## Subject: Fecal Incontinence Treatments

### Policy Number: NMP325

#### Effective Date*: March 2007

#### Updated: November 2015

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**This National Medical Policy is subject to the terms in the IMPORTANT NOTICE at the end of this document**

For Medicaid Plans: Please refer to the appropriate State's Medicaid manual(s), publication(s), citations(s) and documented guidance for coverage criteria and benefit guidelines prior to applying Health Net Medical Policies

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**The Centers for Medicare & Medicaid Services (CMS)**

For Medicare Advantage members please refer to the following for coverage guidelines first:

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Instructions
- Medicare NCDs and National Coverage Manuals apply to ALL Medicare members in ALL regions.
- Medicare LCDs and Articles apply to members in specific regions. To access your specific region, select the link provided under “Reference/Website” and follow the search instructions. Enter the topic and your specific state to find the coverage determinations for your region. *Note: Health Net must follow local coverage determinations (LCDs) of Medicare Administration Contractors (MACs) located outside their service area when those MACs have exclusive coverage of an item or service. (CMS Manual Chapter 4 Section 90.2)
- If more than one source is checked, you need to access all sources as, on occasion, an LCD or article contains additional coverage information than contained in the NCD or National Coverage Manual.
- If there is no NCD, National Coverage Manual or region specific LCD/Article, follow the Health Net Hierarchy of Medical Resources for guidance.

Current Policy Statement
Health Net, Inc. considers any of following treatments for severe, chronic fecal incontinence medically necessary when the criteria have been met:

Biofeedback
Health Net, Inc. considers biofeedback training medically necessary for the treatment of fecal incontinence in individuals who can contract the external anal sphincter and who have at least some rectal sensation. Please refer to the Health Net Medical Policy on Biofeedback for more information.

Sacral Nerve Stimulation
Health Net, Inc. considers sacral nerve stimulation medically necessary when all of the following criteria have been met:

1. Inadequate response to conservative treatments (E.g. pharmacotherapy, dietary management, strengthening exercises); and
2. Weak but structurally intact anal sphincter.

Artificial Bowel Sphincter (Acticon Neosphincter)
Health Net, Inc. considers the artificial bowel sphincter medically necessary for members 18 years of age or older with severe fecal incontinence that have failed, or are not candidates for medical or surgical interventions.

Contraindications to the Artificial Bowel Sphincter include either of the following:

- Individuals with incontinence complicated by an irreversibly or obstructed proximal segment of bowel;

OR

- Individuals who are poor candidates for surgery or due to physical or mental conditions.
Not Medically Necessary
Health Net, Inc. considers any of the following treatments for fecal incontinence not medically necessary because there is a lack of randomized, controlled clinical trials and evidence-based data is insufficient to support the safety and effectiveness of these treatments:

- Transanal radiofrequency therapy (Secca procedure)
- Anal electrical stimulation

Investigational
Health Net, Inc. considers injectable bulking agents [e.g. dextranomer/hyaluronic acid (Solesta)] for the treatment of fecal incontinence investigational due to a low quality of evidence in the peer review literature evaluating this treatment. There is a paucity of randomized controlled trials and studies are limited by their small study sizes. In addition, there lacks long-term data regarding durability of this treatment. Further studies to confirm the effects of this and other bulking agents on symptoms and anorectal functions in fecal incontinence are needed. Large, independent, randomized, controlled studies are needed to further evaluate the efficacy, durability, and safety of this treatment.

Definitions
SNS  Sacral Nerve Stimulation
QOL  Quality of Life
FI   Fecal Incontinence
CCFIS Cleveland Clinic Florida Fecal Incontinence Score
FIQL Fecal Incontinence Quality of Life
AE   Adverse events

Codes Related To This Policy
NOTE:
The codes listed in this policy are for reference purposes only. Listing of a code in this policy does not imply that the service described by this code is a covered or non-covered health service. Coverage is determined by the benefit documents and medical necessity criteria. This list of codes may not be all inclusive.

On October 1, 2015, the ICD-9 code sets used to report medical diagnoses and inpatient procedures have been replaced by ICD-10 code sets.

ICD-9 Codes
787.60  Incontinence of feces

ICD-10 Codes
R15-R15-9  Fecal incontinence
R15.9   Full incontinence of feces

CPT Codes
46999  Unlisted procedure, anus
64561  Percutaneous implantation of neurostimulator electrodes; sacral nerve (transforaminal placement) including image guidance, if performed
64581  Incision for implantation of neurostimulator electrodes; sacral nerve (transforaminal placement)
64585  Revision or removal of peripheral neurostimulator electrodes

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64590  Insertion and replacement of peripheral or gastric neurostimulator pulse generator or receiver, direct or inductive coupling
64595  Revision or removal of peripheral or gastric neurostimulator pulse generator or receiver
95970  Electronic analysis of implanted neurostimulator pulse generator system (e.g., rate, pulse amplitude, pulse duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); simple or complex brain, spinal cord, or peripheral (i.e., cranial nerve, peripheral nerve, sacral nerve, neuromuscular) neurostimulator pulse generator/transmitter, without reprogramming
95971  Electronic analysis of implanted neurostimulator pulse generator system (e.g., rate, pulse amplitude. Pulse duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); simple or complex brain, spinal cord, or peripheral (i.e., cranial nerve, peripheral nerve, sacral nerve, neuromuscular) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming
95972  Electronic analysis of implanted neurostimulator pulse generator system (e.g., rate, pulse amplitude. Pulse duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); complex spinal cord or peripheral (i.e, peripheral nerve, sacral nerve, neuromuscular) except cranial nerve) neurostimulator pulse/generator/transmitter, with intraoperative or subsequent programming, up to one hour (code description revised in 2016)
95973  Electronic analysis of implanted neurostimulator pulse generator system (e.g., rate, pulse amplitude, pulse duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); (i.e, peripheral nerve, sacral nerve, neuromuscular) complex spinal cord, or peripheral (except cranial nerve) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming, each additional 30 minutes after first hour (List separately in addition to code for primary procedure (code deleted 12/2015)
0288T  Anoscopy, with delivery of thermal energy to the muscle of the anal canal (eg, for fecal incontinence)
0377T  Anoscopy with directed submucosal injection of bulking agent for fecal incontinence

2016 CPT Code Revision
95972  Electronic analysis of implanted neurostimulator pulse generator system (e.g., rate, pulse amplitude, pulse duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); complex spinal cord or peripheral (i.e, peripheral nerve, sacral nerve, neuromuscular) (except cranial nerve) neurostimulator pulse/generator/transmitter, with intraoperative or subsequent programming

HCPCS Codes
A4290  Sacral nerve stimulation test lead, each
C9716  Creations of thermal anal lesions by radiofrequency energy (code deleted in 2012)
C9738  Anoscopy; with directed submucosal injections, any substance (code deleted in 2015)
Scientific Rationale – Update November 2015
The American Society of Colon and Rectal Surgeons’ Clinical Practice Guideline for the Treatment of Fecal Incontinence (Jul 2015) made the following recommendations regarding injection of biocompatible bulking agents:

Injection of biocompatible bulking agents into the anal canal may help to decrease episodes of passive fecal incontinence. Grade of Recommendation: Weak recommendation based on moderate-quality evidence, 2B. Per the guideline, injectable compounds may play a role for patients with mild incontinence. The ideal injectable agent would be a biocompatible compound that is small enough to inject, yet large enough to minimize migration. Results of studies have been inconsistent and difficult to interpret owing to the multiple compounds and injection techniques that have been used. Although some studies showed modest short-term improvements, no study evaluated the long-term benefits of these therapies. They note some materials appeared to work better than others. The guidelines notes further, a nonanimal stabilized hyaluronic acid dextranomer gel for submucosal injection was FDA approved in 2011, however. the clinical evidence for this treatment is limited, because no comparisons with other treatments are available.

