2.01.64	Biofeedback as a Treatment of Fecal Incontinence or Constipation		
Original Policy Date:	December 15, 2014	**Effective Date:**	February 1, 2024
Section:	2.0 Medicine	**Page:**	Page 1 of 17

Policy Statement

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

II. Biofeedback is considered **investigational** as a treatment of constipation in adults and children in all other situations.

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

NOTE: Refer to Appendix A to see the policy statement changes (if any) from the previous version.

Policy Guidelines

Rome IV diagnostic criteria for functional constipation is as follows:

1. Must include 2 or more of the following[b]:
   a. Straining during more than one-fourth (25%) of defecations
   b. Lumpy or hard stools (Bristol Stool Form Scale1 to 2) for more than one-fourth (25%) of defecations
   c. Sensation of incomplete evacuation for more than one-fourth (25%) of defecations
   d. Sensation of anorectal obstruction/blockage for more than one-fourth (25%) of defecations
   e. Manual maneuvers to facilitate more than one-fourth (25%) of defecations (e.g., digital evacuation, support of the pelvic floor)
   f. Fewer than 3 spontaneous bowel movements 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 opioid-induced constipation should not be given a diagnosis of functional constipation because it is difficult to distinguish between opioid side effects and other causes of constipation. However, clinicians recognize that these 2 conditions might overlap.

Rome IV diagnostic criterion for dyssynergic defecation is "inappropriate contraction of the pelvic floor as measured with anal surface EMG [electromyography] or manometry with adequate propulsive forces during attempted defecation."[c]

[c] 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

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 for fecal incontinence and constipation.

Related Policies

- Biofeedback as a Treatment of Urinary Incontinence in Adults
- Sacral Nerve Neuromodulation/Stimulation

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]) prohibits 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.

Regulatory Status

A variety of biofeedback devices have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. These devices are designated by the FDA as class II with special controls and are exempt from premarket notification requirements. The 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 (eg, brain alpha wave activity, muscle activity, skin temperature, etc.) so that the patient can control voluntarily these physiological parameters."[1],

Rationale

Fecal Incontinence and Constipation
Adults
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 the 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 the 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 schedules, and medications (e.g., bulking or antidiarrheal agents).

Constipation refers to infrequent bowel movements and difficulty expelling stool during defecation. Primary constipation is 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, the 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.

Children

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 to restore 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

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 the 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 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 feedback of pelvic floor muscles. The purpose is to strengthen the force of the pelvic floor muscle 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 pelvic floor muscle contractions in a simultaneous feedback display. The purpose of coordination training is to synchronize the contraction of the external anal sphincter with the relaxation of the internal anal sphincter.

Biofeedback techniques convert the physiologic measures from an intra-anal electromyography sensor, anal manometric probe (measuring intra-anal pressure), or perianal surface electromyography electrodes to either a 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.

Literature Review

Evidence reviews assess the clinical evidence to determine whether the use of technology improves the net health outcome. Broadly defined, health outcomes are the length of life, quality of life (QOL), and ability to function-including benefits and harms. Every clinical condition has specific outcomes that are important to patients and 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 technology, two domains are examined: the relevance, and 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.

Promotion of greater diversity and inclusion in clinical research of historically marginalized groups (e.g., People of Color [African-American, Asian, Black, Latino and Native American]; LGBTQIA (Lesbian, Gay, Bisexual, Transgender, Queer, Intersex, Asexual); Women; and People with Disabilities [Physical and Invisible]) allows policy populations to be more reflective of and findings more applicable to our diverse members. While we also strive to use inclusive language related to these groups in our policies, use of gender-specific nouns (e.g., women, men, sisters, etc.) will continue when reflective of language used in publications describing study populations.

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.

Fecal Incontinence

Clinical Context and Therapy Purpose

The purpose of biofeedback in individuals who have fecal incontinence is to provide a treatment option that is an alternative to or an improvement on existing therapies.
The following PICO was used to select literature to inform this review.

Populations
The relevant population of interest are individuals with fecal incontinence.

Interventions
The therapy being considered is biofeedback. Biofeedback teaches individuals 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 the delay in response to a sensation of distension.

Comparators
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.

Outcomes
The relevant clinical outcome for biofeedback as a treatment for fecal incontinence should be an overall change in an individual'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, defecation dynamics) does not correspond with symptom relief (ie, clinical outcomes). Anorectal physiology measurements are a poor proxy for changes in clinical symptoms. Individual symptoms are usually assessed through a diary, questionnaire, or interview (completed by the affected individual and, in the case of children, parents).

