Medical Policy

Blue Cross Blue Shield Blue Care Network of Michigan

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***Current Policy Effective Date: 5/1/25**
(See policy history boxes for previous effective dates)

Title: Fecal Incontinence—Investigational Treatments

Description/Background

Fecal Incontinence

Fecal incontinence is the involuntary loss of flatus, liquid or stool from the rectum and anal canal. Although it is considered a benign disorder, severe fecal incontinence is a distressing and socially isolating medical condition. Fecal continence depends on a complex interplay of anal sphincter function, pelvic floor function, stool transit time, rectal capacity, and sensation. There are a variety of etiologies, including injury from vaginal delivery, anal surgery, neurologic disease, and the normal aging process. It is estimated that the disorder affects ten percent of the adult population.

Treatments

Medical management includes dietary measures, such as the addition of bulk-producing agents to the diet and elimination of foods associated with diarrhea. Anti-diarrheal drugs can be used for mild degrees of incontinence. Bowel management programs, commonly used in patients with spinal cord injuries, may also be effective in patients with fecal incontinence. Biofeedback has been investigated as well. For some individuals with a sphincter defect, surgical procedures such as direct sphincter repair (sphincteroplasty), post anal repair, or total pelvic floor repair may be attempted. For individuals with severe fecal incontinence who have failed medical interventions and who are not candidates for sphincter repair, an alternative is a permanent ostomy.

Other new therapies for fecal incontinence are emerging. Some of these therapies include transanal radiofrequency therapy, perianal electrical stimulation, posterior tibial nerve stimulation, pudendal nerve latency measurement, topical estrogen, injectable bulking agents autologous myoblast cells, Eclipse System and Transobturator Posterior Anal Sling (TOPAS).

Regulatory Status

Transanal Radiofrequency Therapy (46999)
The Secca® System (Mederi Therapeutics Inc.) is regulated via the FDA 510(k) process as a Class II (moderate risk) device. The FDA has classified this system as an electrosurgical cutting and coagulation device and it received FDA approval (K014216) on March 21, 2002. This 510(k) approval was granted to Curon Medical Inc., which filed for bankruptcy on November 13, 2006. The assets of Curon Medical Inc. were subsequently acquired by Mederi Therapeutics Inc.

Injectable Bulking Agents (0377T)
Solesta® (Oceana Therapeutics, Inc., Edison, NJ, USA) received pre-market FDA-approval (P100014) in May 2011. It is approved for the treatment of fecal incontinence in patients 18 years and older who have failed conservative therapy (e.g., diet, fiber therapy, anti-motility medications). Solesta is a sterile, viscous gel that is prepackaged in a disposable 1 mL assembled glass syringe with a standard Luer-Lok fitting. Solesta consists of dextranomer microspheres, 50 mg/mL, and stabilized sodium hyaluronate, 15 mg/mL, in phosphate buffered 0.9 % sodium chloride solution. Deflux, which is a treatment for children with vesico-ureteral reflux, is the comprised of the same material as Solesta.

Eclipse System (A4563)
The Eclipse System (Pelvalon Inc.) received FDA 510(k) clearance (K150558) through the FDA De Novo Reclassification process on November 12, 2015. FDA identifies this generic type of device as a Rectal Control System: A rectal control system is a prescription device intended to treat fecal incontinence by controlling the size of the rectal lumen. The device is inserted in the vagina and includes a portion that expands to reduce the rectal lumen to prevent stool leakage and retracts to allow normal passage of stool. The device includes an external regulator to control the state of expansion.

Transobturator Posterior Anal Sling (TOPAS) (46999)
The TOPAS System is currently under FDA review. The proposed PMA indication restricts use to women with FI that has not responded to treatments that are more conservative. The System is not intended for use in women who are pregnant or who are planning a future pregnancy. Prospects for approval seem favorable. An FDA advisory committee tasked with reviewing the TOPAS PMA unanimously agreed that the benefits of the device outweigh the risks. The FDA did not explicitly ask the committee to vote on whether or not the device should be approved. However, TOPAS safety issues may linger, despite the advisory committee endorsement. FDA reviewers raised concerns in an advisory panel briefing document about several adverse events (AEs) involving pain, infection, or pelvic organ prolapse seen in TRANSFORM trial participants. Trial investigators adjudicated these Aes as “non-device and/or non-treatment related” but FDA reviewers were not convinced, noting that “we are unable to exclude the mesh as a precipitating factor in these Aes” because similar Aes are associated with transvaginal mesh tape applications.

Magnetic Anal Sphincter Device (46999)
The FENIX Continence Restoration System received a Humanitarian Device approval from the FDA on December 18, 2015 for use in patients who are not candidates for or have previously failed conservative treatment and less invasive therapy options (e.g., injectable bulking agents,

radiofrequency ablation, and sacral nerve stimulation. The effectiveness of this device for use has not been demonstrated.

In 2011, NASHA Dx, marketed as Solesta (Q-Med now Palette Life Sciences), was approved by FDA through the premarket approval process as a bulking agent to treat fecal incontinence in patients 18 years and older who have failed conservative therapy. FDA product code: LNM.

Medical Policy Statement

The below listed therapies for the treatment of fecal incontinence are experimental/investigational. They have not been scientifically demonstrated to improve patient clinical outcomes better than conventional treatment.

- Transanal Radiofrequency Therapy
- Perianal electrical stimulation
- Posterior tibial nerve stimulation
- Pudendal nerve terminal motor latency measurement
- Injectable bulking agents
- Topical estrogen
- Autologous Myoblast Cell Injections
- Eclipse System
- Transobturator Posterior Anal Sling (TOPAS)
- Magnetic Anal Sphincter Device

Inclusionary and Exclusionary Guidelines

N/A

CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure.)*

Established codes:

N/A

Other codes (investigational, not medically necessary, etc.):

A4335	46999	G0283	64566*	J3490
L8605	A4563			

*These codes are not payable when the procedure or test is done for fecal incontinence.

Rationale

FECAL INCONTINENCE

Clinical Context and Therapy Purpose
The purpose of transanal radiofrequency (RF) in patients who have fecal incontinence is to provide a treatment option that is an alternative to or an improvement on existing therapies.
The question addressed in this evidence review is:
The following **PICOs** were used to select literature to inform this review.

Populations
The relevant population of interest is individuals with fecal incontinence who have failed conservative treatment.

Interventions The following therapies being considered are:

- Transanal Radiofrequency Therapy
- Perianal electrical stimulation
- Posterior tibial nerve stimulation
- Pudendal nerve terminal motor latency measurement (PNTMLM)
- Injectable bulking agents
- Topical estrogen
- Autologous Myoblast Cell Injections
- Eclipse System
- Transobturator Posterior Anal Sling (TOPAS)
- Magnetic Anal Sphincter Device

Comparators
The following therapies are currently being used to treat fecal incontinence: medical management, biofeedback, and sphincteroplasty.

Outcomes
The general outcomes of interest are the frequency of incontinent episodes and the impact on quality of life.

A beneficial outcome would be a decrease in the frequency of incontinence and improvement in quality of life.

A harmful outcome would be damage to the anal sphincter and an increase in incontinence frequency.

Procedural morbidity would be assessed within 30 days after the procedure. The impact of the treatment on incontinence would be assessed after 3 months to allow for remodeling, and after 3 to 5 years to assess durability.

TRANSANAL RADIOFREQUENCY THERAPY (46999)

Systematic Reviews

An Agency for Healthcare Research and Quality Comparative Effectiveness Review, conducted by Forte et al (2016), assessed surgical treatments for fecal incontinence, including transanal RF treatment.[1] Reviewers identified only case series, which they addressed only under a key question related to adverse effects, not a key question related to comparative effectiveness. Reviewers concluded that the evidence for transanal RF treatment was insufficient to support its use for fecal incontinence.

Noncomparative Studies

Abbas et al (2012) published results of their retrospective review of 27 patients who underwent the Secca™ procedure over a 6-year period (2004-2010) at Kaiser Permanente Los Angeles Medical Center.[2] Thirty-one procedures were performed for moderate to severe fecal incontinence. Most study patients were women with a mean age of 64 years, and the most common cause of the incontinence was obstetrical injury. Median length of symptoms was 3 years. Biofeedback had failed in more than half of patients, and more than 20% of patients had previous surgical intervention to treat the incontinence. No major complications occurred following the Secca™ procedure, and minor complications were observed in five patients (19%; anal bleeding in 4 and swelling of the vulva in 1). A treatment response was noted in 21 patients (78%) (mean Cleveland Clinic Florida Fecal Incontinence [CCF-FI] Score: 16 [baseline] and 10.9 [3 months postoperatively]). Previous studies have suggested that a CCF-FI of greater than nine indicates a significant impairment of quality of life.[3] However in the study by Abbas et al only 6 patients (22%) had a sustained long-term response without any additional intervention, and 14 patients (52%) underwent or are awaiting additional intervention for persistent or recurrent incontinence over a mean follow-up period of 40 months.

