


MEDICAL POLICY	Fecal Incontinence Treatments (All Lines of Business Except Medicare)	
Effective Date: 1/1/2021  1/1/2021	Section: SUR	Policy No: 224
	Technology Assessment Committee Approved Date: 1/12 Medical Policy Committee Approved Date: 1/13; 3/14; 8/15; 6/16; 8/17; 10/18; 2/19; 11/19; 8/2020; 12/2020	
Medical Officer	Date	

See Policy CPT/HCPCS CODE section below for any prior authorization requirements

SCOPE:

Providence Health Plan, Providence Health Assurance, Providence Plan Partners, and Ayin Health Solutions as applicable (referred to individually as “Company” and collectively as “Companies”).

APPLIES TO:

All lines of business

BENEFIT APPLICATION

Medicaid Members

Oregon: Services requested for Oregon Health Plan (OHP) members follow the OHP Prioritized List and Oregon Administrative Rules (OARs) as the primary resource for coverage determinations. Medical policy criteria below may be applied when there are no criteria available in the OARs and the OHP Prioritized List.

POLICY CRITERIA

Initial 14-Day Trial Period of Sacral Nerve Stimulation

- I. A trial period of sacral nerve stimulation with a temporarily implanted lead may be considered **medically necessary and covered** for testing over a 14-day trial period when **all** of the following (A.-C.) criteria are met:
 - A. A diagnosis of chronic fecal incontinence, defined as averaging more than two incontinent episodes per week for more than six months, or for more than 12 months after vaginal childbirth; **and**
 - B. Documented failure or intolerance to conventional therapy (e.g. dietary management, pharmacotherapy, strengthening exercises); **and**

- C. None of the following (1.-4.) contraindications are present:
 - 1. Significant anorectal malformation (e.g., congenital anorectal malformation; defects of the external anal sphincter over 60 degrees; visible sequelae of pelvic radiation; active anal abscesses and fistulae); **or**
 - 2. Chronic inflammatory bowel disease involving the anus; **or**
 - 3. Fecal incontinence secondary to another neurological condition (e.g. peripheral neuropathy, complete spinal cord injury); **or**
 - 4. Patient has had rectal surgery in the previous 12 months, or in the case of cancer, the patient has had rectal surgery in the past 24 months.

II. A trial period of sacral nerve stimulation with a temporarily implanted lead is considered **investigational and is not covered** when criterion I. above is not met.

Permanently Implanted Sacral Nerve Stimulator

III. Permanent implantation of a sacral nerve stimulator may be considered **medically necessary and covered** for patients who meet **both** of the following (A.-B.) criteria:

- A. All of criteria in I. (A.-C.) above are met; **and**
- B. The 14-day trial stimulation period demonstrates a 50 percent or greater improvement in reported symptoms.

IV. Permanent implantation of a sacral nerve stimulator is **considered investigational and is not covered** when criterion III. above is not met.

V. Removal or replacement of a sacral nerve stimulator is considered **not medically necessary and not covered** if the initial device remains functional.

Investigational Treatments

VI. Other treatments of fecal incontinence are considered **investigational and are not covered**, including but not limited to, the following (A.-G.):

- A. Biofeedback
- B. Injectable bulking agents
- C. Transanal radiofrequency therapy (Secca procedure)
- D. Anal sphincter replacement (i.e. Acticon Neosphincter)
- E. Posterior tibial nerve stimulation (PTNS)
- F. Eclipse™ Vaginal Insert System

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VII. Peristeen anal irrigation system is considered **not medically necessary and not covered** for the treatment of fecal incontinence.

Note: Reimbursement for anal irrigation devices must be consistent with what is reasonable and medically necessary to serve the intended purpose. Therefore, payment for an anal irrigation device does not include customized or additional features beyond the function of an anal irrigation device and are the least costly alternative.

