Fecal Incontinence

Number: 0611

Policy

*Please see amendment for Pennsylvania Medicaid at the end of this CPB.

I. Aetna considers the following diagnostic tests medically necessary for fecal incontinence:

A. Anorectal manometry (see CPB 0616 - Gastrointestinal Manometry);
B. Anorectal ultrasonography; and
C. Rectal sensory testing.

II. Aetna considers the following conservative treatments medically necessary for fecal incontinence:

A. Biofeedback (see CPB 0132 - Biofeedback);
B. Bowel training;
C. Defecation programs;
D. Diet modification; and
E. Pharmacotherapy.

III. Aetna considers an anal sphincter repair medically necessary for members with severe fecal incontinence who have failed, or are not candidates for, medical interventions (e.g.,
biofeedback, dietary management, pharmacotherapy, strengthening exercises).

IV. Aetna considers a colostomy medically necessary for members with severe fecal incontinence who have failed, or are not candidates for, medical interventions (e.g., biofeedback, dietary management, pharmacotherapy, strengthening exercises) or surgical sphincter repair (e.g., post-anal repair, sphincteroplasty, or total pelvic floor repair).

V. Aetna considers the Acticon Neosphincter artificial bowel sphincter medically necessary for members 18 years of age or older with severe fecal incontinence who have failed, or are not candidates for, medical interventions (e.g., biofeedback, dietary management, pharmacotherapy, strengthening exercises) or surgical sphincter repair (e.g., post-anal repair, sphincteroplasty, or total pelvic floor repair). For purposes of this policy, fecal incontinence is considered severe when it results in the involuntary loss of solid stool or liquid stool on a weekly or more frequent basis.

Aetna considers the Acticon Neosphincter artificial bowel sphincter experimental and investigational when criteria are not met.

Aetna considers the Acticon Neosphincter artificial bowel sphincter experimental and investigational for persons with any of the following contraindications to its use:

A. Individuals with incontinence complicated by an irreversibly obstructed proximal segment of bowel; or
B. Individuals who are poor candidates for surgery or anesthesia due to physical or mental conditions.

VI. Aetna considers transanal radiofrequency therapy for the treatment of fecal incontinence (also known as the Secca procedure) experimental and investigational because its effectiveness has not been established.

VII. Aetna considers sacral nerve stimulation (sacral neuromodulation) medically necessary for the treatment of
members with chronic fecal incontinence, who have had an inadequate response to conservative treatments (e.g., biofeedback, dietary management, pharmacotherapy, strengthening exercises), and who have a weak but structurally intact anal sphincter. Initially, a temporary percutaneous peripheral nerve electrode is considered medically necessary for testing over a 2- to 3-week period. Implantation of a permanent implantable pulse generator is considered medically necessary for members who have a 50 percent or greater improvement in incontinence symptoms from the temporary percutaneous peripheral nerve stimulation. (Note: Sacral nerve stimulation can be administered via InterStim). Aetna considers sacral nerve stimulation experimental and investigational when these criteria are not met.

VIII. Aetna considers perianal electrical stimulation for the treatment of fecal incontinence experimental and investigational because its effectiveness has not been established.

IX. Aetna considers the use of injectable bulking agents for the treatment of fecal incontinence experimental and investigational because their effectiveness for this indication has not been established.

X. Aetna considers vaginal bowel control (e.g., Eclipse system) experimental and investigational for fecal incontinence because its effectiveness for this indication has not been established.

XI. Aetna considers injection of autologous myoblast cells or mesenchymal stem cells for the treatment of fecal incontinence experimental and investigational because its effectiveness for this indication has not been established.

XII. Aetna considers topical estrogen for the treatment of fecal incontinence experimental and investigational because its effectiveness for this indication has not been established.

XIII. Aetna considers posterior tibial nerve stimulation for the treatment of fecal incontinence experimental and
investigational because its effectiveness has not been established.

XIV. Aetna considers measurement of pudendal nerve terminal motor latency for evaluation of fecal incontinence experimental and investigational because its effectiveness has not been established.

XV. Aetna considers anal sling, pubo-rectal sling, and the Fenix Continence Restoration System experimental and investigational for the treatment of fecal incontinence because the effectiveness of these approaches has not been established.

See also CPB 0132 - Biofeedback.

**Background**

Fecal incontinence is the involuntary loss of flatus, liquid, or stool. Fecal incontinence may be caused by damage to the anal sphincter (eg, childbirth, surgery), diarrhea, fecal impaction, illnesses that cause the inability to expand and store fecal matter (eg, inflammatory bowel disease [IBD], Crohn’s disease or injury). Although it is considered a benign disorder, severe fecal incontinence is a distressing and socially isolating medical condition. Individuals who suffer from this condition often alter their lifestyle to minimize the likelihood of bowel accidents in public places. Over time, this can result in progressive social isolation and work incapacity.

Prior to treatment for fecal incontinence, an evaluation must be performed. The initial assessment includes basic office tests, a history and physical, and laboratory tests. Anorectal manometry is a test that uses a pressure sensitive tube to check the sensitivity and function of the rectum. It also measures the ability of the anal sphincter muscles to respond to signals. Anorectal ultrasonography is an ultrasound that is specific to the anus and rectum. This is utilized to evaluate the structure of the anal sphincter muscles. Rectal sensory testing is utilized to detect abnormal rectal sensation. When rectal sensation is reduced, stool may leak before the external sphincter contracts.
The majority of cases of fecal incontinence are mild-to-moderate, and can be managed with medical interventions including anti-diarrheal medications (loperimide, codeine, diphenoxylate, atropine), treatment of underlying infections or inflammatory disorders as indicated, pelvic floor biofeedback, and dietary management (increase dietary fiber with psyllium products or synthetic analogues).

Biofeedback is therapy that utilizes sensors to help the individual identify and contract the anal sphincter muscles which help maintain continence.

Defecation programs (bowel training) are designed to help individuals with disabilities or mental health issues by setting a schedule for sitting on the toilet at a regular time every day after a meal which purportedly may help with incontinence if the bowels are emptied regularly.

Vaginal bowel control (eg, Eclipse system) is a device that includes an inflatable balloon, which is placed in the vagina, which upon inflation exerts pressure on the vaginal wall supposedly closing off the rectum. Reportedly, bowel evacuation is completed by deflating the device and re-inflating using an external pump.

For some patients with a sphincter defect, surgical procedures such as direct sphincter repair (sphincteroplasty), post-anal repair, or total pelvic floor repair may be attempted. Sphincteroplasty is utilized to repair a defect in the sphincter muscle in which the two ends of the muscle are cut and overlapped onto one another and then sewn into place to restore the complete circle of muscle.

For individuals with severe fecal incontinence who have failed medical interventions and who are not candidates for sphincter repair, the choices are limited. An alternative surgical procedure, a dynamic muscle transposition, may be used in patients where the anal sphincter is either denervated or anatomically absent. It involves the transposition of muscle, usually the gracilis (gracilisplasty) or gluteus maximus, to create a barrier to the passage of stool.
Another alternative is a permanent ostomy that would allow bodily wastes to be expelled through the abdominal wall. A colostomy involves the construction of an artificial opening from the colon through the abdominal wall, which bypasses a diseased portion of the lower intestine and permits the passage of stool to a bag outside of the body; typically used as the last attempt to correct fecal incontinence. However, neither a dynamic muscle transposition nor permanent ostomy provides normal bowel function and fecal continence.

Acticon Neosphincter:

Artificial anal sphincter (eg, Acticon Neosphincter) is an implantable, fluid filled device that consists of an inflatable silicon cuff, a pressure-regulating balloon and a control pump, which reportedly maintains continence by using the pressure of the fluid filled cuff to occlude the anal canal. When there is a need to defecate (bowel movement), the individual squeezes and releases the pump mechanism, which releases the compressive force around the anal canal. The Acticon Neosphincter simulates normal anal sphincter function by allowing the anal canal to open at the control of the patient.

The device consists of 3 interconnected components: (i) an occlusive cuff, (ii) a pressure-regulating balloon and (iii) a control pump. The occlusive cuff is implanted around a segment of the anal canal. The device maintains continence in the patient by using the pressure of the fluid-filled cuff to occlude the anal canal. To evacuate the bowel, the patient squeezes and releases the pump mechanism, located in the labium or scrotum, several times to move fluid from the cuff to the pressure-regulating balloon implanted in the abdomen. This movement of fluid empties and collapses the cuff, resulting in the release of the compressive force around the anal canal. Residual pressure within the balloon allows fluid to flow back into the cuff, automatically refilling the cuff within a few minutes.

Because of implantation of a silicone device in the perianal area, the peri-operative infection rate is high, and device removal due to infection may be necessary. Additionally, the sphincter may
need replacement as often as every 5 years because of device wear.

Results from clinical trials submitted to the Food and Drug Administration (FDA) for approval indicated slightly more than half (51.3%) of all patients who were implanted with the Acticon Neosphincter had resolution or clinically significant reduction in their symptoms after one year. For the subset of patients who were able to maintain a functional device for 12 months, approximately 85% had meaningful improvements in their incontinence.

A majority of the patients implanted experienced at least one device-related adverse event. Besides pain, the two most common adverse events were infection (31% of implanted patients) and device erosion (21%). Surgical intervention was required to address 36% of these adverse events. Half of the implanted patients required at least 1 additional surgical device revision after the original implantation procedure and 30% required total device explantation due to adverse events.

In approving the device, the FDA took into account the adverse event rates for other colorectal surgeries. The FDA cited a study examining the overall mortality and morbidity for patients undergoing resection of the colon or rectum, where 361 out of 971 patients undergoing elective surgery experienced at least 1 post-operative complication. In another study, 36 to 39% of patients who had elective surgery for colorectal disease suffered from complications.

The FDA concluded that the Acticon Neosphincter is indicated “to treat fecal incontinence in males and females eighteen years and older who have failed, or are not candidates for, less invasive forms of therapy.”

