Protocol

Biofeedback as a Treatment of Fecal Incontinence or Constipation

(20164)

Medical Benefit		**Effective Date**: 07/01/13	**Next Review Date**: 03/15
Preauthorization	No	**Review Dates**: 09/07, 09/08, 09/09, 09/10, 09/11, 07/12, 03/13, 03/14	

The following Protocol contains medical necessity criteria that apply for this service. It is applicable to Medicare Advantage products unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. ***Preauthorization is not required but is recommended if, despite this Protocol position, you feel this service is medically necessary.*** *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.*

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

Background

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

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

Constipation refers to infrequent bowel movements and difficulty expelling stool during defecation. Primary constipation is generally categorized into 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, stool moves more slowly through the colon and individuals often experience a limited urge to defecate. The third type, dyssynergic defecation, refers to a loss of ability to coordinate contractions of the pelvic floor muscles and to relax the anal sphincter during defecation. Patients often report an inability to defecate despite the urge to do so. There are also secondary causes of constipation such as the use of certain medications, including opioids and psychoactive drugs; neurologic, endocrine, or metabolic disorders; structural abnormalities; and lifestyle factors. Conventional

treatment includes dietary changes (i.e., adequate fiber and fluid intake), use of supplemental bulking substances, exercises, and medications.

In children, most cases of fecal incontinence and constipation are functional, in which structural, endocrine, or metabolic diseases have been ruled out. Factors contributing to functional incontinence and constipation are fear and/or pain associated with large, hard stools. This leads to retentive posturing in approximately half the children with chronic constipation (i.e., the avoidance of defecation by 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 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 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 (EMG) feedback of pelvic floor muscles (PFM). The purpose is to strengthen the force of the PFM contraction without including rectal distention. Some training increases endurance (duration of external anal sphincter contraction), as well as peak strength. Coordination training uses pressure feedback of intra-rectal balloon distention using a water-perfused catheter or Schuster-type balloon probe and PFM contractions in a simultaneous feedback display. The purpose of coordination training is to synchronize the contraction of the external anal sphincter with relaxation of the internal anal sphincter.

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

Regulatory Status

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

Related Protocols

Biofeedback as a Treatment of Urinary Incontinence in Adults

Transanal Radiofrequency Treatment of Fecal Incontinence

Sacral Nerve Neuromodulation/Stimulation

Policy (Formerly Corporate Medical Guideline)

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 III 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 EMG;
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 Guideline

Rome III Diagnostic Criteria for Functional Gastrointestinal Disorders, available on line at: (http://www.romecriteria.org/assets/pdf/19_RomeIII_apA_885-898.pdf):

Rome III 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

*Criteria fulfilled for the last three months with symptom onset at least six months prior to diagnosis

Rome III diagnostic criterion for dyssynergic defecation:

Inappropriate contraction of the pelvic floor or less than 20% relaxation of basal resting sphincter pressure with adequate propulsive forces during attempted defecation

Guidance on biofeedback protocol:

The recommended treatment course for patients with constipation who meet criteria is up to six biofeedback sessions over three months. This is consistent with the protocol used in key randomized trials showing benefit of biofeedback for selected patients.

Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are

considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment 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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