Link to [Policy Summary](#)

BILLING GUIDELINES

- The “C” codes listed below are only applicable when billed under the hospital outpatient prospective payment system (OPPS) and they should be submitted in place of HCPCS code A4240.
- CPT codes 90875, 90876, and/or 90901 may be used to bill biofeedback for the treatment of fecal incontinence, which is considered investigational and not covered.
- CPT code 64566 will deny as investigational and not covered when billed with ICD-10 codes F98.1, R151, R152, R150, R159 for fecal incontinence.

CPT/HCPCS CODES

All Lines of Business Except Medicare	
Prior Authorization Required	
64561	Percutaneous implantation of neurostimulator electrode array; sacral nerve (transforaminal placement) including image guidance, if performed
64581	Incision for implantation of neurostimulator electrode array; sacral nerve (transforaminal placement)
64585	Revision or removal of peripheral neurostimulator electrode array
64590	Insertion or replacement of peripheral or gastric neurostimulator pulse generator or receiver, direct or inductive coupling
64595	Revision or removal of peripheral or gastric neurostimulator pulse generator or receiver
A4290	Sacral nerve stimulation test lead, each
C1767	Generator, neurostimulator (implantable), non-rechargeable
C1778	Lead, neurostimulator (implantable)
C1787	Patient programmer, neurostimulator

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C1823	Generator, neurostimulator (implantable), non-rechargeable, with transvenous sensing and stimulation leads
C1897	Lead, neurostimulator test kit (implantable)
L8679	Implantable neurostimulator, pulse generator, any type
L8680	Implantable neurostimulator electrode, each
L8685	Implantable neurostimulator pulse generator, single array, rechargeable, includes extension
L8686	Implantable neurostimulator pulse generator, single array, non-rechargeable, includes extension
L8687	Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension
L8688	Implantable neurostimulator pulse generator, dual array, non-rechargeable, includes extension
<p>No PA Required</p> <p><u>Note:</u> The following codes will deny as investigational when billed with a fecal incontinence diagnosis code.</p>	
64566	Posterior tibial neurostimulation, percutaneous needle electrode, single treatment, includes programming
90911	TERMED 12/31/19 Biofeedback training, perineal muscles, anorectal or urethral sphincter, including EMG and/or manometry
90912	Biofeedback training, perineal muscles, anorectal or urethral sphincter, including EMG and/or manometry, when performed; initial 15 minutes of one-on-one physician or other qualified health care professional contact with the patient
90913	Biofeedback training, perineal muscles, anorectal or urethral sphincter, including EMG and/or manometry, when performed; each additional 15 minutes of one-on-one physician or other qualified health care professional contact with the patient (List separately in addition to code for primary procedure)
<p>Not Covered</p>	
0377T	TERMED 12/31/19 Anoscopy with directed submucosal injection of bulking agent for fecal incontinence
46762	TERMED 12/31/18 Sphincteroplasty, anal, for incontinence, adult; implantation artificial sphincter
A4459	Manual pump enema system, includes balloon, catheter and all accessories, reusable, any type
A4563	Rectal control system for vaginal insertion, for long term use, includes pump and all supplies and accessories, any type each
L8605	Injectable bulking agent, dextranomer/hyaluronic acid copolymer implant, anal canal, 1 ml, includes shipping and necessary supplies.

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<p>Unlisted Codes All unlisted codes will be reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is billed related to services addressed in this policy then prior-authorization is required.</p>	
46999	Unlisted procedure, anus

DESCRIPTION

Fecal incontinence (FI)

Fecal Incontinence is the recurrent and involuntary loss of solid or liquid feces due to insufficient restriction of the anal canal.¹ FI may occur passively without the patient’s awareness, with an urgent need to defecate, or with some combination of both.² Among noninstitutionalized U.S. adults, prevalence is estimated at 8.3%, with 0.9% reporting daily FI episodes.² The majority of patients experiencing FI have previously suffered some form of physiological change (e.g. childbirth, anal surgery) although FI symptoms are rarely attributable to a single factor. First-line treatment modalities include dietary modifications, pharmacotherapy and pelvic floor muscle-strengthening exercises.