Investigators from Adelaide Health Technology Assessment conducted a systematic review of literature on implantation of the Acticon Neosphincter in the management of fecal incontinence (Buckley et al, 2007). The investigators compared the safety, effectiveness, and cost-effectiveness of
the Acticon to colostomy, dynamic graciloplasty, and conservative management. An advisory panel with expertise in this area then evaluated the evidence and provided advice to the Australian Medicare Services Advisory Committee (MSAC). The MSAC found no evidence comparing the Acticon with colostomy and limited evidence comparing it with conservative management and dynamic graciloplasty. The MSAC found that the evidence suggested that Acticon implantation is not as safe as conservative management and that it is likely to be at least as safe as dynamic graciloplasty. The MSAC found that the Acticon is more clinically effective than both conservative management and dynamic graciloplasty. The MSAC found that relative cost-effectiveness of the Acticon and the comparators could not be assessed due to lack of data. The comparison of the estimated total costs indicates that the cost to the Australian health system of the Acticon is less than for dynamic graciloplasty.

Transanal Radiofrequency Therapy (The Secca Procedure):

Radiofrequency ablation (eg, Secca System) is a minimally invasive procedure that uses alternating electrical current to cause controlled heating of the tissue in the anal sphincter which supposedly remodels the treated tissue by stimulating the formation of connective tissue.

The Secca procedure received FDA clearance through Investigational Device Exemption in March 2002. The Secca procedure entails delivery of temperature controlled radiofrequency (RF) energy to the sphincteric complex of the anal canal. It offers a less-invasive option for treatment of fecal incontinence, as compared to surgery, and is performed on an outpatient basis using conscious sedation. Although the Secca procedure is cleared by the FDA, its clinical effectiveness has not been established.

In a small non-randomized study (n = 10), Takahashi et al (2002) examined the durability and long-term safety of the Secca procedure for the treatment of fecal incontinence. These investigators reported that significant improvements in symptoms of fecal incontinence and quality of life persisted 24 months after
RF delivery to the anal canal. While the findings of this study are promising, it does not provide adequate evidence to allow conclusions regarding long-term outcomes. The authors noted that an additional randomized, sham-controlled, double-blind clinical trial is underway to further evaluate the procedure.

Takahashi-Monroy et al (2007) reported an extension of the follow-up from their original study. The Cleveland Clinic Florida Fecal Incontinence Scale (CCF-FI) (0 to 20), fecal incontinence-related quality of life (QOL) score, and Medical Outcomes Study Short-Form 36 were administered to 5 years. Differences between baseline and follow-up were analyzed by using paired t-test. A total of 19 patients were treated and followed for 5 years, including 18 females (aged 57.1 years; range of 44 to 77). The mean duration for fecal incontinence was 7.1 years (range of 1 to 21). At 5-year follow-up, the mean fecal incontinence score had improved from 14.37 to 8.26 (p < 0.00025) with 16 patients (84.2 %) demonstrating greater than 50 % improvement. All fecal incontinence-related QOL scores improved, including lifestyle (2.43 to 3.15; p < 0.00075), coping (1.73 to 2.6; p < 0.00083), depression (2.24 to 3.15; p < 0.0002), and embarrassment (1.56 to 2.51; p < 0.0003). The social function component of the Short-Form 36 improved from 38.3 to 60 (p < 0.05). There was a trend toward improvement in the mental component summary of the Short-Form 36 (SF-36) from 38.1 to 48.14. There were no long-term complications. The authors concluded that significant and sustained improvements in fecal incontinence symptoms and QOL are seen at 5 years after treatment with the Secca procedure.

In an open-label, single arm, non-randomized, multi-center study, Efron et al (2003) evaluated the safety and effectiveness of the Secca procedure. A total of 43 women and 7 men (average age 61 years, range of 29 to 80) were enrolled, treated, and followed for 6 months. Mean duration of fecal incontinence prior to treatment was 15.6 years. At 6 months, the mean CCF-FI score improved significantly from 14.5 to 11.1 (p < 0.0001). Parameters in the fecal incontinence QOL were improved, including lifestyle (from 2.5 to 3.1; p = 0.0001), coping (from 1.9 to 2.3; p = 0.005), depression (from 2.8 to 3.1; p = 0.0008), and embarrassment (from 1.9 to 2.5; p < 0.0001). The mean SF-36 mental composite
score improved from 45.3 to 48.3 ($p = 0.06$), and the mean SF-36 social function sub-score improved from 64.0 to 77.3 ($p = 0.003$). Patient diaries showed that there was a significant reduction in days with any fecal incontinence ($p < 0.0001$). A clinical response (greater than 10 % improvement) was noted by visual analogue scale in 60 % of patients.

It is interesting to note that the study by Efron et al (2003) did not report the same level of improvements as reported in the study by Takahashi et al (2002). The overall reduction in scores based on CCF-FI was 8.5 points in the study by Takahashi and colleagues and 3.5 points in the study by Efron and co-workers. Furthermore, the overall response rate was 80 % in the study by Takahashi et al and 60 % in the study by Efron et al. The findings of these studies need to be validated by prospective, randomized controlled studies with large sample sizes and long-term follow-up.

Felt-Bersma and colleagues (2007) examined the effectiveness of RF and possible changes in the anal sphincter with 3D-ultrasound in patients with fecal incontinence. A total of 11 women, mean age 61 years (range of 49 to 73) with long-standing fecal incontinence were included in this study. Patients with large sphincter defects and anal stenosis were excluded. The Secca procedure was carried out under conscious sedation and local anesthesia. Oral antibiotics were given. In 4 quadrants on 4 or 5 levels (depending upon length of the anus) RF was delivered with multiple needle electrodes. Patients were evaluated at 0, 6 weeks, 3 and 6 months and 1 year. Three-dimensional anal ultrasound was performed at 0 (before and after the procedure), 6 weeks and 3 months. Anal manometry and rectal compliance measurement were performed at 0 and 3 months. At 3 months, 6 of 11 patients improved, which persisted during follow-up of 1 year. The Vaizey score changed from 18.8 to 15.0 ($p = 0.03$) and in those improved from 18.3 to 11.5 ($p = 0.03$). Anal manometry and rectal compliance showed no significant changes, there was a tendency to increased rectal sensitivity concerning urge and maximal tolerated volume (both $p = 0.3$). Responders compared with non-responders showed no difference in test results. Side effects were local hematoma ($n = 2$), bleeding 3 days ($n = 1$), pain
persisting 1 to 3 weeks (n = 4) and laxatives-related diarrhea during 1 to 3 weeks (n = 4). The authors concluded that the Secca procedure seems to be promising for patients with fecal incontinence with a persisting effect after 1 year. No significant changes in tests were found.

Kim and associates (2009) evaluated the safety and effectiveness of the Secca procedure (n = 8). The Fecal Incontinence Severity Index (FISI) score and the Fecal Incontinence-related Quality of Life (FIQL) scale were completed at baseline and after the procedure. Anorectal manometry and endoanal ultrasound also were conducted. Seven of the 8 patients were women, and the median age of the patients was 59 years (range of 28 to 73). The mean FISI score and all of the parameters in the FIQL scale with the exception of the embarrassment scale measured at 6 months after the procedure was not improved significantly. No changes in the anal manometry and endoanal ultrasound parameters were observed. Complications associated with the procedure developed in 7 of the 8 patients, including anal bleeding, anal pain, and anal mucosal discharge. The authors concluded that the FISI score and FIQL scale were not improved significantly after the Secca procedure, and considerable complications were associated with the procedure.

The National Institute for Health and Clinical Excellence's guideline on endoscopic radiofrequency therapy of the anal sphincter for fecal incontinence (2011) stated that "[t]he evidence on endoscopic radiofrequency therapy of the anal sphincter for fecal incontinence raises no major safety concerns. There is evidence of efficacy in the short-term, but in a limited number of patients. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research. . . . Further research into endoscopic radiofrequency therapy of the anal sphincter for fecal incontinence should clearly define the patient groups being treated. It should also report the clinical impact in terms of quality of life and long-term outcomes".

Abbas et al (2012) evaluated the short- and long-term outcome of the radiofrequency treatment for moderate-to-severe FI. Patients
who underwent the radiofrequency procedure were included. The primary outcomes measured were the complication rate, short- and long-term response, and the rate of subsequent intervention for incontinence. A total of 27 patients underwent 31 radiofrequency procedures (81% women; mean age of 64 years). Median length of symptoms was 3 years. Biofeedback had failed for 52% of patients, and 23% of patients had previous surgical intervention. Thirty-eight percent of patients had a sphincter defect. Minor complications were observed in 19% of the patients. A treatment response was noted in 78% of the patients (mean Cleveland Clinic Florida Fecal Incontinence Score: 16 (baseline) and 10.9 (3 months post-operatively)). However, a sustained long-term response without any additional intervention was noted in 22% of the patients, and 52% of the patients underwent or are awaiting additional intervention for persistent or recurrent incontinence (mean follow-up of 40 months). The authors concluded that the radiofrequency procedure was safe, but a long-term benefit was noted in a minority of patients with moderate-to-severe FI; additional interventions were needed in more than 50% the patients. Moreover, they stated that larger studies are needed to determine the impact of various patient-related factors on the outcome of the radiofrequency treatment to identify the ideal patient for this therapy. This study is limited by its retrospective nature and the limited number of subjects.

Felt-Bersma (2014) evaluated the clinical response and sustainability of Secca for patients with anal incontinence (AI). Only original clinical studies retrieved from PubMed and Medline were included. The outcome measures, FI scores, definition of response, clinical results and anorectal evaluation were analyzed. A total of 10 studies were included, which involved 150 original patients; 3 studies reported a long-term follow-up. The 1-year follow-up showed a moderate effect, which declined somewhat over time. Only minor temporary side-effects were reported and none of the patients declined treatment. The authors concluded that Secca is a safe and well-tolerated procedure that is easy to perform without any serious short- or long-term complications, but with only a moderate clinical effect that declines over time. They stated that results of randomized, sham-controlled controlled trials are awaited.
In a prospective cohort study, Lam and colleagues (2014) evaluated clinical response and sustainability of Secca for FI. This study involved patients who had failed full conservative management for FI, and performed between 2005 and 2010. Fecal incontinence was scored using the Vaizey score (VS). A clinically significant response to Secca was defined as greater than or equal to 50% reduction in incontinence score. Impact of FI on QOL was measured using the FIQL. Data were obtained at baseline, at 6 months and at 1 and 3 years. Anal endosonography as well as anal manometry were performed at 3 months and compared to baseline. A total of 31 patients received Secca. During follow-up, 5/31 (16%), 3/31 (10%) and 2/31 (6%) of patients maintained a clinically significant response after the Secca procedure. Mean VS of all patients was 18 (SD 3), 14 (SD 4), 14 (SD 4) and 15 (SD 4), at baseline, 6 months and 1 and 3 years, respectively. No increases in anorectal pressures or improvements in rectal compliance were found. Coping improved between baseline and t = 6 months. No predictive factors for success were found. The authors concluded that the findings of this prospective non-randomized trial showed disappointing outcomes of the Secca procedure for the treatment of FI. The far minority of patients reported a clinically significant response of seemingly temporary nature. They stated that Secca might be valuable in combination with other interventions for FI, but this should be tested in strictly controlled randomized trials.

Sacral Nerve Stimulation (Sacral Neuromodulation):

Sacral nerve stimulation (eg, InterStim) involves the implantation of electrodes at the sacral nerve to improve muscle control of the anal sphincter and improve rectal sensation.

Sacral nerve stimulation, also known as sacral neuromodulation, has been used successfully to treat urinary incontinence as well as non-obstructive urinary retention. However, its mechanism of action remains unclear. Sacral neuromodulation is also a novel treatment for fecal incontinence. It appears to be a promising procedure because of its relative simplicity and low morbidity. However, experience with sacral nerve stimulation for this indication is limited. Studies with longer follow-up are needed to
better evaluate this procedure. In a review on sacral nerve stimulation for the treatment of female pelvic floor dysfunction including fecal incontinence, Pettit et al (2002) stated that while the data are encouraging in these new arenas of pelvic floor disorders, investigators acknowledge the need for multicenter, statistically powered studies to assess the validity of these findings. An evidence review prepared for the National Institute for Clinical Excellence (2004) stated that sacral nerve stimulation has shown good results in patients with fecal incontinence due to a functional deficit; however, longer-term follow-up is needed. The National Institute for Clinical Excellence (2004) concluded that “[c]urrent evidence of the safety and efficacy of sacral nerve stimulation for faecal incontinence does not appear adequate to support the use of this procedure without special arrangements for consent and for audit or research.”

The National Institute of Clinical Excellence (NICE, 2004) concluded that there is adequate evidence to support the use of sacral nerve stimulation for fecal incontinence in persons with a weak but structurally intact anal sphincter who are refractory to conservative measures. This conclusion was based on the results of a systematic evidence review (Fraser et al, 2004) that identified 6 case series studies of sacral nerve stimulation involving 266 persons with chronic refractory fecal incontinence. The systematic review found that complete continence was achieved in 41 to 75 % (19/46 to 12/16) of patients with permanent implants, whereas 75 to 100 % (3/4 to 16/16) of patients with permanent implants experienced a decrease of 50 % or more in the number of incontinence episodes. Commonly, the procedure is tested in each patient over a 2- to 3-week period, with a temporary percutaneous peripheral nerve electrode attached to an external stimulator (NICE, 2004). If significant benefit is achieved, then the permanent implantable pulse generator can be implanted.

The effectiveness of sacral nerve stimulation in treating fecal incontinence has been demonstrated in clinical studies (Kenefick and Christiansen, 2004; Matzel et al, 2004; and Jarrett et al, 2004). Kenefick and Christiansen (2004) noted that sacral nerve stimulation appears to be an alternative treatment that is
successful, has low morbidity, is maintained in the medium term and associated with an improved QOL. The technique has the advantage of a minimally invasive test procedure with high predictive value and the surgery is minor. Matzel et al (2004) stated that sacral nerve stimulation greatly improved continence and QOL in selected patients with morphologically intact or repaired sphincter complex offering a treatment for patients in whom treatment options are limited. Jarrette and associates (2004) concluded that sacral nerve stimulation is a safe and effective treatment, in the medium to long term, for fecal incontinence when conservative treatment has failed.

An assessment by the Australian Medical Services Advisory Committee (MSAC, 2005) recommended that "there is evidence of safety for sacral nerve stimulation in adults with faecal incontinence refractory to conservative, non-surgical treatment and who have an anatomically intact but functionally deficient anal sphincter. The total number of patients is small; there is some evidence of effectiveness and cost-effectiveness. MSAC supports public funding in these circumstances."

An assessment by the Ludwig Boltzmann Institute for Health Technology Assessment (Fischer and Zechmeister, 2011) summarized current evidence on the effectiveness and safety of sacral nerve stimulation for fecal incontinence. The authors identified and analyzed 7 publications, including 5 reviews, 1 meta-analysis and 1 randomized controlled clinical study. The authors concluded that sacral nerve stimulation seems to be effective and safe for a selected group of patients. "However, the poor study design means that results are subject to considerable uncertainty and new studies could have an impact on the estimated effect."

**Perianal Electrical Stimulation:**

Transanal electrical stimulation is electrical stimulation that is applied to the anal canal to supposedly stimulate muscle contraction.

Perianal electrical stimulation has also been tried in treating fecal
incontinence. A Cochrane review (Hoster et al, 2000) concluded that there are insufficient data to allow reliable conclusions to be drawn on the effects of electrical stimulation in the management of fecal incontinence. The report also concluded that there is a suggestion that electrical stimulation may have a therapeutic effect, but this is not certain; larger, more generalizable trials are needed. Since publication of the Cochrane review, Riedy et al (2000) reported on a study of perianal electrical stimulation of 5 healthy spinal cord injury patients. These researchers reported that 4 of the 5 subjects had strong anal contractions with perianal electrical stimulation. However, this study did not examine the effect of perianal electrical stimulation on fecal incontinence.

Mahoney et al (2004) reported on a randomized controlled clinical trial of intra-anal electromyographic (EMG) biofeedback versus EMG biofeedback augmented with electrical stimulation of the anal sphincter in the treatment of 60 women with post-partum fecal incontinence. These investigators reported that the addition of electrical stimulation of the anal sphincter did not enhance the symptomatic outcome of women with post-partum fecal incontinence.

Vitton and co-workers (2009) examined the usefulness of transcutaneous posterior tibial nerve stimulation to treat fecal incontinence in inflammatory bowel disease (IBD). A total of 12 patients (7 Crohn's disease, 2 undetermined colitis, 3 ulcerative colitis) were treated by applying transcutaneous posterior tibial nerve electrical stimulation daily for 3 months. A clinical evaluation was performed at the end of treatment, with Wexner's score and Harvey-Bradshaw index and analog scales to assess symptoms and QOL. At 3 months, 5 patients (41.6 %) reported a significant symptomatic and QOL improvement, although only 1 reported a significant modification in the Wexner score. The authors concluded that these preliminary results are encouraging, although further studies are necessary.

Leroi et al (2012) showed that although transcutaneous electrical tibial nerve stimulation (TENS) is being increasingly used to treat FI, its efficacy has never been proved using controlled trials. In this randomized, double-blind, sham-controlled trial, a total of
144 patients aged 30 to 82 years from 9 centers were randomly assigned to receive either active or sham stimulations for 3 months. The primary end point was the response to treatment based on the number of incontinence and urgency episodes. Secondary end points were severity scores, quality of life scores, delay to postpone defecation, patient self-assessment of treatment efficacy, physician assessment of TENS efficacy, anorectal manometry, and adverse events. No statistically significant difference was seen between active and sham TENS in terms of an improvement in the median number of FI/urgency episodes per week. Thirty-four patients (47 %) who received the active TENS treatment exhibited a greater than 30 % decrease in the FI severity score compared with 19 patients (27 %) who received the sham treatment (odds ratio [OR] 2.4, 95 % confidence interval [CI]: 1.1 to 5.1, p = 0.02). No differences in delay to postpone defecation, patient self-assessment of treatment efficacy, or anorectal manometry were seen between the two groups. The evaluating physicians rated the active stimulations as more effective than the sham stimulations (p = 0.01). One minor therapy-related adverse event was observed (1.5 %). The authors concluded that they failed to demonstrate any benefit of TENS on the primary end-point.

**Injectable Bulking Agents:**

Injectable bulking agents (eg, Solesta injectable gel) involves the injection of collagen, autologous fat or other materials into the anal sphincter area in order to increase the surface area, which purportedly provides a better seal for the anal canal.

A dysfunctional internal anal sphincter can result in fecal incontinence. Previous preliminary attempts to restore functional continuity have included a cutaneous flap to fill an anal canal defect, as well as the use of bulking agents (e.g., polytetrafluoroethylene, collagen, or autologous fat). In a pilot study, Malouf et al (2001) evaluated the effectiveness of single or multiple injections of the silicone-based product Bioplastique for the symptoms of passive fecal incontinence caused by an anatomically disrupted or intact but weak internal anal sphincter. A total of 10 patients (4 men and 6 women; median age of 64
years with a range of 41 to 80 years) with passive incontinence secondary to a weak \( n = 6 \) or disrupted \( n = 4 \) internal anal sphincter were injected either circumferentially or at a single site, respectively. Patients were assessed before and 6 weeks after treatment by clinical assessment, 2-week bowel diary card, anorectal physiologic testing, and endoanal ultrasound. Patients failing to show improvement after the first injection were offered a second injection 6 weeks after the first injection. Clinical assessment was further repeated at 6 months, and 5 patients had a further ultrasound examination. At 6 weeks, 6/10 patients showed either marked improvement \( n = 3 \) or complete cessation of leakage \( n = 3 \). Another patient was greatly improved after a second injection. Three patients were not improved. At 6 months, 2/7 patients had maintained marked improvement, and 1 patient had maintained minor improvement; all of these 3 patients had circumferential multiple injections. Maximum resting and squeeze anal pressures did not differ significantly between before versus 6 weeks after versus 6 months after injection. At 6 weeks, endoanal ultrasound \( n = 9 \) confirmed the presence and correct position of the silicone in all but 1 patient who had experienced obvious external leakage of the product. At 6 months the silicone remained in the correct position in the 5 endosonographically assessed patients. Five of the initial patients experienced pain or minor ulceration at the injection site. These researchers concluded that although clinically effective immediately after injection, the benefit of an injectable biomaterial was maintained in only a minority of patients. This occurred despite the continued presence of material in the correct anatomical site. Patients with diffuse weakness treated by circumferential injection seemed to be the most responsive, but further studies are needed to clarify this finding.

