

# Protocol

## Biofeedback as a Treatment of Fecal Incontinence or Constipation

(20164)

<b>Medical Benefit</b>		<b>Effective Date:</b> 07/01/13	<b>Next Review Date:</b> 03/21
<b>Preauthorization</b>	No	<b>Review Dates:</b> 09/07, 09/08, 09/09, 09/10, 09/11, 07/12, 03/13, 03/14, 03/15, 03/16, 03/17, 03/18, 03/19, 03/20	

### ***Preauthorization is not required.***

*The following protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.*

<b>Populations</b>	<b>Interventions</b>	<b>Comparators</b>	<b>Outcomes</b>
Individuals: <ul style="list-style-type: none"><li>• With fecal incontinence</li></ul>	Interventions of interest are: <ul style="list-style-type: none"><li>• Biofeedback</li></ul>	Comparators of interest are: <ul style="list-style-type: none"><li>• Medical management</li><li>• Sphincteroplasty</li></ul>	Relevant outcomes include: <ul style="list-style-type: none"><li>• Symptoms</li><li>• Functional outcomes</li><li>• Quality of life</li></ul>
Individuals: <ul style="list-style-type: none"><li>• With constipation other than dyssynergia-type constipation</li></ul>	Interventions of interest are: <ul style="list-style-type: none"><li>• Biofeedback</li></ul>	Comparators of interest are: <ul style="list-style-type: none"><li>• Medical management</li></ul>	Relevant outcomes include: <ul style="list-style-type: none"><li>• Symptoms</li><li>• Functional outcomes</li><li>• Quality of life</li></ul>
Individuals: <ul style="list-style-type: none"><li>• With dyssynergia-type constipation</li></ul>	Interventions of interest are: <ul style="list-style-type: none"><li>• Biofeedback</li></ul>	Comparators of interest are: <ul style="list-style-type: none"><li>• Medical management</li></ul>	Relevant outcomes include: <ul style="list-style-type: none"><li>• Symptoms</li><li>• Functional outcomes</li><li>• Quality of life</li></ul>

### **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.

### **SUMMARY OF EVIDENCE**

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. 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 an 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.

## POLICY

Biofeedback for constipation in adults may be considered **medically necessary** for patients with dyssynergia-type constipation as demonstrated by meeting all three of the following criteria:

1. Symptoms of functional constipation that meet ROME IV criteria (see Policy Guidelines);
2. Objective physiologic evidence of pelvic floor dyssynergia (see Policy Guidelines) demonstrated by inappropriate contraction of the pelvic floor muscles or less than 20% relaxation of basal resting sphincter pressure by manometry, imaging or electromyography;
3. Failed a three-month trial of standard treatments for constipation including laxatives, dietary changes, and exercises (as many of the previous as are tolerated).

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

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

## POLICY GUIDELINES

Rome IV diagnostic criteria for functional gastrointestinal disorders for functional constipation include (Mearin et al. Bowel disorders. *Gastroenterology*. 2016;150(6):1393-1407):

### C2. Diagnostic Criteria<sup>a</sup> for Functional Constipation

1. Must include two or more of the following<sup>b</sup>:
  - a. Straining during more than one-fourth (25%) of defecations
  - b. Lumpy or hard stools (Bristol Stool Form Scale 1-2) more than one-fourth (25%) of defecations
  - c. Sensation of incomplete evacuation more than one-fourth (25%) of defecations
  - d. Sensation of anorectal obstruction/blockage 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 three spontaneous bowel movements per week
2. Loose stools are rarely present without the use of laxatives
3. Insufficient criteria for irritable bowel syndrome

<sup>a</sup> Criteria fulfilled for the last three months with symptom onset at least six months prior to diagnosis.

<sup>b</sup> 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 two conditions might overlap.

Rome IV diagnostic criterion for dyssynergic defecation includes (Rao et al. Functional anorectal disorders. Gastroenterology. 2016;150(6):1430-1442):

#### F3b. Diagnostic Criteria for Dyssynergic Defecation

“Inappropriate contraction of the pelvic floor as measured with anal surface electromyography or manometry with adequate propulsive forces during attempted defecation.”<sup>c</sup>

<sup>c</sup> 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 six biofeedback sessions over three months. This is consistent with the protocol used in key randomized trials showing benefit of biofeedback for selected patients.

## BACKGROUND

### 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 three 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 (i.e., 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 (i.e., 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 three 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, non-arousing 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."<sup>1</sup>

## RELATED PROTOCOLS

Biofeedback as a Treatment of Urinary Incontinence in Adults

Sacral Nerve Neuromodulation/Stimulation

Transanal Radiofrequency Treatment of Fecal Incontinence

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Services that are the subject of a clinical trial do not meet our Technology Assessment and Medically Necessary Services Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment and Medically Necessary Services Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

## REFERENCES

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

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