Sanchez et al (2015) aimed to establish the validity and responsiveness of ≥50% reduction in fecal incontinence (FI) episodes (responder50) as the threshold indicative of clinically meaningful response. Adults with a Cleveland Clinic Florida fecal incontinence score ≥10 were randomized to receive nonanimal stabilized hyaluronic acid/dextranomer (NASHA/Dx) injection or sham treatment in a 6-month trial. Validity and responsiveness of the primary end point were evaluated post hoc. The data were compared using different thresholds for defining a responder for a number of end points. Data from 206 patients (NASHA/Dx, n=136; sham, n=70) were evaluated. Incremental patient response threshold increases showed that although the percentage of patients who achieved response decreased with increasing threshold, the difference between treatments remained significant up to an 80%
response threshold (NASHA/Dx, 23%; sham, 10%; P=0.02). Response thresholds between 40% and 80% demonstrated evidence for convergent validity, with the strongest correlation with the number of FI episodes, the number of FI episodes when the patient was awake, and the number of FI-free days observed at ≥40% and ≥50% thresholds. Further examination of the responder50 threshold indicated that, regardless of treatment (NASHA/Dx or sham), responders performed significantly better than nonresponders on nearly all secondary efficacy end points. The authors concluded the study demonstrates the responsiveness, validity, and clinical applicability of the ≥50% response threshold in clinical studies of patients with FI receiving treatment with NASHA/Dx.

The American Society of Colon and Rectal Surgeons’ Clinical Practice Guideline for the Treatment of Fecal Incontinence (Jul 2015) made the following recommendations regarding Radiofrequency Energy Delivery:

- Application of temperature-controlled radiofrequency energy to the sphincter complex may be used to treat fecal incontinence. Grade of Recommendation: Weak recommendation based on moderate-quality evidence, 2B. They guidelines states, because of the limitations in the available data, alternative treatments should be pursued before considering radiofrequency energy delivery.

**Scientific Rationale – Update November 2014**
The American College of Gastroenterology Clinical Guideline on the Management of Benign Anorectal Disorders (Aug 2014) makes the following recommendations for minimally invasive procedures in the treatment of fecal incontinence:

- Minimally invasive procedures such as injectable anal bulking agents may have a role in patients with FI who do not respond to conservative therapy (weak recommendation, moderate-quality of evidence).
- There is insufficient evidence to recommend radiofrequency ablation treatment to the anal sphincter (SECCA) at this time (no recommendation, insufficient evidence).

Per the guidelines:

“Injectable bulking agents are used to augment the urethral sphincter and to treat urinary incontinence. One substance was recently approved by the Food and Drug Administration (FDA) for managing FI. In a multicenter, placebo-controlled randomized trial of a perianal bulking agent (nonanimal stabilized hyaluronic acid / dextranomer (NASHA / Dx)) in 206 patients with FI (103), a 50 % reduction in incontinence episodes was reported more frequently for NASHA / Dx (52 % of patients) than placebo (31 %) at 12 months, of whom 6 % became completely continent. With the exception of 2 serious adverse events (i.e., rectal abscess and prostatic abscess), most of the 128 adverse events were minor. An accompanying editorial observed that without baseline severity data it is challenging to interpret the 50 % reduction in episodes in absolute terms. Treatment did not affect embarrassment scores related to FI. ARM and imaging were not performed; hence, patient characteristics and mechanisms of action were unknown. It is unclear whether 4 – 8 ml of a substance can mechanically occlude the anus, which has a wide lumen, or whether this substance migrates. In summary, although these results seem promising, further studies to confirm the effects of this and other bulking agents on symptoms and anorectal functions in fecal continence are awaited.”

Mellgren et al (2014) reported on a prospective multicenter trial of 136 patients with fecal incontinence (FI) who received the NASHA Dx bulking agent. Treatment success was
Fecal Incontinence

defined as a reduction in number of FI episodes by 50% or more compared with baseline (Responder50). Change from baseline in Cleveland Clinic Florida Fecal Incontinence Score (CCFIS) and Fecal Incontinence Quality of Life Scale (FIQL), and adverse events were also evaluated. Successful decrease in symptoms was achieved in 52% of patients at 6 months and this was sustained at 12 months (57%) and 36 months (52%). Mean CCFIS decreased from 14 at baseline to 11 at 36 months (p < 0.001). Quality-of-life scores for all four domains improved significantly between baseline and 36 months of follow-up. Severe adverse events were rare and most adverse events were transient and pertained to minor bleeding and pain or discomfort. The investigators concluded submucosal injection of NASHA Dx provided a significant improvement of FI symptoms in a majority of patients and this effect was stable during the course of the follow-up and maintained for 3 years.

Lam et al (2014) evaluated clinical response and sustainability of Secca for FI in a non-randomised study prospective cohort study. The study involved patients who had failed full conservative management for FI. FI was scored using the Vaizey score (VS). A clinically significant response to Secca was defined as ≥50% reduction in incontinence score. Impact of FI on quality of life (QOL) was measured using the FIQL. Data was obtained at baseline, at 6 months and at 1 and 3 years. Anal endosonography and anal manometry were performed at 3 months and compared to baseline. Thirty-one patients received Secca. During follow-up, 5/31 (16%), 3/31 (10%) and 2/31 (6%) of patients maintained a clinically significant response after the Secca procedure. Mean VS of all patients was 18 (SD 3), 14 (SD 4), 14 (SD 4) and 15 (SD 4), at baseline, 6 months and 1 and 3 years. No increases in anorectal pressures or improvements in rectal compliance were found. Coping improved between baseline and t=6 months. No predictive factors for success were found. The authors reported the study showed disappointing outcomes of the Secca procedure for the treatment of FI. The far minority of patients reported a clinically significant response of seemingly temporary nature. Secca might be valuable in combination with other interventions for FI, but this should be tested in strictly controlled randomised trials.

Felt-Bersma (2014) reviewed the clinical response and sustainability of SECCA for patients with anal incontinence (AI). The outcome measures, fecal incontinence scores, definition of response, clinical results and anorectal evaluation were analysed. Ten studies were included, which involved 150 original patients. Three studies reported a long-term follow-up. The one-year follow-up shows a moderate effect, which declines somewhat over time. Only minor temporary side-effects are reported and none of the patients declined treatment. The reviewers concluded SECCA is a safe and well-tolerated procedure that is easy to perform without any serious short- or long-term complications, but with only a moderate clinical effect that declines over time. Results of randomized, sham-controlled controlled trials are awaited.