Vaizey and Kamm (2005) noted that studies on the use of injectable bulking agents for the treatment of patients with fecal incontinence are mainly confined to a small number of pilot studies. The authors noted that although bulking agents have been used to treat urinary incontinence for more than 4 decades, their use in fecal incontinence has so far been limited. The large choice of products now available and the lack of a defined
injection strategy will hamper efforts to produce meaningful prospective, randomized controlled trials.

Maeda et al (2007) examined the long-term effectiveness of silicone biomaterial (PTQ; Uroplasty BV, Geleen, The Netherlands) injection in the treatment of fecal incontinence. Six patients (median age of 53 years at the time of injection with PTQ) were followed-up at 61 months. A validated fecal incontinence score, treatment-specific questionnaire and SF-36 health survey questionnaire were completed. At 61-month follow-up, 1 patient had undergone a colostomy for fecal incontinence. In the remaining 5 patients the incontinence score was little changed: 11 (8 to 20) versus 13 (9 to 19). However, there was a substantial improvement in physical and social function on the SF-36 scores. Satisfaction scores were high at a median 7 of 10 (range of 0 to 8). Subjectively, 3 patients were improved; 1 of them had undergone a further set of injections and 1 improved after a course of biofeedback. After the follow-up period, 1 of the 5 patients had a colostomy for recto-vaginal fistula. The authors concluded that the results of perianal injection of PTQ for passive fecal incontinence are variable in the long-term. They noted that more extensive evaluation in the short-term, and possibly repeated treatment, may be needed.

An assessment of injectable bulking agents for fecal incontinence by the National Institute for Health and Clinical Excellence (2007) concluded: "Current evidence on the safety and efficacy of injectable bulking agents for faecal incontinence does not appear adequate for this procedure to be used without special arrangements for consent and for audit or research, which should take place in the context of a clinical trial or formal audit protocol that includes information on well-defined patient groups."

In a pilot study, Dehli and co-workers (2007) reported the findings of a new bulking agent (hyaluronic acid and dextranomere) and a new injection technique for the treatment of fecal incontinence. An anoscope was used to inject Zuidex (4 x 1.4 ml) submucosally (proximal to the dentate line and distally to the puborectal muscle) in 4 patients with severe fecal incontinence, who were deemed unfit for other treatment. No anesthesia or antibiotic-
prophylaxis was used. All patients tolerated the treatment well, and there were no adverse events. The treatment had an effect in 3 of 4 patients; there was a median fall in St. Mark’s score of 3.5 points. The injection technique was well-tolerated, easy to perform within an outpatient setting and with promising short-term results. The method has been implemented in a randomized controlled trial.

Altomare and colleagues (2008) assessed the safety and effectiveness of carbon-coated microbeads (Durasphere) anal injection for the treatment of fecal incontinence. A total of 33 unselected patients with incontinence (24 females; mean age of 61.5 +/- 14 years; range of 22 to 83) underwent anal bulking agent submucosal injection with Durasphere in the outpatient regimen. The causes of incontinence were obstetric lesions in 18.2 %, iatrogenic in 36.4 %, rectal surgery in 12.1 %, and idiopathic in 33.3 %. Previous unsuccessful treatments for fecal incontinence included diet and drugs in 16 patients, biofeedback training in 7 patients, sacral nerve modulation in 6 patients, sphincteroplasty in 2 patients, artificial bowel sphincter in 1 patient, and PTQ macroplastique bulking agent in 1 patient. Under local anesthesia and antibiotic prophylaxis, a mean of 8.8 (range of 2 to 19) ml of Durasphere were injected into the submucosa by using a 1.5-inch, angled, 18-gauge needle. After a median follow-up of 20.8 months (range of 10 to 22), the median Cleveland Clinic continence score decreased significantly from 12 to 8 (p < 0.001) and the median American Medical System score from 89 to 73 (p = 0.0074), but the FIQL did not change significantly (74 to 76, p = not significant). Anal manometry significantly improved (resting pressure increasing from 34 to 42 mm Hg; p = 0.008) and squeezing pressure from 66 to 79 mm Hg (p = 0.04). Two patients complained of moderate anal pain for a few days after the implant, 1 patient had asymptomatic leakage of the injected material through a mucosa perforation, and 2 had distal migration of the Durasphere along the dentate line. The authors concluded that anal bulking agent injection is a safe treatment and can mitigate the severity of fecal incontinence by increasing anal pressure but does not significantly improve the QOL.
Ganio et al (2008) evaluated prospectively the effects of calcium hydroxylapatite ceramic microspheres (Coaptite) as a bulking agent to treat patients with passive fecal incontinence (n = 10). All patients were assessed by clinical examination, anal ultrasonography and anal manometry. The severity of incontinence and QOL were assessed using the Fecal Incontinence Scoring System (FISS) and FIQL questionnaire at baseline and at 3, 6 and 12 months after the Coaptite injection. Eight patients (80 %) had a marked improvement in continence, with a significant reduction in FISS from 85.6 +/- 9.4 to 28.0 +/- 29.0 (p = 0.008) at 12 months. There was an improvement in global QOL scores, which was significant in 3 subscales (lifestyle, coping/behavior and embarrassment). Manometry showed a significant improvement from baseline in the mean resting anal canal pressure after the Coaptite injection (p= 0.018). The authors concluded that Coaptite is a promising and safe bulking agent for the treatment of passive fecal incontinence.

Soerensen et al (2009) assessed the functional efficacy of intersphincteric injected silicone biomaterial (PTQ) in patients with fecal incontinence. A total of 33 patients (male-female ratio: 9:24; median age of 53 years (range of 21 to 75 years) with fecal incontinence of varied etiology were included in this study. The PTQ was injected under general anesthesia with antibiotic cover. All patients had anorectal manometry, endoanal ultrasonography and responded to fecal incontinence severity questionnaire (Wexner score) and SF-36 short-form health survey questionnaire before and 3 months post-operatively. At time of final follow-up, the continence status and QOL questionnaire were re-assessed. The mean follow-up was 12.9 months (range of 3 to 22 months). The Wexner Continence Score was significantly reduced short-term from 12.7 to 11.0 (p = 0.03) and long-term to 10.4 (p = 0.02). The long-term effect on liquid stool incontinence continued to improve significantly (p < 0.01). Six patients (18 %) reported major improvement in Wexner Continence Score at the time of final follow-up. Anorectal manometry was not affected except for the maximum tolerable rectal volume, which was significantly reduced (p < 0.05). The SF-36 short-form questionnaire showed no significant improvement in QOL after treatment with PTQ. The authors concluded that treatment with
inter-sphincteric injection of PTQ implants can provide improvement in patients with fecal incontinence of varied etiology. However, the improvement is mainly limited to soiling and minor leakage; and a majority of patients still have severe incontinence, both short-term and long-term.

In a preliminary study, Aigner and associates (2009) evaluated if the injection of carbon beads can significantly improve anal continence. Consecutive patients presenting with fecal incontinence were evaluated with standardized incontinence grading and QOL grading scores, by anoproctoscopy, endoanal ultrasound, and anomanometry before, 3, 6, 12, and 24 months after injection. Injection therapy was carried out in patients with anatomically intact anal sphincters. Patients kept a 2-week incontinence diary. Data were obtained from a 2-year follow-up period. A total of 11 women with a mean age of 66 years (range of 56 to 74) met the inclusion criteria. Mean incontinence score was 12.27 +/- 0.97 at baseline, 6.82 +/- 1.64 at 3-month, 6.73 +/- 1.47 at 6-month, 5.91 +/- 0.95 at 1-year, and 4.91 +/- 0.87 at 2-year follow-up (p = 0.003). Quality-of-life items like coping and embarrassment improved significantly from baseline 2.3 to 3.0 at 3 months and 2.8 at 6 months (p < 0.05). Anomanometry showed a trend toward increase in measured pressures. No major complications occurred. The authors concluded that the injection of carbon beads via an inter-sphincteric approach is a promising new treatment option for old patients with idiopathic fecal incontinence.

In a Cochrane review, Maeda and colleagues (2010) examined the effectiveness of perianal injection of bulking agents for the treatment of fecal incontinence in adults. All randomized or quasi-randomized controlled trials comparing use of injectable bulking agents for fecal incontinence with any alternative treatments or placebo were reviewed to evaluate the therapeutic effects. Case-control and cohort studies were also reviewed to assess risks and complications associated with the treatment. Two reviewers assessed the methodological quality of eligible trials and independently extracted data from included trials using a range of pre-specified outcome measures. Four eligible randomized trials were identified with a total of 176 patients. All
trials but 1 were at an uncertain or high risk of bias. Most trials reported a short-term benefit from injections regardless of the material used as outcome measures improved over time. A silicone biomaterial (PTQ), was shown to provide some advantages and was safer in treating fecal incontinence than carbon-coated beads (Durasphere) in the short-term. Similarly, there were short-term benefits from injections delivered under ultrasound guidance compared with digital guidance. However, PTQ did not demonstrate obvious clinical benefit compared to control injection of normal saline. No long-term evidence on outcomes was available and further conclusions were not warranted from the available data. The authors concluded that a definitive conclusion can not be drawn regarding the effectiveness of perianal injection of bulking agents for fecal incontinence due to the limited number of identified trials together with methodological weaknesses. Within the available data, however, these investigators found no reliable evidence for effectiveness of one treatment over another in improving fecal incontinence. They stated that larger well-designed trials with adequate numbers of subjects using reliable validated outcome measures are needed to allow definitive assessment of the treatment for both safety and effectiveness.

Graf et al (2011) stated that injection of a bulking agent in the anal canal is an increasingly used treatment for fecal incontinence, but effectiveness has not been shown in a controlled trial. These researchers evaluated the effectiveness of injection of dextranomer in stabilized hyaluronic acid (NASHA Dx) for treatment of fecal incontinence. In this randomized, double-blind, sham-controlled trial, patients aged 18 to 75 years from centers in United States and Europe were randomly assigned (2:1) to receive either transanal submucosal injections of NASHA Dx or sham injections. Randomization was stratified by sex and region in blocks of 6, and managed with a computer generated, real-time, web-based system. Patients and investigators were masked to assignment for 6 months when the effect on severity of fecal incontinence and quality of life was assessed with a 2-week diary and clinical assessments. The primary endpoint was response to treatment based on the number of incontinence episodes. A response to treatment was defined as a reduction in number of
episodes by 50 % or more. Patients in the active treatment group are still being followed-up. A total of 278 patients were screened for inclusion, of whom 206 were randomized to receive NASHA Dx (n = 136) or sham treatment (n = 70). A total of 71 patients who received NASHA Dx (52 %) had a 50 % or more reduction in the number of incontinence episode, compared with 22 patients who received sham treatment (31 %; OR 2·36, 95 % CI: 1·24 to 4·47, p = 0·0089). These investigators recorded 128 treatment-related adverse events, of which 2 were serious (1 rectal abscess and 1 prostatic abscess). The authors concluded that the role of injectable agents in the treatment algorithm for fecal incontinence is not established. They stated that a refinement of selection criteria for patients, optimum injected dose, ideal site of injection, and long-term results might further increase the acceptance of this minimally invasive treatment.

Commenting on the study by Graf et al (2011), Norton (2011) stated that "Graf and colleagues' study as published, would be difficult to replicate because there is little detailed information about characterisation of patients' symptoms (did the patients report passive, urge, or both symptoms of faecal incontinence?). Other data not reported include changes in objective criteria such as anal pressures, ultrasound appearance, or sensation, which might give clues about the mechanism of action. How many patients had functional or structural impairment of the internal anal sphincter was not reported, nor how many faecal incontinence secondary to loose stool. If the treatment's presumed mechanism of action is sphincter occlusion, some categories of faecal incontinence would have little potential for benefit. So, although Graf and colleagues' study might change the conclusion of an updated Cochrane review on the subject, should it change clinical practice? Maybe, but until we ask patients what they think, we cannot be sure whether a statistically significant result will actually change peoples' lives".

On May 27, 2011, the FDA approved Solesta, a sterile, injectable dextranomer hyaluronic acid gel to treat fecal incontinence (FI). The Solesta gel is injected into a layer of tissue beneath the anus lining and may help build tissue in that area. By growing the surrounding tissue, the opening of the anus narrows and the
patient may be able to better control those muscles. The FDA based its approval on results from a clinical study of 206 patients. In the primary study, most patients received 2 treatments, consisting of 4 injections each, for a total of 8 injections. After 6 months, more than half of the patients injected with Solesta experienced a 50% reduction in the number of FI episodes. However, one-third of patients who received no Solesta in the study also experienced a similar reduction. Overall, a greater proportion of patients treated with Solesta experienced improvements, indicating the gel provides benefit. Solesta is approved for use in patients aged 18 years and older who have failed conservative therapies (e.g., diet change, fiber therapy or anti-motility medications) failed. It should not be used in patients who have active inflammatory bowel disease, immunodeficiency disorders, previous radiation treatment to the pelvic area, significant rectal prolapse, active infections, bleeding, tumors or malformations in the anorectal area, rectal distended veins, an existing implant in the anorectal region, or allergy to hyaluronic acid based products. The most common side effects associated with Solesta include injection area pain and bleeding. Infection and inflammation of anal tissue are more serious risks, but are less common.

In a systematic review, Luo et al (2010) examined the safety and effectiveness of injectable bulking agents for passive FI in adults. Electronic searches were performed for MEDLINE, EMBASE, ISI Web of Knowledge and other relevant databases. Hand searching of relevant conference proceedings was undertaken. Studies were considered if they met the pre-defined inclusion criteria of more than 10 adult patients and receiving an injectable bulking agent for passive FI with a validated means of assessing pre-operative and post-operative incontinence. A total of 13 case series studies and 1 randomized controlled trial (RCT) were included with a total of 420 patients. Two completed RCTs with placebo control were identified but results were unobtainable. Coaptite, Contigen, Durasphere (carbon-coated beads), EVOH and PTQ (silicone biomaterial) injections were assessed with 24, 73, 83, 21 and 208 patients respectively. Most studies reported a statistically significant improvement in incontinence scores and quality of life. No statistically significant difference was found
between the treatment and placebo arms in the RCT. No serious adverse events were reported. The authors concluded that currently there is little evidence for the effectiveness of injectable bulking agents in managing passive FI. The inability to obtain results from 2 further RCTs concerned the reviewers and hindered their ability to make strong recommendations. The identified injectable bulking agents appear to be safe with only minor complications reported.

Schwandner et al (2011) analyzed safety and functional outcome of transanal submucosal injection of dextranomer hyaluronic acid ("bulking agents therapy") in patients with passive FI. All patients who underwent transanal injection therapy were prospectively enrolled in this study. Inclusion criteria included FI (internal anal sphincter dysfunction) after failed conservative treatment. The procedure was performed in a standardized technique, including submucosal injection of 4 × 1 mL dextranomer hyaluronic acid 5 mm above the dentate line. The primary endpoint focused on symptom improvement provided as the change in incontinence status and quality of life using validated scores (Wexner incontinence score, symptom-specific Fecal Incontinence Quality of Life [FIQoL] scale, and generic EQ-5D-Visual Analogue Scale [EQ-5D-VAS]). Within the observation period (July 2007 to May 2009), a total of 21 patients (17 women) with passive FI were treated. Neither morbidity nor adverse events were documented. Three months post-operatively, 61.1 % (11/18) showed significant improvement of symptoms (reduction of incontinence episodes and soiling), which was sustained after 20 months in 55.6 % (10/18). Wexner incontinence score decreased from 16.8 to 12.3 (p > 0.05). Significant improvement was documented for FIQoL and EQ-5D-VAS (p < 0.05). The authors concluded that these findings indicated that injection therapy using hyaluronic acid is an innovative and minimally invasive procedure with no morbidity. Although Wexner incontinence score is not significantly influenced, a significant improvement in quality of life was observed in more than 50 % of patients.

Leung (2011) stated that novel treatments are needed to augment medical therapy for fecal incontinence. The author reviewed observational studies (OS) and RCTs related to injection
of bulking agent for the treatment of FI. A total of 22 observational studies and 4 RCTs were identified. OS mostly with limited sample sizes reported promising results. Repeated injection was necessary in some patients. Effect on anal sphincter pressures was highly variable. Significant improvements in the length of anal high-pressure zone, asymmetry index and maximum tolerable rectal volume were suggested. Four RCTs (n = 176) revealed: (i) Short-term benefits from injection of Bioplastique under ultrasound guidance compared with digital guidance; (ii) Silicone biomaterial (PTQ) provided some advantages and was safer than carbon-coated beads (Durasphere); (iii) PTQ did not demonstrate clinical benefit compared to control injection of saline; and (iv) There was significant improvement at 6 weeks post-injection, but no difference between Bulkamid and Permacol. A 2010 Cochrane review, however, noted that these data were inconclusive due to limited number and methodological weaknesses. The author concluded that further studies are needed to assess patient-centered outcomes (e.g., adequate relief) in addition to the attenuation of severity of incontinence symptoms in ambulatory patients. In nursing home residents, cost-effectiveness studies combining injection treatment and prompted voiding (to mitigate constraints of immobility and dementia) in preventing peri-anal skin complications deserves to be considered.

Ullah et al (2011) examined the safety and effectiveness of injectable bulking agents for the management of FI. A total of 13 procedures were performed on 11 patients with FI during 2002 to 2007. Patients with internal anal sphincter defect and low incontinence score (Cleveland score less than 10) revealed improvement. Patients with higher incontinence score and external sphincter defect secondary to obstetric damage required further intervention. At a median follow-up of 43 months, 7 (63 %) patients showed improvement in incontinence score and 4 (32 %) showed marked improvement in their symptoms. Fifty six percent of the patients described this as an effective procedure, though the level of effectiveness varied from person to person. Anal injectable collagen was found safe and effective in the management of FI. The authors concluded that long-term follow-ups are needed to re assess and consider definitive procedure in
failed cases.

An UpToDate review on "Treatment of chronic functional constipation and fecal incontinence in infants and children" (Ferry, 2012) does not mention the use of bulking agents in the treatment of FI. Moreover, an UpToDate review on "Fecal incontinence in adults" (Robson and Lembo, 2012) states that "Injection of dextranomer/hyaluronic acid (Solesta™) is used for the treatment of urinary incontinence and has been studied in patients with fecal incontinence. Studies suggest dextranomer/hyaluronic acid is effective for the treatment of fecal incontinence". However, the authors did not include injectable bulking agents in the "Summary and Recommendations" of this review.

Furthermore, the National Association For Continence (NAFC, 2012) lists injectable bulking agents (Solesta) as one of the less invasive surgical options that offer promise for selected patients. The NAFC also lists phenylephrine gel (for improvement in resting tone of anal muscles) as one of the treatments undergoing testing.

Hoy and colleagues (2012) noted that dextranomer in stabilized sodium hyaluronate (Solesta), hereafter referred to as dextranomer/hyaluronic acid, is a biocompatible bulking agent administered by submucosal injection. It is hypothesized to expand the submucosal layer of the proximal anal canal, thereby augmenting bowel control. Treatment with dextranomer/hyaluronic acid was associated with symptomatic improvements in adult patients with fecal incontinence participating in a randomized, double-blind, sham-controlled, multi-national study as well as a non-comparative, multinational study. In the double-blind study, patients in the dextranomer/hyaluronic acid group met the primary efficacy objective in that a significantly higher proportion of patients responded to treatment (greater than or equal to 50 % reduction from baseline in the number of incontinence episodes) at the 6-month post-treatment time-point than in the sham group (2 of 3 primary response criteria), with the durability of the treatment response (greater than or equal to 25 % reduction from baseline...
in the number of incontinence episodes) confirmed at the 12-month post-treatment time-point (3rd primary response criterion). For the most part, dextranomer/hyaluronic acid did not significantly differ from the sham treatment in terms of quality of life and various other symptomatic endpoints at 6 months post-treatment in the double-blind study, although there were significant improvements from baseline in various parameters, such as the mean number of incontinence-free days, the median number of incontinence episodes and mean Fecal Incontinence Quality of Life domain scores, at 12 months post-treatment. In general, dextranomer/hyaluronic acid was well-tolerated for up to 18 months post-treatment, with the majority of treatment-related adverse events considered mild or moderate in intensity.

In an Agency for Healthcare Research and Quality’s report (AHRQ, 2012), a total of 7 experts, with clinical, research, and health systems backgrounds, offered perspectives on the use of Solesta for the treatment of FI. The experts generally agreed that an important unmet need exists for effective fecal incontinence treatment for this patient population, based on the current lack of effective therapies and their associated cost and risk of adverse events. One clinical expert opined that few patients seek proper care for fecal incontinence and that those patients who seek treatment often receive conservative treatment or no treatment at all. However, one expert opined that effective alternative therapies and “protective garments” are available for fecal incontinence management and that the need for improved options was incremental. Most experts stated this intervention has potential to improve health outcomes. Basing their opinions on preliminary results, they thought the tissue-bulking agent would not always completely resolve fecal incontinence. Most experts wanted to see additional trial results. One expert with a clinical perspective found it difficult to determine this intervention’s potential to improve health outcomes, stating that “This will not work for everyone. Those with muscle disruptions will probably need surgery. Even ‘perfect’ candidates will sometimes not be successful”. Experts generally agreed that this intervention has the potential to affect the current care model and patient management and to shift care setting from inpatient
surgery to office visits. One clinical expert opined that if this treatment is proven effective, it has the potential to dramatically shift the staff needed to treat the condition, because colorectal surgeons who perform the surgical procedures would be supplanted by gastroenterologists delivering minimally invasive injections during an office visit. Another clinical expert commented on this intervention’s potential to “reduce the number of individuals needed to care for incontinent patients (decreased number of aides, LPNs [licensed practical nurses], etc.). It would also decrease the individual’s costs for cleaning materials and local treatments (e.g., creams and ointments”). One research expert added that this intervention would reduce the number of procedures performed in operating rooms.

In a Cochrane review, Maeda et al (2013) examined the effectiveness of perianal injection of bulking agents for the treatment of fecal incontinence in adults. These investigators searched the Cochrane Incontinence Group Specialised Register of trials (May 25, 2012), ZETOC (May 3, 2012), clinical trials registries (May 3, 2012) and the reference lists of relevant articles. All randomized or quasi-randomized controlled trials comparing the use of injectable bulking agents for fecal incontinence with any alternative treatments or placebo were reviewed to evaluate the therapeutic effects. Case-control and cohort studies were also reviewed to assess risks and complications associated with the treatments. Two review authors assessed the methodological quality of eligible trials and independently extracted data from the included trials using a range of pre-specified outcome measures. A total of 5 eligible randomized trials with a total of 382 patients were identified; 4 of the trials were at an uncertain or high-risk of bias. Most trials reported a short-term benefit from injections regardless of the material used, including placebo saline injection. One study demonstrated dextranomer in stabilized hyaluronic acid (NASHA Dx) to be more effective than sham injection but with more adverse effects. Dextranomer in stabilized hyaluronic acid (NASHA Dx) was better than sham injections at 6 months (65/136, 48 % versus 48/70, 69 % participants not improved, defined as less than 50 % reduction in incontinence episodes, RR 0.70, 95 % CI: 0.55 to 0.88; with more incontinence free days (3.1 days
compared with 1.7 in the sham treatment group, MD 1.40 days, 95 % CI: 0.33 to 2.47). Another study comparing silicone material (PTQ™) to saline injections was too small to demonstrate a clinical benefit compared to the control injection of normal saline. A silicone biomaterial (PTQ™) was shown to provide some advantages and was safer in treating fecal incontinence than carbon-coated beads (Durasphere®) in the short-term. Similarly, there were short-term benefits from injections delivered under ultrasound guidance compared with digital guidance. No long-term evidence on outcomes was available and further conclusions were not warranted from the available data. None of the studies reported patient evaluation of outcomes and thus it is difficult to gauge whether the improvement in incontinence scores matched practical symptom improvements that mattered to the patients. The authors concluded that 1 large randomized controlled trial has shown that this form of treatment using dextranomer in stabilized hyaluronic acid (NASHA Dx) improves continence for a little over 50 % of patients in the short-term. However, the number of identified trials was limited and most had methodological weaknesses.

Nandivada and Nagle (2014) reviewed the most recent surgical options for the treatment of FI within the context of established therapies. Overlapping sphincteroplasty is an established therapy that improves continence and QOL, although results deteriorate over time. Implanted artificial bowel sphincter has a 100 % complication rate and 80 % are explanted over time. Sacral nerve stimulation has minimal risk and more durable long-term improvement in continence. Less invasive versions of nerve stimulation are being researched. Injectable biomaterials have shown some promise, although durability of results is not clear. Novel therapies, including muscle cell transfer and pelvic slings are currently being investigated. The authors concluded that surgical therapies for FI continue to evolve and show promise in improving QOL with a lower risk profile. Effective valuation of these therapies is currently limited by heterogeneous studies, short duration of follow-up, and inconsistent outcome measures.

An UpToDate review on “Fecal incontinence in adults: Management” (Robson and Lembo, 2015a) stated that “Injectable
anal bulking agents -- It is hypothesized that injection of anal bulking agents may enhance resting anal pressures and thereby improve fecal continence, especially in patients with passive fecal incontinence. Studies suggest that dextranomer stabilized in hyaluronic acid has limited efficacy in the treatment of fecal incontinence in the short term. Long-term follow-up data are lacking”.

In a systematic review and meta-analysis, Hong and colleagues (2017) examined the mid-term outcomes of treatment with injectable bulking agents and identified predictive factors for improvement in FI. PubMed, Embase, Web of Science, and Cochrane Library databases were searched using the terms injection, bulking agents, and fecal incontinence. Studies with a minimum follow-up of 1 year were included. The improvement rate in FI was calculated by percent change in validated FIS following injection treatment. To explore the impact of predictive factors on improvement in incontinence, univariate meta-regressions were conducted using the random-effect model. A total of 889 patients in 23 articles were included. The weighted mean follow-up duration was 23.7 months (95 % CI: 19.3 to 28.2); 11 different bulking agents were used and 4 validated FISs were used. The Cleveland Clinic Fecal Incontinence score (CC-FIS) was used in 19 studies. Most studies reported a statistically significant improvement in FIS. The pooled mean pre-operative CC-FIS (n = 637) was 12.4 (95 % CI: 11.4 to 13.3). The pooled mean CC-FIS at last follow-up (n = 590) was 7.7 (95 % CI: 6.1 to 9.3). The weighted mean difference in CC-FIS between pre-operative visit and last follow-up was 4.9 (95 % CI: 4.0-5.8). Hence, the rate of improvement in FI was 39.5 % based on CC-FIS. Meta-regression revealed that the peri-anal injection route and implants intact on endo-anal ultrasonography were predictive of greater improvement in incontinence. The manometric data revealed that the initial increase in the mean resting pressure following injection was attenuated over time. The pooled rate of adverse events (AEs) was 18.0 % (95 % CI: 10.0 to 30.1). In most cases, AEs were minor and resolved within a couple of weeks. The authors concluded that administration of injectable bulking agents resulted in significant mid-term improvement in FIS. They stated that peri-anal injection route and implants intact on EAUS
were predictive of higher improvement in FI; however, given the paucity of RCTs in the literature, further research is needed to improve the quality of the evidence.

Injection of Autologous Myoblast Cells/Mesenchymal Stem Cells:

In a pilot study, Frudinger and colleagues (2010) examined the effectiveness of injection of autologous myoblast cells in the treatment of anal incontinence as a result of obstetric trauma. A total of 10 women suffering from anal incontinence due to obstetric anal sphincter injury, refractory to conventional non-surgical therapy were included in this study. Autologous myoblasts were cultured from a pectoralis muscle biopsy, harvested, and injected into the external anal sphincter defect using direct ultrasound guidance. Main outcome measures included Wexner incontinence score, anal squeeze pressures, and QOL 12 months after injection. The procedure was well-tolerated and no adverse events were observed. At 12 months the Wexner incontinence score had decreased by a mean of 13.7 units (95% CI: -16.3 to -11.2), anal squeeze pressures were unchanged, and overall QOL scores improved by a median of 30 points (95% CI: 25 to 42). Anal squeeze pressures rose significantly at 1 month and 6 months post-injection (p = 0.03). The authors concluded that injection of autologous myoblasts is safe, well-tolerated, and significantly improves symptoms of anal incontinence due to obstetric anal sphincter trauma. The findings of this small pilot study need to be validated by well-designed studies.

Park et al (2016) examined the safety and effectiveness of using allogeneic-adipose-derived mesenchymal stem cells in the treatment of the anal sphincter of patients with FI. This study is a randomized, prospective, dose escalation, placebo-controlled, single-blinded, single-center trial with 2 parallel groups. The safety test is performed by an injection of allogeneic-adipose-derived mesenchymal stem cells (ALLO-ASCs) into the anal sphincter with dose escalation (3 × 10(7), 6 × 10(7) and 9 × 10(7) cells, sequentially). After confirming the safety of the stem cells, an effectiveness test is performed by this dose in the experimental group. The experimental group will receive ALLO-
ASCs mixed with fibrin glue into the anal sphincter, and the placebo group will receive 0.9 % normal saline injection mixed with fibrin glue. The primary end-point is to evaluate the safety of ALLO-ASCs after the injection into the anal sphincter, and the secondary end-point is to compare the efficacy of ALLO-ASC injection with fibrin glue in patients with FI. The study protocol was approved by the Ministry of Food and Drug Safety and the Ministry of Health & Welfare, in the Republic of Korea. The informed consent form was approved by the institutional review board of Gangnam Severance Hospital (IRB approval number 3-2014-0271). Dissemination of the results will be presented at a conference and in peer-reviewed publications.

**Topical Estrogen:**

In a prospective, randomized, double-blind study, Pinedo and co-workers (2009) evaluated the effect of topical estrogens (TE) in controlling symptoms of fecal incontinence in post-menopausal women. Patients were randomized into 2 groups: (i) topical estriol, and (ii) placebo. In both groups, the ointment was applied 3 times daily for a period of 6 weeks. Wexner's fecal incontinence score and the fecal incontinence QOL scale were compared before commencing and after 6 weeks of TE application. A total of 36 patients were evaluated (average age of 67 years; range of 48 to 84). Group (i): 18 patients and group (ii): 18 patients, 1 patient was excluded. Wexner's fecal incontinence score in group (i) was 11 (5 to 18) and 7 (0 to 19) with pre- and post-application, respectively (p = 0.002). Wexner's fecal incontinence score in group (ii) was 12 and 9 with pre- and post-application, respectively (p = 0.013). When results between both groups were compared, these were not statistically significant (p = 0.521). The authors concluded that there is improvement of continence in both groups that had the ointment applied; nonetheless this study could not show that TE improves fecal incontinence more than a placebo does.