Treatments of Fecal Incontinence

Sacral Nerve Stimulation (SNS)

SNS is the surgical application of a mild electrical pulse to a sacral nerve, which influences the functioning of the bladder, bowel, anal sphincter, and the pelvic floor muscles.^{1,2} The implanted electrode connects to an external pulse generator, which provides continuous stimulation to the pelvic floor musculature, thereby improving pelvic floor function. Patients are initially enrolled in a two-week trial stimulation with the device. Patients that experience at least 50% improvement in symptoms following this trial are subsequently eligible for permanent implantation of the pulse generator, which is connected to a stimulator surgically embedded in the subcutaneous pouch of the upper buttock.^{1,2}

Biofeedback

Biofeedback is a treatment that attempts to increase patient awareness of physiological processes that are not typically considered to be under voluntary control. Electromyographic surface electrodes are attached to an anal plug and the abdominal wall to measure the tightening and relaxation of the external anal sphincter. Accompanying visual or audio feedback equipment aims to assist the patient in improving their ability to both perceive rectal distentions, and to strengthen and coordinate abdominal wall and pelvic floor musculature in response to these distentions.^{1,3}

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Injectable Bulking Agents

Bulking agents, dextranomer stabilized in hyaluronic acid, are injected into the submucosal layer of the anal canal. It is hypothesized that the agent enhances resting anal pressures by narrowing the anal canal, thereby improving the patient’s sphincter control.¹

Transanal Radiofrequency

Transanal radiofrequency (Secca procedure) delivers radiofrequency energy to the anorectal junction to create thermal lesions in the sphincteric complex of the anal canal. When these lesions heal, the surrounding tissue contracts, purportedly improving continence as a result.¹

Artificial Sphincter Replacement (i.e. Acticon Neosphincter)

In artificial sphincter replacement, an occlusive cuff is surgically placed around the anal canal. Tubing from the cuff runs along the perineum and is connected to a control pump placed in the scrotum or labia. A pressure regulating-balloon is placed in the abdominal wall. The user squeezes the control pump to permit defecation.¹

Posterior Tibial Nerve Stimulation (PTNS)

Posterior (also called Percutaneous) Tibial Nerve Stimulation delivers an electrical current to the sacral nerve plexus via an electrode placed in a superficial branch of the posterior tibial nerve in the ankle. The low-voltage pulse hypothetically stimulates and alters pelvic floor function such that incontinence improves.¹

Eclipse™ Vaginal Insert System

The Eclipse™ Vaginal Insert System is a device comprising an inflatable balloon that, when inserted into the vagina, presses on the rectal vault, supposedly closing off the rectum and preventing stool from passing involuntarily. When a bowel movement is needed, the patient uses an external pump to deflate and re-inflate the balloon, thereby completing the bowel evacuation.⁴

Manual Pump Enema Systems

Manual pump enema systems (also known as transanal irrigation) refer to devices that empty the lower bowel by introducing water into the bowel using a rectal catheter. Devices typically consist of an enema bag, a rectal catheter with an inflatable balloon and a pump.

REVIEW OF EVIDENCE

A review of the ECRI, Hayes, Cochrane, and PubMed databases was conducted regarding the use of sacral nerve stimulation and other treatments for fecal incontinence. Below is a summary of the available evidence identified through May 2020.

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Systematic Reviews

Sacral Nerve Stimulation (SNS)

- In 2020, Hayes published an annual update of its 2016 evidence review on the staged approach to sacral nerve stimulation (SNS) for fecal incontinence (FI).² The review searched the literature through November 2015 and examined eighteen publications from 15 studies (2 RCTs, 2 randomized crossover trials, 3 nonrandomized comparative studies, 8 pretest/posttest studies, and 3 follow-up reports). All patients (n=16 to 172) presented with severe fecal incontinence symptoms and had previously failed to respond to more conservative treatments. Study outcomes of interest were quality of life (QOL), disease severity, postimplantation surgical procedures and adverse events.