Scientific Rationale – Update November 2013

La Torre and de la Portilla et al (2013) reported that NASHA/Dx gel, a biocompatible, nonallergenic bulking agent consisting of nonanimal stabilized hyaluronic acid and dextranomer microspheres, has demonstrated efficacy and safety for up to 12 months after treatment. They sought to evaluate the long-term efficacy and safety of NASHA/Dx, assessed 24 months after treatment. This study was a 24-month follow-up assessment of patients treated with NASHA/Dx under open-label conditions. Data on FI episodes and quality of life measures were collected from diaries over the 28-day period immediately preceding the 24-month assessment. Adverse events were collected. Eighty-three of 115 patients completed the 24-month follow-up assessment. At 24 months, 62.7% of patients were considered responders and experienced a ≥ 50% reduction in the total number of FI episodes. The median number of FI episodes declined by 68.8% (P < 0.001). Episodes of both solid and liquid stool incontinence decreased. The mean number of incontinence-free
days increased from 14.6 at baseline to 21.7 at 24 months (P < 0.001). Incontinence scores and FI quality of life scores also showed significant improvements. The most common adverse events (AEs) were proctalgia (13.3%) and pyrexia (9.6%). The majority of AEs were mild to moderate, self-limited and resolved within 1 month of the injection. Investigators concluded NASHA/Dx is safe, effective and durable over a 24-month period with a majority of patients experiencing significant improvement in multiple symptoms associated with FI.

Morris et al (2013) sought to compare two synthetic injectable bulking agents, with known efficacy (PTQ: a silicone biomaterial and Durasphere: pyrolytic carbon-coated beads), in the form of a randomized clinical trial. Circumferential injection of either agent was performed under local anesthesia and sedation as a day-case procedure. The primary outcome measure was the Wexner incontinence scale. Secondary measures were the short-form 36 (SF-36) quality of life assessment and manometry (maximum resting and squeeze pressures). Follow-up was at 6 weeks, 6 and 12 months. Thirty-five patients were randomised, 17 to PTQ and 18 to Durasphere. Early closure of the trial occurred, due to the removal of the agent PTQ, from the Australian Pharmaceutical Benefits scheme. Wexner incontinence scores were significantly better than baseline, in both groups, at 6 weeks and 6 months (P < 0.05), although the improvements were not significant at 12 months. There was no significant improvement for either agent, from baseline, in mean SF-36 scores at any follow-up sessions. There was no significant difference between the two bulking agents, with regard to both Wexner and SF-36 scores, at any of the follow-up sessions. Complications occurred in one patient in the PTQ group (perianal abscess) and did not occur in any of the patients in the Durasphere group. Investigators concluded the trial appears to show that both synthetic agents PTQ and Durasphere are effective and safe, although long-term improvement is limited. In this trial, there appears to be no difference in efficacy between the two agents, over a 12-month follow-up period.

Frascio et al (2013) reviewed clinical studies of radiofrequency energy to treat patients with fecal incontinence. Twelve studies were included. Outcomes analyzed included quality of life, Wexner incontinence score, anorectal manometry, and endoanal ultrasound findings. A total of 220 patients from 10 studies were included. In the majority of clinical studies, the SECCA procedure has been shown to effectively treat mild-to-moderate fecal incontinence. Reviewers concluded when patient selection is appropriate, this treatment has demonstrated clinically significant improvements in symptoms as demonstrated by statistically significant reductions in the Wexner incontinence and quality of life scores.

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

Salix Pharmaceuticals is enrolling participants by invitation only to participate in a clinical trial that will evaluate the long term safety and efficacy of Solesta Injectable Bulking Agent for the treatment of fecal incontinence.

Scientific Rationale – Update November 2012

According to the U. S. Food and Drug Administration approval, Solesta is indicated 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 biocompatible tissue bulking agent which is to be injected submucosally in the proximal part of the high pressure zone of the anal canal. For each treatment, a series of 4 equally spaced injections with 1 mL of Solesta each is performed approximately 5 mm proximal to the dentate line. The aim is to expand the submucosal layer in the proximal anal canal and thereby improve bowel control. The efficacy of Solesta in treatment of fecal incontinence has only been studied in patients with an intact or partially functioning anorectal sphincter.

The FDA based its approval of Solesta on a prospective, randomized, subject/evaluator blinded, sham-controlled study performed within a clinical setting in 13 sites across the US (8 sites), the UK (1 site), Germany (1 site), and Sweden (3 sites). In addition, clinical data from an additional outside United States (OUS) Open Label study and a single center proof-of-concept study were used as support.

Graf et al (2011) reported results of this randomized, double-blind, sham-controlled trial. Patients aged 18-75 years were randomly assigned (2:1) to receive either transanal submucosal injections of NASHA Dx or sham injections. Randomization was stratified by sex and region in blocks of six, and managed with a computer generated, real-time, web-based system. Patients and investigators were masked to assignment for 6 months when the effect on severity of fecal incontinence and quality of life was assessed with a 2-week diary and clinical assessments. The primary endpoint was response to treatment based on the number of incontinence episodes. A response to treatment was defined as a reduction in number of episodes by 50% or more. Patients in the active treatment group are still being followed up. 278 patients were screened for inclusion, of whom 206 were randomised assigned to receive NASHA Dx (n=136) or sham treatment (n=70). 71 patients who received NASHA Dx (52%) had a 50% or more reduction in the number of incontinence episode, compared with 22 patients who received sham treatment (31%) The mean increase in number of incontinence–free days at six months was greater in the active treatment group than the sham treatment group, but no significant difference was noted at
3 months. The median decrease in number of incontinence episodes was not significantly greater in the active treatment group than in the sham treatment group at both 3 months and six months. Investigators recorded 128 treatment-related adverse events, of which two were serious (1 rectal abscess and 1 prostatic abscess). Investigators concluded anal injection of NASHA Dx is an effective treatment for fecal incontinence. A refinement of selection criteria for patients, optimum injected dose, ideal site of injection, and long-term results might further increase the acceptance of this minimally invasive treatment.

Schwandner et al (2011) analyzed safety and functional outcome of transanal submucosal injection of dextranomer hyaluronic acid ("bulking agents therapy") in patients with passive fecal incontinence in a prospective study. 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 × 1 mL dextranomer hyaluronic acid 5 mm above the dentate line. The primary endpoint focused on symptom improvement provided as the change in incontinence status and quality of life using validated scores (Wexner incontinence score, symptom-specific Fecal Incontinence Quality of Life [FIQoL] scale, and generic EQ-5D-Visual Analogue Scale [EQ-5D-VAS]). Within the observation period (July 2007 to May 2009), a total of 21 patients (17 women) with passive fecal incontinence were treated. Neither morbidity nor adverse events were documented. Three months postoperatively, 61.1% (11/18) showed significant improvement of symptoms (reduction of incontinence episodes and soiling), which was sustained after 20 months in 55.6% (10/18). Wexner incontinence score decreased from 16.8 to 12.3. Significant improvement was documented for FIQoL and EQ-5D-VAS. Investigators concluded the results indicate that injection therapy using hyaluronic acid is an innovative and minimally invasive procedure with no morbidity. Although Wexner incontinence score is not significantly influenced, a significant improvement in quality of life was observed in more than 50% of patients.

Danielson et al (2009) evaluated NASHA Dx gel as an injectable anal canal implant for the treatment of fecal incontinence. Thirty-four patients (5 males, 29 females; median age, 61 years; range, 34 to 80) were injected with 4 × 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 percent) at 12 months. No long-term side effects or serious adverse events were reported. Investigators concluded submucosal injection of NASHA Dx gel is an effective treatment for fecal incontinence. The effect is sustained for at least 12 months. The treatment is associated with low morbidity.

Solesta is contraindicated in patients with any of the following conditions:

- Active inflammatory bowel disease
- Immunodeficiency disorders or ongoing immunosuppressive therapy
- Previous radiation treatment to the pelvic area.
- Significant mucosal or full thickness rectal prolapse
- Active anorectal conditions including: abscess, fissures, sepsis, bleeding, proctitis, or other infections
- Anorectal atresia, tumors, or malformation
- Rectocele
- Allergy to hyaluronic acid based products
• Rectal varices
• Presence of existing implant (other than Solesta) in anorectal region

Guidelines from the American College of Gastroenterology on the Diagnosis and Management of Fecal Incontinence (2004) state, “Anal plug devices, sphincter bulking therapies or electrical stimulation should be considered as experimental and merit controlled clinical trials.”

Guidance from the National Institute of Clinical Excellence (NICE) on injectable bulking agents for fecal incontinence (2007) states, “Evidence on the safety and efficacy of injectable bulking agents for faecal incontinence does not appear adequate for this procedure to be used without special arrangements for consent and for audit or research, which should take place in the context of a clinical trial or formal audit protocol that includes information on well-defined patient groups.”

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

Dodi et al (2010) evaluated the safety and efficacy of NASHA/Dx gel in the treatment of fecal incontinence (FI). One hundred fifteen eligible patients suffering from FI received 4 injections of 1 mL NASHA/Dx gel. Primary efficacy was based on data from 86 patients that completed the study. This study demonstrated a ≥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 (P < .001) 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 adverse events (Aes) (94.9%) were mild or moderate intensity, and (98.7%) of AEs resolved spontaneously, or following treatment, without sequelae. Investigators concluded the results of this study indicate 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 randomized, blinded, multicenter Study to evaluate NASHA/Dx for the treatment of fecal incontinence is ongoing.

Scientific Rationale – Update December 2010
According to guidelines on fecal incontinence from the American College of Gastroenterology (ACG), “Biofeedback therapy is a safe and effective treatment. It improves symptoms of fecal incontinence, restores quality of life, and improves objective parameters of anorectal function. It is useful in patients with weak sphincters and/or impaired sensation.” The ACG notes further, anal plug devices, sphincter bulking therapies and electrical stimulation should be considered investigational.
A practice parameter from the American Society of Colon and Rectal Surgeons (2007) states “Biofeedback is recommended as an initial treatment for motivated patients with incontinence with some voluntary sphincter contraction”. Per the ASCRS, “Biofeedback may be considered a first-line option for many patients with fecal incontinence who have not responded to simple dietary modification or medication. The benefit of biofeedback is variable and improvement in as many as 64 to 89 percent of patients has been reported. Biofeedback is performed to improve sensation, coordination, and strength.” Biofeedback has also been recommended by the American Gastroenterological Association for patients with fecal incontinence associated with structurally intact sphincter rings.

Heymen et al (2009) compared manometric biofeedback with pelvic floor exercises for the treatment of fecal incontinence in a randomized controlled trial controlling for nonspecific treatment effects. After excluding patients who were adequately treated with medication, education, and behavioral strategies (21%), 108 patients (83 females; average age, 59.6 years) underwent either pelvic floor exercises alone (n = 63) or manometric biofeedback plus pelvic floor exercises (n = 45). Patients in both groups were taught behavioral strategies to avoid incontinence. At three-month follow-up, biofeedback patients had significantly greater reductions on the Fecal Incontinence Severity Index (P = 0.01) and fewer days with fecal incontinence (P = 0.083). Biofeedback training increased anal canal squeeze pressure more than pelvic floor exercises did (P = 0.014) and with less abdominal tension during squeeze (P = 0.001). Three months after training 76% of patients treated with biofeedback vs. 41% patients treated with pelvic floor exercises reported adequate relief. Before treatment, the groups did not differ on demographic, physiologic, or psychologic variables, symptom severity, duration of illness, quality-of-life impact, or expectation of benefit. At 12-month follow-up, biofeedback patients continued to show significantly greater reduction in Fecal Incontinence Severity Index scores and more patients continued to report adequate relief. The investigator concluded the investigation provides definitive support for the efficacy of biofeedback. Biofeedback training resulted in greater reductions in fecal incontinence severity and days with fecal incontinence. Biofeedback was also more effective than pelvic floor exercises alone in producing adequate relief of fecal incontinence symptoms in patients for whom conservative medical management had failed.

Naimy et al (2007) evaluated the effect of biofeedback and electrostimulation in a randomized, clinical trial for the treatment of patients with postdelivery anal incontinence. Forty-nine females who sustained third-degree or fourth-degree perineal rupture with a mean age of 36 (range, 22-44) years were included in the study. The females were randomized to biofeedback or electrostimulation treatment. Forty females completed the study: 19 in the biofeedback and 21 in the electrostimulation group. Biofeedback or electrostimulation sessions were performed two times daily for eight weeks in each group. Wexner incontinence score, fecal incontinence quality of life scores, and reduced quality of life on visual analog scale were registered before and after treatment. Patients' self-rating of treatment effect also was registered in both groups. The primary outcome measure was the Wexner incontinence score. There were no differences in treatment effect between groups. Comparing pretreatment status to posttreatment in each group showed no improvement in Wexner score, reduced quality of life, or any of the fecal incontinence quality of life scores. Patients' self-rating of the treatment effect, however, showed a subjective improvement of symptoms both in the biofeedback and in the electrostimulation group (median, 7 vs. 5.) The investigator concluded the study showed that there was no difference in effect between biofeedback and electrostimulation. Neither biofeedback nor electrostimulation treatments improved Wexner incontinence score, reduced quality of life, or fecal incontinence quality of life scores. Both treatments resulted in improvement of patients' subjective perception of incontinence control.
According to the Practice Parameter on the treatment of fecal incontinence from the American Society of Colon and Rectal Surgeons, “The SECCA (safety and effectiveness of temperature-controlled radio-frequency energy delivery to the anal canal) procedure may be useful for selected patients with moderate fecal incontinence. [Level of Evidence, IV (well-designed, nonexperimental studies, such as comparative and correlational descriptive and case studies); Grade of Recommendation, C (evidence of Type II, III, or IV but inconsistent findings”).]

Ruiz et al (2010) evaluated improvement in fecal incontinence and quality of life after the Secca radiofrequency procedure at 1-year follow-up. Twenty four patients with fecal incontinence (23 females) for at least 3 months were prospectively recruited and underwent the Secca procedure. The Cleveland Clinic Florida Fecal Incontinence Score and the Fecal Incontinence Quality of Life Questionnaire were completed at the first visit and then at 12-month follow-up. Wilcoxon signed rank test was used to analyze the difference between baseline and follow-up. Sixteen patients were available at the 12-month follow-up visit. The main causes of fecal incontinence were either idiopathic or included obstetric injury, aging, and trauma from previous anorectal surgeries. The mean operative time was 45.5 +/- 8.3 minutes, and the mean number of radiofrequency lesions in the anal canal was 65.5 +/- 13.8. There were 3 self-limited episodes of postoperative bleeding and 1 instance of constipation that was resolved with laxatives. There were no delayed complications. The mean Cleveland Clinic Florida Fecal Incontinence Score improved from a mean of 15.6 (+/- 3.2) at baseline to 12.9 (+/- 4.6) at 12 months (P = .035). The mean Fecal Incontinence Quality of Life Questionnaire score improved in all subsets except for the depression subscore. The investigators concluded radiofrequency is a safe, minimally invasive tool for treating patients with fecal incontinence. Improvement in fecal incontinence and quality of life was maintained at 12 months without delayed morbidity. The actual significance of this improvement is yet to be determined.

