Biofeedback as a Treatment of Fecal Incontinence or Constipation

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Policy
Blue Cross and Blue Shield of Kansas City (Blue KC) will not provide coverage for biofeedback as a treatment of fecal incontinence or constipation. This is considered investigational.

Biofeedback and biofeedback devices are specifically excluded under many benefit plans. In addition, biofeedback and biofeedback devices are considered behavioral training and education/training in nature, and such services are specifically excluded under many benefit plans.

When Policy Topic is covered
Biofeedback for constipation in adults may be considered medically necessary for patients with dyssynergia-type constipation as demonstrated by meeting all 3 of the following criteria:

1. Symptoms of functional constipation that meet ROME IV criteria (see Considerations).
2. Objective physiologic evidence of pelvic floor dyssynergia (see Considerations) demonstrated by inappropriate contraction of the pelvic floor muscles or less than 20% relaxation of basal resting sphincter pressure by manometry, imaging or EMG;
3. 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 Policy Topic is not covered
Biofeedback is considered investigational as a treatment of constipation in adults and children in all other situations.

Biofeedback is considered investigational as a treatment of fecal incontinence in adults and children.
**Considerations**


C2. 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

   a Criteria fulfilled for the last 3 months with symptom onset at least 6 months prior to diagnosis.
   b For research studies, patients meeting criteria for OIC should not be given a diagnosis of FC because it is difficult to distinguish between opioid side effects and other causes of constipation. However, clinicians recognize that these 2 conditions might overlap.


F3b. Diagnostic Criteria 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”

These criteria are defined by age- and sex-appropriate normal values for the technique.

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.

**Description of Procedure or Service**

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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 possible indications, biofeedback is proposed as a treatment of fecal incontinence and constipation.

For individuals who have fecal incontinence who receive biofeedback, the evidence includes randomized controlled trials (RCTs) and systematic reviews. Relevant outcomes are symptoms, functional outcomes, and quality of life. Whereas an 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 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.

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.
Background
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 may affect quality of life by 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 (eg, fiber), bowel and toilet scheduling, and medications (eg, 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 (ie, 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 (ie, the avoidance of defecation by purposefully contracting the external anal sphincter, also termed anismus or paradoxical sphincter contraction). Customary 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, a technique intended to teach patients self-regulation of certain physiologic processes not normally considered to be under voluntary control, is used for various conditions and is proposed as a treatment of fecal incontinence and constipation.

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 intrarectal balloon distention with 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 have been cleared for marketing by the U.S. Food and Drug Administration through the 510(k) process. These devices are designated by the U.S. Food and Drug Administration as class II with special controls and are exempt from premarket notification requirements. The Food and Drug Administration 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.”

1.
**Rationale**

This evidence review was created in December 2003 and has been updated regularly with searches of the MEDLINE database. The most recent literature update was performed through September 4, 2018.

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function, including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

**Biofeedback**

**Clinical Context and Therapy Purpose**

Several specific 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 some studies have reported 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 might account for successful results attributed to biofeedback. These are nonspecific therapeutic factors, some of which can be considered placebo effects. Moreover, it is important that studies demonstrate 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 purpose of biofeedback in patients who have fecal incontinence or constipation is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The question addressed in this evidence review is: Does the use of biofeedback improve the net health outcome in patients with fecal incontinence or constipation?

The following PICOTS were used to select literature to inform this review.

**Patients**
The relevant populations of interest are:
- Patients with fecal incontinence;
- Patients with constipation other than dyssynergia-type constipation; and
- Patients with dyssynergia-type constipation.

**Interventions**
The therapy being considered is biofeedback. Biofeedback teaches patients self-regulation of certain physiologic processes not normally considered to be under voluntary control. Biofeedback attempts to improve rectal sensory perception, strength, coordination, or some combination of these 3 components.

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, biofeedback aims to teach patients how to tighten and relax their external anal sphincter to facilitate bowel movements.

**Comparators**
For fecal incontinence, the comparators of interest are medical management and sphincteroplasty. Medical management consists of bulking agents and anti-diarrheal agents. If anti-diarrheal agents are ineffective, bile acid binders may be recommended. Sphincteroplasty, which is recommended when conservative therapies have failed, involves the surgical reconstruction of a sphincter muscle. For constipation, the comparator of interest is medical management, which may consist of fiber supplementation, laxatives, or osmotic agents.

