# 02.01.51 Fecal Incontinence Management

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**Original Effective Date:** September 2013

**Review Date:** December 2025

**Revised:** May 2023

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## Related Policies:

- 02.01.70 Biofeedback as a Treatment of Anorectal Disorders 08.01.21 Sacral Nerve Stimulation/Neuromodulation

## Summary

## Description

Fecal continence depends on a complex interplay of anal sphincter function, pelvic floor function, stool transit time, rectal capacity, and sensation. Fecal incontinence is the involuntary leakage of stool from the rectum and anal canal. Numerous devices and techniques have been investigated as a treatment of fecal incontinence, some of which are discussed throughout this policy.

## Summary of Evidence

### Anal Inserts

For individuals who utilize an anal insert for the treatment of fecal incontinence (FI) the evidence includes systematic and observational reviews. Relevant outcomes are symptoms, change in disease status, quality of life, and treatment-related morbidity. The reviews did not find that anal inserts are superior to control interventions for treating fecal incontinence. While an anal plug/anal insert device may reduce FI for some individuals these devices are not well tolerated. Further studies are needed to compare it with other treatments and establish its position in the treatment pathway to elucidate long-term usability, efficacy, and safety. The evidence is insufficient to determine that the technology results in an improvement in the net health outcomes.

### Bulking Agents

For individuals who have fecal incontinence who receive injectable bulking agents, the evidence includes RCTs, systematic reviews of RCTs, and uncontrolled trials. 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.

### Electrical Pelvic Floor Stimulation (PFS)

For individuals who have fecal incontinence who receive electrical PFS, the evidence includes systematic reviews and RCTs. Relevant outcomes are symptoms, change in disease status, quality of life, and treatment-related morbidity. Among the RCTs that have evaluated electrical PFS as a treatment for fecal incontinence, only 1 trial was sham-controlled, and it did not find that electrical stimulation improved the net health outcome. Systematic reviews of RCTs have not found that electrical stimulation is superior to control interventions for treating fecal incontinence. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

### Magnetic Pelvic Floor Stimulation (PFS)

For individuals who have fecal incontinence who receive magnetic PFS, no relevant evidence was identified. Relevant outcomes are symptoms, change in disease status, quality of life, and treatment-related morbidity. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

### Percutaneous Tibial Nerve Stimulation (PTNS)

For individuals who have fecal incontinence who receive PTNS, the evidence includes, several RCTs, systematic reviews, and nonrandomized studies. Relevant outcomes are symptoms, change in disease status, functional outcomes, quality of life, and treatment-related morbidity. The available RCTs have not found a clear benefit of PTNS. None of the sham-controlled trials found that active stimulation was superior to sham for achieving a reduction in mean weekly fecal incontinence episodes. The larger sham-controlled randomized trial did find a significantly greater decrease in the absolute number of weekly incontinence episodes in the active treatment group, but the overall trial findings did not suggest the superiority of PTNS over sham treatment. An additional sham-controlled randomized trial did not identify a benefit of PTNS over sham stimulation. A meta-analysis of a single RCT and several observational studies reported that patients receiving sacral nerve stimulation experienced significant benefits compared with patients receiving PTNS. A post hoc analysis of the larger trial suggested a subset of patients with fecal incontinence (those without concomitant obstructive defecation) may benefit from

PTNS. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome. without concomitant obstructive defecation) may benefit from PTNS. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

### Surgical Sling

For individuals who utilize a surgical sling for the treatment of fecal incontinence the evidence includes uncontrolled trials. Relevant outcomes are symptoms, change in disease status, functional outcomes, quality of life, and treatment-related morbidity. Based on the available literature regarding the surgical placement of slings (i.e., Trans-Obturator Posterior Anal Sling (TOPAS) System) for the treatment of fecal incontinence limitations were noted including the study population was not from a diverse background. The study was a single arm trial with no control group and was done with a very specialized group of clinical investigators. While the studies have been promising further randomized controlled trials (RCTs) are needed to determine long term efficacy of this device. The evidence is insufficient to determine the effects of the technology on net health outcomes.

### Transanal Radiofrequency

For individuals who have fecal incontinence who receive transanal radiofrequency treatment, the evidence includes a systematic review and noncomparative studies. Relevant outcomes are symptoms, change in disease status, quality of life, and treatment-related morbidity. Studies include a small number of patients, and estimates of treatment differences are very imprecise. Study follow-up periods vary and need to be considerably longer and involve larger numbers of patients to evaluate long-term outcomes properly which currently have demonstrated conflicting results with limited efficacy. Three-year follow-up of a small cohort showed decrement in response over time. RCTs are lacking. Multicenter RCTs with sufficient power are required to evaluate the continuing use of this procedure as an alternative to other surgical interventions, physical therapies, or as an adjunctive treatment option for fecal incontinence. The evidence is insufficient to determine the effects of the technology on health outcomes.

### Vaginal Inserts

For individuals who utilize vaginal inserts for the treatment of fecal incontinence (FI) the evidence includes systematic reviews and noncomparative studies. Relevant outcomes are symptoms, change in disease status, quality of life, and treatment-related morbidity. Based on review of the available literature while this device may show promise in reducing FI episodes in XX individuals, the study was non-randomized and was only evaluated for one month. Data regarding vaginal and anal mechanical inserts for the treatment of FI, albeit limited, may be a promising therapeutic option for an individual with FI. Further studies are needed. RCTs with longer-term follow-up are needed to elucidate long-term usability, efficacy, and safety of this device. The evidence is insufficient to determine the effects of the technology on net health outcomes.

### Additional Information

None

## OBJECTIVE

The objective of this evidence review is to determine whether the use of the following therapies improves the net health outcomes in individuals with fecal incontinence:

- Anal inserts for bowel control
- Electrical or magnetic pelvic floor stimulation
- Injectable bulking agents
- Percutaneous tibial nerve stimulation

- Surgical placement of slings for bowel control
- Transanal radiofrequency treatment
- Vaginal bowel control systems

## PRIOR APPROVAL

Not applicable.

## POLICY

The treatment of fecal incontinence (FI) to include but are not limited to the following devices are considered **investigational** because the evidence is insufficient to determine the effects of the technology on net health outcomes:

- Anal inserts for bowel control (e.g., Renew Anal Insert)
- Electrical pelvic floor stimulation (e.g., InToneMV)
- Injectable bulking agents (e.g., Solesta or autologous fat)
- Magnetic pelvic floor stimulation (e.g., Translumbosacral Neuromodulation Therapy [TNT])
- Percutaneous tibial nerve stimulation (e.g., PTNS)
- Surgical placement of slings for bowel control (e.g., TOPAS System)
- Transanal radiofrequency therapy (e.g., Secca procedure)
- Vaginal bowel control systems (e.g., Eclipse System)

ALL Category III codes will be considered investigational unless the code is explicitly addressed as a covered service in a Wellmark BlueCross BlueShield Medical Coverage Policy.

## POLICY GUIDELINES

### Coding

See the Codes table for details.

## BACKGROUND

### Incontinence

Incontinence is a common condition and can have a substantial impact on quality of life. Estimates from the National Center for Health Statistics have suggested that, among noninstitutionalized persons 65 years of age and older, 17% reported issues with fecal incontinence.

Fecal incontinence (FI) is the involuntary loss of flatus, liquid, or stool. It may be caused by damage to the anal sphincter (e.g., childbirth, surgery), diarrhea, fecal impaction, illnesses that cause the inability to expand and store fecal matter (e.g., inflammatory bowel disease [IBD], Crohn's disease or injury). Fecal continence depends on a complex interplay of anal sphincter function, pelvic floor function, stool transit time, rectal capacity, and sensation. Etiologies vary and include injury from vaginal delivery, anal surgery, neurologic disease, and the normal aging process. Although it is considered a benign disorder, severe fecal incontinence (FI) is a distressing and socially isolating medical condition. Individuals who suffer from this condition often alter their lifestyle to minimize the likelihood of bowel accidents in public places. Over time, this can result in progressive social isolation and work incapacity.

Prior to treatment for fecal incontinence (FI), an evaluation must be performed. The initial assessment includes basic office tests, a history and physical, and laboratory tests. Anorectal manometry is a test that

uses a pressure sensitive tube to check the sensitivity and function of the rectum. It also measures the ability of the anal sphincter muscles to respond to signals. Anorectal ultrasonography is an ultrasound that is specific to the anus and rectum utilized to evaluate the structure of the anal sphincter muscles. Rectal sensory testing is utilized to detect abnormal rectal sensation. When rectal sensation is reduced, stool may leak before the external sphincter contracts.

The majority of cases of fecal incontinence (FI) are mild-to-moderate and can be managed with medical interventions including anti-diarrheal medications (loperimide, codeine, diphenoxylate, atropine), treatment of underlying infections or inflammatory disorders as indicated, pelvic floor biofeedback, defecation programs (bowel training), and dietary management (increase dietary fiber with psyllium products or synthetic analogues).

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. Sphincteroplasty is utilized to repair a defect in the sphincter muscle in which the two ends of the muscle are cut and overlapped onto one another and then sewn into place to restore the complete circle of muscle. For individuals with severe fecal incontinence (FI) who have failed medical interventions and who are not candidates for sphincter repair, the choices are limited, and alternative treatment options have been proposed and investigated to include the following:

- Anal insert (i.e., Renew Anal Insert)
- Injectable perianal bulking agents (i.e., Solesta or autologous fat) - Bulking agents are injectable substances used to increase tissue bulk. They can be injected perianally to treat fecal incontinence. The U.S. Food and Drug Administration (FDA) has approved one for treating fecal incontinence.
- Pelvic floor stimulation (PFS) (i.e., electrical [InToneMV] or magnetic [translumbosacral neuromodulation therapy [TNT]) - PFS is proposed as a nonsurgical treatment option of fecal incontinence. This approach involves either electrical stimulation of pelvic floor musculature or extracorporeal pulsed magnetic stimulation.
- Percutaneous tibial nerve stimulation (PTNS; also known as posterior tibial nerve stimulation) is an electrical neuromodulation technique used primarily for treating voiding dysfunction.
- Surgical placement of slings for bowel control (TOPAS System) – Surgical slings are a minimally invasive, permanent implant (i.e., mesh) designed to restore and maintain anatomic support of the pelvic floor muscles in genotypical XX individuals with fecal incontinence who have failed conservative therapy.
- Transanal radiofrequency ablation - In this outpatient procedure using conscious sedation, temperature-controlled radiofrequency energy is delivered to the sphincteric complex of the anal canal (i.e., anorectal junction) to create discrete thermal lesions in the muscle while preserving mucosal integrity. RFA is a minimally invasive treatment for fecal incontinence that takes less than one hour to perform and is generally performed under local anesthesia and sedation. Over several months, these lesions heal and the tissue contracts, changing the tone of the tissue and improving continence. This may also be referred to as the Secca procedure.
- Vaginal bowel control, vaginal insert (Eclipse System) - Vaginal bowel control (e.g., Eclipse system) is a device that includes an inflatable balloon, which is placed in the vagina, which upon inflation exerts pressure on the vaginal wall supposedly closing off the rectum. Reportedly, bowel evacuation is completed by deflating the device and re-inflating using an external pump.

## Anal Insert

The anal insert (i.e., Renew) has been a purposed discreet treatment aid for individuals who suffer from passive FI / those with minor mucus or stool leakage. The inserts are typically available by prescription for individuals with accidental bowel leakage (ABL) or fecal bowel incontinence. They are made of silicone

and are self-inserted, single-use item to comfortably seal the rectum. They are naturally expelled with a bowel movement.

### Surgical Sling

The TOPAS system is comprised of a knitted, Type 1 polypropylene monofilament mesh, which is covered by removable insertion sheaths, and two insertion needles. Implantation is through a transobturator approach via two small incisions in both the thighs and buttocks, requiring about 30 minutes for implantation and a short period for recovery. The implanted mesh is self-fixating and permanent with tissue in-growth providing additional anatomical support to the anorectum.

The FDA approval for the TOPAS system was based on the following pre-market approval study that reported 1- year outcomes in a prospective multicenter study evaluating this treatment modality. A total of 152 women were implanted with the TOPAS system at 14 centers in the United States. Fecal incontinence (FI) was assessed preoperatively and at the 12-month follow up with a 14-day bowel diary, Cleveland Clinic Incontinence Scores, and FI Quality of Life questionnaires. Treatment success was defined as reduction in number of FI episodes of ≥50% compared to baseline. Missing bowel diary data were considered treatment failures. The Wilcoxon signed rank test was used to compare changes observed at 12 months versus baseline. Mean age was 59.6 years old (SD 9.7). The mean duration of FI was 110 months (range 8-712 months). Mean length of the implant procedure was 33.4 (SD 11.6) minutes. Mean EBL was 12.9 (SD 10.5) mL. Average follow-up was 24.9 months. At 12 months, 69.1% of patients met the criteria for treatment success, and 19% of subjects reported complete continence. FI episodes/week decreased from a median of 9.0 (range 2-40) at baseline to 2.5 (range 0-40) ($P < .001$). FI days decreased from a median of 5.0 (range 1.5-7) at baseline to 2.0 (range 0-7) ($P < .001$) over a 7-day period. FI associated with urgency decreased from a median at baseline of 2.0 (range 0-26) to 0 (range 0-14.5) ($P < .001$). The mean Cleveland Clinic Incontinence Scores decreased from 13.9 at baseline to 9.6 at 12 months ($P < .001$). FI Quality of Life scores for all 4 domains improved significantly from baseline to 12 months ($P < .001$). A total of 66 subjects experienced 104 procedure and/or device-related adverse events (AEs). Most AEs were short in duration and 97% were managed without therapy or with nonsurgical interventions. No treatment-related deaths, erosions, extrusions, or device revisions were reported. The most common AE categories were pelvic pain (n = 47) and infection (n = 26). Those subjects experiencing pelvic pain had a mean pain score (0-10 scale, 0 = no pain) during the 12-month follow-up of 1.2 (SD 2.4). Based on the FDA approval (2016) for the TOPAS system the patients currently enrolled in the TOPAS PMA study will be followed through 5 years (60 months) of follow-up to monitor the long-term performance and safety of the TOPAS system.

### Perianal Bulking Agents

After the success of periurethral bulking agents for treating SUI, bulking agents injected into the anal canal have been proposed to treat fecal incontinence. In particular, bulking agents are a potential treatment for passive fecal incontinence associated with internal anal sphincter dysfunction. The bulking agent is injected into the submucosa of the anal canal to increase tissue bulk in the area, which narrows the opening of the anus. Current treatment options for fecal incontinence include conservative measures (e.g., dietary changes, pharmacotherapy, pelvic floor muscle exercises), sacral nerve stimulation, and surgical interventions to correct an underlying problem.

Several agents identical or similar to those used for urinary incontinence (e.g., Durasphere, silicone biomaterial) have been studied for the treatment of fecal incontinence. To date, only 1 bulking agent has been approved by FDA for fecal incontinence. This formulation is a non-animal-stabilized hyaluronic acid/dextranomer in stabilized hyaluronic acid (NASHA Dx), marketed by Q-Med as Solesta. A hyaluronic acid/dextranomer formulation (Deflux™) from the same company has been commercially available for a number of years for the treatment of vesicoureteral reflux in children.

Autologous fat and autologous ear chondrocytes have also been used as perianal bulking agents; autologous substances do not require FDA approval. Polytetrafluoroethylene (Teflon®) has been investigated as an implant material but does not have FDA approval. A more recently explored alternative is cellular therapy with myoblasts, fibroblasts, or stem cells (muscle-derived or adipose-derived). In addition to their use as periurethral bulking agents, it has been hypothesized that transplanted stem cells would undergo self-renewal and multipotent differentiation, which could result in the regeneration of the sphincter and its neural connections.

### Pelvic Floor Stimulation (PFS)

Pelvic floor stimulation (PFS) involves electrical stimulation of pelvic floor muscles using either a probe wired to a device for controlling the electrical stimulation or, more recently, extracorporeal electromagnetic (also called magnetic) pulses. Methods of electrical PFS have varied in location (e.g., vaginal, rectal), stimulus frequency, stimulus intensity or amplitude, pulse duration, pulse to rest ratio, treatments per day, number of treatment days per week, length of time for each treatment session, and overall time period for device use between clinical and home settings. Variations in the amplitude and frequency of the electrical pulse are used to mimic and stimulate the different physiologic mechanisms of the voiding response, depending on the etiology of the incontinence (i.e., either detrusor instability, stress incontinence, or a mixed pattern). Magnetic PFS does not require an internal electrode.

Individuals receiving electrical PFS may undergo treatment in a physician's office or physical therapy facility, or individuals may undergo initial training in a physician's office followed by home treatment with a rented or purchased pelvic floor stimulator. Magnetic PFS may be administered in the physician's office.

### Percutaneous Tibial Nerve Stimulation (PTNS)

Altering the function of the posterior tibial nerve with PTNS has been proposed as a treatment for fecal incontinence. It is believed to improve voiding function and control. The mechanism of action is believed to be retrograde stimulation of the lumbosacral nerves (L4-S3) via the posterior tibial nerve located near the ankle. The lumbosacral nerves control the bladder detrusor and perineal floor.

Administration of PTNS consists of inserting a needle above the medial malleolus into the posterior tibial nerve followed by the application of low-voltage (10 mA, 1-10 Hz frequency) electrical stimulation that produces sensory and motor responses as evidenced by a tickling sensation and plantarflexion or fanning of all toes. Noninvasive PTNS has also been delivered with transcutaneous or surface electrodes. The recommended course of treatment is an initial series of 12 weekly office-based treatments followed by an individualized, indefinite maintenance treatment schedule, with each of these phases having different treatment protocols.

## Transanal Radiofrequency

Radiofrequency (RF) energy also has been investigated as a minimally invasive treatment of fecal incontinence; a procedure referred to as the Secca procedure. In this outpatient procedure using conscious sedation, RF energy is delivered to the sphincteric complex of the anal canal to create discrete thermal lesions. Over several months, these lesions heal and the tissue contracts, changing the tone of the tissue and potentially improving continence.

RF energy is a surgical tool that has been used for tissue ablation and more recently for tissue remodeling. For example, RF energy has been investigated as a treatment for gastroesophageal reflux disease (i.e., the Stretta procedure), in which RF lesions are designed to alter the biomechanics of the lower esophageal sphincter; in orthopedic procedures to remodel the joint capsule; or in an intradiscal electrothermal annuloplasty procedure, in which the treatment is intended in part to modify and

strengthen the disc annulus. In all these procedures, non-ablative levels of RF thermal energy are used to alter collagen fibrils, which results in a healing response characterized by fibrosis. Recently, RF energy has been explored as a minimally invasive treatment option for fecal incontinence.

### Vaginal Insert for Bowel Control

A vaginal insert (i.e., Eclipse™ Vaginal Insert) is a non-surgical therapy for individuals experiencing loss of bowel control. The inflatable vaginal insert is designed to exert pressure on the rectal vault to treat fecal incontinence. For the Eclipse™ system, according to the manufacturer, it consists of a vaginal insert and a pressure-regulated pump. The insert, consisting of a silicone-covered stainless-steel base and a posteriorly directed balloon, is placed in the vaginal vault, and inflated. The balloon is deflated via the pump when the user needs to have a bowel movement, and the balloon is inflated again when the bowel movement is finished. The initial fitting and inflation is performed by a clinician, and a trial period is provided for one week or so for the individual to decide if the insert fits well and whether it is right. If the trial period is successful, the individual may begin using the Eclipse insert which is intended for long-term use, in which the patient can inflate and deflate the device as needed at home.

## Regulatory Status

After the success of periurethral bulking agents for treating SUI, bulking agents injected into the anal canal have been proposed to treat fecal incontinence. In particular, bulking agents are a potential treatment for passive fecal incontinence associated with internal anal sphincter dysfunction. The bulking agent is injected into the submucosa of the anal canal to increase tissue bulk in the area, which narrows the opening of the anus. Current treatment options for fecal incontinence include conservative measures (e.g., dietary changes, pharmacotherapy, pelvic floor muscle exercises), sacral nerve stimulation, and surgical interventions to correct an underlying problem.

Several agents identical or similar to those used for urinary incontinence (e.g., Durasphere, silicone biomaterial) have been studied for the treatment of fecal incontinence. To date, only 1 bulking agent has been approved by the FDA for fecal incontinence. This formulation is a non-animal-stabilized hyaluronic acid/dextranomer in stabilized hyaluronic acid (NASHA Dx), marketed by Palette Life SciencesQ-Med as Solesta. A hyaluronic acid/dextranomer formulation (Deflux®™) from the same company has been commercially available for a number of years for the treatment of vesicoureteral reflux in children (see evidence review 02.01.77 Periureteral Bulking Agents as a Treatment of Vesicoureteral Reflux).

Autologous fat and autologous ear chondrocytes have also been used as perianal bulking agents; autologous substances do not require FDA approval. Polytetrafluoroethylene (Teflon®) has been investigated as an implant material but does not have FDA approval. A more recently explored alternative is cellular therapy with myoblasts, fibroblasts, or stem cells (muscle-derived or adipose-derived). In addition to their use as periurethral bulking agents, it has been hypothesized that transplanted stem cells would undergo self-renewal and multipotent differentiation, which could result in the regeneration of the sphincter and its neural connections.

The current indication cleared by the U.S. Food and Drug Administration (FDA) for PTNS is overactive bladder and associated symptoms of urinary frequency, urinary urgency, and urge incontinence. The devices are not FDA cleared for other indications, such as the treatment of fecal incontinence.

The following devices have been approved by the U.S. Food Drug Administration (FDA) through the premarket approval. (*This is not intended to be an all-inclusive list*)

| Device | 510(k) Approval | Information |
|---|---|---|
| Eclipse System | 2015 | The FDA approved the vaginal insert which was designed to provide bowel control in XX individuals with fecal incontinence. |
| InTone® MV | 2014 | It is a non-implantable device that provides electrical stimulation and/or biofeedback via manometry. The device is intended to treat fecal incontinence. |
| NASHA Dx marketed as Solesta® | 2011 | 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. |
| NURO™ Neuromodulation System | | The device has been cleared by the FDA treat individuals for other indications. *It has not been FDA cleared for indications, such as the treatment of fecal incontinence.* |
| Secca System | 2002 | In 2002, the Secca™ System (Mederi Therapeutics) was cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process for "general use in the electrosurgical coagulation of tissue and is intended for use specifically in the treatment of fecal incontinence in those patients with incontinence to solid or liquid stool at least once per week and who have failed more conservative therapy." FDA product code: GEI |
| TOPAS Treatment (hereafter TOPAS System) | 2016 | It is a mesh implant with minimally invasive delivery, to provide support to the anorectum and reduce the incidence of fecal incontinence (FI) episodes in genotypical XX individuals who have failed conservative therapies. |
| Urgent® PC Neuromodulation System | 2005 | The device has been cleared by the FDA treat individuals for other indications. *It has not been FDA cleared for indications, such as the treatment of fecal incontinence.* |
| ZIDA Wearable Neuromodulation System | 2021 | The device has been cleared by the FDA treat individuals for other indications. *It has not been FDA cleared for indications, such as the treatment of fecal incontinence.* |

## RATIONALE

This evidence review was created in September 2013 and has been updated regularly with searches of the PubMed database. The most recent literature update was performed through December 2025.

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function-including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to

ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent 1 or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. Randomized controlled trials are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

## Anal Inserts

### *Clinical Context and Therapy Purpose*

The purpose of anal inserts (i.e., Renew®) in individuals 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: Does the use of Anal Inserts (i.e., Renew®) improve the net health outcome in individuals with fecal incontinence?

The following PICO was used to select literature to inform this review.

### *Populations*

The relevant population of interest is individuals with fecal incontinence. Fecal incontinence can have a substantial impact on quality of life. Estimates from the National Center for Health Statistics have suggested that among noninstitutionalized persons, 65 years of age or older, 17% have reported issues with fecal incontinence. Risk factors for fecal incontinence are similar in XY and XX individuals: older age, diarrhea, fecal urgency, urinary incontinence, and diabetes.

### *Interventions*

The therapy being considered is the Anal Inserts (i.e., Renew®).

### *Comparators*

The following therapies are currently being used to make decisions about fecal incontinence: conservative therapy, sacral nerve stimulation, and surgery.

### *Outcomes*

The general outcomes of interest are symptom reduction, symptom recurrence, and treatment related adverse events.

### Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.

- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

## Review of Evidence

### Systematic Review

In 2023, a systematic review conducted to inform the American Society of Colon and Rectal Surgeons (ASCRS) guidelines on the management of fecal incontinence on anal inserts the authors found evidence in small series that reported modest improvements in FI; the most common adverse events reported were discomfort and device slippage. The largest prospective study evaluating this approach reported that 62% of 91 patients achieved a 50% or more reduction in FI episodes. This study had no comparison group and did not report any quality-of-life metrics. A recent pilot study randomly assigned 50 patients to treatment either with an anal insert (n = 25) or with percutaneous tibial neuromodulation and reported a 50% or more reduction in FI episodes in 19 patients (76%) treated with an anal insert compared to 12 patients (48%) treated with tibial nerve stimulation (p = 0.04). Although these data provide some insight, studies of a number of various anal insert devices during the past 20 years have reported limited long-term tolerability or efficacy beyond 3 months; the utility of these devices for treating FI remains unclear."

Buono et al (2018) completed a systematic review of mechanical inserts for the treatment of fecal incontinence. They identified 35 unique citations. After title review and exclusion of articles not reporting original research, eight publications were included in the final review: two focused on vaginal inserts and six focused on anal inserts. They concluded data regarding vaginal and anal mechanical inserts for the treatment of FI, albeit limited, suggest that inserts can be included in a discussion of therapeutic options for a patient with FI. Further studies are needed to elucidate long-term usability, efficacy, and safety.

In a Cochrane review by Deutekom and Dobben (2015) plugs for FI were reviewed. Out of the studies searched 4 studies with 136 individuals were included. Plugs vs. no plugs were compared in 2 studies and 1 study compared the same brand in 2 different sizes and one study compared 2 different brands of plugs. There was a 35 % drop out rate (48 individuals) before study was completed. 'Pseudo-continence' was reported by individuals with continues use in the short-term. When comparing the 2 different types of plugs the polyurethane polys vs polyvinyl-alcohol plugs had less reported there was greater satisfaction and less plug loss. Overall, the author's concluded, "the available data were limited and incomplete, and not all pre-specified outcomes could be evaluated. Consequently, only tentative conclusions are possible. The available data suggest that anal plugs can be difficult to tolerate. However, if they are tolerated, they can be helpful in preventing incontinence. Plugs could then be useful in a selected group of people either as a substitute for other forms of management or as an adjuvant treatment option. Plugs come in different designs and sizes; the review showed that the selection of the type of plug can impact on its performance."

### Observational Study

Leo et al (2019) studied the Renew Anal Insert as a recent treatment for patients who suffer from passive FI in a single arm noncomparative observational study. These researchers studied the effectiveness of the insert and patients' satisfaction with it. A retrospective audit of individuals who were treated with the Renew Anal Insert was undertaken. The St Mark's Incontinence Score was used to evaluate clinical outcome. Renew size, the number of inserts used per day and per week had also been recorded. Subjective assessment of symptoms, how beneficial Renew was and how satisfied individuals were with the device were all recorded. Major events and side effects were also noted. A total of 30 patients received Renew as a treatment for passive FI in 2016. The median St Mark's Incontinence Score was 15 (range of 7 to 18) at baseline and 10 (range of 2 to 18) at first follow-up ($p < 0.0001$) at a median of 11

(range of 8 to 14) weeks; 11 (37%) patients used the regular size and 19 (63%) the large size. Patients used an average of 1.67 inserts per day (range of 1 to 3) on an average of 3.58 days per week (1 to 7); 3 patients reported a deterioration in symptoms, 7 (23%) had no change and 20 (67%) showed a significant improvement; 6 patients (20%) did not like the device; while 24 (80%) liked it; 17 patients (57%) wanted to continue this treatment in the long-term. The authors concluded that the Renew device appeared to be an acceptable and effective therapeutic option for passive FI. However, these researchers stated that further work is needed to compare it with other treatments and establish its position in the treatment pathway.

**Section Summary**: **Anal Inserts**
RCTs have evaluated anal inserts (Renew®) for treating fecal incontinence. Systematic reviews of RCTs have not found that anal inserts to treat fecal incontinence is superior to control interventions for treating fecal incontinence.

## Perianal Bulking Agents

### *Clinical Context and Therapy Purpose*
The purpose of injectable bulking agents in individuals who have fecal incontinence is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following PICO was used to select literature to inform this review.

### *Populations*
The relevant population of interest is individuals with fecal incontinence.

### *Interventions*
The therapy being considered is injectable bulking agents.

### *Comparators*
The following therapies are currently being used to make decisions about fecal incontinence: conservative therapy, sacral nerve stimulation, and surgery.

### *Outcomes*
The general outcomes of interest are symptom reduction, symptom recurrence, and treatment-related adverse events. Bulking agents may or may not be curative, and follow-up injection may be necessary within 6 months. Beneficial effects may last between 3 and 12 months.

### Study Selection Criteria
- Methodologically credible studies were selected using the following principles:
- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies;
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought;
- Studies with duplicative or overlapping populations were excluded.

## Review of Evidence

### Systematic Reviews

A comparative effectiveness review, conducted by Forte et al (2016) for the Agency for Healthcare Research and Quality, which has since been archived, evaluated treatments for fecal incontinence.28, Reviewers found low strength of evidence from 2 RCTs that dextranomer anal bulking injections (NASHA Dx, Solesta) were more effective than sham injections on some outcome measures (ie, 50% reduction in episodes, number of incontinence-free days, quality of life) but not more effective than sham on fecal incontinence severity or frequency, and no more effective than pelvic floor muscle training with biofeedback on fecal incontinence severity or quality of life. There was moderate strength of evidence from 2 RCTs comparing Durasphere with a non-FDA approved bulking agent that off-label use of Durasphere reduced fecal incontinence severity for up to 6 months, with diminishing improvements after that time.

Maeda et al (2013) updated a Cochrane review assessing perianal injectable bulking agents for treating fecal incontinence. Reviewers identified 5 RCTs (N=382) 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. The 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 the lack of (or unclear) blinding of outcome assessment and the 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.

### Randomized Controlled Trials

The RCT evaluating Solesta, included in the Cochrane review, was an industry-sponsored multicenter trial, reported by Graf et al (2011), that compared Solesta with sham treatment in 206 adults. To be eligible for inclusion, patients had 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 failure of 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 (86%) patients in the active treatment group and 61 (87%) patients 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 trial 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 (96%) of 206 randomized patients completed 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: 2.36; 95% CI, 1.24 to 4.47; p=.009). Findings for secondary outcomes at 6 months were mixed. For example, the mean increase in the number of incontinence-free days was significantly higher in the active treatment group (3.1) than the sham group (1.7; p=.016), but the median decrease in the number of incontinence episodes did not differ significantly between groups (6.0 vs. 3.0, respectively; p=.09). Moreover, change in the Cleveland Clinic Florida Fecal Incontinence Score did not differ significantly between groups at 6 months (2.5 points for active treatment vs. 1.7 points

for sham treatment). 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 group than in 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. Trialists did not report the proportion of patients' 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 (14%) patients (vs. 2 [3%] patients in the sham group). Moreover, 10 (7%) patients in the active treatment group and 1 (1%) patient in the sham group had a rectal hemorrhage. Injection site bleeding occurred in 12 (17%) patients in the sham group and in 7 (5%) patients in the active treatment group. Two serious adverse events were reported, both in the active treatment group (1 rectal abscess, 1 prostate abscess).

Mellgren et al (2014) published long-term follow up from the 136 patients originally treated with active treatment in the 6-month trial and found sustained response at both 12 months (57.4%) and 36 months (52.2%). Mean CCFIS decreased from 14.3 at baseline to 10.5 at month 36. Overall incontinence-free days increased from 4.4 at baseline to 8.1 at 36 months. A total of 20 additional treatment-related adverse events after the 6-month randomized phase were documented. The most frequent events were injection site nodule (n=3) and proctalgia (n=3).

Dehli et al (2013) published findings of an RCT evaluating Solesta. A total of 126 adults with fecal incontinence were randomized to 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 Fecal Incontinence Grading System score, which ranges from 0 (perfect continence) to 24 (maximal incontinence). A St. Mark's score of at least 4 was required for study participation. Ten (8%) patients 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 agent's 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. This difference between groups in St. Mark's score reduction was not statistically significant. In addition, change in St. Mark's score did not differ between groups at 24 months, and only 61 (49%) patients completed the 24-month follow-up. Three of the first 10 patients in the bulking agent group developed 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 an uncontrolled study conducted by La Torre et al (2013). A total of 115 patients in Europe and Canada with fecal incontinence received 1 Solesta treatment and an optional retreatment after 1 month. Eighty-three (72%) of 115 patients completed the 24-month follow-up. The primary efficacy end point was a response to treatment, defined as a minimum 50% reduction from baseline in the number of fecal incontinence episodes recorded in a 28-day diary. At the 24-month follow-up, 52 (63%) of 83 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 lacked a comparison group and had a high dropout rate.

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. 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.

### Section Summary: Perianal 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 an effective treatment for fecal incontinence. Corroboration of the single comparative positive trial is needed, and controlled trials with longer follow-up are important to determine the durability of any treatment effect.

## Pelvic Floor Stimulation (PFS): Electrical

### *Clinical Context and Therapy Purpose*

The purpose of PFS in individuals who have fecal incontinence is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following PICO was used to select literature to inform this review.

### *Populations*

The relevant population of interest is individuals with fecal incontinence. Fecal incontinence can have a substantial impact on quality of life. Estimates from the National Center for Health Statistics have suggested that among noninstitutionalized persons, 65 years of age or older, 17% have reported issues with fecal incontinence. Risk factors for fecal incontinence are similar in XY and XX individuals: older age, diarrhea, fecal urgency, urinary incontinence, and diabetes.

### *Interventions*

The therapy being considered is electrical PFS for fecal incontinence.

### *Comparators*

The following therapies are currently being used to make decisions about fecal incontinence: nonsurgical treatment options and behavioral therapies. Nonsurgical treatment options for incontinence may include pharmacologic therapy, bowel training exercises, and magnetic stimulation. Behavioral therapies include pelvic floor muscle training and diet.

### *Outcomes*

The general outcomes of interest include a reduction in symptoms (e.g., number of incontinence episodes) and improvements in quality of life and cure rates. Electrical PFS therapy generally continues for 6 to 8 weeks.,

## Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

## Review of Evidence

## Systematic Reviews

A systematic review by Vonthein et al (2013) searched for studies on the impact of biofeedback and/or electrical PFS for treating fecal incontinence in adults. They identified 13 RCTs that used 1 or both of these treatments and reported health outcomes (e.g., remission or response rates using validated scales). A pooled analysis of trial results did not find statistically significant differences in rates of remission when comparing electrical PFS with a control intervention (RR, 0.47; 95% CI, 0.13 to 1.72). A pooled analysis of studies comparing electrical PFS plus biofeedback with electrical PFS alone found a significantly higher rate of remission with the combination intervention (RR, 22.97; 95% CI, 1.81 to 291.69). The latter analysis focused on the efficacy of biofeedback and not electrical PFS. Additionally, the confidence interval was very wide, indicating an imprecise estimate of the treatment effect. The Vonthein et al. (2013) review included only 2 RCTs on electrical PFS17,18, that were published after a Cochrane review (below). These 2 trials included the combination of amplitude-modulated medium-frequency stimulation and biofeedback. Electrical PFS was not evaluated in the absence of biofeedback.

A Cochrane review by Hosker et al (2007) identified 4 RCTs evaluating electrical stimulation as a treatment of fecal incontinence in adults. One trial was sham-controlled, another compared electrical PFS with levatorplasty, and 2 used electrical PFS as an adjunct treatment. Reviewers did not pool study findings; they concluded that there is insufficient evidence to draw conclusions on the efficacy of electrical PFS for treating fecal incontinence.

## Randomized Controlled Trials

An RCT by Cohen-Zubary et al (2015) allocated 42 women with fecal incontinence to 6 weeks of electrical stimulation (n=22) or biofeedback training (n=20). Biofeedback sessions were conducted in-clinic and electrical PFS sessions at home following an initial training in-clinic. Thirty-six (86%) women completed the trial and were included in the analysis; the analysis was not intention-to-treat. The trial's primary endpoints were an improvement in frequency of fecal, urine, and gas incontinence, assessed using visual analog scale scores. There were no statistically significant differences between groups for the primary outcomes. The mean visual analog scale score (standard deviation) for solid stool incontinence at baseline in the stimulation group was 2.9 (2.8), which decreased to 0.9 (0.9) at follow-up. In the biofeedback group, the baseline visual analog scale score was 1.1 (2.1) and 0.3 (0.5) at follow-up. The between-group difference for this outcome was not statistically significant. For within-group changes, the electrical stimulation group improved significantly on solid stool incontinence-but not on liquid stool or gas incontinence and the biofeedback group did not improve significantly on any of the fecal incontinence outcomes.

Norton et al (2006) in the U.K. published a sham-controlled randomized trial that included 90 adults with fecal incontinence. Patients used a home electric PFS device for 8 weeks. Patients allocated to active treatment had the stimulation set at 35 Hz, with a 0.5-second ramped pulse. The sham stimulator looked

identical, but stimulation was set at 1 Hz below the level tested for therapeutic effect. Patients were blinded to the treatment group; although nurses who trained patients on device use were not. The primary outcome was patient self-report of efficacy, using a rating scale ranging from -5 to +5 to indicate symptom change. Seventy (78%) of the 90 patients completed the trial. In an intention-to-treat analysis (assigning patients who dropped out a value of 0), there was no statistically significant difference between groups in patient ratings of symptom change. On a scale of -5 to +5, there was a median rating of 0 in each group (p=.92). In a completer analysis, the median change in symptoms was 2 in the active treatment group and 1 in the sham group (p=.74). Groups did not differ significantly on other secondary outcomes such as the frequency of urge or passive incontinence after treatment.

### Section Summary: Electrical Pelvic Floor Stimulation for Fecal Incontinence

Several RCTs have evaluated electrical stimulation for treating fecal incontinence. Only one was sham-controlled, and it did not find that active stimulation produced better results than sham stimulation. Systematic reviews of RCTs have not found that electrical stimulation is superior to control interventions for treating fecal incontinence.

## Pelvic Floor Stimulation for Fecal Incontinence: Magnetic

### *Clinical Context and Therapy Purpose*

The purpose of PFS in individuals who have fecal incontinence is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following PICO was used to select literature to inform this review.

### *Populations*

The relevant population of interest is patients with fecal incontinence. Risk factors for fecal incontinence are similar in XY and XX individuals: older age, diarrhea, fecal urgency, urinary incontinence, and diabetes. For XX individuals, current and past use of hormone therapy is an added risk factor. Fecal incontinence can have a substantial impact on quality of life. Estimates from the National Center for Health Statistics have suggested that among noninstitutionalized persons, 65 years of age or older, 17% have reported issues with fecal incontinence.

### *Interventions*

The therapy being considered is magnetic PFS for fecal incontinence. The mechanism of action of a magnetic PFS procedure is similar to the electrical procedure, though using magnetic pulses to activate the pelvic floor musculature. The magnetic pulses are delivered without a probe, with patients sitting fully clothed in a specialized chair with an embedded magnet.

### *Comparators*

The following therapies are currently being used to make decisions about fecal incontinence: nonsurgical treatment options and behavioral therapies. Nonsurgical treatment options for incontinence may include pharmacologic therapy, bowel training exercises, and electrical stimulation. Behavioral therapies include pelvic floor muscle training and diet.

### *Outcomes*

The general outcomes of interest include a reduction in symptoms (e.g., number of incontinence episodes) and improvements in quality of life and cure rates. Treatment is for approximately 8 weeks, and follow-up is generally up to 6 months.

### Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought
- Studies with duplicative or overlapping populations were excluded.

### Review of Evidence

No studies were identified that evaluated magnetic PFS as a treatment of fecal incontinence.

### Section Summary: Magnetic PFS for Fecal Incontinence

Current evidence is insufficient to draw conclusions about the efficacy of magnetic PFS to treat fecal incontinence.

## Percutaneous Tibial Nerve Stimulation (PTNS)

### *Clinical Context and Therapy Purpose*

The purpose of PTNS in individuals who have fecal incontinence is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following PICO was used to select literature to inform this review.

### *Populations*

The relevant population of interest is individuals with fecal incontinence.

### *Interventions*

The therapy being considered is PTNS. During PTNS, a needle is inserted above the medial malleolus into the posterior tibial nerve followed by the application of low-voltage (10 mA, 1-10 Hz frequency) electrical stimulation. Noninvasive PTNS may be delivered with transcutaneous or surface electrodes. The recommended course of treatment is an initial series of 12 weekly office-based treatments followed by an individualized maintenance treatment schedule.

Devices are not FDA cleared for the treatment of fecal incontinence.

### *Comparators*

The following therapies are currently being used to make decisions about fecal incontinence: conservative therapies (e.g., medical management, retraining of pelvic floor and abdominal wall musculature, dietary changes), medications, and SNS.

Sacral nerve stimulation may be conducted in an outpatient clinical setting using temporary wire leads. Due to the incidence of lead migration, a 2-step process in a surgical setting is recommended. In the initial test phase, wire leads are inserted under the skin, and if improvement is reported after 2 weeks, the patient may elect permanent implantation with a pacemaker-like stimulator. If the test phase is unsuccessful, the leads are then removed.

### *Outcomes*

The general outcomes of interest are reduced symptoms (e.g., self-reported assessment of symptoms, a decrease in the number of voids per day) and improved quality of life. Outcomes are measured following the 6- to 12-week treatment regimen.

## Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

## Review of Evidence

## Systematic Reviews

Luo et al (2024) published a meta-analysis evaluating PTNS versus sham electrical stimulation for treatment of fecal incontinence in adults. The literature search was done through May 2022 and identified 4 RCTs (N=439). The analysis concluded that when compared to the control group, PTNS showed greater efficacy in lowering weekly episodes of fecal incontinence (MD, −1.6; 95% CI −2.94 to −0.26; p=.02; I2=30%). A greater number of patients in the PTNS group also reported a weekly decrease in fecal incontinence episodes of more than 50% compared to the control group (RR, 0.73; 95% CI, 0.57 to 0.94; p=.02; I2=6%). None of the fecal incontinence quality of life or St Mark's incontinence scores showed any significant differences between groups.

Sarveazad et al (2019) conducted a systematic review and meta-analysis investigating the role of tibial nerve stimulation versus sham in the control of fecal incontinence. A literature search conducted through December 2016 identified 5 studies including 249 patients treated with PTNS and 239 treated with sham. Studies utilizing transcutaneous stimulation were also eligible. A significant decrease in the number of fecal incontinence episodes was found in the PTNS group (standardized mean difference [SMD], -0.38; 95% CI, -0.67 to 0.10; $I^2$=32.8%; p=.009). However, no significant effect on incontinence scores (SMD, 0.13; 95% CI, -0.49 to 0.75; $I^2$=88.0%; p=.68), resting pressure (SMD, 0.12; 95% CI, -0.14 to 0.37; $I^2$=28.8%; p=.67), squeezing pressure (SMD, -0.27; 95% CI, -1.03 to 0.50; $I^2$=85.5%; p=.50), or maximum tolerable volume (SMD, -0.10; 95% CI, -0.40 to 0.20; $I^2$=0.0%; p=.52) was reported.

Tan et al (2019) published a systematic review and meta-analysis reporting placebo response rates in electrical nerve stimulation trials for fecal incontinence and constipation. A literature search was conducted through April 2017 identifying 10 randomized sham-controlled trials. Sham stimulation resulted in significant improvements in fecal incontinence episodes by 1.3 episodes per week (95% CI, -2.53 to -0.01; p=.05) and Cleveland Clinic Severity Scores by 2.2 points (95% CI, 1.01 to 3.36; p=.0003). The authors note that these findings highlight the importance of sham controls in nerve stimulation trials.

Simillis et al (2018) conducted a systematic review and meta-analysis comparing PTNS with SNS for the treatment of fecal incontinence. The literature search identified 4 studies (1 RCT, 3 nonrandomized prospective studies) including 302 patients (109 undergoing SNS, 193 undergoing PTNS). The Cochrane Collaboration's risk of bias tool was used to assess study quality. Because none of the studies blinded participants and personnel, the risk of performance and detection biases were high. Attrition and

publication biases were not detected. Meta-analysis showed that patients undergoing SNS experienced significant improvements compared with patients undergoing PTNS as measured on the Wexner Fecal Incontinence Score (weighted mean difference [WMD], 2.3; 95% CI, 1.1 to 3.4) and fecal incontinence episodes per week (WMD, 8.1; 95% CI, 4.1 to 12.1).

Edenfield et al (2015) conducted a literature search through November 2013 and identified 17 studies (4 RCTs, 13 case series) on the use of tibial nerve stimulation (percutaneous and transcutaneous) for the treatment of fecal incontinence. Three of the RCTs evaluated TENS and the other PTNS. The 1 RCT and 4 case series using PTNS reported significant decreases in weekly fecal incontinence episodes following 12 weeks of treatment. The quality-of-life domain scores (e.g., depression, embarrassment, coping, lifestyle) showing significant improvements differed across the PTNS studies.

Horrocks et al (2014) conducted a literature search through February 2013 and identified 12 articles, 6 related to PTNS, 5 related to transcutaneous nerve stimulation, and 1 comparing both methods. One RCT, by George et al (2013), discussed below, was included in the Horrocks et al (2014) and the Edenfield et al (2015) reviews. Horrocks et al (2014) identified 5 case series and an RCT that reported the outcome of 50% or greater reduction in the number of fecal incontinence episodes per week immediately after PTNS treatment. In these studies, a median of 71% of patients (range, 63%-82%) reported at least a 50% reduction in episodes. The Horrocks (2014) analysis did not report on control groups.

### Randomized Controlled Trails

George et al (2013) published the first sham-controlled trial. Thirty patients (28 women) who had failed conservative therapy for fecal incontinence were randomized to PTNS (n=11), TTNS (n=11), or sham transcutaneous stimulation (n=8). Patients in all groups received a total of 12 treatments given twice weekly for 6 weeks. (This differed from the PTNS manufacturer's recommended course of 12 weekly treatments.) The primary study endpoint was at least a 50% reduction in the mean number of incontinence episodes per week at the end of the 6-week treatment period. Only 1 patient failed to complete the trial, and data were analyzed on an intention-to-treat basis. Nine of 11 patients in the PTNS group, 5 of 11 in the TTNS group, and 1 of 8 in the sham group attained the primary endpoint (p=.035). The mean number of incontinence episodes per week (standard deviation) at the end of the study was 1.8 (0.8), 5.1 (4.2), and 4.7 (3.5) in the PTNS, transcutaneous nerve stimulation, and sham groups, respectively (p=.04). These findings are limited by the small sample size and short-term follow-up.

A large sham-controlled randomized trial, known as CONFIDeNT, was by Knowles et al (2015). The trial was double-blind and multicenter. A total of 227 patients with fecal incontinence sufficiently severe to warrant intervention (according to the principal investigator at each site) were randomized to PTNS (n=115) or sham stimulation (n=112). Both groups received 12 weekly, 30-minute sessions. The primary outcome was at least a 50% reduction in the mean number of episodes of fecal incontinence per week compared with baseline. The mean number of episodes was calculated from 2-week bowel diaries. Twelve patients withdrew from the trial. After treatment, 39 (38%) of 103 in the PTNS group and 32 (31%) of 102 in the sham group had at least a 50% reduction in the number of fecal incontinence episodes per week. The difference between groups was not statistically significant (adjusted odds ratio, 1.28; 95% CI, 0.72 to 2.28; p=.396). There was also no significant difference between the PTNS and sham groups in the proportion of patients achieving more than 25%, more than 75%, or 100% reduction in mean weekly episodes. There was, however, a significantly greater reduction in the absolute mean number of weekly fecal incontinence episodes in the PTNS group. The mean number of weekly fecal incontinence episodes in the PTNS group was 6.0 at baseline and 3.5 after treatment compared with 6.9 and 4.8, respectively, in the sham group (MD, -2.26; 95% CI, -4.18 to -0.35; p=.021).

Horrocks et al (2017) conducted a post hoc analysis of data from the CONFIDeNT trial, to evaluate factors associated with the efficacy of PTNS for fecal incontinence. Results from the multivariable logistic regression on the outcome of 50% improvement in weekly fecal incontinence episodes found that age, fecal urgency, stool consistency, and severity of fecal incontinence did not affect response to PTNS. The presence of obstructive defecation was the only variable that negatively affected response to PTNS (OR, 0.4; 95% CI, 0.2 to 0.9). Excluding patients with obstructive defecation (n=112) resulted in a significant effect of PTNS compared with sham (49% vs 18%, p=.002).

Thin et al (2015) published data on PTNS versus SNS for fecal incontinence. Forty women were randomized, 17 to PTNS and 23 to SNS. Patients in the PTNS group had an initial course of 12 weekly sessions and received 3 maintenance treatments during the following 2 months. Sacral nerve stimulation was provided using a 2-stage approach: a test stimulation was conducted first, followed by permanent stimulation if they achieved a decrease in fecal incontinence episodes of at least 50% over the 2-week test period. The primary outcome was a reduction of at least 50% in fecal incontinence episodes per week (as determined by 2-week bowel diaries). Fifteen women passed temporary SNS and underwent permanent implantation. The proportion of patients who achieved the primary outcome at 6 months was 11 (61%) of 18 in the SNS group and 7 (47%) of 15 in the PTNS group. Rates at 3 months were 9 (47%) of 19 in the SNS group and 6 (38%) of 16 in the PTNS group. The authors did not conduct a direct statistical comparison of SNS and PTNS because the study was a pilot.

A single-center, investigator-blinded RCT compared PTNS (n=25) to anal inserts (n=25) in patients with fecal incontinence. At 3 months, a 50% reduction in weekly episodes of fecal incontinence, as calculated by a prospectively completed 2-week bowel diary, was found in 76% (19/25) of patients in the anal insert group and 48% (12/25) of patients in the PTNS group (p=.04). Both groups had similar improvements in St Mark's fecal incontinence scores and the International Consultation on Incontinence Questionnaire.

Zyczynski et al (2022) conducted the Neuromodulation for Accidental Bowel Leakage (NOTABLe) sham-controlled trial of PTNS in women with fecal incontinence (N=166). Women with greater than or equal to 3 months of moderate-to-severe fecal incontinence were randomized to PTNS (n=111) or sham stimulation (n=55). Stimulation was delivered in 12 weekly 30-minute sessions to a single lower extremity. The primary outcome was change from baseline in St. Mark score (a 7-item, validated patient-reported outcome) measured after 12 weekly treatments. Secondary outcomes included stool consistency, bowel movement, and stool leakage episodes per week. There was no significant difference between the PTNS group (-5.3 points) and the sham group (-3.9 points) in terms of improvement from baseline in St. Mark scores (adjusted difference -1.3; 95% CI, -2.8 to 0.2). There also was no significant difference in reduction in weekly fecal incontinence episodes from baseline between the PTNS group (-2.1 episodes) and sham group (-1.9 episodes) (adjusted difference -0.26; 95% CI, -1.85 to 1.33).

### Nonrandomized Studies

Sanagapalli et al (2018) conducted a retrospective chart review of consecutive patients with multiple sclerosis-related fecal incontinence who had failed conservative therapy and who were subsequently treated with PTNS. Patients (N=33) received 8 weekly treatments of PTNS, with responders receiving an additional 4 weeks of treatment. Subjects were classified as responders based on the Wexner Fecal Incontinence Score if scores at the end of treatment were either half of the baseline score or if the score was less than 10. Twenty-six (79%) of the patients were classified as responders. Responders tended to be more symptomatic at baseline and had greater improvements in quality-of-life scores.

### Section Summary: Percutaneous Tibial Nerve Stimulation (PTNS)

Few RCTs evaluating PTNS for the treatment of fecal incontinence have been published to date. The available RCTs have not found a clear benefit of PTNS. None of the sham-controlled trials found that

active stimulation was superior to sham for achieving a reduction in mean incontinence episodes. The sham-controlled randomized trial by Knowles et al found a significantly greater decrease in the absolute number of weekly incontinence episodes in the active treatment group, but the overall trial findings did not suggest the superiority of PTNS over sham treatment. The sham-controlled randomized trial by Zyczynski et al did not indicate a benefit of PTNS over sham stimulation either. A meta-analysis of 1 RCT and several observational studies reported that individuals receiving SNS experienced significant benefits compared with individuals receiving PTNS. A post hoc analysis of the larger trial suggested a subset of patients with fecal incontinence, those without concomitant obstructive defecation, might benefit from PTNS.

## Surgical Sling

### *Clinical Context and Therapy Purpose*

The purpose of surgically placed perianal / pubo-rectal slings in individuals who have fecal incontinence is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following PICO was used to select literature to inform this review.

### *Populations*

The relevant population of interest is individuals with fecal incontinence. Fecal incontinence can have a substantial impact on quality of life. Estimates from the National Center for Health Statistics have suggested that among noninstitutionalized persons, 65 years of age or older, 17% have reported issues with fecal incontinence. Risk factors for fecal incontinence are similar in XY and XX individuals: older age, diarrhea, fecal urgency, urinary incontinence, and diabetes.

### *Interventions*

The therapy being considered is surgically placed perianal / pubo-rectal slings.

### *Comparators*

The following therapies are currently being used to make decisions about fecal incontinence: conservative therapy, sacral nerve stimulation, and surgery.

### *Outcomes*

The general outcomes of interest are symptom reduction, symptom recurrence, and treatment related adverse events.

### Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

### Review of Evidence

### Uncontrolled Trials

In 2016, Mellgren et al completed a patient prospective, multicenter study (single-arm interventional study) reporting 1-year outcome in a under investigational device exemption, evaluating this new treatment modality. A total of 152 women were implanted with the TOPAS system at 14 centers in the United States. FI was assessed preoperatively and at the 12-month follow up with a 14-day bowel diary, Cleveland Clinic Incontinence Scores, and FI Quality of Life questionnaires. Treatment success was defined as reduction in number of FI episodes of $\geq$ 50% compared to baseline. Missing bowel diary data were considered treatment failures. The Wilcoxon signed rank test was used to compare changes observed at 12 months vs baseline. Mean age was 59.6 years old (SD 9.7). The mean duration of FI was 110 mo (range 8-712) months. Mean length of the implant procedure was 33.4 (SD 11.6) minutes. Mean EBL was 12.9 (SD 10.5) mL. Average follow-up was 24.9 months. At 12 months, 69.1% of patients met the criteria for treatment success, and 19% of subjects reported complete continence. FI episodes/wk decreased from a median of 9.0 (range 2-40) at baseline to 2.5 (range 0-40) ($P < .001$). FI days decreased from a median of 5.0 (range 1.5-7) at baseline to 2.0 (range 0-7) ($P < .001$) over a 7-day period. FI associated with urgency decreased from a median at baseline of 2.0 (range 0-26) to 0 (range 0-14.5) ($P < .001$). The mean Cleveland Clinic Incontinence Scores decreased from 13.9 at baseline to 9.6 at 12 months ($P < .001$). FI Quality of Life scores for all 4 domains improved significantly from baseline to 12 months ($P < .001$). A total of 66 subjects experienced 104 procedure- and/or device-related adverse events (AEs). Most AEs were short in duration and 97% were managed without therapy or with nonsurgical interventions. No treatment-related deaths, erosions, extrusions, or device revisions were reported. The most common AE categories were pelvic pain (n = 47) and infection (n = 26). Those subjects experiencing pelvic pain had a mean pain score (0-10 scale, 0 = no pain) during the 12-month follow-up of 1.2 (SD 2.4). The authors concluded the TOPAS system provides significant improvements in FI symptoms and quality of life with an acceptable AE profile and may therefore be a viable minimally invasive treatment option for FI in women. Limitations noted included the study was a single arm trial with no control group. The study population was not from a diverse background. Study was done with a very specialized group of clinical investigators from two medical sub-specialties, Colorectal Surgeons and Urogynecologists.

### Section Summary: Surgical Sling

Mellgren evaluated the impact of the TOPAS system with reported improvements in FI symptoms and quality of life. TOPAS may be a viable minimally invasive treatment option for FI in XX individuals. There are limitations to this study. This study was a small, single arm, noncomparative study with no control group. The identified population was not from a diverse background. Also, 66 of the 152-participant reported experienced 104 procedure- and/or device-related adverse events (AEs). Additional studies are needed to assess long-term effectiveness and safety using standardized questionnaires to measure outcomes in additional RCTs with large sample and treatment comparison groups.

## Transanal Radiofrequency

### *Clinical Context and Therapy Purpose*

The purpose of transanal radiofrequency (RF) in individuals who have fecal incontinence is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following PICO was 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 therapy being considered is transanal RF.

### *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 elimination of incontinence, reductions in the frequency of incontinence, and improvements 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.

## Study Selection Criteria
Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

## Review of Evidence
In a systematic review conduction to inform the ASCRS guidelines on the management of fecal incontinence on radiofrequency energy to the sphincter the authors found evidence that the reported evidence for radiofrequency treatment is relatively sparse and has relevant limitations. Most studies reviewed have been small, single-center series with short-term follow-up. In addition, the authors observed that while long-term follow-up is very limited, any clinical benefit achieved in the short term appears to be sustained in the long term. The authors also noted that individuals with inflammatory bowel disease (IBD), chronic constipation, diarrhea, and history of pelvic radiation were not included in the studies reviewed. They stated that “because of the limitations in the available data, alternative treatments should be pursued before considering radiofrequency energy delivery.”

## 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. 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) retrospectively reviewed 27 patients who underwent the Secca procedure during a 6-year period (2004-2010) at a single medical center. Thirty-one procedures were performed for moderate-to-severe fecal incontinence. Most patients were women (mean age, 64 years), and the most common cause of incontinence was obstetrical injury. The 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 incontinence. No major complications occurred after the Secca procedure, and minor complications were observed in 5 (19%) patients (anal bleeding in, vulvar swelling in 1). A treatment response was noted in 21 (78%); mean Cleveland Clinic Florida Fecal Incontinence (CCF-FI) score was 16 at baseline and 10.9 at 3 months postoperatively. Studies have suggested that a CCF-FI score greater than 9 indicates a significant impairment of quality of life. However, in the Abbas study, only 6 (22%) patients had a sustained long-term response without any additional intervention, and 14 (52%) patients underwent or were 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. Twelve-month results were available for 16 (67%) patients. Mean CCF-FI score improved from 15.6 at baseline to 12.9 at 12 months ($p=0.035$). Mean Fecal Incontinence Quality of Life (FIQL) score improved in all subsets except for the depression subscore. Authors' conclusions on the actual clinical significance of this improvement were uncertain.

Felt-Bersma et al (2007) published results of an uncontrolled study on the Secca procedure in 11 women with fecal incontinence who underwent baseline and posttreatment testing. 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%) patients, moderate in 2, and severe in 1. Lam et al (2014) reported 3-year outcomes of this cohort plus 20 other patients who underwent the Secca procedure for fecal incontinence. Of the total cohort of 31 patients, 5 (16%) maintained a clinically significant response (defined as $\geq$50% reduction in Vaizey Incontinence Questionnaire 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.

Efron et al (2003) published an open-label, single-arm, nonrandomized study of 50 patients who underwent the Secca procedure and was followed for 6 months. Patients served as their own controls. The study assessed change in fecal incontinence symptom scores and quality of life between baseline and follow-up. Fecal incontinence was assessed with CCF-FI score, and quality of life was assessed with the 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 from 2.5 to 3.1 for the FIQL. Of 44 patients who had an initial baseline CCF-FI score greater than 9, a total of 15 (34%) achieved CCF-FI score less than 10 at 6 months. Improvement also was assessed using the Medical Outcomes Study 36-Item Short-Form Health Survey, focusing on mental and social parameters. Mean social function subscore improved from 64.3 to 34.4, and mental health subscore improved from 65.8 to 73.8. Fourteen-day diary data demonstrated significant improvement in all 9 parameters (e.g., days with any fecal incontinence dropped from 10 in a

14-day period to 7). In contrast, there were no differences in objective measures of anal sphincter function (i.e., there were no differences in manometry measures, rectal sensation volumes, pudendal nerve motor latency, or internal or external sphincter defects), as noted on endoanal ultrasound. Authors noted that determining the mechanism of action for the procedure was not a study objective. Three significant procedure-related complications occurred during the trial. Two patients developed anal ulceration, and 1 developed bleeding from a hemorrhoidal vein. Twenty-six minor adverse events occurred, including minor bleeding in 5 patients, transient worsening of incontinence in 4 patients, and anal pain in 5 patients. Three other very small case series (n=15, 19, 8) were performed outside the United States. In 2, no clear benefit was noted for the procedure.

Three other very small case series (n=15, 19, 8) were performed outside the United States. In 2, no clear benefit was noted for the procedure.

### Section Summary: Transanal Radiofrequency Therapy

A small body of observational studies or noncomparative, single-arm trials have reported on changes in incontinence symptoms after the Secca procedures. Given the small number of studies 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, short-term follow-up), the efficacy of RF therapy for fecal incontinence is not supported in the literature.

## Vaginal Insert

### *Clinical Context and Therapy Purpose*

The purpose of a vaginal insert in individuals who have fecal incontinence is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following PICO was used to select literature to inform this review.

### *Populations*

The relevant population of interest is individuals with fecal incontinence. Risk factors for fecal incontinence are similar in XY and XX individuals: older age, diarrhea, fecal urgency, urinary incontinence, and diabetes. For XX individuals, current and past use of hormone therapy is an added risk factor. Fecal incontinence can have a substantial impact on quality of life. Estimates from the National Center for Health Statistics have suggested that among noninstitutionalized persons, 65 years of age or older, 17% have reported issues with fecal incontinence.

### *Interventions*

The therapy being considered is vaginal insert for fecal incontinence. The vaginal insert is a balloon-like device attached to a pressure-regulated pump that is inflated to occlude the rectum. The occlusion of the rectum using the device has been shown to reduce episodes of incontinence by fifty percent at one month of use by eighty percent of females.

### *Comparators*

The following therapies are currently being used to make decisions about fecal incontinence: Nonsurgical treatment options for incontinence may include pharmacologic therapy, bowel training exercises, and electrical stimulation. Behavioral therapies include pelvic floor muscle training and diet.

The general outcomes of interest include a reduction in symptoms (e.g., number of incontinence episodes) and improvements in quality of life and cure rates.

### *Outcomes*

The general outcomes of interest include a reduction in symptoms (e.g., number of incontinence episodes) and improvements in quality of life and cure rates.

### Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

### Review of Evidence

### Systematic Review

Buono et al. (2018) completed a systematic review of mechanical inserts for the treatment of fecal incontinence. They identified 35 studies eight publications were included in the final review: two focused on vaginal inserts. They concluded data regarding vaginal and anal mechanical inserts for the treatment of FI, albeit limited, suggest that inserts can be included in a discussion of therapeutic options for a patient with FI. Further studies are needed to elucidate long-term usability, efficacy, and safety.

### Noncomparative Studies

Richter et al (2019) completed a prospective open-label study on individuals with FI who had previously been fit for a vaginal bowel control system and completed the 2-week trial time. The individuals who achieved 50% or more decrease in episodes of FI from their baseline were followed 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).” “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.” The authors reported some limitations with the study include that not all individuals were able to be successfully fit A vaginal length that is shorter and previous prolapse surgery may reduce the chance of a successful fitting. The population study had severe FI, with at least 4 major times with FI within 2 weeks thus, results may not be able to be generalized to less severe FI cases. Additionally, there is no control group. The authors indicate, “Future efforts should focus on long-term, comparative studies, which include the evaluation of this safe and effective VBC system.”

In a single-arm noncomparative study, Richter et al (2015) evaluated the effectiveness and safety of a vaginal bowel-control device and pump system (Eclipse System) for fecal incontinence treatment. Women with a minimum of four fecal incontinence episodes over 2 weeks were fit with the intravaginal device. 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. This study has several limitations. Optimally, a randomized trial would have minimized bias. The inclusion of a control arm, although desirable, is uncommon in trials of fecal incontinence therapies because of the nonuniform presentation of the condition and the lack of a gold standard treatment. A common methodology in fecal incontinence intervention trials, as selected in this study, was for participants to serve as their own controls. Although this method is subject to inherent treatment, selection, and recall bias, it does serve to minimize individual variation in disease presentation, a significant factor in studies regarding fecal incontinence. In addition to study design, the length of follow-up was short. Because this is a completely new treatment option, it was important to investigate the potential side effects and tolerability in addition to efficacy. A longer-term outcome study is needed to provide this important information.

### Section Summary: Vaginal Insert

For individuals with FI who utilize a vaginal insert the evidence includes systematic reviews of uncontrolled studies which have failed to elucidate long-term usability, efficacy, and safety.

## SUPPLEMENTAL INFORMATION

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

### 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

Guidelines or position statements will be considered for inclusion in ‘Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

### *American College of Gastroenterology (ACG)*

In 2021 the American College of Gastroenterology (ACG) issued guidelines on the Management of Benign Anorectal Disorders which stated the following information:

- Anal plugs
    - Anal plugs are mechanical barrier devices. Renew is a silicone anal insert that is disposable. In 1 study of 30 patients with FI, 20% disliked the device, 23% showed no change, and 12% reported worse symptoms of FI; however, 57% of patients wished to continue using the device (248). In a second study, the Renew device was used in 15 patients with an ileoanal pouch (249): 8 of 15 (53%) found the Renew device to be acceptable, and 6 of 15 (40%) reported it to be effective. The Peristeen anal plug is available in Europe. One review concluded that plugs are difficult to tolerate but may be useful in a select group of patients and may be used as an adjunct to other treatments.
    - The Eclipse vaginal bowel control device is a balloon that is inserted into the vagina and acts as a mechanical barrier, compressing the anterior wall of the rectum. The correct-sized balloon has to be selected for each patient, and manual dexterity is required to deflate, inflate, insert, and remove the device. Two case series were published: In the first series, 61 patients were evaluated for 1 month. A 50% reduction in FI was reported by 86%, and quality of life improved. Adverse events such as cramping and abdominal pain were reported during the fitting period. Another study showed reductions in urgency, frequency, and incomplete evacuations in more than 50% of the patients.

- Injectable bulking agents
    - Injectable bulking agents, which are used to augment the urethral sphincter and treat urinary incontinence, were approved by the US Food and Drug Administration for managing FI. In a multicenter, placebo-controlled randomized trial of a perianal bulking agent (dextranomer in stabilized hyaluronic acid [NASHA Dx]) in 206 patients with FI, a > 50% reduction in incontinence episodes was reported more frequently for NASHA Dx (52% patients) than placebo (31% patients). The number of patients who became completely continent was not provided. Two serious adverse events occurred (i.e., rectal abscess and prostatic abscess), but most adverse events were minor. Treatment did not affect embarrassment scores related to FI. Anorectal physiological tests and imaging were not performed; hence, patient characteristics and mechanisms of action were unknown.
    - A prospective multicenter trial in 136 FI patients found that fecal continence improved in 52% of patients in 6 months, and this was sustained after 36 months (255). Further studies to compare the effects of bulking agents to biofeedback therapy in FI are ongoing (256). The guidelines indicated that there is insufficient evidence to recommend radiofrequency ablation to the anal sphincter as treatment for fecal incontinence. The College also asserted that the biologic rationale for this type of treatment is unproven.

- Pelvic Floor Stimulation
    - PFS is not mentioned as a treatment option.

- Radiofrequency stimulation (SECCA procedure)
    - The SECCA procedure involves radiofrequency stimulation of the muscles in the anal canal to increase muscle connective tissue ratio and scarring (257) via a probe with needles in the anal canal performed under local anesthesia and sedation. Despite initial positive studies including a multi-center trial from 2003 (258), more recent reports suggest poor long-term results.

- Miscellaneous devices
    - Numerous attempts have been made to artificially enhance the anal sphincter to improve continence. Most of these devices have shown unacceptable complication rates or explant rates (271–273) and are not currently available. The newest of these devices, which is a thin expandable prosthesis that is implanted in the intersphincteric space, has only been evaluated in very few patients.

### *American College of Obstetricians and Gynecologists (ACOG)*

In 2019 (reaffirmed 2023) the American College of Obstetricians and Gynecologists (ACOG) published a practice bulletin on the clinical management of fecal incontinence in women. The College stated, "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 (AGA)*

In 2017 the American Gastroenterological Association (AGA) published an expert review and clinical practice update on surgical interventions and device-aided therapy for the treatment of fecal incontinence. The update stated that, “until further evidence is available, percutaneous tibial nerve stimulation should not be used for managing FI [fecal incontinence] in clinical practice."

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. The AGA recommends, "Perianal bulking agents such as intra-anal injection of dextranomer may be considered when conservative measures and biofeedback therapy fail."

### *American Society of Colon and Rectal Surgeons (ASCRS)*

In 2023, the American Society of Colon and Rectal Surgeons updated an evidence-based clinical practice guideline, the Management of Fecal Incontinence, using GRADE methodology on 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.”
- They reported vaginal and anal mechanical inserts are not routinely recommended for FI with a conditional recommendation strength and a very low-GRADE quality of evidence.
- Applicable of temperature-controlled radiofrequency energy to the sphincter complex is not recommended to treat FI based on a conditional recommendation strength and a very low-GRADE quality of evidence.

Dietary interventions and medical management are considered first-line treatments; PFS was not included in the recommendations.

### *National Institute for Health and Clinical Excellence (NICE)*

In 2016, the NICE published a Medtech innovation briefing on the Secca system for fecal incontinence. These briefings aim to aid in the decision-making process by describing the technology, its role in the treatment pathway, the relevant published evidence, and cost information. These briefings do not contain recommendations. The briefing noted that “Secca therapy is a minimally invasive treatment option available for people with incontinence of solid or liquid stool at least once a week, in whom conservative management options have not controlled symptoms.”

The NICE issued guidance on radiofrequency treatment for fecal incontinence in 2011. NICE concluded that “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.”

In 2007, the National Institute for Health and Clinical Excellence (NICE) published guidance on injectable bulking agents for treating fecal incontinence. The guidance stated that there is insufficient evidence to support the safety and efficacy of injectable bulking agents for fecal incontinence.

In 2007, the NICE issued guidance on fecal incontinence in adults. This guidance was last reviewed by NICE in 2018. The document stated that the evidence on *electrical stimulation for treatment* of fecal incontinence was inconclusive. The NICE recommended that patients who continue to have episodes of fecal incontinence after initial treatment be considered for specialized management, which may include electrical PFS. Magnetic PFS is not mentioned.

### Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this review can be located at clinicaltrials.gov.

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## CODES

To report provider services, use appropriate CPT codes, HCPCS codes, Revenue codes, and/or ICD diagnosis codes.

| Codes | Number | Description |
|---|---|---|
| CPT | | |
| | 46999 | Unlisted procedure, anus (*may be indicated for bulking agents using Solesta or autologous fat; Eclipse System, anal sling TOPAS system or transanal radiofrequency therapy*) |
| | 58999 | Unlisted procedure, female genital system (nonobstetrical) *(when indicated for Eclipse system or Vaginal Insert*) |
| | 64566 | Posterior tibial neurostimulation, percutaneous needle electrode, single treatment, includes programming |
| | 97014 | Application of a modality to 1 or more areas; electrical stimulation (unattended) (*when indicated for pelvic floor stimulation [PFS]*) |
| | 97032 | Application of a modality to 1 or more areas; electrical stimulation (manual), each 15 minutes (*when indicated for pelvic floor stimulation [PFS])* |
| | 1001T | Autologous muscle cell therapy, injection of muscle progenitor cells into the external anal sphincter, including ultrasound guidance, when performed |
| | | |

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|---|---|---|
| HCPCS | | |
| | A4337 | Incontinence supply rectal insert, any type each (*when indicated for Renew Anal Insert*) |
| | A4563 | Rectal control system for vaginal insertion, for long term use, includes pump and all supplies and accessories, any type each (*when indicated for Eclipse System*) |
| | E0740 | Incontinence treatment system, pelvic floor stimulator, monitor, sensor, and/or trainer |
| | L8605 | Injectable bulking agent, dextranomer/hyaluronic acid copolymer implant, anal canal, 1 ml, includes shipping and necessary supplies |
| | | |
| Type of Service | Surgery | |
| Place of Service | Inpatient/ Outpatient | |

## POLICY HISTORY

| Date | Reason | Action |
|---|---|---|
| December 2025 | Annual Review | Policy Renewed |
| December 2024 | Annual Review | Policy Renewed |
| May 2024 | Annual Review | Policy Renewed |
| May 2023 | Annual Review | Policy Revised |
| May 2022 | Annual Review | Policy Revised |
| May 2021 | Annual Review | Policy Revised |
| June 2020 | Interim Review | Policy Revised |
| May 2020 | Annual Review | Policy Revised |
| November 2019 | Interim Review | Policy Revised |
| May 2019 | Annual Review | Policy Revised |
| May 2018 | Annual Review | Policy Revised |
| May 2017 | Annual Review | Policy Revised |

| Date | Reason | Action |
|---|---|---|
| June 2016 | Annual Review | Policy Revised |
| July 2015 | Annual Review | Policy Revised |
| August 2014 | Annual Review | Policy Revised |
| September 2013 | New Policy | New Policy |

New information or technology that would be relevant for Wellmark to consider when this policy is next reviewed may be submitted to:

Wellmark Blue Cross and Blue Shield
Medical Policy Analyst
PO Box 9232
Des Moines, IA 50306-9232

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