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

Study Selection Criteria
Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies;
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought;
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence
Adults

Systematic Reviews
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 the treatment of fecal incontinence.[2,] 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.[3] Most studies used multifaceted interventions (e.g., 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.[4] Two RCTs were excluded, 1 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 versus 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 to 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=.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

An RCT published subsequent to the systematic reviews randomized 300 women with fecal incontinence to biofeedback or patient education, plus loperamide or placebo.[5] The primary outcome of the study was change from baseline in St. Mark's Fecal Incontinence severity scale score. A -5 point change in score was determined *a priori* as clinically meaningful. After 24 weeks follow-up, there was no statistical or clinical difference in fecal incontinence score between the biofeedback and education groups (mean difference, -0.7; 95% CI, -2.6 to 1.2; p=.47) or between the biofeedback plus loperamide versus biofeedback plus placebo groups (mean difference, -1.9; 95% CI, -4.1 to 0.3; p=.09). In patient-reported bowel diaries, the combination of biofeedback plus loperamide was associated with less stool leakage (p=.04) and more continent days per week (p=.03) relative to biofeedback plus placebo.

Heymen et al (2009), included in the Vonthein systematic review, 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).[6] 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). The study reported a greater reduction in Fecal Incontinence Severity Instrument scores in the biofeedback group than in the exercise-only group (p=.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=.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.

Children

Systematic Reviews

An updated Cochrane review by Brazzelli et al (2011) assessed behavioral and cognitive interventions for children with fecal incontinence.[7] 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 3 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. The pooling results of the studies were 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, Other Than Dyssynergic Type Constipation

Clinical Context and Therapy Purpose

The purpose of biofeedback in individuals who have constipation other than dyssynergia-type constipation to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest are individuals with constipation other than 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 aims to teach patients how to tighten and relax their external anal sphincter to facilitate bowel movements.

Comparators

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 constipation other than dyssynergia-type constipation is an overall change in patient symptoms. The main clinical outcome is an increase in voluntary bowel movements. Achieving normal defecation dynamics (e.g., 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).

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies;
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought;
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence

Adults

Systematic Reviews

Several systematic reviews of RCTs have been published on constipation other than dyssynergia-type constipation. A Cochrane review by Woodward et al (2014) identified 17 trials (N=931) addressing the efficacy of biofeedback for treating adults with idiopathic constipation.[8,] Seven trials compared biofeedback with conventional nonsurgical treatment, 6 compared alternative approaches with biofeedback, 2 compared biofeedback with surgical intervention, 1 compared biofeedback with electrical stimulation, and 1 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 et al (2009) review, discussed in the Fecal Incontinence section, also reviewed the literature on biofeedback for constipation and conducted several meta-analyses.[4,] Eight RCTs conducted in adults were identified. Four compared 2 types of biofeedback; a 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=.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<.001). Results of this systematic review were limited by heterogeneity in patient populations, comparator treatments, and outcome measures.

Children

Systematic Reviews

A systematic review conducted by Wegh et al. (2021) assessed the effectiveness of nonpharmacological interventions for functional constipation in children.[9,] Studies included in the review were RCTs that enrolled children aged 0 to 18 years with functional constipation as defined by Rome III or IV criteria and reported defecation outcomes and/or QOL outcomes. The review included 3 RCTs comparing biofeedback alone with biofeedback in conjunction with laxative use. The trials were all assessed as having a high risk of bias. Meta-analysis found no difference between groups in study-defined treatment success (risk difference, 0.23; 95% CI, -0.08 to 0.54) and heterogeneity was high (I^2=86%). Other clinical outcomes and harms of treatment were not reported.

Randomized Controlled Trials

An RCT conducted by Van Ginkel et al (2001) selected 212 Dutch children who were at least 5 years old and had 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.[10,] 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 patients in the standard treatment group and 6 (7%) of 91 patients 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 patients 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: Constipation, Other Than Dyssynergic-Type Constipation

For adults with constipation other than dyssynergic-type 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, and does not show a significant benefit with biofeedback. For children, the evidence includes a systematic review of 3 RCTs and a separate single RCT not included in the systematic review. Neither the review nor the RCT found statistically significant differences for biofeedback regarding most treatment outcomes.

Dyssynergic-Type Constipation

Clinical Context and Therapy Purpose

The purpose of biofeedback in individuals who have dyssynergic-type constipation to provide a treatment option that is an alternative to or an improvement on existing therapies.
The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest are individuals 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 aims to teach patients how to tighten and relax their external anal sphincter to facilitate bowel movements.

Comparators

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 dyssynergia-type constipation is an overall change in patient symptoms. Increase in voluntary bowel movements is the primary clinical outcome. Achieving normal defecation dynamics (e.g., 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).

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies;
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought;
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence

Systematic Reviews

A systematic review of 11 RCTs (N=725) compared biofeedback with various interventions for dyssynergic constipation in adults.[11,] Both the Heyman and Rao trials, discussed below, were included in the review. Biofeedback was compared with a variety of interventions, including oral medications, botulinum toxin injection, and sham biofeedback. Pooled evidence from 6 of the trials (including Heyman and Rao) found a significant benefit of biofeedback versus no biofeedback in global clinical improvement (OR, 3.63; 95% CI, 1.10 to 11.93) but heterogeneity was high (I^2=87%). Resolution of dyssynergia favored biofeedback based on pooled evidence from 4 trials, but the risk estimate was very imprecise (OR, 9.43; 95% CI, 0.80 to 111.20; I^2=93%). Due to variance in reporting, the review did not report pooled estimates for other outcomes.

Randomized Controlled Trials

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 (e.g., evidence of inadequate propulsive forces and incomplete evacuation).[12,] 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 versus 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 ($p<.001$) or placebo ($p<.017$). A strength of this study design was its attempt to control for nonspecific effects of biofeedback (e.g., 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).[13,] All

participants had failed routine management of constipation. Seventy-seven patients were randomized for 3 months to 1 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<.05) and the standard treatment group (p<.062). Additionally, a greater proportion of patients in the biofeedback group reported improved global bowel satisfaction compared with the sham feedback group (p=.04), but the difference from the standard treatment group was not statistically significant. 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<.001 for both analyses). Moreover, balloon expulsion time during simulated defecation decreased significantly more in the biofeedback group than in the sham (p=.003) or standard treatment (p=.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 patients 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 a 1-year follow-up. Mean change in complete spontaneous bowel movements (the primary outcome) favored the biofeedback group (increase, 2.9) compared to the standard treatment group (decrease, 0.2). The small number of patients who completed 1 year of 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 and a systematic review have reported improvements in constipation symptoms.

Supplemental Information

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American College of Gastroenterology

In 2021, the American College of Gastroenterology (ACG) published an update to their guideline on the management of benign anorectal disorders.[15,] The guideline notes: "We recommend that instrumented anorectal biofeedback therapy should be used to manage symptoms in DD [defecation disorder] (strong recommendation; minimal risk of harm; quality of evidence: moderate)." Furthermore, the guideline notes the following key concepts related to biofeedback in the setting of DD:

- "Biofeedback should involve 4 to 6 sessions with well-trained therapists aimed at normalizing rectoanal coordination, ensuring good rectal pressure on strain, sensory retraining, and balloon expulsion retraining.
- Baseline ARM [anorectal manometry] and balloon expulsion is useful to predict the outcome and guide biofeedback therapy
- Defecography (MR [magnetic resonance] or barium) may be indicated in patients with DD who fail conservative therapy and biofeedback."

The guideline also provides a suggested treatment protocol for anorectal biofeedback.

American Gastroenterological Association

In 2013, the American Gastroenterological Association (AGA) 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)."[16,]

In 2017, the AGA published an expert review on surgical interventions and device-aided therapy for the treatment of fecal incontinence and defecation disorders.[17,] 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.

American Neurogastroenterology and Motility Society & European Society of Neurogastroenterology and Mobility

In 2015, the American Neurogastroenterology and Motility Society and the European Society of Neurogastroenterology and Mobility jointly published a consensus guideline on biofeedback therapy for anorectal disorders.[18,] The guideline 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

In 2015, the American Society of Colon and Rectal Surgeons (ASCRS) updated its guideline on the treatment of fecal incontinence.[19,] Those guidelines were updated in 2023.[20,] Biofeedback is no longer considered first line, but may still be considered for patients with fecal incontinence (conditional recommendation, low quality of evidence).