Takahashi-Monroy et al (2008) evaluated the long-term (5-year) durability of radiofrequency energy delivery for fecal incontinence. This was an extension of the follow-up from an original prospective study in which patients who suffered from fecal incontinence were treated with the SECCA system for radiofrequency energy delivery to the anal canal muscle. The Cleveland Clinic Florida Fecal Incontinence Scale (0-20), fecal incontinence-related quality of life score, and Medical Outcomes Study Short-Form 36 were administered to five years. Differences between baseline and follow-up were analyzed by using paired t-test. A total of 19 patients were treated and followed for five years, including 18 females. The mean duration for fecal incontinence was 7.1 (range, 1-21) years. At five-year follow-up, the mean fecal incontinence score had improved from 14.37 to 8.26 (P<0.00025) with 16 patients (84.2 percent) demonstrating>50 percent improvement. All fecal incontinence-related quality of life scores improved, including lifestyle (2.43 to 3.15; P<0.00075), coping (1.73 to 2.6; P<0.00083), depression (2.24 to 3.15; P<0.0002), and embarrassment (1.56 to 2.51; P<0.0003). The social function component of the Short-Form 36 improved from 38.3 to 60 (P<0.05). There was a trend toward improvement in the mental component summary of the Short-Form 36 from 38.1 to 48.14. There were no long-term complications. The investigator concluded significant and sustained improvements in fecal incontinence symptoms and quality of life are seen at five years after treatment with the SECCA system. They noted this treatment should be considered for patients suffering from fecal incontinence not amenable to surgery and who have failed conservative management.

According to the Practice parameter for the treatment of fecal incontinence from the American Society of Colon and Rectal Surgeons, “The artificial bowel sphincter has a role in the treatment of severe fecal incontinence, especially in patients with significant sphincter
Ruiz et al (2009) evaluated the long-term morbidity, functional results and quality of life (QOL) after treatment of severe fecal incontinence (FI) with the Acticon Neosphincter. Seventeen consecutive patients (14 female, 3 male; median age 46) underwent sphincter implantation. Clinical evaluation, incontinence severity and QOL were assessed. Anorectal manometry, endoanal ultrasound and pudendal nerve latency were performed preoperatively and at several stages of follow-up. Mean follow-up was 68 months (range: 3-133). Morbidity occurred in 100% of patients from which 65% required at least one re-operation. After the first implant, 11 devices had to be removed (65%). Seven patients had a new implant. At the final stage, Acticon was activated in 9 cases (53%). Severity of FI improved from a median of 17.5 preoperatively to 9, 5.5, and 10 at 6, 12 months and at the end of follow-up, respectively. There was a significant improvement in QOL in all postoperative controls. Severity of FI did not show a correlation with QOL in the preoperative period, but did at 6, 12 months and at the end of follow-up. Mean maximum resting pressure significantly increased with the full anal cuff. The investigator concluded there is a high rate of morbidity, surgical re-interventions and explants after Acticon implant and patients should be clearly informed about this before surgery. However, patients who have not had Acticon Neosphincter explanted, experience a significant improvement in anal continence and QOL.

Meurette et al (2009) compare sacral nerve stimulation (SNS) to artificial bowel sphincter (ABS) implanted patients to assess the rationale of this approach in achieving satisfying functional results and improved quality of life (QoL). Among 27 patients tested, 15 patients were successfully managed with SNS. They were compared to 15 matched patients implanted with ABS in a previous period (control group). Assessment of continence level (Cleveland Clinic score), constipation score (Knowles, Eccersley, Scott Score) and QoL (Short-Form 36) were prospectively collected. Both groups were comparable for clinical parameters (age, gender, anal testing and etiology of incontinence) and anal physiology. The mean postoperative continence score was significantly higher in the SNS group [9.4 (+/-3.3) vs 5.7 (+/-3.9), P < 0.01]; however, the mean constipation score was higher in the ABS group (6.3 +/- 6.3 vs 12.8 +/- 5.7, P < 0.01). The mean QoL score was similar in both groups. The mean follow-up after implantation was 15 (+/-9) months in the SNS group, and 43 (+/-33) months in the ABS group. The authors concluded SNS offers satisfying results in terms of QoL, similar to that of ABS. Although it seems to be less effective in restoring continence level, symptoms of outlet obstruction are more frequent after ABS. This SNS approach should be proposed as a first-line treatment of fecal incontinence in selected patients. ABS should remain an option that can improve function.

Maeda et al (2010) performed a Cochrane review to determine the effectiveness of perianal injection of bulking agents for the treatment of fecal incontinence in adult. Two reviewers assessed the methodological quality of eligible trials and independently extracted data from included trials using a range of pre-specified outcome measures. Four eligible randomized trials were identified with a total of 176 patients. All trials but one were at an uncertain or high risk of bias. Most trials reported a short-term benefit from injections regardless of the material used as outcome measures improved over time. A silicone biomaterial (PTQ), was shown to provide some advantages and was safer in treating fecal incontinence than carbon-coated beads (Durasphere) in the short term. Similarly, there were short-term benefits from injections delivered under ultrasound guidance compared with digital guidance. However, PTQ did not demonstrate obvious clinical benefit compared to control
injection of normal saline. No long-term evidence on outcomes was available and further conclusions were not warranted from the available data. The reviewers concluded a definitive conclusion cannot be drawn regarding the effectiveness of perianal injection of bulking agents for fecal incontinence due to the limited number of identified trials together with methodological weaknesses. Within the available data, however, they found no reliable evidence for effectiveness of one treatment over another in improving fecal incontinence. Larger well-designed trials with adequate numbers of subjects using reliable validated outcome measures are needed to allow definitive assessment of the treatment for both effectiveness and safety.

According to guidelines on fecal incontinence from the ACG, "Anal plug devices, sphincter bulking therapies or electrical stimulation should be considered as experimental and merit controlled clinical trials."

**Scientific Rationale**

Fecal or bowel incontinence is considered severe when it results in the involuntary loss of solid or liquid stool on a weekly or more frequent basis, sufficient enough to result in impaired quality of life for the individual. The American Psychiatric Association defines fecal incontinence as continuous or recurrent uncontrolled passage of fecal material (>10 mL) for at least one month in an individual older than four years of age.

Fecal incontinence is estimated to affect approximately 5.5 million people in the U.S., 3%-8% of adults and children, and is severe enough to interfere with the quality of life and work in 6%. It is more common in women and in older adults, but is not a normal part of aging. Often, embarrassment, unpredictability of fecal loss and the stigma associated with this condition, prevent people from seeking treatment, even when incontinence affects his or her quality of life. Many people resort to altering their social and physical activities, even their employment, to cope with the problem, which often leads to social isolation.

There are many causes of bowel incontinence including any of the following:

- Congenital abnormalities such as spina bifida and myelomeningocele with resultant spinal cord damage can result in fecal incontinence;
- Damage to the anal sphincter from vaginal delivery (Injury to the nerves and muscles of the rectum and anus while giving birth can cause fecal incontinence);
- Surgical procedures. (EG. Surgery to treat hemorrhoids can cause damage to the anus and result in fecal incontinence);
- Neoplastic processes;
- Several inflammatory bowel conditions;
- Diabetes Mellitus (People with diabetes could have damage to the nerves that help control defecation);
- Stroke;
- Spinal cord trauma. (EG. Paralysis);
- Degenerative disorders of the nervous system. (EG. Multiple Sclerosis);
- Late-stage Alzheimer's disease (Fecal incontinence is often a sign of this disease, in which both dementia and nerve damage play a role);

and/or

- Radiation treatment to the lower pelvic region.