**Outcomes**
The relevant clinical outcome for biofeedback as a treatment for incontinence should be an overall change in patient 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 (eg, anal pressure, squeeze pressure, sensory threshold, rectal inhibitory reflex, defecation dynamics) does not correspond with symptom relief (ie, clinical outcomes). Anorectal physiology measurements are a poor proxy for changes in clinical symptoms. Patient
symptoms are usually assessed through a diary, questionnaire, or interview (completed by the patient and, in the case of children, parents).

**Timing**

Biofeedback training may take several weeks. Follow-up of patients occurs after training and should continue for several months.

**Setting**

Biofeedback training typically takes place in an outpatient clinic. Some techniques require returning to the clinic while others can be practiced in the patient’s home.

**Fecal Incontinence**

**Adults**

**Systematic Reviews**

Numerous RCTs and several systematic reviews of RCTs on biofeedback treatment for fecal incontinence in adults have been published. A systematic review by Vonthein et al (2013) identified 13 RCTs on biofeedback, electrical stimulation, or their combination for treatment of fecal incontinence. Ten trials compared biofeedback with an alternative treatment; some of the biofeedback interventions involved other components such as sensory training and pelvic floor exercises. A meta-analysis of studies comparing biofeedback with a control intervention significantly favored biofeedback (relative risk, 2.12; 95% confidence interval [CI], 1.42 to 3.16). Reviewers did not isolate the effect of biofeedback in multicomponent interventions that included pelvic floor exercise or other treatments.

A Cochrane review by Norton et al (2012) identified 21 RCTs evaluating biofeedback and/or sphincter exercises for treating fecal incontinence in adults. Most studies used multifaceted interventions (eg, biofeedback, education, sphincter exercise). Additionally, a wide variety of control interventions were used. Three trials compared biofeedback plus sphincter exercises with sphincter exercises alone, and a single trial compared biofeedback plus 1 type of exercise with biofeedback plus another type of exercise. Reviewers did not pool study findings due to heterogeneity among trials.

Enck et al (2009) identified 11 RCTs evaluating the efficacy of biofeedback therapy for fecal incontinence in adults. 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 comprised 5 comparisons of different biofeedback modalities and 6 comparisons of electromyographic (EMG) biofeedback vs other types of therapy, mainly pelvic floor exercises. (Two studies had multiple treatment groups and were included in both categories.) The total number of patients included in the 9 studies was 540 (sample size ranges, 18-171 patients). A meta-analysis of 5 studies did not find a significant difference in the efficacy of different types of biofeedback (odds ratio [OR], 1.23; 95% CI, 0.74 to 2.20; p=0.38). Similarly, a meta-analysis of studies comparing biofeedback with other
therapies did not find a significant difference in efficacy (OR=1.19; 95% CI, 0.69 to 2.05). Outcome measures used were not always specified and appeared to vary from study to study.

**Randomized Controlled Trials**

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

Heymen et al (2009) randomized 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 a decrease in scores on the Fecal Incontinence Severity Instrument, 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 (15 patients dropped out). Reviewers reported a greater reduction in Fecal Incontinence Severity Instrument scores in the biofeedback group than in the exercise-only group (p=0.01; exact scores were not reported). Complete continence (no staining) was reported by 13 (21%) of 63 patients in the exercise-only group and 20 (44%) of 45 in the biofeedback group (p=0.008). A trial limitation was that only 108 (64%) of 168 randomized patients received the intervention and, therefore, baseline imbalances in the treatment groups might have affected outcomes. A stronger design would have been to randomize patients after, not before, a run-in period.

Norton et al (2003) randomized 171 patients with fecal incontinence to one of 4 treatment 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.

Solomon et al (2003) randomized 120 patients with mild-to-moderate fecal incontinence to one of 3 treatment 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**

An updated Cochrane review by Brazzelli et al (2011) assessed behavioral and cognitive interventions for children with fecal incontinence. Of 21 included studies, 9 compared conventional treatment alone (ie, laxatives, toilet training, dietary advice) with 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). Four trials included children who had fecal incontinence due to constipation, and three others included children who had fecal incontinence due to constipation and pelvic floor dyssynergia. When data from the 9 studies were combined, 133 (51%) of 260 children in the conventional treatment plus biofeedback group were not cured or improved at follow-up compared with 121 (48%) of 250 children in the conventional treatment-only group. In a meta-analysis, this difference was not statistically significant (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. Reviewers concluded that findings from RCTs did 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 could not evaluate the effects of biofeedback in children with organic fecal incontinence.

Section Summary: Fecal Incontinence
The available evidence on biofeedback for fecal incontinence in adults and children includes RCTs and systematic reviews of those RCTs. Pooling results of the studies was limited by the heterogeneity of the interventions, comparators, and follow-up durations used. The studies generally failed to report significant differences between biofeedback and comparison groups in outcome improvements.

Constipation

Idiopathic Constipation, Not Specifically Dyssynergic Type

Adults
Several systematic reviews of RCTs have been published on idiopathic constipation. More recently, a Cochrane review by Woodward et al (2014) identified 17 trials (total N=931 patients) addressing the efficacy of biofeedback for treating adults with idiopathic constipation. Seven trials compared biofeedback with conventional nonsurgical treatment, six compared alternative approaches with biofeedback, two compared biofeedback with surgical intervention, one compared biofeedback with electrical stimulation, and one used a sham control. Sample sizes ranged from 21 to 109 patients (mean, 48 patients per trial). Sixteen RCTs were judged to be at high risk of bias due to lack of blinding of patients and outcome assessment. Blinding in the remaining study was unclear. Trials all used different biofeedback protocols and 11 used EMG biofeedback. Length of follow-up varied; 4 trials followed patients to the end of the intervention and 7 trials followed patients for 1 year. In most trials, a symptom scoring system was used as an outcome, with scores varying by symptoms included. Due to heterogeneity among trials, meta-analyses were not conducted. Reviewers concluded that there was insufficient evidence to determine the efficacy of any particular biofeedback protocol used to treat chronic constipation in adults.

The Enck review (2009), discussed in the Fecal Incontinence section, also reviewed the literature on biofeedback for constipation and conducted several
meta-analyses. Eight RCTs conducted in adults were identified. Four compared 2 types of biofeedback; meta-analysis of these 4 studies did not find a significant benefit for 1 technique over another (OR=1.44; 95% CI, 0.69 to 3.09; p=0.32). The other 4 studies compared biofeedback with another treatment (1 study each): botulinum toxin, laxatives, diazepam, and best supportive care (diet, exercise, 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. Meta-analysis of the 4 studies comparing 1 treatment with another (using the active intervention arm as the comparator in the 3-arm trials) found a significantly greater benefit of biofeedback in improving constipation symptoms (OR=3.23; 95% CI, 1.88 to 5.58; p<0.001). Results of this systematic review were limited by heterogeneity in patient populations, comparator treatments, and outcome measures.

**Children**

No systematic reviews or meta-analyses on biofeedback for constipation in children, not associated with fecal incontinence, were identified. The literature search identified a single RCT published since 2000. Van Ginkel et al (2001) selected 212 Dutch 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. Participants were randomized to 6 weeks of standard treatment (ie, education, laxatives [n=111]) or standard treatment plus 2 sessions of anorectal manometry (n=91). During the manometry sessions, children were asked to squeeze the sphincter as tightly as possible 5 times. Squeeze pressure data were digitally converted; data could be viewed on a computer by the child and parent. Data were discussed after the sessions, and instructions were given on how to perform defecation exercises at home. Ten (5%) of 212 randomized patients did not receive treatment; the remainder completed the intervention. Treatment success was defined as achieving 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 (4%) of 111 in the standard treatment group and 6 (7%) of 91 in the biofeedback group were considered to have successful treatment; this difference was not statistically significant. There was also no statistically significant difference between groups at any other follow-up point. At the final follow-up, 36 (43%) of 83 patients in the standard treatment group and 23 (35%) of 65 in the biofeedback group were considered treatment successes. Data on 30% of randomized patients were missing at the final follow-up. This trial did not control for nonspecific effects of biofeedback.

**Section Summary: Idiopathic Constipation, Not Specifically Dyssynergic Type**

For adults with idiopathic constipation, the evidence for biofeedback consists of multiple randomized trials, which have been summarized in several systematic reviews. Overall, the evidence is limited by the heterogeneity of patient populations, comparator groups, biofeedback interventions, and outcome measures.
measures, and does not show a significant benefit with biofeedback. For children, the evidence is more limited, with a single RCT published since 2000; it did not find any statistically significant differences for biofeedback regarding most treatment outcomes.

**Dyssynergic-Type Constipation**

Heymen et al (2007) assessed adults who met Rome II diagnostic criteria for pelvic floor dyssynergia, had at least 2 symptoms of functional constipation for at least 12 weeks in the past year, and had manometry or EMG findings consistent with chronic constipation (eg, evidence of inadequate propulsive forces and incomplete evacuation). Patients participated in a 4-week run-in period comprising 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 (84/117 [72%]) were randomized 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 received 6 biweekly visits over 3 months, each lasting approximately 50 minutes. Patients and investigators were blinded to which patients received active vs placebo medication but not to whether 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 with diazepam (p<0.001) or placebo (p<0.017). A strength of this study design was its attempt to control for nonspecific effects of biofeedback (eg, increased contact with a health care provider, 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 (2007) included patients who met Rome 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). All participants had failed routine management of constipation. Seventy-seven patients were randomized for 3 months to one of 3 therapies: education and 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 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 the treatment group, but the manometry reader was unaware of treatment assignment. In 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). Additionally, a greater proportion of patients in the biofeedback group reported improved global bowel satisfaction compared with the sham feedback group (p=0.04), but the difference from the standard treatment group was not statistically significant. (The trialists did not report exact
numbers for either of these preceding primary analyses.) For primary physiologic parameters, 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 with the other groups (p<0.001 for both analyses). Moreover, balloon expulsion time during simulated defecation decreased significantly more in the biofeedback group than in the sham (p=0.003) or standard treatment (p=0.03) groups (exact times not reported for ITT analysis).

In a follow-up publication, Rao et al (2010) reported on 1-year findings for 13 (62%) of 21 patients in the biofeedback group and 13 (57%) of 23 in the standard treatment group.14 Patients in the sham group were not included in this follow-up. The extension study included visits at 3-month intervals, with additional advice provided as needed. Seven (54%) of the 13 biofeedback patients and all 13 patients in the standard treatment group completed 1-year follow-up. Mean change in complete spontaneous bowel movements (the primary outcome) favored the biofeedback group (increase, 2.9) compared with the standard treatment group (decrease, 0.2). The small numbers of patients who completed 1-year follow-up limited conclusions that can be drawn, however, the follow-up study suggested longer term effectiveness of biofeedback for this patient population.

**Section Summary: Dyssynergic-Type Constipation**
For patients with dyssynergic constipation treated with biofeedback, several RCTs have reported improvements in constipation symptoms.

**Summary of Evidence**
For individuals who have fecal incontinence who receive biofeedback, the evidence includes RCTs and systematic reviews. The relevant outcomes are symptoms, functional outcomes, and quality of life. One RCT reported a significantly greater decrease in fecal incontinence symptoms with biofeedback plus exercise training compared with exercise training alone, however, most trials have not shown a significant benefit. Systematic reviews have not found that biofeedback plus conventional therapy provides additional benefit compared with conventional therapy alone. The evidence is insufficient to determine the effects of the technology on health outcomes.

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 (which combined both dyssynergia-type and non-dyssynergia-type), comparator groups, and outcome measures, and biofeedback was not clearly beneficial for non-dyssynergia types of constipation. 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.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

American Neurogastroenterology and Motility Society et al
The American Neurogastroenterology and Motility Society and the European Society of Neurogastroenterology and Mobility (2015) jointly published consensus guidelines on biofeedback therapy for anorectal disorders. The guidelines included the following recommendations:

- “Biofeedback is recommended for the short-term and long-term treatment of constipation with dyssynergic defecation.”
- “Biofeedback therapy is recommended for the short-term and long-term treatment of fecal incontinence.”
- “Biofeedback therapy is not recommended for the routine treatment of children with functional constipation, with or without overflow fecal incontinence.”