Ruiz et al (2010) reported on 1-year quality-of-life and continence outcomes for a series of 24 patients treated with RF energy for fecal incontinence between 2003 and 2004.[4] Twelve-month results were available for 16 patients (67%). Mean CCF-FI score improved from 15.6 at baseline to 12.9 at 12 months (p=0.035). Mean FIQL Questionnaire score improved in all subsets except for the depression subscore. The authors comment that the actual clinical significance of this improvement were uncertain.

Felt-Bersma et al (2007) published the results of an uncontrolled study on the Secca™ procedure in 11 women with fecal incontinence that underwent baseline and post treatment testing.[5] Six (55%) patients reported improvement; Vaizey Incontinence Questionnaire scores improved 13%, but no changes were observed in anal manometry, rectal compliance measurement, or 3-dimensional anal ultrasound. Postoperative pain was reported to be slight in 8 (73%), moderate in 2, and severe in 1 patient. Investigators suggested that this procedure merited further testing and noted that a randomized, controlled trial was underway. Lam et al (2014) reported 3-year outcomes of this cohort plus 20 other patients who underwent the Secca procedure for fecal incontinence.[6] Of the total cohort of 31 patients, 5 (16%) maintained a clinically significant response (defined as ≥50% reduction in Vaizey score) for 6 months, 3 (10%) maintained response for 1 year, and 2 (6%) maintained response for 3 years. Improvements from baseline in anal manometry (increased anorectal pressures or enhanced rectal compliance) were not observed.

In 2003, Efron et al published an open-label, single-arm, nonrandomized study of 50 patients who underwent the Secca procedure and were followed-up for 6 months.[7] Patients served as

their own controls. The study assessed changes in fecal incontinence symptom scores and quality of life between the baseline and follow-up. Fecal incontinence was assessed with the CCF-FI score, and quality of life was assessed with the Fecal Incontinence Quality of Life (FIQL) score. Both the CCF-FI and FIQL scores improved in a steady gradual manner over a 6-month period, from 14.6 to 11.1 for the CCF-FI and 2.5 to 3.1 for the FIQL. Of the 44 patients with an initial baseline CCF-FI score greater than nine, a total of 15 (34%) achieved a CCF-FI less than 10 at 6 months. Improvement was also assessed using the Medical Outcomes Study Short-Form 36 (SF-36), focusing on mental and social parameters. Mean social function subscore improved from 64.3 to 34.4, while the mental health subscore improved from 65.8 to 73.8. Fourteen-day diary data demonstrated significant improvement in all nine parameters; for example, the days with any fecal incontinence dropped from 10 in a 14-day period to seven. In contrast, there were no differences in objective measures of anal sphincter, i.e., there were no differences based on manometry measures, rectal sensation volumes, pudendal nerve motor latency, or internal or external sphincter defects, as noted on endoanal ultrasound. The authors noted that determining the mechanism of action for the procedure was not an objective of the study. Three significant procedure-related complications occurred during the trial. Two patients developed anal ulceration, and one developed bleeding from a hemorrhoidal vein. Twenty-six minor adverse events occurred, including minor bleeding in five patients, transient worsening of incontinence in 4 patients, and anal pain in 5 patients.

Three additional very small case series (n=15, 19, 8) were performed outside the U.S.[8-10] In 2 of these small trials, no clear benefit was noted for the procedure. Given the small number of studies that have been conducted and the limitations of those trials (i.e., small number of patients, lack of control arm and randomization, inconsistencies with inclusion and exclusion criteria, and short-term follow-up, efficacy of RF therapy for fecal incontinence is not supported in the literature.

Summary of Evidence: Transanal Radiofrequency for Fecal Incontinence
Studies described in this policy include a small number of patients, and the estimates of treatment differences are very imprecise. Study follow-up periods are variable and need to be considerably longer in larger numbers of patients to properly evaluate long-term outcomes. No new studies on this procedure have been published since the last update. 3-year follow-up of a small cohort of patients showed decrement in response over time. Multicenter randomized controlled trials with sufficient power are required to evaluate the continuing use of this procedure as an alternative to other surgical interventions or physical therapies or as an adjunct treatment option for fecal incontinence. Given the insufficient evidence available to evaluate the impact of the technology on net health outcome, this surgical procedure is considered experimental/investigational.

PERIANAL ELECTRICAL STIMULATION (G0283)

Systematic Reviews
Perianal electrical stimulation has also been tried in treating fecal incontinence. A Cochrane review conducted by Hosker 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.[10] 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.[11] 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.

Randomized Controlled Trial
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.[12] 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.

Section Summary: Perianal Electrical Stimulation
There is insufficient evidence that perianal electrical stimulation improves the net health outcome for patients with fecal incontinence. Thus, this therapy is considered investigational for treating fecal incontinence.

POSTERIOR TIBIAL NERVE STIMULATION (64566)
Findlay and Maxwell-Armstrong (2011) stated that fecal incontinence is a common and important multi-factorial disorder with a range of treatment options.[13] 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.

Systematic Reviews
Thomas et al (2013)[14] evaluated the published results 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 endpoints 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.[15] 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.[16] 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.

Randomized Controlled Trials

In a multi-center, parallel-arm, double-blind, RCT, Horrocks et al (2015)[17] evaluated the effectiveness of PTNS compared with sham electrical stimulation in the treatment of patients with FI in whom initial conservative strategies have failed.[21] 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.

Horrocks and associates (2017)[18] stated that a recent randomized, multi-center, phase-III clinical trial, performed in the United Kingdom (Control of Fecal Incontinence using Distal Neuromodulation Trial), demonstrated no significant clinical benefit of PTNS compared to sham stimulation in patients with FI. However, this study did not analyze predictors of response. These researchers used data from this trial to identify factors that predict the efficacy of PTNS in adults with FI. The study population comprised 205 patients from the Control of Fecal Incontinence using Distal Neuromodulation Trial. The primary outcome was a binary indicator of success (greater than or equal to 50 % reduction in weekly FI episodes after 12 weeks of treatment) or failure, as per the original trial characteristics including baseline FI symptom type, defecatory urgency, and co-existent symptoms of baseline liquid stool consistency and obstructive defecation (OD) were defined a priori. Uni-variable and multi-variable analyses were performed to explore these factors as predictors of response to PTNS and sham. In both uni-variable and multi-variable analysis, the presence of OD symptoms negatively predicted outcome in patients who received PTNS (OR, 0.38; 95 % CI: 0.16 to 0.91; p = 0.029), and positively predicted sham response (OR, 3.45; 95 % CI: 1.31 to 9.21; p = 0.012). No other tested variable affected outcome. Re-analysis of the primary outcome excluding patients with OD symptoms (n = 112) resulted in a significant clinical effect of PTNS compared to sham (48.9 % versus 18.2 % response, p = 0.002; multi-variable OR, 4.71; 95 % CI: 1.71 to 12.93; p = 0.003). The authors concluded that concomitant OD symptoms

negatively affected the clinical outcome of PTNS versus sham in a major RCT. They stated that future appropriately designed studies could further explore this observation with potential for future stratified patient selection.

Pilot Study

In a pilot study, Sanagapalli and colleagues (2018) evaluated the efficacy of PTNS in treating multiple sclerosis-related FI.[19] Consecutive multiple sclerosis patients with FI that had failed conservative therapy received PTNS between 2012 and 2015. All patients had previously undergone anorectal physiology tests and EAUS. Patients whose Wexner incontinence score reduced below 10 post-therapy or halved from baseline were deemed responders. A total of 33 patients (25 women, median age of 43 years) were included; 23 (70 %) had urge, 4 (12 %) passive, and 9 (27 %) mixed FI; 26 (79 %) were classified as responders. The majority of subjects had relapsing-remitting multiple sclerosis (67 %); those had a significantly higher response rate (95 % versus 67 % and 50 % in primary and secondary progressive respectively, $p < 0.05$). Responders tended to be more symptomatic at baseline and had greater improvements in bowel symptom scores and QOL scores with therapy. The authors concluded that PTNS demonstrated potential as an effective therapy for FI in multiple sclerosis. They stated that these findings provided the basis for more definitive controlled studies.

Section Summary: Posterior Tibial Nerve Stimulation

There is insufficient evidence that posterior tibial nerve stimulation improve the net health outcome for patients with fecal incontinence. Thus, this therapy is considered investigational for treating fecal incontinence.

PUDENDAL NERVE TERMINAL MOTOR LATENCY MEASUREMENT (PNTML)

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.

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 state “The PNTML cannot be recommended for evaluation of patients with fecal incontinence”.[24]

Weledji (2017) noted that pudendal neuropathy is not a predictor of surgical intervention for FI, but independent predictors include the presence of a prolapse, a functional sphincter length of less than 1 cm, an external anal sphincter defect, and a Cleveland Clinic Incontinence Score greater than or equal to 10.[25] In clinical assessments, pudendal nerve studies are of particular value in patients with FI, but not in those with solitary rectal ulcer syndrome, hemorrhoids or the complexity of obstructive defecation syndrome as many of the associated problems or pathologies may not be immediately apparent. In addition, pudendal nerve motor latency (PNML) is operator-dependent and has a poor correlation with clinical symptoms and histological findings. The investigation only examines the fastest conducting fibers of the pudendal nerve, so PNML can still be normal even in the presence of abnormal sphincter innervation. The authors stated that pudendal nerve testing may not, therefore, contribute to surgical decision-making in patients with FI; and the American Gastroenterology Association

does not, therefore, recommend the use of pudendal nerve testing for the evaluation of patients with FI.

Saraidaridis and colleagues (2018)[26] stated that pudendal nerve terminal motor latency (PNTML) testing is a standard recommendation for the evaluation of FI. Its role in guiding therapy for FI has been previously questioned. These researchers examined the relationship between PNTML testing and anorectal dysfunction. This was a retrospective analysis of data collected prospectively from patients who presented to a pelvic floor disorder center from 2007 to 2015. The relationship between PNTML (normal versus delayed) and anorectal manometry, FI severity, and FI-related QOL scores was assessed using the Wilcoxon-Mann-Whitney test. A total of 269 patients underwent PNTML testing, and 91.1 % were women (n = 245) (median age of 62.2 years). Normal PNTML was observed in 234 (87.0 %) patients. Among 268 patients who underwent anorectal manometry, delayed PNTML was only significantly associated with median maximum anal squeeze pressure (p = 0.04). Delayed PNTML was not associated with a decrease in median FI severity or FI-related QOL scores (n = 99). The authors concluded that PNTML was only associated with median maximum anal squeeze pressure, and it was not associated with patient-reported severity of symptoms of FI, changes in QOL attributable to FI, median mean resting anal pressure, or median maximum resting anal pressure. They stated that PNTML testing may not be relevant to current therapeutic algorithms for FI and its routine use should be questioned.

Section Summary: Pudendal Nerve Terminal Motor Latency Measurement
There is insufficient evidence that PNTML improves the net health outcome for patients with fecal incontinence. Thus, this testing is considered investigational for the evaluation of fecal incontinence.

TOPICAL ESTROGEN (J3490)

Randomized Controlled Trial
In a prospective, randomized, double-blind study, Pinedo and co-workers (2009)[21] 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.

Section Summary: Topical Estrogen
There is insufficient evidence that the use of topical estrogen improves the net health outcome for patients with fecal incontinence. Thus, this therapy is considered investigational for treating fecal incontinence.

INJECTABLE BULKING AGENTS (0377T)

Systematic Reviews

Maeda et al (2013) updated a Cochrane review assessing the use of injectable bulking agents as a treatment for fecal incontinence in adults.[22] Reviewers identified 5 RCTs (total N=382 patients) comparing bulking agents with placebo, no intervention, or an alternative intervention. The 5 trials all included adults with internal anal sphincter dysfunction or passive fecal incontinence who had failed previous conservative treatments (e.g., pelvic floor muscle training). One of the 5 trials (detailed next) used the FDA-approved bulking agent dextranomer in stabilized hyaluronic acid (Solesta). Two trials used a placebo or sham control, 2 compared different bulking agents, and the fifth trial compared 2 methods of injecting the same agent. Length of follow-up ranged from 3 to 12 months. Four trials were judged to be of high or uncertain risk of bias. The greatest potential source of bias was lack (or unclear) blinding of outcome assessment and lack of blinding of surgeons performing the procedure. Due to heterogeneity among trials, study findings were not pooled. Overall, conclusions on efficacy were limited by the small number of RCTs identified, most of which had methodologic limitations, and lack of long-term follow-up.

Previously, 2 systematic reviews were published that included observational studies and RCTs evaluating bulking agents for treating fecal incontinence.[23-25] Hussain et al (2011) included 1070 patients from 39 studies in a safety analysis. Adverse events occurred in 139 patients (13.5%). The most common complication was pain, which occurred in 67 patients (6.5%) followed by leakage of injected material, which was reported by 58 patients (5.6%). The authors did not report the number of serious adverse events.

Randomized Controlled Trials

The RCT evaluating Solesta that was included in the Cochrane review was published in 2011.[28] This was an industry sponsored multicenter RCT that compared Solesta with sham treatment in 206 adult patients. To be eligible for inclusion, patients needed to have a Cleveland Clinic Florida Fecal Incontinence Score (CCFIS) of 10 or higher, at least 4 documented incontinence episodes in 2 weeks, symptoms for at least 12 months and have failed at least 1 medically supervised conservative treatment (which could include dietary modification, fiber supplements or loperamide hydrochloride). Patients received an initial injection, and those with persistent symptoms, and no substantial adverse effects at 1 month were offered a second injection. A total of 112 patients (86%) in the active treatment group and 61 patients (87%) in the sham group received a second procedure. Response to treatment was defined as a reduction in the number of incontinence episodes by 50% or more compared with baseline. The study was double-blind for the first 6 months of follow-up; at 6 months, patients in the sham group were offered active treatment. Thus, the primary efficacy outcome was assessed at 6 months.

A total of 197 of 206 (96%) of randomized patients completed the 6-month follow-up and were included in the primary efficacy analysis. Seventy-one (52%) in the active treatment group and 22 (31%) in the sham group had a 50% or greater reduction in incontinence episodes at 6

months. The difference between groups was statistically significant (odds ratio [OR], 2.36; 95% confidence interval [CI], 1.24 to 4.47; p=0.009). Findings on secondary outcomes at 6 months were mixed. For example, the mean increase in number of incontinence-free days was significantly higher in the active treatment group than the sham group (3.1 vs. 1.7, respectively; p=0.016), but the median decrease in number of incontinence episodes did not differ significantly between groups (6.0 vs. 3.0, respectively; p=0.09). Moreover, change in the CCFIS did not differ significantly at 6 months (2.5 points in the active treatment group vs. 1.7 points in the sham treatment group). Quality of life was measured by the fecal incontinence quality of life instrument, which has 4 subscales. One of the 4 subscales (coping and behavior) improved significantly more in the treatment than the sham group at 6 months. Change in scores on the other 3 subscales (lifestyle, depression and self-perception, embarrassment) did not differ significantly between groups at 6 months. The authors did not report the proportion of patients who were continent at follow-up, either as a primary or secondary outcome.

During the 6-month blinded treatment phase, 128 adverse events were reported in the active treatment group and 29 in the sham group. The most common adverse event in the active treatment group was proctalgia, which occurred in 19 patients (14%). In contrast, 2 patients (3%) in the sham group reported proctalgia. Moreover, 10 patients (7%) in the active treatment group and 1 patient (1%) in the sham group had rectal hemorrhage. Infection site bleeding occurred in 12 patients (17%) in the sham group and 7 patients (5%) in the active treatment group. Two serious adverse events were reported, both in the active treatment group; there was 1 rectal abscess and 1 prostate abscess.