In 2016, the ASCRS published a guideline on the evaluation and management of constipation.[21,] The guideline stated that biofeedback therapy is a first-line treatment for symptomatic pelvic floor dyssynergia (strong recommendation, moderate quality of evidence).

National Institute for Health and Care Excellence

In 2017, NICE updated its guidance on constipation in children and young people.[22,] The guidance indicated that biofeedback should not be used for ongoing treatment.

In 2007, the NICE issued guidance on fecal incontinence in adults which was reaffirmed in 2018.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."[22,]

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 1. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT03811821	Comparative Effectiveness of Biofeedback, Sacral Nerve Stimulation, and Injectable Bulking Agents for Treatment of Fecal Incontinence: The Fecal Incontinence Treatment (FIT) Study	285	Dec 2025
Unpublished			
NCT02888899	Percutaneous Tibial Nerve Stimulation in Combination with Biofeedback in Patients with Fecal Incontinence: a Randomized Controlled Trial	NR	Mar 2019

NCT: national clinical trial; NR: not reported

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Documentation for Clinical Review

Please provide the following documentation:

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

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

Post Service (in addition to the above, please include the following):

- Procedure report(s)

Coding

This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy.

The following codes are included below for informational purposes. Inclusion or exclusion of a code(s) does not constitute or imply member coverage or provider reimbursement policy. Policy Statements are intended to provide member coverage information and may include the use of some codes for clarity. The Policy Guidelines section may also provide additional information for how to interpret the Policy Statements and to provide coding guidance in some cases.

Type	Code	Description
CPT®	90875	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
	90876	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); 45 minutes
	90901	Biofeedback training by any modality
HCPCS	E0746	Electromyography (EMG), biofeedback device

Policy History

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

Effective Date	Action
12/15/2014	Policy title change from Biofeedback Policy revision with position change effective 02/15/2015
02/15/2015	Policy revision with position change
03/01/2016	Policy revision without position change
02/01/2017	Policy revision without position change
01/01/2018	Policy revision without position change
01/01/2019	Policy revision without position change
02/01/2024	Policy reactivated. Previously archived from 04/01/2020 to 01/31/2024.

Definitions of Decision Determinations

Medically Necessary: Services that are Medically Necessary include only those which have been established as safe and effective, are furnished under generally accepted professional standards to treat illness, injury or medical condition, and which, as determined by Blue Shield, are: (a) consistent

with Blue Shield medical policy; (b) consistent with the symptoms or diagnosis; (c) not furnished primarily for the convenience of the patient, the attending Physician or other provider; (d) furnished at the most appropriate level which can be provided safely and effectively to the patient; and (e) not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the Member's illness, injury, or disease.

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 and Feedback (as applicable to your plan)

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 be directed to the Prior Authorization Department at (800) 541-6652, or the Transplant Case Management Department at (800) 637-2066 ext. 3507708 or visit the provider portal at www.blueshieldca.com/provider.

We are interested in receiving feedback relative to developing, adopting, and reviewing criteria for medical policy. Any licensed practitioner who is contracted with Blue Shield of California or Blue Shield of California Promise Health Plan is welcome to provide comments, suggestions, or concerns. Our internal policy committees will receive and take your comments into consideration.

For utilization and medical policy feedback, please send comments to: MedPolicy@blueshieldca.com

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.

Appendix A

POLICY STATEMENT	
BEFORE	**AFTER** **Blue font: Verbiage Changes/Additions**
Reactivated Policy **Policy Statement:** N/A	**Biofeedback as a Treatment of Fecal Incontinence or Constipation 2.01.64** **Policy Statement:** I. Biofeedback for constipation in adults may be considered **medically necessary** for individuals with dyssynergia-type constipation as demonstrated by meeting all 3 of the following criteria: A. Symptoms of functional constipation that meet Rome IV criteria (see Policy Guidelines section). B. Objective physiologic evidence of pelvic floor dyssynergia (see Policy Guidelines section) demonstrated by inappropriate contraction of the pelvic floor muscles or less than 20% relaxation of basal resting sphincter pressure by manometry, imaging, or electromyography. C. Failed a 3-month trial of standard treatments for constipation including laxatives, dietary changes, and exercises (as many of the previous as are tolerated). II. Biofeedback is considered **investigational** as a treatment of constipation in adults and children in all other situations. III. Biofeedback is considered **investigational** as a treatment of fecal incontinence in adults and children.