Of the fifteen studies measuring QOL, ten reported improvements among patients treated with SNS, while all eight studies examining disease severity reported significant improvements. Follow-up for both outcomes ranged from eight months to five years. The most common side effects of the SNS device and/or surgery were pain and paresthesias. Hayes concluded that SNS entails potentially significant risks for postimplantation surgeries and related complications. Despite designating 14 of the 15 included studies as being of either “low” or “very low” quality, Hayes rated the overall evidence base as “moderate,” given the consistent improvements across studies among two outcomes (QOL and disease severity), high patient importance and the representativeness of patient populations studied.

Hayes gave the following ratings for sacral nerve stimulation for fecal incontinence:

- **B (some proven benefit):** for use of the staged approach to SNS among patients with severe FI who both fail to respond to earlier treatments, and who experienced at least 50% improvement in FI symptoms during a preliminary trial. Further patient selection criteria was not established due to a lack of evidence.
 - **D2 (insufficient evidence):** for long-term use of SNS due to a lack of evidence beyond 5 years of follow-up.
- In 2016, the Agency for Healthcare Research and Quality (AHRQ) published a systematic review examining several treatment modalities for fecal incontinence (FI).⁵ Of the 63 studies that met pre-defined inclusion criteria, five addressed sacral nerve stimulation (SNS). Review authors searched published and gray literatures through June 2015, assessing all studies individually. AHRQ concluded that the evidence base was insufficient to recommend SNS. All five studies showed moderate- to high-risk of bias stemming from limitations in design (heterogenous treatment-outcome combinations) and unrepresentative patient populations (women over 60 years). The review further noted two shortcomings of the device/surgery: the stimulator battery requires surgical replacement approximately every five years; and the patient’s nervous system may adapt to the stimulator, potentially lessening the device’s efficacy over time.

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- In 2015, Cochrane conducted a systematic review examining the use of sacral nerve stimulation (SNS) in the treatment of both constipation and fecal incontinence (FI).⁶ Eight studies (six crossover trials and two parallel group trials) assessing FI met pre-defined inclusion criteria and were individually assessed by the two review authors. In the largest included study (Tjandra et al. 2008),⁷ 53 participants experienced fewer FI episodes than those receiving optimum medical therapy in the control group. Adverse events included pain, seroma and excessive tingling in the vaginal region. The review concluded that “the limited evidence from the included trial suggests that SNS can improve continence in a proportion of patients with fecal incontinence,” and called for additional rigorous, high quality studies to better establish the efficacy of SNS in the treatment of FI.⁶

Biofeedback

- In 2016, the Agency for Healthcare Research and Quality (AHRQ) published a systematic review examining several treatment modalities for fecal incontinence (FI).⁵ Of the 63 studies that met pre-defined inclusion criteria, 16 (13 RCT’s and 3 observational studies) addressed biofeedback when used in conjunction with pelvic floor muscle training (PFMT). Outcomes of interest were disease severity, quality of life (QOL), and patients’ perceived improvement in symptoms. AHRQ found insufficient evidence to recommend PFMT plus biofeedback over standard treatments (e.g. dietary modifications, pharmacotherapy), noting that most studies attempted to improve on purported benefits of the treatment, rather than establishing the treatment’s efficacy. Other limitations included a lack of RCTs using PFMT-alone as a control; statistically insignificant differences in FI outcomes between exposure and control groups; and short follow-up periods (only four randomized studies reported outcomes beyond six months). All studies were assessed to have moderate to high levels of bias.
- In 2012, Cochrane conducted a systematic review of biofeedback and/or sphincter exercises for the treatment of fecal incontinence (FI).⁸ Searching published and gray literatures through January 2012, the authors identified 21 publications (n=1525) that met predefined inclusion criteria. Outcomes of interest varied widely – eleven trials reported quality of life evaluations; eight trials reported changes in manometric data as a surrogate outcome; eight studies used a patient-completed diary; five trials reported patient evaluation of the outcome as the primary outcome measure. Follow-up periods ranged from three weeks to one year. One trial found biofeedback supplementing exercises was better than exercises alone, while another found that adding biofeedback to electrical stimulation was better than electrical stimulation alone. The review concluded that “the limited number of identified trials together with methodological weaknesses of many do not allow a definitive assessment of the role of anal sphincter exercises and biofeedback therapy in the management of people with fecal incontinence.”⁸

Injectable Bulking Agents

In 2016 (archived 2017), Hayes gave bulking agents a score of D2 (insufficient evidence), assessing the overall quality of evidence as low due to small study sizes, high dropout rates and a lack of sham-controlled trials.⁹

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Transanal Radiofrequency (Secca procedure)

The 2016 AHRQ systematic review evaluating treatments for fecal incontinence found no RCTs or observational studies with control groups evaluating transanal radiofrequency,⁵ rendering the safety and efficacy of the treatment indeterminate.

Artificial Sphincter Replacement (i.e. Acticon Neosphincter)

The 2016 AHRQ systematic review evaluating treatments for fecal incontinence judged the evidence for artificial sphincter replacement as insufficient when compared to traditional medical management.⁵

Posterior Tibial Nerve Stimulation (PTNS)

PTNS is currently not FDA-approved for fecal incontinence.

Eclipse™ Vaginal Insert System

One non-randomized controlled trial was identified evaluating the Eclipse™ Vaginal Insert System. Findings were limited by the study’s small sample size, inadequate follow-up, and a lack of comparison groups.¹⁰ Additional, well-designed studies are necessary to determine the device’s safety and efficacy.

Manual Pump Enema Systems (e.g. Peristeen® anal irrigation system)

- In 2006, Christensen and colleagues published results of a randomized trial of transanal irrigation versus conservative bowel management in spinal cord-injured patients.¹¹ Eighty-seven patients with spinal cord injury and neurogenic bowel dysfunction were randomized to either transanal irrigation (TAI) or conservative bowel management for a 10-week trial period. The mean (SD) scores for TAI vs conservative care were as follows: Cleveland Clinic constipation scoring system (range, 0–30, 30 = severe symptoms) was 10.3 (4.4) versus 13.2 (3.4) (P = .0016), St. Mark’s fecal incontinence grading system (range, 0–24, 24 = severe symptoms) was 5.0 (4.6) versus 7.3 (4.0) (P = .015), and the Neurogenic Bowel Dysfunction Score (range, 0–47, 47 = severe symptoms) was 10.4 (6.8) versus 13.3 (6.4) (P = .048). The modified American Society of Colorectal Surgeon fecal incontinence scores (for each subscale, range is 0–4, 4 = high quality of life) were: lifestyle 3.0 (0.7) versus 2.8 (0.8) (P = .13), coping/behavior 2.8 (0.8) versus 2.4 (0.7) (P = .013), depression/self-perception 3.0 (0.8) versus 2.7 (0.8) (P = .055), and embarrassment 3.2 (0.8) versus 2.8 (0.9) (P = .024). Limitations of the study include small sample size and short follow up. Long term safety was not addressed. The authors concluded that TAI improves constipation, fecal incontinence, and symptom-related quality of life compared to conservative bowel management.
- In 2019, Rosen and colleagues published results from a randomized trial of prophylactic transanal irrigation (TAI) versus supportive therapy to prevent symptoms of low anterior resection syndrome after rectal resection.¹² Thirty-seven patients were randomized to TAI or supportive care and

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reported maximum number of defecation episodes per day for 3 months. Maximum number of stool episodes per day and night were significantly lower in the TAI group at 1 month and 3 months compared to the control group. Lower anterior resection syndrome scores were significantly better in the TAI group as well. Limitations of the study include small sample size and short follow up. Long term safety was not addressed.

A number of nonrandomized trials were identified on the effectiveness of Peristeen for adults with fecal incontinence and constipation.¹³⁻¹⁵ All suffered from limitations due to small sample size and retrospective study design.

CLINICAL PRACTICE GUIDELINES

Sacral Nerve Stimulation (SNS)

American College of Obstetrics and Gynecology (ACOG)

In 2019, the ACOG published a clinical practice guideline assessing fecal incontinence.¹⁶ On the basis of limited evidence, investigators stated that sacral nerve stimulation can be considered as a surgical treatment option for patients with or without anal sphincter disruption who have failed conservative treatments.

National Institute for Health and Care Excellence (NICE)

In 2018, NICE reviewed relevant research published since its 2007 guidance on management of fecal incontinence in adults.¹⁷ The surveillance review reported that the quantity and quality of the evidence had not progressed enough to warrant an update to the guideline. The 2007 guidance had previously concluded that “a trial of temporary sacral nerve stimulation should be considered for people with faecal incontinence in whom sphincter surgery is deemed inappropriate.”¹⁷

American Society of Colon and Rectal Surgeons (ASCRS)

In 2015, the ASCRS deemed SNS a “first line surgical option for patients with and without sphincter defects,” granting the surgery a 1B rating (strong recommendation, moderate-quality evidence; benefits clearly outweigh risk and burdens).¹⁸

American College of Gastroenterology

In 2014, the American College of Gastroenterology gave SNS a “strong recommendation” on the basis of moderate-quality evidence for patients who do not respond to more conservative treatments.¹⁹

Injectable Bulking Agents

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American College of Obstetrics and Gynecology (ACOG)

In 2019, the ACOG published a clinical practice guideline assessing fecal incontinence.¹⁶ On the basis of limited evidence, investigators stated that bulking agents may be effective at up to 6-months, and may be considered as a short-term option for patients that have failed more conservative treatments.

Biofeedback

American Society of Colon and Rectal Surgeons (ASCRS)

In its 2015 guideline, the ASCRS strongly recommended biofeedback “as an initial treatment for patients with incontinence and some preserved voluntary sphincter contraction.”¹⁸ However, the guideline also noted the treatment’s lack of established efficacy in the literature, noting that no randomized trials compare biofeedback to sham therapy, and that many smaller studies with positive outcomes suffer from methodological weaknesses and heterogenous designs. The ASCRS called for larger, randomized studies to establish biofeedback’s validity as a therapy for fecal incontinence.¹⁸

American Neurogastroenterology and Motility Society (ANMS)

In 2015, ANMS strongly recommended biofeedback for both short- and long-term treatment of fecal incontinence in patients who have not responded to more conservative treatments, and who lack contraindications including spinal cord injury and severe internal anal sphincter injuries.³ The guideline nonetheless noted the inconsistency of findings among RCTs of biofeedback, as well as heterogenous design criteria and a lack of power among certain trials. The ANMS called for more, higher quality studies to standardize treatment protocol and outcome measures.³

National Institute for Health and Care Excellence (NICE)

In its 2007 guidance, NICE listed biofeedback as one of several “specialist continence service[s]” that patients might consider if initial treatments proved ineffective.¹⁷ In its 2018 surveillance of the guidance, NICE clarified that biofeedback was included as a recommendation due to “consensus,” but noted that the treatment lacked evidence demonstrating efficacy. NICE also examined four studies published since 2007 examining biofeedback as therapy for fecal incontinence (two RCTs, one non-randomized study, and the above mentioned Cochrane Review), reporting that these studies’ outcomes “suggested no effect, or uncertainty in their effects.”¹⁷

Artificial Sphincter Replacement

American Society of Colon and Rectal Surgeons (ASCRS)

In 2015, the American Society of Colon and Rectal Surgeons issued a “strong recommendation based on low-or very low-quality evidence” for artificial sphincter replacement in its guidelines, noting that all relevant studies showed a high rate of post-operative complications.¹⁸ Given the comparative success of

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SNS, the ASCRS recommended artificial sphincter replacement only in patients for whom all other treatments have failed.¹⁸

American College of Gastroenterology

In 2014, the American College of Gastroenterology issued a “weak recommendation” for artificial sphincter replacement in its guidelines, stating that studies were limited to case series with small sample sizes, limited follow-up periods, high rates of adverse events, and a lack of control groups.¹⁹

Posterior Tibial Nerve Stimulation

National Institute for Health and Care Excellence (NICE)

In 2011, NICE published an interventional procedures guidance, in which investigators stated that PTNS “showed evidence of efficacy in the short term in a limited number of patients.”²⁰

Transanal Radiofrequency Therapy (Secca Procedure)

National Institute for Health and Care Excellence (NICE)

In 2016, NICE published a Medtech innovation briefing evaluating the Secca System for the treatment of fecal incontinence.²¹ On the basis of low-quality evidence, investigators stated that the procedure “shows short-term improvements in both fecal incontinence and quality of life, with no significant improvements in the relevant patient-reported scores in the medium and long term (1 and 3 years).”²¹

Manual Pump Enema Systems

In 2018, NICE published a “medical technologies guidance” addressing the use of the Peristeen® transanal irrigation system.²² Investigators concluded that evidence supported the use of Peristeen to reduce the severity of incontinence, improve quality of life and promote dignity and independence. This recommendation was made on the basis of one small RCT (n=87) with 10 weeks’ follow-up and 12 case series assessed as being at high risk of bias.

Other Treatments

No clinical practice guidelines addressing the Eclipse™ Vaginal Insert System were identified.

POLICY SUMMARY

Current evidence supports trial use of sacral nerve stimulation (SNS) in the treatment of fecal incontinence (FI) among patients who have failed previous, more conservative treatments. While evidence is lacking beyond five years of follow-up, medium-term evidence supports permanent implantation among patients who experience a 50% or greater improvement in reported symptoms

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following the trial period. Despite noting the low quality of many SNS studies, two high-quality systematic reviews (Hayes and Cochrane) consider the evidence base sufficient to recommend SNS. Hayes also notes significant risks for of postimplantation surgical procedures and adverse events, and one high-quality systematic review (AHRQ) considers SNS investigational based on biases in studies to date. All three clinical practice guidelines that address SNS strongly recommend the procedure.

While biofeedback therapy is commonly used as a first-line treatment for fecal incontinence, peer-reviewed studies have yet to establish the treatment’s efficacy. Two high-quality systematic reviews (AHRQ and Cochrane) consider the evidence base insufficient due to the small, non-randomized, and uncontrolled nature of studies conducted to date. All three clinical practice guidelines (ANMS, ASCRS and NICE) recommend biofeedback, yet each of these guidelines stress a lack of evidence to support this recommendation. The peer-reviewed literature similarly considers the evidence base insufficient to support the safety or clinical utility of other treatments for FI (e.g. injectable bulking agents, transanal radiofrequency therapy (Secca procedure), anal sphincter replacement (i.e. Acticon Neosphincter), manual pump enema systems (e.g. Peristeen irrigation system), posterior tibial nerve stimulation (PTNS), and the Eclipse™ Vaginal Insert System).

INSTRUCTIONS FOR USE

Company Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. Company Medical Policies are reviewed annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. The Companies reserve the right to determine the application of Medical Policies and make revisions to Medical Policies at any time. Providers will be given at least 60-days notice of policy changes that are restrictive in nature.

The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and Company Medical Policy will be resolved in favor of the coverage agreement.

REGULATORY STATUS

Food and Drug Administration (FDA)

In 2011, the FDA approved the Medtronic InterStim Therapy System for Bowel Control (Medtronic Inc.) for the treatment of chronic fecal incontinence for patients who did not respond to earlier treatments.² The accompanying “summary of safety and effectiveness data” lists the following contraindications:

“Implantation of an InterStim neurostimulation system is contraindicated for the following patients:

- Patients who have not demonstrated an appropriate response to test stimulation; or
- Patients who are unable to operate the neurostimulator.

After implantation of any system component, the following contradiction applies:

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Diathermy – Do not use shortwave diathermy, microwave diathermy or therapeutic ultrasound diathermy (all now referred to as diathermy) on any patients implanted with a neurostimulation system. Energy from diathermy can be transferred through the implanted system and can cause tissue damage at the location of the implanted electrodes, resulting in severe injury or death.”²³

Mental Health Parity Statement

Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

REFERENCES

1. UpToDate. Fecal incontinence in adults: Management. <https://www.uptodate.com/contents/fecal-incontinence-in-adults-management#H978871679>. Published 2018. Updated May 2020. Accessed 6/3/2020.
2. Hayes Inc. Staged Approach to Sacral Nerve Stimulation for Treatment of Fecal Incontinence. <https://evidence.hayesinc.com/report/dir.staged3295>. Published 2015 (updated 2020). Accessed 6/3/2020.
3. Rao SSC, Benninga MA, Bharucha AE, Chiarioni G, Di Lorenzo C, Whitehead WE. ANMS-ESNM position paper and consensus guidelines on biofeedback therapy for anorectal disorders. *Neurogastroenterology & Motility*. 2015;27(5):594-609. http://www.singem.it/wp-content/uploads/2018/05/2015_NM_Rao_et_al.pdf
4. Pelvalon Inc. Eclipse System. <http://eclipsesystem.com/>. Published 2018. Accessed 6/3/2020.
5. Forte ML, Andrade KE, Butler M, et al. *Treatments for Fecal Incontinence*. Rockville, MD: Agency for Healthcare Research and Quality. U.S. Department of Health and Human Services;2016.
6. Thaha MA, Abukar AA, Thin NN, Ramsanahie A, Knowles CH. Sacral nerve stimulation for faecal incontinence and constipation in adults. *Cochrane Database Systematic Reviews*. 2015. <https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD004464.pub3/full?highlightAstract=nerv%7Csacral%7Cstimul%7Cnerve%7Cstimulation>
7. Tjandra JJ, Chan MK, Yeh CH, Murray-Green C. Sacral nerve stimulation is more effective than optimal medical therapy for severe fecal incontinence: a randomized, controlled study. *Diseases of the Colon & Rectum*. 2008;51(5):494-502.
8. Norton C, Cody JD. Biofeedback and/or sphincter exercises for the treatment of faecal incontinence in adults. *Cochrane Database of Systematic Reviews*. 2012(7).
9. Hayes Inc. Solesta (NASHA Dx; Q-Med AB) For Treatment Of Fecal Incontinence. <https://evidence.hayesinc.com/report/htb.solesta2617>. Published 2014 (reviewed 2016; archived 2017). Accessed 6/3/2020.
10. Richter HE, Matthews CA, Muir T, et al. A vaginal bowel-control system for the treatment of fecal incontinence. *Obstetrics & Gynecology*. 2015;125(3):540-547.

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- https://journals.lww.com/greenjournal/Fulltext/2015/03000/A_Vaginal_Bowel_Control_System_for_the_Treatment.3.aspx
11. Christensen P, Bazzocchi G, Coggrave M, et al. A Randomized, Controlled Trial of Transanal Irrigation Versus Conservative Bowel Management in Spinal Cord–Injured Patients. *Gastroenterology*. 2006;131(3):738-747.
<http://www.sciencedirect.com/science/article/pii/S0016508506012339>
 12. Rosen HR, Kneist W, Fürst A, Krämer G, Hebenstreit J, Schiemer JF. Randomized clinical trial of prophylactic transanal irrigation versus supportive therapy to prevent symptoms of low anterior resection syndrome after rectal resection. *BJS Open*. 2019;3(4):461-465.
<https://bjssjournals.onlinelibrary.wiley.com/doi/abs/10.1002/bjs5.50160>
 13. Christensen P, Krogh K, Buntzen S, Payandeh F, Laurberg S. Long-Term Outcome and Safety of Transanal Irrigation for Constipation and Fecal Incontinence. *Diseases of the Colon & Rectum*. 2009;52(2):286-292.
https://journals.lww.com/dcrjournal/Fulltext/2009/02000/Long_Term_Outcome_and_Safety_of_Transanal.17.aspx
 14. Del Popolo G, Mosiello G, Pilati C, et al. Treatment of neurogenic bowel dysfunction using transanal irrigation: a multicenter Italian study. *Spinal Cord*. 2008;46(7):517-522.
<https://doi.org/10.1038/sj.sc.3102167>
 15. López Pereira P, Salvador OP, Arcas JA, Martínez Urrutia MA, Romera RL, Monereo EJ. