6 biweekly visits over 3 months, each lasting approximately 50 minutes. Patients and investigators were blinded to which patients received active versus placebo medication but not to whether or not they received biofeedback. In an intention-to-treat (ITT) analysis after the 3-month intervention, the proportion of patients reporting adequate relief of constipation symptoms was 70% in the biofeedback group, 23% in the diazepam group, and 38% in the placebo group; biofeedback had a significantly greater benefit when compared either with diazepam (p<0.001) or placebo (p<0.017). A strength of this study was that it attempted to control for nonspecific effects of biofeedback (e.g., increased contact with a health care provider and lifestyle modification advice), by including a run-in period and similar follow-up visits for all groups. Moreover, randomization did not occur until after the run-in period, so treatment groups were more likely to be similar at the start of the treatment phase.

Rao et al included patients who met Rome II diagnostic criteria for functional constipation, had dyssynergia-type constipation and, when expelling a simulated stool, had either prolonged difficulty (at least 1 minute) or prolonged delay (at least 20% marker retention in colonic transfer). (11) All participants had failed routine management of constipation. A total of 77 patients were randomly assigned to receive 3 months of standard therapy, i.e., education, dietary advice (n=24), standard therapy and biofeedback therapy (n=28), or standard therapy and sham feedback (n=24). Patients receiving active biofeedback received up to 6 biweekly 1-hour sessions: training was performed using a rectal manometry probe and software for displaying the biofeedback data. In the sham treatment group, patients also used a rectal manometry probe but did not receive visual and verbal feedback. Patients were not blinded to treatment group, but the manometry reader was unaware of treatment assignment. In an ITT analysis, after
the 3-month intervention, patients in the biofeedback group reported a significantly
greater increase in complete spontaneous bowel movements than the sham feedback
group (p<0.05) and the standard treatment group (p<0.062). In addition, a greater
proportion of the patients in the biofeedback group reported improved global bowel
satisfaction compared to the sham feedback group (p=0.04), but the comparison with
the standard treatment group was not significantly different. (The authors did not report
exact numbers for either of these preceding primary analyses). Of the primary
physiologic parameters, the ITT analysis found that the dyssynergia pattern was
corrected in 79% of those in the biofeedback group, 4% in the sham group, and 8% in the
standard treatment group. This difference was statistically significant in favor of the
biofeedback group compared to each of the other groups (p<0.001 for both analyses).
Moreover, the balloon expulsion time during simulated defecation decreased
significantly more in the biofeedback group compared with sham (p=0.003) or standard
treatment (p=0.03) (exact times not reported for the ITT analysis).

A 2010 publication reported on 1-year findings of the Rao study in 13 of 21 (62%) patients
in the biofeedback group and 13 of 23 (57%) in the standard treatment group.(12)
Patients in the sham group were not included in this follow-up study. The extension study
included visits at 3-month intervals, with additional advice provided as needed. Seven of
the 13 (54%) biofeedback patients and all 13 patients in the standard treatment group
completed the 1-year follow-up. Mean change in complete spontaneous bowel
movements (the primary outcome) favored the biofeedback group (increase of 2.9)
compared to the standard treatment group (decrease of 0.2). The follow-up study
suggests longer-term effectiveness of biofeedback for this patient population. However,
the small numbers of patients who completed the 1-year follow-up, along with the drop-
out rate in the biofeedback group, limit the conclusions that can be reached.

A 2012 RCT by Hart et al included 21 patients with constipation who failed to respond to
dietary and medical therapies.(13) (The study was not limited to patients with
dyssynergia-type constipation.) The experimental arm consisted of biofeedback with an
EMG rectal probe. Patients were taught to isolate the anal sphincter and receive
feedback on the muscle activity of the external anal sphincter. In the control
intervention, investigators attempted to control for the nonspecific effects of
biofeedback by using biofeedback but no rectal probe. The comparison intervention
involved biofeedback with bilateral EMGs in conjunction with surface electrodes placed
on the trapezius or temporalis muscle and muscle tension reduction instruction. Both
groups were given 6 treatment sessions (every other week for 12 weeks). A total of 15 of
21 patients (71%) completed the study and were included in the follow-up evaluation.
The 2 primary outcome measures were the Constipation Severity Instrument (CSI) and the
Irritable Bowel Syndrome Quality of Life Scale (IBS-QOL); both of these are multi-item self-
report instruments. For the CSI, a lower score represents less severe symptoms and for the
IBS-QOL, a higher score represents a higher quality of life. The authors did not report the
possible maximum scores for either measure. The change in scores from baseline to
follow-up assessments did not differ significantly between groups for either outcome
measure. Mean scores on the CSI decreased from 46.5 to 30.0 in the anorectal
biofeedback group and 41.2 to 34.9 in the biofeedback control group. Mean scores on
IBS-QOL increased from 80.8 to 96.1 in the anorectal biofeedback group and from 90.6 to
96.7 in the biofeedback control group. The study had a small sample size and was likely
underpowered to statistically significant difference between groups.

Children

No systematic reviews or meta-analyses on biofeedback for constipation in children, not
associated with fecal incontinence, were identified. The literature search did identify the
1 RCT published since 2000. Van Ginkel et al in the Netherlands included 212 children at least 5 years old with constipation who met at least 2 of the following 4 criteria: (1) stool frequency fewer than 3 times per week; (2) 2 or more soiling and/or encopresis episodes per week; (3) periodic passage of very large amounts of stool every 7 to 30 days; or (4) a palpable abdominal or rectal fecal mass. (14) Participants were randomly assigned to 6 weeks of standard treatment, i.e., education, laxatives (n=111) or standard treatment plus 2 sessions of anorectal manometry (n=91). During the manometry sessions, the child was asked to squeeze the sphincter as tight as possible 5 times. Squeeze pressure data were converted to digital values and transmitted to a computer; the data could be viewed by the child and parent. The data were discussed after the sessions, and instructions were given on how to perform defection exercises at home. Ten of 212 (5%) randomly assigned patients did not receive treatment, and the remainder completed the intervention. Treatment success was defined as achievement of 3 or more bowel movements per week and fewer than 1 soiling and/or encopresis episodes per 2 weeks while not receiving laxatives. At 6 weeks, 4 of 111 (4%) in the standard treatment group and 6 of 91 (7%) in the biofeedback group were considered to have successful treatment; this difference was not significantly different. There was also no statistically significant difference between groups at any other follow-up point. At the final 104-week follow-up, 36 of 83 (43%) patients in the standard treatment group and 23 of 65 (35%) in the biofeedback group were considered treatment successes. Data on 30% of the randomized patients were missing at the final follow-up. This intervention did not control for the nonspecific effects of biofeedback.

**Ongoing Clinical Trials**

Comparison of PTNS and Biofeedback for Fecal Incontinence (NCT01882101): This open-label study is randomizing 50 adults with fecal incontinence to treatment with posterior tibial nerve stimulation (PTNS) or EMG biofeedback. The primary outcome is change in weekly episodes of fecal incontinence. The expected date of completion is December 2014.

**Summary**

There is a relatively large body of literature (i.e., randomized controlled trials [RCTs] and systematic reviews) evaluating the efficacy of biofeedback for treating fecal incontinence and constipation. For the treatment of fecal incontinence, systematic reviews have not found that biofeedback provides additional benefit when offered in conjunction with conventional therapy, compared with conventional therapy alone. While 1 recent RCT found that there was a significantly greater decrease in fecal incontinence symptoms with biofeedback plus exercise training than with exercise training alone, the majority of trials do not show a significant benefit. Overall, the evidence is insufficient to conclude that biofeedback improves the net health outcome for adults and children with fecal incontinence; therefore, this treatment is considered investigational.

For the treatment of constipation, a systematic review of RCTs found a benefit of biofeedback as a treatment of constipation in adults. Conclusions of the systematic review were limited by variability in patient populations, comparison groups and outcomes measures. However, detailed examination of several well-conducted RCTs focusing on patients with dyssynergia-type constipation suggests benefits in a subgroup of patients who meet criteria similar to trial participants. Thus, biofeedback may be considered medically necessary in adult patients with dyssynergia-type constipation who meet selection criteria and investigational for other patients with constipation.
Practice Guidelines and Position Statements

In 2013, the American Gastroenterological Association updated their position statement on constipation. The following statement on biofeedback was included: “Pelvic floor retraining by biofeedback therapy rather than laxatives is recommended for defecatory disorders (Strong Recommendation, High-Quality Evidence).”(16)

In May 2010, the National Institute for Clinical Excellence issued a guideline on constipation in children and young people. The guideline states that biofeedback should not be used for ongoing treatment.(17) In June 2007, they issued a guideline on fecal incontinence in adults which states the following regarding biofeedback: “The evidence we found did not show biofeedback to be more effective than standard care, exercises alone, or other conservative therapies. The limited number of studies and the small number of participants in each group of the studies make it difficult to come to any definitive conclusion about its effectiveness.”(18)

In 2008, the National Institutes of Health issued a state-of-the-science statement on fecal and urinary incontinence based on a consensus conference held in December 2007.(19) Included in the conclusions was the following statement, “pelvic floor muscle training and biofeedback are effective in preventing and reversing fecal and urinary incontinence in women for the first year after giving birth...”

In December 2007, an Evidence Report/Technology Assessment, Prevention of Urinary and Fecal Incontinence in Adults,(20) based on research conducted by the Minnesota Evidence-based Practice Center under contract to the Agency for Healthcare Research and Quality, was issued. One of the research objectives was to review the effectiveness of clinical interventions to reduce the risk of incontinence. The authors identified 1 RCT that found twice the rate of control of fecal incontinence in women who had obstetric and sphincter trauma after biofeedback training with pelvic floor muscle training compared to muscle training alone. The review concluded that limited evidence supports a reduction in fecal incontinence after complex behavioral interventions, which include exercises augmented with biofeedback.

In October 2007, the American Society of Colon and Rectal Surgeons released Practice Parameters for the Treatment of Fecal Incontinence.(21) The report stated that biofeedback can be considered as a treatment option for patients who have not responded to dietary modification or medication (Level of Evidence: III; Grade of Recommendation: B). It also states that biofeedback may be considered in the early post-partum period for women with symptomatic sphincter weakness. Also, in 2007, they published Practice Parameters for the Evaluation and Management of Constipation.(22) They recommend biofeedback therapy for patients with symptomatic pelvic floor dyssynergia (Level of Evidence: Class II; Grade of Recommendation: B).

Medicare National Coverage

National Coverage Determination (NCD) for Biofeedback (30.1)

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.(23)
References


**Documentation Required for Clinical Review**

- History and physical and/or consultation report including:
  - Specific diagnosis requiring biofeedback
  - Symptoms meeting the ROME III criteria
  - Past treatment and responses including treatment duration

- Objective testing results (e.g., manometry, imaging, EMG)

**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.

**MN/IE**

The following service/procedure may be considered medically necessary in certain instances and investigational in others. Services may be medically necessary when policy criteria are met. Services are considered investigational when the policy criteria are not met or when the code describes application of a product in the position statement that is investigational.

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# Medical Policy

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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 investigative 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.