American Society of Colon and Rectal Surgeons
The American Society of Colon and Rectal Surgeons (2015) updated its guidelines on the treatment of fecal incontinence. The guidelines recommended that biofeedback be considered as an initial treatment for patients with fecal incontinence who have some preserved voluntary sphincter contraction ability.

The Society (2016) published guidelines on the evaluation and management of constipation. The guidelines stated that biofeedback therapy is a first-line treatment for symptomatic pelvic floor dyssynergia (strong recommendation, moderate quality of evidence).

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

The Association (2017) published an expert review on surgical interventions and device-aided therapy for the treatment of fecal incontinence and defecation disorders. The Association stated that surgical options may be considered in patients with fecal incontinence and defecation disorders, but only after conservative therapy has failed. Examples of conservative therapies include dietary modification, fiber supplements, bowel training programs, pelvic floor exercises, medications, or biofeedback.
**National Institute for Health and Care Excellence**
The National Institute for Health and Care Excellence (2017) updated its guidance on constipation in children and young people.\(^{20}\) The guidance indicated that biofeedback should not be used for ongoing treatment.

The Institute (2007) issued guidance on fecal incontinence in adults; the guidance stated the following on 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."\(^{21}\)

**American College of Gastroenterology**
The American College of Gastroenterology (2014) published guidelines on the management of fecal incontinence.\(^{22}\) The guidelines indicated that pelvic floor rehabilitation techniques (eg, biofeedback, therapeutic exercises) are effective in patients with fecal incontinence who have not responded to conservative measures (strong recommendation, moderate quality of evidence).

**U.S. Preventive Services Task Force Recommendations**
The U.S. Preventive Services Task Force has not addressed biofeedback for fecal incontinence or constipation.

**Medicare National Coverage**
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 pathologic muscle abnormalities of spasticity, incapacitating muscle spasm, or weakness, and more conventional treatments (heat, cold, massage, exercise, support) have not been successful.\(^{23}\) This therapy is not covered for the treatment of ordinary muscle tension states or psychosomatic conditions.

**Ongoing and Unpublished Clinical Trials**
Some currently unpublished trials that might influence this review are listed in Table 1.

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>NCT00584571</td>
<td>Randomized Controlled Trial of Treating Rectal Hypersensitivity - Comparing Escitalipram with Sensory Adaptation Training</td>
<td>60</td>
<td>Dec 2018</td>
</tr>
<tr>
<td>NCT02888899</td>
<td>Percutaneous Tibial Nerve Stimulation in Combination with Biofeedback in Patients with Fecal Incontinence: a Randomized Controlled Trial</td>
<td>NR</td>
<td>Mar 2019</td>
</tr>
</tbody>
</table>

NR: not reported
REFERENCES


Billing Coding/Physician Documentation Information

**90875** Individual psychophysiological therapy incorporating biofeedback training by any modality (face-to-face with the patient), with psychotherapy (eg, insight oriented, behavior modifying or supportive psychotherapy); 30 minutes

**90876** Individual psychophysiological therapy incorporating biofeedback training by any modality (face-to-face with the patient), with psychotherapy (eg, insight oriented, behavior modifying or supportive psychotherapy); 45 minutes

**90901** Biofeedback training by any modality

**90911** Biofeedback training, perineal muscles, anorectal or urethral sphincter, including EMG and/or manometry

**E0746** Electromyography (EMG), biofeedback device

ICD-10 Codes

**K59.00-K59.09** Constipation code range (there is no specific code for dyssynergia-type constipation)

Additional Policy Key Words

N/A

Policy Implementation/Update Information

7/1/08 New policy; considered investigational.
7/1/09 No policy statement changes.
7/1/10 No policy statement changes.
7/1/11 Scope expanded to include constipation and title changed to reflect this change. Policy statement on constipation added which states that it is investigational.
7/1/12 No policy statement changes.
3/1/13 Statement added that biofeedback for constipation in adults may be considered medically necessary for patients with dyssynergia-type constipation who meet criteria. Investigational statement on constipation modified to indicate that it applies to all patients who do not meet criteria in medically necessary statement.
7/1/13 No policy statement changes.
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