**Posterior Tibial Nerve Stimulation:**

In percutaneous tibial nerve stimulation (PTNS) (eg, Urgent PC, Nuro Neuromodulation System) a nonimplanted electrode is
utilized to produce tibial nerve stimulation that purportedly travels to the sacral nerve plexus to control incontinence.

Findlay and Maxwell-Armstrong (2011) stated that fecal incontinence is a common and important multi-factorial disorder with a range of treatment options. Over the last 2 decades, neuromodulation via sacral nerve stimulators has been shown to be effective for both fecal and urinary incontinence, although associated with complications. Peripheral neuromodulation, via the posterior tibial nerve, is widely used in urinary incontinence; however, its use in fecal incontinence, while evolving is limited to 8 small heterogeneous studies. These 8 studies were discussed in the context of the methodology and underlying neurophysiology of peripheral neuromodulation, as are thus far unanswered questions. The 8 studies include a total of 129 patients with fecal incontinence (of variable etiology), all of whom had failed conservative management. One study was prospective and controlled, 6 were uncontrolled and 1 was retrospective and uncontrolled. Five different neuromodulatory protocols were used over 6 different study periods. Outcome measures varied, but short-term primary end point success ranged from 30.0 % to 83.3 %. The limitations to this early evidence, while encouraging, are significant, and it remains to be seen whether this novel treatment modality represents the minimally invasive, well-tolerated, cost-effective and flexible panacea hoped for this common and debilitating disease. The authors noted that 3 upcoming multi-center, placebo-controlled trials will better be able to delineate its role.

Thomas et al (2013) evaluated the published results of posterior tibial nerve stimulation for FI. A search was performed of PubMed, MEDLINE and Embase to identify studies describing the clinical outcome of posterior tibial nerve stimulation for FI. A total of 13 studies were identified. These described the outcome of posterior tibial nerve stimulation for FI in 273 patients; 4 described transcutaneous posterior tibial nerve stimulation (TTNS), 8 percutaneous posterior tibial nerve stimulation (PTNS) and 1 compared both methods of posterior tibial nerve stimulation with a sham transcutaneous group. One investigated patients with FI and spinal cord injury and another with
inflammatory bowel disease. There was marked heterogeneity of the treatment regimens and of the end-points used. All reported that posterior tibial nerve stimulation improved FI. A greater than 50% improvement was reported in episodes of FI in 63 to 82% of patients. An improvement was seen in urgency (1 to 5 mins). Improvement was also described in the Cleveland Clinic fecal incontinence score in 8 studies. Patients with urge and mixed incontinence appear to benefit more than those with passive incontinence. Treatment regimens ranged in duration from 1 to 3 months. A residual therapeutic effect is seen after completion of treatment. Follow-up ranged from 1 to 30 months. The authors concluded that posterior tibial nerve stimulation is effective for FI. However, many of the published studies are of poor quality. Comparison between studies was difficult owing to differences in the outcome measures used, technique of posterior tibial nerve stimulation and the timing and duration of treatment.

Horrocks and colleagues (2014) noted that 2 forms of posterior tibial nerve stimulation are used to treat FI: (i) PTNS and (ii) TTNS. These investigators appraised the literature on both procedures. A systematic review was performed adhering to the PRISMA framework. A comprehensive literature search was conducted, with systematic methodological quality assessment and data extraction. Summary measures for individual outcome variables were reported. A total of 12 articles met eligibility criteria; 6 related to PTNS, 5 to TTNS, and 1 to both procedures. These included 10 case series and 2 RCTs. Case series were evaluated using the National Institute for Health and Care Excellence quality assessment for case series, scoring 3 to 6 of 8. Randomized controlled trials were evaluated using the Jadad score, scoring 4 of a possible 5 marks, and the Cochrane Collaboration bias assessment tool. From 1 RCT and case series reports, the success rate of PTNS, based on the proportion of patients who achieved a reduction in weekly FI episodes of at least 50%, was 63 to 82%, and that of TTNS was 0 to 45%. In a RCT of TTNS versus sham, no patient had a reduction in weekly FI episodes of 50% or more, whereas in a RCT of PTNS versus TTNS versus sham, 82% of patients undergoing PTNS, 45% of those having TTNS, and 13% of patients in the sham group had
treatment success. The authors concluded that PTNS and TTNS resulted in significant improvements in some outcome measures; however, TTNS was not superior to sham stimulation in a large, adequately powered, RCT. Moreover, they stated that as no adequate RCT of PTNS versus sham has been conducted, conclusions cannot be drawn regarding this treatment.

Edenfield et al (2015) systematically reviewed the literature regarding the effectiveness of PTNS as a treatment of FI. These investigators searched MEDLINE/PubMed, EMBASE, and Cochrane databases from inception through November 2013. They included English-language full-text articles reporting outcomes for FI with either percutaneous PTNS or transcutaneous techniques (TENS). They used the Grades of Recommendation, Assessment, Development, and Evaluation (GRADE) system to assess study quality. The search yielded 1,154 citations; 129 abstracts and 17 articles were included for full-text review. There were 13 case series and 4 RCTs; 15 studies were of low quality, none was of fair quality, and 2 studies were of good quality based on the GRADE system. In total, 745 subjects were studied, and of those, 90% were women and 10% were men. Studies involved percutaneous PTNS in 57% (428/745) of the subjects, TENS in 30% (223/745), and sham technique in 13% (94/745). Therapy frequency, maintenance therapy, and follow-up time varied across studies. A total of 11 studies assessed FI episodes and bowel movement deferment time; all but 1 showed statistical improvement after therapy; 10 of the 11 studies that used the Cleveland Clinic Florida Fecal Incontinence score reported statistically significantly improved scores after treatment. The authors concluded that multiple low-quality studies showed improvement in FI after PTNS. They stated that high-quality studies with comparison groups and clinically meaningful outcome measures would further establish the utility of PTNS for FI.

In a multi-center, parallel-arm, double-blind, RCT, Horrocks et al (2015) evaluated the effectiveness of PTNS compared with sham electrical stimulation in the treatment of patients with FI in whom initial conservative strategies have failed. Participants aged greater than 18 years with FI who have failed conservative
treatments and whose symptoms were sufficiently severe to merit further intervention were included in this study; PTNS was delivered via the Urgent(®) PC device (Uroplasty Limited, Manchester, UK), a hand-held pulse generator unit, with single-use leads and fine-needle electrodes. The needle was inserted near the tibial nerve on the right leg adhering to the manufacturer's protocol (and specialist training). Treatment was for 30 minutes weekly for a duration of 12 treatments. Validated sham stimulation involved insertion of the Urgent PC needle subcutaneously at the same site with electrical stimulation delivered to the distal foot using transcutaneous electrical nerve stimulation. Outcome measures were assessed at baseline and 2 weeks following treatment. Clinical outcomes were derived from bowel diaries and validated, investigator-administered questionnaires. The primary outcome classified patients as responders or non-responders, with a responder defined as someone having achieved greater than or equal to 50 % reduction in weekly FI episodes (FIEs). A total of 227 patients were randomized from 373 screened: 115 received PTNS and 112 received sham stimulation. There were 12 trial withdrawals: 7 from the PTNS arm and 5 from the sham arm. Missing data were multiply imputed. For the primary outcome, the proportion of patients achieving a greater than or equal to 50 % reduction in weekly FIEs was similar in both arms: 39 in the PTNS arm (38 %) compared with 32 in the sham arm (31 %) [odds ratio 1.28, 95 % CI: 0.72 to 2.28; p = 0.396]. For the secondary outcomes, significantly greater decreases in weekly FIEs were observed in the PTNS arm than in the sham arm (beta -2.3, 95 % CI: -4.2 to -0.3; p = 0.02), comprising a reduction in urge FIEs (p = 0.02) rather than passive FIEs (p = 0.23). No significant differences were found in the St Mark's Continence Score or any QOL measures. No serious adverse events related to treatment were reported. The authors concluded that PTNS did not show significant clinical benefit over sham electrical stimulation in the treatment of FI based on number of patients who received at least a 50 % reduction in weekly FIE. It would be difficult to recommend this therapy for the patient population studied.

Pudendal Nerve Terminal Motor Latency:
Pudendal nerve terminal motor latency (PNTML) measures the neuromuscular integrity between the terminal portion of the terminal nerve and the anal sphincter. This test is utilized to determine if there is weak sphincter muscle.

Pudendal nerve terminal motor latency (PNTML) is determined by measuring the time required after stimulating the pudendal nerves with an electrode as it crosses the ischial spine to induce a contraction of the external anal sphincter. Normal delay is approximately 2.0 msec; prolongation of the PNTML suggests damage to the nerve. However, this technique is operator-dependent and has poor correlation with clinical symptoms and histologic findings. Guidelines from the American Gastroenterological Association (1999) stated "The PNTML cannot be recommended for evaluation of patients with fecal incontinence".

An UpToDate review on “Functional fecal incontinence in infants and children: Definition, clinical manifestations and evaluation” (Sood, 2015) does not mention the use of PNTML measurements. Furthermore, an UpToDate review on “Fecal incontinence in adults: Etiology and evaluation” (Robson and Lembo, 2015b) states that “Pudendal nerve terminal latency (PNTL) and saline infusion test have no role in the evaluation of fecal incontinence”.

**Rectal Banding:**

An UpToDate review on “Fecal incontinence in adults: Management” (Robson and Lembo, 2015a) does not mention rectal banding as a therapeutic option.

**Surgical Treatments:**

Meyer and Richter (2016) noted that surgical management of FI is considered invasive and provided only short-term success with high complication rates. Recent research has provided additional data on the existing treatments as well as the development of less invasive options and new investigational treatments.

Forte and colleagues (2016) evaluated the effectiveness,
comparative effectiveness, and harms of surgical treatments for FI in adults. Ovid Medline, Embase, Physiotherapy Evidence Database, Cumulative Index to Nursing and Allied Health Literature, Allied and Complementary Medicine, and the Cochrane Central Register of Controlled Trials, as well as hand searches of systematic reviews, were used as data sources. Two investigators screened abstracts for eligibility (surgical treatment of FI in adults, published 1980 to 2015, RCT or observational study with comparator; case series were included for AEs). Full-text articles were reviewed for patient-reported outcomes. These researchers extracted data, assessed study risk of bias, and evaluated strength of evidence for each treatment-outcome combination. Main outcome measures were FI episodes/severity, QOL, urgency, and pain were measured. A total of 22 studies met inclusion criteria (13 randomized trials and 9 observational trials); 53 case series were included for harms. Most patients were middle-aged women with mixed FI etiologies. Intervention and outcome heterogeneity precluded meta-analysis. Evidence was insufficient for all of the surgical comparisons. Few studies examined the same comparisons; no studies were high quality. Functional improvements varied; some authors excluded those patients with complications or lost to follow-up from analyses. Complications ranged from minor to major (infection, bowel obstruction, perforation, and fistula) and were most frequent after the artificial bowel sphincter (22% to 100%). Major surgical complications often required re-operation; few required permanent colostomy. The authors concluded that available evidence was insufficient to support clinical or policy decisions for any surgical treatments for FI in adults. More invasive surgical procedures had substantial complications. The lack of compliance with study reporting standards is a modifiable impediment in the field. They stated that future studies should focus on longer-term outcomes and attempt to identify subgroups of adults who might benefit from specific procedures. The major drawbacks of this study were: (i) most evidence was intermediate term, (ii) small patient samples and (iii) substantial methodological limitations.

An UpToDate review on “Fecal incontinence in adults: Management” (Robson and Lembo, 2017) states that “Although
implantation of an artificial sphincter device has been associated with a clinically significant improvement in fecal continence, its use is limited by complications including explantation in up to 1/3 of patients ... Diversion of the fecal stream with a colostomy is the only option in patients with intractable symptoms who are not candidates for any other therapy, or in whom other treatments have failed ... Surgical placement of a perianal sling designed to enhance the anorectal angle may be a potential option for patients, but additional studies are needed”.

**Pubo-Rectal Sling:**

In a pilot study, Brochard and associates (2017) described the use of a pubo-rectal sling (placed via a trans-obturator approach with a device used for vaginal vault prolapse) for the treatment of FI and reported long-term outcome at 5 years. A total of 6 women with FI for whom usual treatments (including sacral nerve stimulation) have failed were enrolled in this study. Cleveland Clinic Incontinence Score (CCIS) and FIQL were used to evaluate results. The median CCIS was significantly improved at 12 months (18.5 [15 to 20] versus 7.5 [4 to 20] in post-operative assessment; p = 0.037). The median FIQL was improved at 12 months (6.05 [5.6 to 7] versus 10.2 [5.6 to 12.5]; p = 0.0542). No AE was recorded except the distension of the device in 1 patient. Finally, at 5 years, 3 patients were improved, 1 had recurrence of FI symptoms (at 24 months) and 2 had no change. The authors concluded that this technique is a minimally invasive surgical treatment and constitutes a new therapeutic option for FI in case of failure of conventional treatment. The preliminary findings of this pilot study need to be validated by well-designed studies.

**Fenix Continence Restoration System:**

DeStephano and colleagues (2017) reported a new technique for the surgical management of FI using the Fenix Continence Restoration System in 2 patients. The Fenix System received FDA approval under a humanitarian device exemption and can be used with institutional review board approval in patients who have failed previous medical and surgical management of FI. The device is a small, flexible band of interlinked titanium, magnetic
beads on a titanium string that is placed using a perineal approach around the anal canal. Increased intra-abdominal pressure opens the beads to allow for passage of stool. Placement of the device was performed in 2 patients. Case 1 was a 63-year old female with a long-standing history of FI who failed sphincteroplasty, sacral neuromodulation, and an artificial sphincter cuff and pump. Case 2 was a 60-year old female with a long-standing history of FI secondary to radiation therapy for rectal cancer who failed physical therapy and sacral neuromodulation. The authors concluded that both Fenix Continence Restoration Systems were placed successfully; long-term post-operative effectiveness is currently being evaluated.

### CPT Codes / HCPCS Codes / ICD-10 Codes

**Information in the [brackets] below has been added for clarification purposes. Codes requiring a 7th character are represented by "+":**

#### CPT codes covered if selection criteria are met:

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>64561</td>
<td>Percutaneous implantation of neurostimulator electrode array; sacral nerve (transforaminal placement) including image guidance, if performed</td>
</tr>
<tr>
<td>64581</td>
<td>Incision for implantation of neurostimulator electrodes; sacral nerve (transforaminal placement)</td>
</tr>
<tr>
<td>64590</td>
<td>Insertion or replacement of peripheral or gastric neurostimulator pulse generator or receiver, direct or inductive coupling</td>
</tr>
<tr>
<td>95972</td>
<td>Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude, pulse duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); complex spinal cord, or peripheral (ie, peripheral nerve, sacral nerve, neuromuscular) (except cranial nerve) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming</td>
</tr>
</tbody>
</table>

#### CPT codes not covered for indications listed in the CPB:

*Mesenchymal stem cell injection - no specific code:*
0288T Anoscopy, with delivery of thermal energy to the muscle of the anal canal (e.g., for fecal incontinence)

0377T Anoscopy with directed submucosal injection of bulking agent for fecal incontinence

11950 - 11954 Subcutaneous injection of filling material (e.g., collagen)

64566 Posterior tibial neurostimulation, percutaneous needle electrode, single treatment, includes programming

**Other CPT codes related to the CPB:**

46750 - 46751 Sphincteroplasty, anal, for incontinence or prolapse; adult or child

46760 - 46762 Sphincteroplasty, anal, for incontinence, adult; muscle transplant; levator muscle imbrication (Park posterior anal repair); or implantation artificial sphincter

64550 Application of surface (transcutaneous) neurostimulator

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

97110 Therapeutic procedure, one or more areas, each 15 minutes; therapeutic exercises to develop strength and endurance, range of motion and flexibility

97530 Therapeutic activities, direct (one-on-one) patient contact (use of dynamic activities to improve functional performance), each 15 minutes

97802 - 97804 Medical nutrition therapy

**There is no specific HCPCS code for the Acticon Neosphincter:**

**HCPCS codes covered if selection criteria are met:**

L8680 Implantable neurostimulator electrode, each

L8681 Patient programmer (external) for use with implantable programmable implantable neurostimulator pulse generator

L8682 Implantable neurostimulator radiofrequency receiver

L8683 Radiofrequency transmitter (external) for use with implantable neurostimulator radiofrequency receiver
<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>L8684</td>
<td>Radiofrequency transmitter (external) for use with implantable sacral root neurostimulator receiver for bowel and bladder management, replacement</td>
</tr>
<tr>
<td>L8685</td>
<td>Implantable neurostimulator pulse generator, single array, rechargeable, includes extension</td>
</tr>
<tr>
<td>L8686</td>
<td>Implantable neurostimulator pulse generator, single array, non-rechargeable, includes extension</td>
</tr>
<tr>
<td>L8687</td>
<td>Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension</td>
</tr>
<tr>
<td>L8688</td>
<td>Implantable neurostimulator pulse generator, dual array, non-rechargeable, includes extension</td>
</tr>
<tr>
<td>L8689</td>
<td>External recharging system for battery (internal) for use with implantable neurostimulator</td>
</tr>
<tr>
<td>L8695</td>
<td>External recharging system for battery (external) for use with implantable neurostimulator</td>
</tr>
</tbody>
</table>

**HCPCS codes not covered for indications listed in the CPB:**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>L8605</td>
<td>Injectable bulking agent, dextranomer/hyaluronic acid copolymer implant, anal canal, 1 ml, includes shipping and necessary supplies</td>
</tr>
</tbody>
</table>

**Other HCPCS codes related to the CPB:**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>C9743</td>
<td>Injection/implantation of bulking or spacer material (any type) with or without image guidance (not to be used if a more specific code applies)</td>
</tr>
<tr>
<td>E0740</td>
<td>Incontinence treatment system, pelvic floor stimulator, monitor, sensor and/ or trainer</td>
</tr>
<tr>
<td>E0746</td>
<td>Electromyography (EMG), biofeedback device</td>
</tr>
<tr>
<td>G0283</td>
<td>Electrical stimulation (unattended), to one or more areas for indication(s) other than wound care, as part of a therapy plan of care</td>
</tr>
<tr>
<td>J0460</td>
<td>Injection, atropine sulphate, up to 0.3 mg</td>
</tr>
<tr>
<td>J0745</td>
<td>Injection, codeine phosphate, per 30 mg</td>
</tr>
<tr>
<td>S9470</td>
<td>Nutritional counseling, dietitian visit</td>
</tr>
</tbody>
</table>

**There is no specific code for pudendal nerve terminal motor latency:**

**ICD-10 codes covered if selection criteria are met:**
The above policy is based on the following references:

General references:


Acticon Neosphincter:


Transanal Radiofrequency Therapy (Secca Procedure):


Sacral Nerve Stimulation (Sacral Neuromodulation):


Vienna, Austria: Ludwig Boltzmann Institut for Health Technology Assessment (LBI-HTA); 2011.


**Perianal Electrical Stimulation:**


**Injectable Bulking Agents:**


3. Medical Services Advisory Committee (MSAC). Intersphincteric injection of silicone biomaterial for severe passive faecal incontinence. MSAC Application 1100. Canberra, ACT: Medical Services Advisory Committee (MSAC); 2006.


Injection of Autologous Myoblast Cells/Mesenchymal Stem Cell:


Topical Estrogen:


Posterior Tibial Nerve Stimulation:


2. National Institute for Health and Care Excellence (NICE) Website. Percutaneous tibial nerve stimulation for faecal


Pudendal Nerve Terminal Motor Latency:


Rectal Banding:


Surgical Treatments:


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AETNA BETTER HEALTH® OF PENNSYLVANIA

Amendment to
Aetna Clinical Policy Bulletin Number: 0611 Fecal Incontinence

There are no amendments for Medicaid.

www.aetnabetterhealth.com/pennsylvania  revised 08/22/2017