The conditions noted above may alter normal sensation, feedback, or function of the complex mechanism of anal continence.
The following are diagnostic procedures that may be used to determine the cause of fecal incontinence:

A  Manometry  
B  Anal endosonography (Anal ultrasound)  
C  Nerve studies  
D  Flexible sigmoidoscopy  
E  MRI

**Medical Treatments**
The choice of therapy depends on the etiology of incontinence, the anatomy of the sphincters, and also on the effect of incontinence on the quality of life of the patient.

Treatments for fecal incontinence could include **any** of the following:

1. Pharmacotherapy;  
2. Dietary management;  
3. Bulking agents;  
4. Strengthening exercises;

**Pharmacotherapy**
Any of the following medications could be ordered to treat fecal incontinence, depending on the etiology of this condition, such as:

- Anti-diarrheal drugs - The physician may recommend medications to reduce diarrhea, such as loperamide (Imodium).  
- Laxatives - Chronic constipation could cause incontinence. In this situation, the temporary use of mild laxatives, to help restore normal bowel movements, may be recommended.  
- Stool softeners – These could be recommended to prevent stool impaction.  
- Other medications - If diarrhea is the cause of fecal incontinence, drugs that decrease bowel motility may be prescribed.

**Dietary management**
The physician may recommend dietary changes to help to improve bowel movements. For example, if chronic constipation were responsible for fecal incontinence, an increase in fluids and fiber rich foods would be indicated. If diarrhea is contributing to the problem, the recommendation may be to increase the high fiber foods to add bulk to the stools.

**Bulking Agents**
Oral substances that promote bulkier stools may help control bowel function in people who have liquid stools by absorbing stool water, thereby thickening the consistency of stool. Methylcellulose (a form of fiber) is one type of bulking substance that is commonly used. Increasing dietary fiber may also help to bulk stools.

Injectable bulking agents have been successfully used to treat urinary incontinence for many years. More recently, several of these agents have been adapted for use in the management of fecal incontinence. Examples of these products include (among others) the silicone-based PTQ Implants, pyrolytic carbon-coated zirconium oxide beads (Durasphere), glutaraldehyde cross-linked collagen, and dextranomer-hyaluronic acid copolymer (Zuidex). To date, only small case series have been reported regarding the use of any of these.
products for fecal incontinence. Although initial results are encouraging, randomized clinical trials are needed to establish the efficacy of this approach. In addition, further studies are needed to identify the optimal agent and establish such important details as the injection volume and the location and technique of injection.

**Strengthening Exercises**

Muscle-strengthening exercises (called Kegel exercises or pelvic floor exercises) can be very helpful in treating bowel incontinence. In Kegel exercises, the muscles of the anus, buttocks, and pelvis are contracted and then held as hard as possible for a slow count of five and then the patient relaxes. A series of 30 of these exercises should be done three times daily. The goal of this therapy is to strengthen the pelvic floor muscles and improve the incontinence.

**Anal Electrical Stimulation**

Anal electrical stimulation involves daily home stimulation using an anal probe electrode. A controlled trial suggested that it has only a modest benefit, possibly from increasing sensitization of the anal area. This is considered investigational since there have been few controlled studies and data is insufficient data to draw meaningful conclusions regarding the efficacy of this treatment.

Terra MP, et al (2006) performed a study on electrical stimulation and pelvic floor muscle training with biofeedback in patients with fecal incontinence. A total of 281 patients (252 females) were included. Data about medical history, anal manometry, rectal capacity measurement, and endoanai sonography were collected. Subgroups of patients were defined by anal sphincter complex integrity, and nature and possible underlying causes of fecal incontinence. Subsequently patients were referred for pelvic floor rehabilitation, comprising nine sessions of electric stimulation and pelvic floor muscle training with biofeedback. Pelvic floor rehabilitation outcome was documented with Vaizey score (The Vaizey score is based on an incontinence questionnaire), anal manometry, and rectal capacity measurement findings. Vaizey score improved from baseline in 143 of 239 patients (60 percent), remained unchanged in 56 patients (23 percent), and deteriorated in 40 patients (17 percent). Mean Vaizey score reduced with 3.2 points (P < 0.001). A Vaizey score reduction of >or= 50 percent was observed in 32 patients (13 percent). Pelvic floor rehabilitation leads overall to a modest improvement in severity of fecal incontinence, squeeze pressure, and maximal tolerated volume. Only in a few patients, a substantial improvement of the baseline Vaizey score was observed. Further studies are needed to identify patients who most likely will benefit from electrical stimulation and pelvic floor rehabilitation.

**Transanal Radiofrequency Therapy**

Transanal radiofrequency therapy is a noninvasive procedure being proposed as an alternative to surgical intervention (e.g., Secca procedure). Radiofrequency therapy is based upon the theory that collagen deposition and subsequent scarring may increase one’s ability to recognize and retain stool and permit improved continence (Parisien and Corman, 2005). The Secca procedure is being proposed as an alternative treatment for patients who have not responded to medical therapy and are not good surgical candidates or for those patients where surgical intervention was unsuccessful.

The Secca procedure typically takes 30-45 minutes and is performed in the outpatient setting under local anesthesia and sedation. An anoscopy device uses four electrodes to deliver controlled radiofrequency energy to the sphincter muscles surrounding the anal canal. The energy creates precise, submucosal burns, or lesions, triggering collagen
contraction. The lesions are subsequently resorbed, remodeling the tissue. This remodeling is proposed to improve barrier function of the anal sphincter. Complications reported from clinical trials include anal pain, anoderm ulceration, bleeding, perforation, and transient worsening of incontinence (Efron, et al., 2003; Takahashi, et. al., 2002).

The Secca System (Curon Medical Inc., Sunnyvale, CA), a Class II, 510(k) device, was approved by the FDA for general use for electrosurgical coagulation and specific use in the treatment of fecal incontinence occurring at least once per week and having failed treatment by other conservative methods. The Secca system approval was based upon prior premarket clearance for biofeedback systems used for the treatment of fecal incontinence. The biofeedback systems included BCI-100 Fecal Incontinence System (Biocare International, Wantagh, NC) and Anorectal Biofeedback System 5 (Biosearch Medical Products, Inc. Somerville, NJ).

The American Society of Colon and Rectal Surgeons (ASCRS) published a press release (April 1, 2002) stating that “the results of two new studies demonstrate that the use of radiofrequency energy for the treatment of fecal incontinence safely reduces the symptoms of fecal incontinence and significantly improves patient quality of life.” The ASCRS has not issued a position statement on this technology.

The practice guidelines from the American College of Gastroenterology, “Diagnosis and Management of Fecal Incontinence”, (Rao, 2004) do not mention radiofrequency therapy as a treatment option for the management of fecal incontinence.

Effective 7/1/04, Medicare has approved HCPCS Code C9716 for the creation of thermal anal lesions by radiofrequency energy. This procedure is used for the treatment of fecal incontinence and involving the application of radiofrequency energy to the internal sphincter complex of the anus.

Although promising, due to the limited number of clinical trials that have been conducted and the limitations of those trials, the safety and efficacy of radiofrequency therapy for fecal incontinence is not supported in the evidence-based literature.

**Biofeedback**

Biofeedback is a technique intended to teach patients self-regulation of certain physiologic processes not normally considered to be under voluntary control. The technique involves the feedback of a variety of types of information not normally available to the patient, followed by a concerted effort on the part of the patient to use this feedback to help alter the physiological process in some specific way.