Subsequently, in 2013, Dehli et al in Norway published findings of an RCT evaluating Solesta, an FDA-approved nonanimal stabilized hyaluronic acid/dextranomer in stabilized hyaluronic acid (NASHA Dx) bulking agent.[29] A total of 126 adults with fecal incontinence were randomized to receive injectable bulking agents (n=62) or a 6-month biofeedback intervention (n=64). Patients in the bulking agent group who reported minor or no symptom improvement at 3 months received a second injection. The primary efficacy outcome was incontinence severity, as measured by the St. Mark's score, which can range from 0 (perfect continence) to 24 (maximal incontinence). A St. Mark's score of at least 4 was required for study participation. Ten patients (8%) dropped out of the study before 6 months. At the 6-month follow-up, the mean St. Mark's score in the biofeedback group had decreased from 12.6 points (95% CI, 11.4 to 13.8) at baseline to 9.2 points (95% CI, 7.9 to 10.5). In the bulking agents group, mean scores were 12.9 (95% CI, 11.8 to 14.0) at baseline and 8.9 (95% CI, 7.6 to 10.2) at 6 months. The difference between groups in St. Mark's score reduction at 6 months was not statistically significant. In addition, change in St. Mark's score did not differ between groups at 24 months; only 61 patients (49%) completed the 24-month follow-up. Three of the first 10 patients in the bulking agent group got infections at the injection site and underwent treatment; subsequent patients in this group received prophylactic antibiotics.

Uncontrolled Trials

Longer-term data on Solesta are available from two uncontrolled studies.

Quiroz et al (2023) published an open-label, single-arm, FDA-mandated, long-term study evaluating the long-term efficacy and safety of Solesta in patients (N=283) who had failed conservative therapy.[52] The study was conducted at 18 sites in the US, and patients received 1 dose of Solesta within 3 months of baseline and a repeat dose at approximately 3 months after the first dose if necessary. The primary endpoint evaluated the need for fecal incontinence reintervention at 36 months. The enrolled patients were largely White (91.8%) and female (85.5%). The majority of patients (76.7%) received 2 treatments. At 36 months the need for

reinterventions was 20.8% (95% CI, 15.1 to 26.6). CCFIS scores decreased from 13.5 at baseline to 9.2 at the final visit (p<.0001). There were no serious device-related adverse events or death, but 15.2% of patients reported 92 nonserious device-related adverse events with gastrointestinal-related events the most commonly reported. Limitations of this study include a high dropout rate (32%), limited demographic variability, and lack of a comparison group.

Another longer-term uncontrolled study was conducted by La Torree et al (2013) in Spain.[30] A total of 115 patients with fecal incontinence received 4 injections of Solesta. Eighty-three of 115 patients (72%) completed the 24-month follow-up. The primary efficacy end point was response to treatment, defined as at least a 50% reduction from baseline in the number of fecal incontinence episodes recorded in a 28-day diary. At the 24-month follow-up, 52 of 83 (63%) of patients with data available had responded to treatment. The median number of incontinence-free days in a 28 day period increased from 14.6 at baseline to 21.7 at 24 months. The study is limited by lack of a comparison group and a high dropout rate.
There are also several uncontrolled studies with short term data. A study done by Danielson (2018) evaluated the use of NASHA Dx gel (Solesta) as an injectable anal canal implant for the treatment of fecal incontinence.[31] Thirty-four patients (5 males, 29 females; median age, 61 years; range, 34 to 80) were injected with 4 x 1 ml of NASHA Dx gel, just above the dentate line in the submucosal layer. The primary end point was change in the number of incontinence episodes and a treatment response was defined as a 50 percent reduction compared with pretreatment. All patients were followed up at 3, 6 and 12 months. The median number of incontinence episodes during four weeks was 22 (range-2 to 77) before treatment, at 6 months it was 9 (range, 0 to 46), and at 12 months it was 10 (range, 0 to 70). Fifteen patients (44 percent) were responders at 6 months, compared with 19 (56%) at 12 months. No long-term side effects or serious adverse events were reported. It was concluded that the submucosal injection of NASHA Dx gel appears to be an effective treatment for fecal incontinence. The effect is sustained for at least 12 months and is associated with low morbidity.

In 2011, a prospective study by Schwander et al analyzed the safety and functional outcome of transanal submucosal injection of dextranomer hyaluronic acid (“bulking agents therapy”) in patients with passive fecal incontinence.[33] All patients who underwent transanal injection therapy were prospectively enrolled in this study. Inclusion criteria included fecal incontinence (internal anal sphincter dysfunction) after failed conservative treatment. The procedure was performed in a standardized technique, including submucosal injection of 4 x 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]). The author’s conclusions stated, “… the current long-term results of transanal submucosal injection of dextranomer hyaluronic acid in 18 patients suffering from passive fecal incontinence show that it is a minimally invasive treatment with no morbidity. Although this was not a controlled study, injection therapy was effective in more than 50% of patients. Improvement in continence is related to an increase in quality of life and is sustained after a mean follow-up of 20 months. However, nearly half of the patients did not show a clear benefit of injection treatment. These would be candidates for sacral nerve stimulation. In summary, submucosal injection therapy can be used as a “bridging” therapy in selected patients.” He also states, “there is no objective evidence that injectable bulking agents are an effective tool for fecal incontinence.”

A prospective observation study was completed by Dodi et al in 2010, which involved the treatment of patients with fecal incontinence (FI) with NASHA/Dx gel.[32] This was an open-label, Non-comparative, one group, pre-post design, 15-center study performed in Europe and Canada. A total of 115 eligible patients (100 female, 15 male) with a mean age of ~62 years (range 30–80 years) suffering from FI were treated with NASHA/Dx gel. The patients received 4 injections of 1 mL NASHA/Dx gel. Primary efficacy was based on data from 86 patients that completed the study. Fourteen of these patients withdrew or were lost to follow-up at 6 months and an additional 10 patients withdrew or were lost for follow up at 12 months. During the course of treatment, the patients were offered retreatment of up to 4 treatments. Patients recorded the number of FI episodes per 24 hours in diaries. This study demonstrated a greater than or equal to 50% reduction from baseline in the number of FI episodes in 57.1% of patients at 6 months, and 64.0% at 12 months. Significant improvements were also noted in total number of both solid and loose FI episodes, FI free days, CCFIS, and FIQL scores in all 4 domains. The majority of the treatment related Aes (94.9%) were mild or moderate intensity, and (98.7%) of Aes resolved spontaneously, or following treatment, without sequelae. Results of this study indicated NASHA/Dx gel was efficacious in the treatment of FI. Treatment effect was significant both in reduction of number of FI episodes and disease specific quality of life at 6 months and lasted up to 12 months after treatment. A side effect of treatment was fever, reported in 7% of patients. Six cases of anorectal abscess were reported. The limitations of this study include a small sample size and no comparison group.

Section Summary: Injectable Bulking Agents
Several RCTs and systematic reviews of RCTs on bulking agents for the treatment of fecal incontinence have been published. A 2016 comparative effectiveness review from the Agency for Healthcare Research and Quality evaluated 2 RCTs with the FDA-approved product NASHA Dx (Solesta) and 2 RCTs with Durasphere. One RCT using NASHA Dx found that, compared with sham, NASHA Dx improved some outcomes but not others. The other RCT did not find a significant difference in efficacy between NASHA Dx and biofeedback. Two other RCTs evaluating Durasphere (off-label in the U.S.) found short-term improvements in fecal incontinence severity. Overall, the evidence is not sufficient to conclude that bulking agents are a treatment for fecal incontinence. Corroboration of the single positive trial is needed, and controlled trials with longer follow-up are important to determine the durability of any treatment effect.

AUTOLOGOUS MYOBLAST CELLS (46999)
The most common pathological mechanism of faecal incontinence is the insufficiency of the external anal sphincter (EAS) caused by neurological or myogenic dysfunction. Attempts of auto-transplantation of myoblasts into damaged skeletal muscle were already made in animal models of muscular dystrophy, post-infarction myocardial dysfunction and urethral sphincter insufficiency. The results showed that the transplanted myoblasts might differentiate into muscle fibers, connect with host motoric units, increase the amount of contractile elements in the muscle and improve its contractile activity. Based on those results, a pioneer experimental study was designed in attempt to enhance the function of external anal sphincter using injections of autologous muscle-derived stem cells.

Pilot Studies
In a pilot study, Frudinger (2010) and colleagues examined the effectiveness of injection of autologous myoblast cells in the treatment of anal incontinence because of obstetric trauma.[34] 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.

Romaniszyn et al (2015)[36] recently presented results of the implantation of autologous myoblasts into the external anal sphincter (EAS) in ten patients with fecal incontinence. After anatomical and functional assessment of the patients' EAS, a vastus lateralis muscle open biopsy was performed. Stem cells were extracted from the biopsy specimens and cultured in vitro. Cell suspensions were then administered to the EAS. Patients were scheduled for follow-up visits in 6-week intervals. Total follow-up was 12 months. All biopsy and cell implantation procedures were performed without complications. Nine of the patients completed a full 12-month follow-up. There was subjective improvement in six patients (66.7%). In manometric examinations 18 weeks after implantation, squeeze anal pressures and high-pressure zone length increased in all patients, with particularly significant sphincter function recovery in five patients (55.6 %). Electromyographic (EMG) examination showed an increase in signal amplitude in all patients, detecting elevated numbers of propagating action potentials. Twelve months after implantation two patients experienced deterioration of continence, which was also reflected in the deterioration of manometric and EMG parameters. The remaining four patients (44.4 %) still described their continence as better than before implantation and retained satisfactory functional examination parameters.

The authors concluded that autologous myoblasts give good short-term results not only in a subjective assessment, but also in objective functional tests. It appears that this may be a promising technology that can improve the quality of life in patients with fecal incontinence, but further study is required to achieve better and more persistent results.

Randomized Trial

Park et al (2016)[37] 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 endpoint is to evaluate the safety of ALLO-ASCs after the injection into the anal sphincter, and the secondary endpoint 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.

Section Summary: Autologous Myoblast Cell Injections
There is insufficient evidence that autologous myoblast cell injections improve the net health outcome for patients with fecal incontinence. Two pilot studies showed that the procedure was well tolerated and that some improvement in fecal incontinence was noted. However, further well-designed studies are required for validation of results. Thus, autologous myoblast cell injections are considered investigational for treating fecal incontinence.

ECLIPSE SYSTEM (A4563)
The Eclipse device works by exerting pressure on the rectum through the vaginal wall, effectively closing off the rectum. When a trip to the bathroom is needed, the device is deflated and then re-inflated using an external pump. The Eclipse is initially fitted and inflated by a trained clinician, following which the patient can control it herself.

Prospective Studies
In 2015, Richter et al (2015)[38] evaluated the effectiveness and safety of a vaginal bowel-control device and pump system for fecal incontinence treatment. Women with a minimum of four fecal incontinence episodes over 2 weeks were fit with the intravaginal device.[41] Treatment success, defined as a 50% or greater reduction of incontinent episodes, was assessed at 1 month. Participants were invited into an optional extended-wear period of another 2 months. Secondary outcomes included symptom improvement measured by the Fecal Incontinence Quality of Life, Modified Manchester Health Questionnaire, and Patient Global Impression of Improvement. Adverse events were collected. Intention-to-treat analysis included participants who were successfully fit entering treatment. Per protocol, analysis included participants with a valid 1-month treatment diary. Sixty-one of 110 (55.5%) participants from six clinical sites were successfully fit and entered treatment. At 1 month, intention-to-treat success was 78.7% (48/61, P<001); per protocol success, 85.7% (48/56, P<001) and 85.7% (48/56) considered bowel symptoms “very much better” or “much better.” There was significant improvement in all Fecal Incontinence Quality of Life (P<001) and Modified Manchester (P<007) subscales. Success rate at 3 months was 86.4% (38/44; 95% confidence interval 73-95%). There were no serious adverse events; the most common study-wide device-related adverse event was pelvic cramping or discomfort (25/110 participants [22.7%]), the majority of events (16/25 [64%]) occurring during the fitting period. The authors concluded that in women successfully fit with a vaginal bowel-control device, there was significant improvement in fecal incontinence by objective and subjective measures.

In 2016, Varma and colleagues (2016) [39] studied the impact of a vaginal bowel control system on parameters of bowel function, including frequency, urgency, stool consistency, and evacuation. This was a secondary analysis of a multicenter, prospective clinical trial. The study was conducted at six sites in the United States, including university hospitals and private practices in urogynecology and colorectal surgery. A total of 56 female subjects aged 19-75 years with four or more fecal incontinence episodes on a 2-week bowel diary were included. The study intervention was composed of the vaginal bowel control system, consisting of a vaginal insert and pressure-regulated pump. The authors found the use of the insert was associated with an improvement in bowel function across all four categories. Two-thirds (8/12) of subjects with a high frequency of daily stools (more than 2 per day) shifted to a normal or low frequency of stools. Analysis of Bristol stool scale scores demonstrated a significant reduction in the proportion of all bowel movements reported as liquid (Bristol 6 or 7), from 36%

to 21% (p = 0.0001). On average, 54% of stools were associated with urgency at baseline compared with 26% at 1 month (p < 0.0001). Incomplete evacuations with all bowel movements were reduced from 39% to 26% of subjects at 1 month (p = 0.0034). The authors concluded that the vaginal bowel control system was associated with an improvement in bowel symptoms and function, including reduced bowel movement frequency, less fecal urgency, increased solid consistency, and improved evacuation in patients with significant fecal incontinence.

In 2019, Richter et al.[40] published a prospective open-label study in subjects with FI and successfully fit who underwent an initial 2-week trial period. Those achieving 50% or greater reduction in FI episodes were provided the long-term system. Primary outcome was success at 3 months defined as 50% or greater reduction in baseline FI episodes, also assessed at 6 and 12 months. Secondary outcomes included symptom impact measured with Fecal Incontinence Quality of Life scale, symptom severity by the St Mark's (Vaizey) questionnaire, Patient Global Impression of Improvement, and satisfaction. Adverse events were collected. Primary analysis was intention to treat (ITT). Results: Seventy-three subjects with baseline mean of 14.1 ± 12.15 FI episodes over 2 weeks entered the treatment period. Success rate at 3 months was 72.6% (53/73, P < 0.0001); per-protocol, 84.1% (53/63, P < 0.0001). Significant improvement in all Fecal Incontinence Quality of Life subscales and St Mark's questionnaire meeting minimally important differences was noted. Satisfaction was 91.7%, 89.7%, and 94.4% at 3, 6, and 12 months, respectively; 77.4%, 77.6%, and 79.6% were very much/much better on the Patient Global Impression of Improvement at 3, 6, and 12 months, respectively. Most common adverse event was vaginal wall injury, with most adverse events (90/134, 67%) occurring during fitting period. Conclusions: In women with successful fitting and initial treatment response, durable efficacy was seen at 3, 6, and 12 months by objective and subjective measures, with favorable safety.

Section Summary: Eclipse System for Fecal Incontinence
Published literature for the Eclipse System consists of three small studies. Although initial results appear positive, further studies are needed to assess the safety and impact on health outcomes as well as patient management. Thus, the Eclipse system is considered experimental /investigational for treating fecal incontinence.

TRANSOBTURATOR POSTERIOR ANAL SLING (TOPAS) (46999)
The TOPAS System is a transobturator posterior anal sling that is designed to be implanted around the puborectalis muscle via an ischiopubic minimally invasive procedure. The system consists of a polypropylene mesh sling assembly and two stainless steel curved insertion needles.

Rosenblatt and colleagues (2014)[41] conducted a prospective study at five centers using the TOPAS AMS pelvic floor repair system. This self-fixating polypropylene mesh is intended for use to reinforce soft tissues where weakness exists in the gynecological gastroenterological anatomy. This was a preliminary study conducted to obtain initial clinical experience with the TOPAS system for the treatment of fecal incontinence in women. Women who failed one or more conservative therapies were candidates for the study. Fecal incontinence was assessed with a bowel diary, Cleveland Clinic incontinence scores (CCISs), and Fecal Incontinence Quality of Life (FIQOL) questionnaires and patients were followed prospectively up to 24 months. Treatment success was defined as a reduction in number of FI episodes of 50% or more compared with baseline. A total of 29 women (mean age, 60.6 years) were implanted with the TOPAS system. Mean number of FI episodes per 14 days decreased from 6.9 at

baseline to 3.5 at 24 months of follow-up, and the reduction was significant for the entire follow-up period compared with baseline (P < 0.001). A total of 55.6% of the subjects reported treatment success. The CCIS and FIQOL scores for all domains were significantly improved during the overall follow-up period compared with baseline (P < 0.001). The most common procedure and/or device-related adverse events were de novo urinary incontinence, including bladder spasms (n = 6), worsening FI (n = 2), and constipation (n = 2). No device-related erosions or extrusions were reported.

The authors concluded that the TOPAS system demonstrated a significant improvement in FI episodes, CCIS and FIQOL scores, and a benign safety profile. These results indicate that the TOPAS system has potential as a new therapeutic option for FI, but it needs to be confirmed in a larger study.

Mellgren et al (2016) [42], in the TRANSFORM trial, implanted 152 women with the TOPAS device at eight colorectal surgical and seven urogynecology specialty centers. Participating surgeons underwent special training in the TOPAS procedure before implanting the device in study patients. All patients had FI symptoms for ≥ 6 months, defined as ≥ 4 FI episodes within a 14-day period, and all had failed ≥ 2 conservative FI therapies. The patient population was predominantly white (90.1%) and middle-aged (mean age, 59.6 years). FI etiology was attributed to obstetric trauma in 87 (57.2%) patients and was unknown in 62 (40.8%) patients. Patients were permitted to continue taking medications to treat FI symptoms during the study; 40% were taking some type of FI drug at baseline (e.g., stool bulking agent or opioid-receptor agent).

A total of 104 AEs were reported in 66 patients; 98 AEs were deemed “nonserious” by trial investigators. The most common Aes were pelvic pain (n=47) and infection (n=26). No major complications were deemed by investigators to be directly related to the mesh implant. Of note, FDA reviewers took issue with this adjudication in the TOPAS PMA briefing document. There were no reported cases of implant material extrusion or exposure.

The primary efficacy endpoint was “treatment success” in more than 50% of patients. Treatment success was defined as ≥ 50% reduction in the number of FI episodes from baseline to 12 months, as measured by a 14-day bowel dairy. This endpoint was reached by 69.1% of patients; almost all (65.8%) achieved this goal within 3 months of device implantation. In addition, 19% of patients reported complete restoration of fecal continence at 12 months.

Secondary QOL measures improved significantly in all four domains measured by the FI Quality of Life (FIQOL) questionnaire: Coping, Lifestyle, Embarrassment, and Depression. Of note, FI medication use did not statistically change from baseline to 12-month follow-up among TOPAS responders and nonresponders.

Section Summary: TOPAS System for Fecal Incontinence
Transobturator Posterior Anal Sling (TOPAS) is currently under FDA review. Evidence is insufficient to determine the device’s safety or its efficacy to provide clinically meaningful reductions in fecal incontinence frequency and improvements in quality-of-life (QOL) measures. The best available published evidence is limited to the U.S. pivotal TRANSFORM that did not include a control arm. Thus, the TOPAS system is considered experimental /investigational for treating fecal incontinence.

MAGNETIC ANAL SPHINCTER DEVICE (46999)
The FENIX device is a small, flexible band of interlinked titanium beads with magnetic cores that is placed around the anal canal in the closed position. The magnetic beads will separate temporarily to allow the intentional passage of stool. The magnetic attraction between the beads then brings the device back to the closed position to prevent unexpected opening of the anal canal that may lead to accidental bowel leakage.

Preliminary studies suggest the FENIX MSA is safe, but efficacy data is limited.[43] Williams and colleagues (2016) are currently conducting the SaFaRI trial, a National Institute of Health Research (NIHR) Health Technology Assessment –funded UK multi-site, parallel group, randomized controlled, unblended trial investigating the use of the FENIX MSA, as compared to sacral nerve stimulation, for adult fecal incontinence resistant to conservative management. Twenty sites across the UK experienced in the treatment of fecal incontinence, recruited 350 patients randomized equally to receive either sacral nerve stimulation or FENIX MSA. Participants will be followed-up at 2 weeks post-surgery and at 6,12, and 18 months post-randomization. The primary endpoint is success, as defined by device in use and $\geq$50% improvement in the Cleveland Clinic Incontinence Score at 18 months post-randomization. Secondary endpoints include complications, quality of life and cost effectiveness.

DeStephano and colleagues (2017) reported a new technique for the surgical management of FI using the Fenix Continence Restoration System in 2 patients.[44] 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 sphincteroplasy, 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.

Section Summary: Magnetic Anal Sphincter Device
The FENIX MSA is currently in clinical trial to evaluate this new technology. Evidence is insufficient to determine the device's safety or its efficacy to provide clinically meaningful reductions in fecal incontinence frequency and improvements in quality-of-life (QOL) measures. Therefore, the magnetic anal sphincter device is considered experimental/ investigational for treating fecal incontinence.

Summary of Evidence
For individuals who have stress urinary incontinence (SUI) who receive injectable bulking agents, the evidence includes randomized controlled trials (RCTs) and systematic reviews of RCTs. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The trials vary by bulking agents used and comparator interventions (eg, placebo, conservative therapy, surgical procedure, another bulking agent). Due to this heterogeneity across studies, and the small number of studies in each category, Cochrane reviewers were unable to draw specific conclusions about the efficacy of specific bulking agents compared with alternative treatments. Additionally, authors of another recent

systematic review concluded that bulking agents were less effective than surgical procedures regarding subjective improvement after treatment, with no difference between the interventions with regard to complications. Studies have shown that cross-linked collagen improves the net health outcome (ie, it is effective in some patients who have failed conservative treatment with fewer adverse events than surgery), although products that cross-link in such a way are no longer commercially available. There is evidence that the FDA approved carbon-coated spheres, calcium hydroxylapatite, polyacrylamide hydrogel and polydimethylsiloxane have efficacy for treating incontinence, and further that they produce outcomes with a safety profile similar to cross-linked collagen. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have fecal incontinence who receive injectable bulking agents, the evidence includes RCTs and systematic reviews of RCTs. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. A comparative effectiveness review from the Agency for Healthcare Research and Quality evaluated 2 RCTs with the FDA approved product NASHA Dx (Solesta) and 2 RCTs with Durasphere (off-label in the United States). One RCT comparing NASHA Dx with sham found that NASHA Dx improved some outcomes but not others. The other RCT did not find a significant difference in efficacy between NASHA Dx and biofeedback. Two additional RCTs evaluating Durasphere found only short-term improvements in fecal incontinence severity. Controlled trials with longer follow-up are needed to determine the durability of any treatment effect. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

SUPPLEMENTAL INFORMATION

Clinical Input From Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

2013

In response to requests, input was received from 4 physician specialty societies and 4 academic medical centers while this policy was under review in 2013. There was consensus agreement with all of the policy statements among reviewers who provided responses. In particular, there was unanimous agreement among respondents for the statement that use of perianal bulking agents to treat fecal incontinence is considered investigational.

Practice Guidelines and Position Statements

American Society of Colon and Rectal Surgeons American Society of Colon and Rectal Surgeons website. The American Society of Colon and Rectal Surgeons clinical practice guideline for the treatment of fecal incontinence. 2015.

In 2015, the American Society of Colon and Rectal Surgeons published practice parameters for the treatment of fecal incontinence.[45] The document included the following statement on bulking agents: “When passive fecal incontinence caused by internal sphincter dysfunction is the predominant symptom, injectable therapy seems to be effective and safe, although its long-term efficacy has yet to be defined. Level of Evidence: II; Grade of Recommendation: B.”

American College of Obstetricians and Gynecologists

In 2019 (reaffirmed 2023), ACOG published a practice bulletin on the clinical management of fecal incontinence in women.[53] The College stated that "anal sphincter bulking agents may be effective in decreasing fecal incontinence episodes up to 6 months and can be considered as a short-term treatment option for fecal incontinence in women who have failed more conservative treatments." This recommendation is based on limited or inconsistent scientific evidence.

American Gastroenterological Association

In 2017, the American Gastroenterological Association (AGA) published guidance on surgical interventions and the use of device-aided therapy for the treatment of fecal incontinence and defecatory disorders.[46] The AGA recommends, "Perianal bulking agents such as intra-anal injection of dextranomer may be considered when conservative measures and biofeedback therapy fail."

National Institute for Health and Care Excellence

In 2019, The National Institute for Health and Care Excellence updated its guidance on urinary incontinence in women.[47] The updated guidance recommends "intramural bulking agents to manage stress urinary incontinence if alternative surgical procedures are not suitable for or acceptable to the woman." The patient should be educated that these are permanent injectable materials, repeat injections may be needed, and there is limited evidence on long-term effectiveness and adverse events.

In 2015, the National Institute for Health and Care Excellence updated its guidance on urinary incontinence in women.[48] The updated guidance has recommended considering “intramural bulking agents (silicone, carbon-coated zirconium beads or hyaluronic acid/dextran copolymer) for the management of stress UI [urinary incontinence] if conservative management has failed. Women should be made aware that:

- repeat injections may be needed to achieve efficacy
- efficacy diminishes with time
- efficacy is inferior to that of synthetic tapes or autologous rectus fascial slings.”

The United Kingdom’s National Institute for Health and Care Excellence (NICE)[49] issued guidance on radiofrequency treatment for fecal incontinence in 2011. NICE concluded, “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.

The United Kingdom's National Institute for Health and Care Excellence (NICE) issued guidance on radiofrequency treatment for fecal incontinence in 2011.[50] NICE concluded, "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."

American Society of Colon and Rectal Surgeons
The American Society of Colon and Rectal Surgeons (2023)[51], in their updated its practice parameters for the treatment of fecal incontinence The Society states, "Injection of biocompatible bulking agents into the anal canal is not routinely recommended for the treatment of FI [fecal incontinence]" based on low quality evidence showing limited improvement over placebo, diminishing long-term results, and cost.

Government Regulations

ONGOING AND UNPUBLISHED CLINICAL TRIALS
Some currently unpublished trials that might influence this review are listed in Table 1.

Table 1: Current Clinical Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT03825575	Sacral Neuromodulation as Treatment for Fecal Incontinence (LLLT-FI)	20	Feb 2027 (recruiting)
NCT05616208	Implantation of BioSphincter TM for Treatment of Severe Passive Fecal Incontinence	10	Jul 2027 (recruiting)
NCT05708612	Safety and Performance of a Silicone Implant for Fecal Incontinence Treatment (SimplyFI)	36	Sep 2025 (recruiting)
Unpublished			
Published			
NCT01600755	Autologous cell therapy for treatment of fecal incontinence	50	Feb 2024

NCT: National clinical trial

National:
There are no national or local coverage determinations regarding the use of injectable bulking agents for the treatment of fecal incontinence. Requests would be reviewed on an individual consideration basis. Medicare CMS released the Hospital Outpatient Prospective Payment System on 3/1/2014 which references paying for Solesta. For Medicare, the codes to bill for Solesta are C9735, Anoscopy; with directed submucosal injection(s), any substance and must be billed with L8605, Anoscopy; with directed submucosal injections(s), any substance. The service must be reviewed for medical necessity, showing that the patient has failed other conventional, conservative treatment.

The following codes are not listed on DMEPOS CMS Nation Fee Service List 2024

- A4563, L8605

Local:

Bowel Management Devices

LCD ID
L36267

LCD Title
Bowel Management Devices

Proposed LCD in Comment Period
N/A

Source Proposed LCD
DL36267

Original Effective Date
For services performed on or after 12/01/2015

Revision Effective Date
For services performed on or after 10/01/2021

Revision Ending Date
N/A

Retirement Date
N/A

Notice Period Start Date
10/01/2015

Notice Period End Date
11/30/2015

Issue
Issue Description

The HCPCS code A4453 was added due to the 2021, 4th quarter HCPCS code(s) released notification.
CMS National Coverage Policy
National Coverage Determination Manual (Internet-Only Manual 100-03), Chapter 1, Part 4, §230.15, and §280.1.
Coverage Guidance

Coverage Indications, Limitations, and/or Medical Necessity

For any item to be covered by Medicare, it must 1) be eligible for a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements.
Benefit Category and other statutory requirements are discussed in the related Policy Article NONMEDICAL NECESSITY AND COVERAGE RULES section. Refer to the Policy article for information on these criteria.
The purpose of a Local Coverage Determination (LCD) is to provide information regarding "reasonable and necessary" criteria based on Social Security Act §1862(a)(1)(A) provisions. In addition to the "reasonable and necessary" criteria contained in this LCD there are other payment rules, which are discussed in the following documents, that must also be met prior to Medicare reimbursement:

- The LCD-related Standard Documentation Requirements Article, located at the bottom of this policy under the Related Local Coverage Documents section.
- The LCD-related Policy Article, located at the bottom of this policy under the Related Local Coverage Documents section.
- Refer to the Supplier Manual for additional information on documentation requirements.
- Refer to the DME MAC web sites for additional bulletin articles and other publications related to this LCD.

For the items addressed in this LCD, the "reasonable and necessary" criteria, based on Social Security Act §1862(a)(1)(A) provisions, are defined by the following coverage indications, limitations and/or medical necessity.
Bed Pans (E0275, E0276) are covered for beneficiaries who are bed-confined (see NCD 280.1).

Rectal inserts and related accessories (A4337) will be denied as not reasonable and necessary because they do not meet the medical evidence requirements outlined in the Centers for Medicare & Medicaid Services (CMS) Program Integrity Manual (Internet-only Manual 100-08), Chapter 13, §13.7.1.

Electrical continence aids are in the experimental stage of development and there is no valid scientific documentation of their effectiveness and safety; therefore, they are denied as not reasonable and necessary (see NCD 230.15).
Rectal catheters/tubes and related collection systems will be denied as statutorily non-covered (no benefit – see related Policy Article).
Enema systems (gravity and manual pump), codes A4458 and A4459 respectively, will be denied as statutorily non-covered (no benefit – see related Policy Article).
Pulsed irrigation and evacuation systems (E0350, E0352) will be denied as statutorily non-covered (no benefit – see related Policy Article).
Incontinence garments (e.g., briefs, diapers) coded A4520 will be denied as statutorily non-covered (no benefit – see related Policy Article).
Disposable underpads (A4554) and non-disposable (A4553) underpads will be denied as statutorily non-covered (no benefit – see related Policy Article).
Toilet seats, raised toilet seats, toilet seat lift mechanisms, bidets and bidet toilet seats are discussed in the Commodes Local Coverage Determination and related Policy Article.

GENERAL
A Standard Written Order (SWO) must be communicated to the supplier before a claim is submitted. If the supplier bills for an item addressed in this policy without first receiving a completed SWO, the claim shall be denied as not reasonable and necessary.

For Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) base items that require a Written Order Prior to Delivery (WOPD), the supplier must have received a signed SWO before the DMEPOS item is delivered to a beneficiary. If a supplier delivers a DMEPOS item without first receiving a WOPD, the claim shall be denied as not reasonable and necessary. Refer to the LCD-related Policy Article, located at the bottom of this policy under the Related Local Coverage Documents section.
For DMEPOS base items that require a WOPD, and also require separately billed associated options, accessories, and/or supplies, the supplier must have received a WOPD which lists the base item and which may list all the associated options, accessories, and/or supplies that are separately billed prior to the delivery of the items. In this scenario, if the supplier separately bills for associated options, accessories, and/or supplies without first receiving a completed and signed WOPD of the base item prior to delivery, the claim(s) shall be denied as not reasonable and necessary.
An item/service is correctly coded when it meets all the coding guidelines listed in CMS HCPCS guidelines, LCDs, LCD-related Policy Articles, or DME MAC articles. Claims that do not meet coding guidelines shall be denied as not reasonable and necessary/incorrectly coded.

Proof of delivery (POD) is a Supplier Standard and DMEPOS suppliers are required to maintain POD documentation in their files. Proof of delivery documentation must be made available to the Medicare contractor upon request. All services that do not have appropriate proof of delivery from the supplier shall be denied as not reasonable and necessary.

Summary of Evidence
N/A

Analysis of Evidence (Rationale for Determination)
N/A

Bowel Management Devices-Policy Article
A54516

Original Effective Date
10/01/2015
Revisions Effective Date
10/01/2021

Article Guidance

Article Text

NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES:
For any item to be covered by Medicare, it must 1) be eligible for a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements. Information provided in this policy article relates to determinations other than those based on Social Security Act §1862(a)(1)(A) provisions (i.e. “reasonable and necessary”).
In order for any item to be eligible for coverage under Medicare, the item must be eligible for inclusion into one of the existing coverage Benefit Categories. Rectal inserts and electrical

incontinence aids are covered under the Prosthetic Devices benefit (Social Security Act §1861(s)(9)). Bed pans are covered under the Durable Medical Equipment benefit (Social Security Act §1861(s)(6)). In order for a beneficiary's equipment to be eligible for reimbursement, the reasonable and necessary (R&N) requirements set out in the related Local Coverage Determination must be met. In addition, there are specific statutory payment policy requirements, discussed below, that also must be met.

Many bowel management devices (see bulleted list below, not all inclusive) fail one or more of the relevant requirements in §1861(n) of the Act and are thus statutorily excluded from coverage (see the CMS Nation Coverage Determinations Manual (Internet-only Manual 100-03) Chapter 1, Part 4, §280.1):

- Disposable Sheets and Bags (A4335) – Deny – Non-reusable disposable supplies
- Incontinence Pads (A4553 and A4554) – Deny – Non-reusable supply; Hygienic item
- Diapers (A4520) - Deny – Non-reusable supply; Hygienic item

Manual pump enema systems (e.g., Peristeen - Coloplast, Minneapolis, MN) or gravity-administered enema systems do not meet the Durable Medical Equipment (DME) benefit because these devices do not meet the requirement of durability. In addition, these devices do not meet the Prosthetic Benefit because they do not replace a non-functioning internal body organ.

Rectal catheters/tubes and related collection systems do not meet the Durable Medical Equipment (DME) benefit because these devices do not meet the requirement of durability. In addition, these devices do not meet the Prosthetic Benefit because they do not replace a non-functioning internal body organ.

Pulsed irrigation and evacuation devices (PIE – P.I.E. Medical Inc., Buford, GA) do not meet the DME benefit because they are considered institutional equipment.

Vaginal inserts and related accessories (Eclipse Vaginal Insert system - Pelvalon, Inc) for the treatment of fecal incontinence are not DME MAC jurisdiction. Claims for vaginal inserts and related accessories (A4563 - RECTAL CONTROL SYSTEM FOR VAGINAL INSERTION, FOR LONG TERM USE, INCLUDES PUMP AND ALL SUPPLIES AND ACCESSORIES, ANY TYPE EACH) submitted to the DME MACs will be rejected as wrong jurisdiction.

REQUIREMENTS FOR SPECIFIC DMEPOS ITEMS PURSUANT TO Final Rule 1713 (84 Fed. Reg Vol 217)

Final Rule 1713 (84 Fed. Reg Vol 217) requires a face-to-face encounter and a Written Order Prior to Delivery (WOPD) for specified HCPCS codes. CMS and the DME MACs provide a list of the specified codes, which is periodically updated. The required Face-to-Face Encounter and Written Order Prior to Delivery List is available here.

Claims for the specified items subject to Final Rule 1713 (84 Fed. Reg Vol 217) that do not meet the face-to-face encounter and WOPD requirements specified in the LCD-related Standard Documentation Requirements Article (A55426) will be denied as not reasonable and necessary.

If a supplier delivers an item prior to receipt of a WOPD, it will be denied as not reasonable and necessary. If the WOPD is not obtained prior to delivery, payment will not be made for that item even if a WOPD is subsequently obtained by the supplier. If a similar item is subsequently provided by an unrelated supplier who has obtained a WOPD prior to delivery, it will be eligible for coverage.

POLICY SPECIFIC DOCUMENTATION REQUIREMENTS

In addition to policy specific documentation requirements, there are general documentation requirements that are applicable to all DMEPOS policies. These general requirements are located in the DOCUMENTATION REQUIREMENTS section of the LCD.

Refer to the LCD-related Standard Documentation Requirements article, located at the bottom of this Policy Article under the Related Local Coverage Documents section for additional information regarding GENERAL DOCUMENTATION REQUIREMENTS and the POLICY SPECIFIC DOCUMENTATION REQUIREMENTS discussed below.

CODING GUIDELINES

Rectal inserts are prosthetic devices constructed of rubber, latex, silicone or other similar material and act as a barrier to the passage of fecal matter through the rectum. Use code A4337 (INCONTINENCE SUPPLY, RECTAL INSERT, ANY TYPE, EACH) for this item. Code A4337 includes the insert and any associated supplies or accessories for insertion and maintenance of the device.

Rectal catheters/tubes and related collection systems are products designed to be inserted into the rectum to collect fecal material. They also serve to assist in protection of perianal skin integrity in the patient with fluid and semi-fluid waste.

An electrical continence aid is a prosthetic device consisting of a plastic plug, molded into the shape of the patient's anal canal, which contains two implanted electrodes that are connected by a wire to a small portable generator. An electrical current is produced which stimulates the anal musculature to cause a contraction sufficient to hold the plug in while allowing the patient to ambulate without incontinence.

HCPCS codes A4458 (ENEMA BAG WITH TUBING, REUSABLE) and code A4459 (MANUAL PUMP ENEMA SYSTEM, INCLUDES BALLOON, CATHETER AND ALL ACCESSORIES, REUSABLE, ANY TYPE) describe devices used to empty the lower bowel and to prevent chronic constipation and fecal incontinence or simply as a method of bowel management. An enema system consists of an irrigation fluid holding chamber and a rectal catheter (with or without an inflatable balloon). Fluid is instilled either via gravity or a manual pump.

The Peristeen transanal irrigation system is a device used to empty the lower bowel and to prevent chronic constipation and fecal incontinence or simply as a method of bowel management. The system consists of an enema bag, a rectal catheter with an inflatable balloon and a pump. Effective for claims with dates of service on or after January 1, 2015, the correct code to bill is A4459 (MANUAL PUMP ENEMA SYSTEM, INCLUDES BALLOON, CATHETER AND ALL ACCESSORIES, REUSABLE, ANY TYPE).

HCPCS code A4459 is an all-inclusive code at initial issue. Separate billing of any of the individual components is not allowed at initial issue. For billing refills of the disposable rectal catheter, HCPCS code A4453 (RECTAL CATHETER FOR USE WITH THE MANUAL PUMP-OPERATED ENEMA SYSTEM, REPLACEMENT ONLY) must be used.

HCPCS code E0350 describes a colorectal irrigation system that consists of an irrigation fluid holding chamber, a rectal catheter with an inflatable balloon and an electric pump. Irrigation fluid is administered in a pulsatile manner to hydrate stool to a semi-liquid form and allow the liquefied stool to evacuate. Code E0352 describes all disposable supplies and accessories used with code E0350 including, but not limited to, a water reservoir, speculum, valve mechanism and collection bag or box.

HCPCS codes E0275 (BED PAN, STANDARD, METAL OR PLASTIC) and E0276 (BED PAN, FRACTURE, METAL OR PLASTIC) describe a shallow vessel placed under a bedridden patient to collect feces and urine. To meet Medicare coverage and DME benefit requirements, they must be durable. Disposable bed pans must be billed using code A9270 (NONCOVERED ITEM OR SERVICE).

Suppliers should contact the Pricing, Data Analysis and Coding (PDAC) Contractor for guidance on the correct coding of these items.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

- Biofeedback
- Defecography/Proctography
- Sacral Nerve Neuromodulation/Stimulation

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The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through 12/5/24, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
11/1/16	9/23/16	8/26/16	Joint policy established
5/1/17	2/21/17	2/21/17	Deleted code 0288T. Added the following investigational procedures: perianal electrical stimulation (G0283), posterior tibial nerve stimulation (64566), and topical estrogen (J3490). Updated references. Routine policy maintenance.
5/1/18	2/20/18	2/20/18	Routine policy maintenance. No change in policy status.
5/1/19	2/19/19		Routine policy maintenance. Added references 1, 21-22, 34, 40 and 46. Added code A4563, effective 1/1/19.
5/1/20	2/18/20		Routine policy maintenance. Added references 46 and 47. Deleted code 0377T effective 12/31/19. No change in policy status.
5/1/21	2/16/21		Routine policy maintenance. No change in policy status.
5/1/22	2/15/22		Routine policy maintenance. No change in policy status.
5/1/23	2/21/23		Routine policy maintenance, no change in policy status. (ds)
5/1/24	2/20/24		Routine policy maintenance (jf) Added Ref: 12,13,40 -Updated position statements from: -American Gastroenterological Association and American Society of Colon and Rectal Surgeons Moved Supplemental informational to the end of the policy. (was listed in the body of the policy). Per Optum Encoder 0377T was deleted 1/2020 and replaced with 46999 • 46999 nomenclature updated Vendor managed:

			○ G0283 eviCore (BCNA|HMO) appear to be managed by eviCore; however, there are no guidelines regarding fecal incontinence in the PT, OT and ST guidelines. ○ A4335 Northwood (BCNA|MAPPO|HMO|PPO) ○ Literature Review: Eclipse System remain E/I
5/1/25	2/18/25		Routine maintenance (jf) ○ Vendor managed: Northwood ○ Added ref 52,53 ○ Literature Review: Solesta treatment remain E/I

Next Review Date: 1st Qtr. 2026

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: FECAL INCONTINENCE—INVESTIGATIONAL TREATMENTS

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Not covered
BCNA (Medicare Advantage)	See government section
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the individual member's certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.