In treating fecal incontinence, biofeedback techniques convert the physiologic measures from an intra-anal EMG sensor, anal manometric probe (measuring intra-anal pressure) or perianal surface EMG electrodes to either visual or audio display for feedback. Recently, investigators have also used ultrasound to show patients contraction of the anal sphincter on a screen. The technique requires good clinician rapport, skill in biofeedback techniques, and knowledge of rectal and pelvic floor anatomy and physiology.

In children, the aim of biofeedback has been to teach them how to tighten and relax their external anal sphincter in order to pass bowel movements. Nonspecific components of biofeedback treatment include education, attention, and use of medication.

Biofeedback training for fecal incontinence focuses on improving the ability to voluntarily contract the external anal sphincter and puborectalis muscles in response to rectal filling.
Specifically, biofeedback attempts to improve rectal sensory perception, strength, coordination, or some combination of these three components. Sensory training involves inducing intra rectal pressure using a balloon feedback device. A manometric balloon probe is inserted into the rectum. The balloon is filled with air to produce a sensation of rectal filling. The patient is trained to perceive the stimulation of rectal distention and to respond without delay with an immediate and forceful external anal sphincter contraction to counteract reflex inhibition (relaxation) of the internal anal sphincter. The purpose of sensory training is to increase an awareness of the presence of fecal material in the rectum and to decrease delay in response to sensation of distention. By retraining the sensory threshold, the patient becomes able to discriminate and respond to smaller rectal volumes, thus lowering the threshold for sensing rectal distention. Uncontrolled trials have suggested that biofeedback is associated with outcomes that equal medical management or surgery.

Biofeedback is considered investigational as a treatment of fecal incontinence in adults and children. In summary, because of methodological problems, the evidence is insufficient to support the efficacy and effectiveness of biofeedback for treatment of fecal incontinence in adults. Stronger research with more rigorous quality is needed to allow a reliable assessment of biofeedback therapy in the management of adults with fecal incontinence. There is a necessity for randomized, controlled trials that have replicable standardized interventions; control for factors and bias; and provide valid short and long-term outcome measures and adequate power.

**Surgical Treatments**

Surgery should be offered in selective patients who have failed conservative therapy. Surgery may especially be needed for patients who have experienced anal muscle injuries (as can occur during childbirth). The surgical procedures available for fecal incontinence include percutaneous peripheral nerve electrode, sacral nerve stimulation, sphincteroplasty, artificial bowel sphincter, surgical repair of rectal prolapse, muscle transposition or colostomy.

**Percutaneous Peripheral Nerve Electrode**

Initially, a temporary percutaneous peripheral nerve electrode is considered medically necessary for testing over a 2 to 3 week period. Prior to implantation of the permanent device, patients undergo a peripheral nerve stimulation test to estimate potential response to sacral nerve stimulation or modulation (SNM). This procedure is done under local anesthesia, using a test needle to identify the appropriate sacral nerve(s). Once identified, a temporary wire lead is inserted through the test needle and left in place for several days. This lead is connected to an external stimulator that is carried by patients in their pocket or on their belt.

Implantation of a permanent implantable pulse generator is considered medically necessary for patients who have significant benefit from the temporary percutaneous peripheral nerve stimulation. This is generally done prior to the sacral nerve stimulation.

**Sacral Nerve Stimulation**

The sacral nerves run from the spinal cord to the pelvic muscles. These nerves regulate the sensation and strength of the rectal and anal sphincter muscles. Direct electrical stimulation of these nerves is a promising treatment option for fecal incontinence caused by nerve damage.
Sacral nerve stimulation is carried out in stages. First, four to six small needles are positioned in the lower bowel muscles that are stimulated by an external pulse generator. After a successful response, a permanent pulse generator is implanted in the abdomen.

A wire from the small, battery-driven device is connected to the sacral nerves. Through the wire, the device generates electrical impulses that stimulate the nerves, assisting to regain continence.

The National Institute of Clinical Excellence (NICE, 2004) concluded that there is adequate evidence to support the use of sacral nerve stimulation (i.e., pelvic floor stimulation) for fecal incontinence in persons with a weak but structurally intact anal sphincter who are refractory to conservative measures.

This conclusion was based on the results of a systematic evidence review (Fraser et al, 2004) that identified 6 case studies of sacral nerve stimulation involving 266 persons with chronic refractory fecal incontinence. The systematic review found that complete continence was achieved in 41-75% of patients with permanent implants, whereas 75-100% of patients with permanent implants experienced a decrease of 50% or more in the number of incontinence episodes. Commonly, the procedure is tested in each patient over a 2 to 3 week period, with a temporary percutaneous peripheral nerve electrode attached to an external stimulator. If significant benefit is achieved, then the permanent implantable pulse generator can be implanted.

The effectiveness of sacral nerve stimulation in treating fecal incontinence has also been demonstrated in clinical studies (Kenefick and Christiansen, 2004; Matzel et al, 2004; and Jarrett et al, 2004). Kenefick and Christiansen (2004) noted that sacral nerve stimulation appears to be an alternative treatment that is successful, has low morbidity, is maintained in the medium term and associated with an improved quality of life. The technique has the advantage of a minimally invasive test procedure with high predictive value and the surgery is minor.

Matzel et al (2004) stated that sacral nerve stimulation greatly improved continence and quality of life in selected patients with morphologically intact or repaired sphincter complex offering a treatment for patients in whom treatment options are limited. Jarrett and associates (2004) concluded that sacral nerve stimulation is a safe and effective treatment, in the medium to long term, for fecal incontinence when conservative treatment has failed.

**Sphincteroplasty**

Sphincteroplasty is a surgical procedure to repair a damaged or weakened anal sphincter. In this procedure, an injured area of muscle is identified and its edges are freed from the surrounding tissue. The muscle edges are then brought back and sewn together in an overlapping fashion. This strengthens the muscle, tightening the sphincter.

Rectal prolapse weakens the anal sphincter. In certain circumstances, such as chronic constipation and straining, the ligaments to the rectum can become stretched and lose their ability to hold the rectum in place.

Surgical correction of the rectal prolapse may be needed along with sphincter muscle repair. In women, a protrusion of the rectum into the vaginal wall (rectocele) may need to be treated surgically to correct fecal incontinence. Prolapsed internal hemorrhoids may prevent complete closure of the anal sphincter, leading to fecal incontinence.
Artificial Bowel Sphincter (Acticon Neosphincter)
If conservative treatment or surgical repair of the anal sphincter fails to improve fecal incontinence, an artificial bowel sphincter may be an option.

An artificial anal sphincter can be used to replace a damaged anal sphincter. The device is essentially an inflatable cuff, which is implanted around the anal canal. When inflated, the device keeps the anal sphincter shut until the patient has a bowel movement. A small external pump is used to deflate the device and allow stool to be released. It then reinflates itself about ten minutes later.

Wong et al (2002) performed a multicenter, prospective, nonrandomized clinical trial on 115 patients to evaluate the safety, efficacy, and impact on quality of life of the Acticon artificial bowel sphincter for fecal incontinence. Patients were evaluated with anal physiology, endoanal ultrasonography, a fecal incontinence scoring system, fecal incontinence quality of life assessment, and overall health evaluation. Patients with a fecal incontinence score of 88 or greater (scale, 1-120) were considered candidates for the study. Implanted patients underwent identical reevaluation at 6 and 12 months post-implant. One hundred twelve of 115 patients (86 females) enrolled were implanted. Mean age was 49 (range, 18-81) years. A total of 384 device-related or potentially device-related adverse events were reported in 99 enrolled patients. Of these events, 246 required no intervention or only noninvasive intervention. Seventy-three revisional operations were required in 51 (46 percent) of the 112 implanted patients. Infection rate necessitating surgical revision was 25 percent. Forty-one patients (37 percent) have had their devices completely explanted, of which 7 have had successful reimplantations. In patients with a functioning neosphincter, improvement in quality of life and anal continence was documented. A successful outcome was achieved in 85 percent of patients with a functioning device. Intention to treat success rate was 53 percent. In summary, although morbidity and the need for revisional surgery are high, the artificial bowel sphincter can improve anal incontinence and quality of life in patients with severe fecal incontinence.

Muscle transposition
During this procedure, gluteal or gracilis muscles are used to encircle and strengthen the anal canal. When the inner thigh muscle is used, pacemaker-like electrodes are implanted into the grafted muscle to train it to remain contracted. When the buttock muscle is used, the lower portion of this muscle is freed from the coccyx and wrapped around the anus to construct a new anus. The buttock muscle transposition does not require the use of a pacemaker. This procedure is an option for the small percentage of patients whose condition cannot be successfully treated with sphincteroplasty. The goal of this procedure is to restore muscle tone to the sphincter.

Colostomy
As a last resort, a colostomy may be the most definitive way to correct fecal incontinence. Colostomy is generally considered only after other treatments have failed.

Conclusion
In summary, sacral nerve stimulation and the artificial bowel sphincter (Acticon Neosphincter) are considered medically necessary for the treatment of patients with severe and chronic fetal incontinence, when specific criteria are met.

Anal electrical stimulation, biofeedback, and the use of injectable bulking agents are considered investigational because there is insufficient evidence to support the efficacy and effectiveness of these treatments for fecal incontinence.
Transanal radiofrequency therapy, also known as the Secca procedure is considered investigational for all Commercial members since its effectiveness has not been established. There have been a limited number of clinical trials that have been conducted and the safety and efficacy of this therapy is not supported in evidence based medicine. Since Medicare is now covering the Secca procedure, this must be covered for all Medicare members.

**Review History**

- **March 2007**: Medical Advisory Council Initial Approval
- **December 2010**: Added biofeedback as medically necessary for the treatment of fecal incontinence when criteria is met. Added link to Biofeedback policy. Added Medicare table and links to Medicare policies.
- **September 2011**: Update – no revisions
- **November 2012**: Update – no revisions to policy statement. Added information specific to Solesta in the scientific rationale.
- **February 2013**: Code Updates
- **November 2013**: Update – no revisions
- **November 2014**: Update – no revisions. Code updates
- **November 2015**: Update – no revisions. Code updates

**This policy is based on the following evidenced-based guidelines:**

References – Update November 2015

References – Update November 2014

Reference – Update November 2013

References – Update November 2012


References – Update August 2012

References – Update September 2011

References – Update December 2010


References


Important Notice

General Purpose.
Health Net’s National Medical Policies (the "Policies") are developed to assist Health Net in administering plan benefits and determining whether a particular procedure, drug, service or supply is medically necessary. The Policies are based upon a review of the available clinical information including clinical outcome studies in the peer-reviewed published medical literature, regulatory status of the drug or device, evidence-based guidelines of governmental bodies, and evidence-based guidelines and positions of select national health professional organizations. Coverage determinations are made on a case-by-case basis and are subject to all of the terms, conditions, limitations, and exclusions of the member’s contract, including medical necessity requirements. Health Net may use the Policies to determine whether under the facts and circumstances of a particular case, the proposed procedure, drug, service or supply is medically necessary. The conclusion that a procedure, drug, service or supply is medically necessary does not constitute coverage. The member’s contract defines which procedure, drug, service or supply is covered, excluded, limited, or subject to dollar caps. The policy provides for clearly written, reasonable and current criteria that have been approved by Health Net’s National Medical Advisory Council (MAC). The clinical criteria and medical policies provide guidelines for determining the medical necessity criteria for specific procedures, equipment, and services. In order to be eligible, all services must be medically necessary and otherwise defined in the member’s benefits contract as described this “Important Notice” disclaimer. In all cases, final benefit determinations are based on the applicable contract language. To the extent there are any conflicts between medical policy guidelines and applicable contract language, the contract language prevails. Medical policy is not intended to override the policy that defines the member’s benefits, nor is it intended to dictate to providers how to practice medicine.

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The Policies do not constitute authorization or guarantee of coverage of particular procedure, drug, service or supply. Members and providers should refer to the Member contract to determine if exclusions, limitations, and dollar caps apply to a particular procedure, drug, service or supply.

**Policy Limitation: Member’s Contract Controls Coverage Determinations.**
Statutory Notice to Members: The materials provided to you are guidelines used by this plan to authorize, modify, or deny care for persons with similar illnesses or conditions. Specific care and treatment may vary depending on individual need and the benefits covered under your contract. The determination of coverage for a particular procedure, drug, service or supply is not based upon the Policies, but rather is subject to the facts of the individual clinical case, terms and conditions of the member’s contract, and requirements of applicable laws and regulations. The contract language contains specific terms and conditions, including pre-existing conditions, limitations, exclusions, benefit maximums, eligibility, and other relevant terms and conditions of coverage. In the event the Member’s contract (also known as the benefit contract, coverage document, or evidence of coverage) conflicts with the Policies, the Member’s contract shall govern. The Policies do not replace or amend the Member’s contract.

**Policy Limitation: Legal and Regulatory Mandates and Requirements**
The determinations of coverage for a particular procedure, drug, service or supply is subject to applicable legal and regulatory mandates and requirements. If there is a discrepancy between the Policies and legal mandates and regulatory requirements, the requirements of law and regulation shall govern.

**Reconstructive Surgery**
CA Health and Safety Code 1367.63 requires health care service plans to cover reconstructive surgery. “Reconstructive surgery” means surgery performed to correct or repair abnormal structures of the body caused by congenital defects, developmental abnormalities, trauma, infection, tumors, or disease to do either of the following:

1. To improve function or
2. To create a normal appearance, to the extent possible.

Reconstructive surgery does not mean "cosmetic surgery," which is surgery performed to alter or reshape normal structures of the body in order to improve appearance.

Requests for reconstructive surgery may be denied, if the proposed procedure offers only a minimal improvement in the appearance of the enrollee, in accordance with the standard of care as practiced by physicians specializing in reconstructive surgery.

**Reconstructive Surgery after Mastectomy**
California Health and Safety Code 1367.6 requires treatment for breast cancer to cover prosthetic devices or reconstructive surgery to restore and achieve symmetry for the patient incident to a mastectomy. Coverage for prosthetic devices and reconstructive surgery shall be subject to the co-payment, or deductible and coinsurance conditions, that are applicable to the mastectomy and all other terms and conditions applicable to other benefits. "Mastectomy" means the removal of all or part of the breast for medically necessary reasons, as determined by a licensed physician and surgeon.

**Policy Limitations: Medicare and Medicaid**
Policies specifically developed to assist Health Net in administering Medicare or Medicaid plan benefits and determining coverage for a particular procedure, drug, service or supply for Medicare or Medicaid members shall not be construed to apply to any other Health Net plans and members. The Policies shall not be interpreted to limit the benefits afforded Medicare and Medicaid members by law and regulation.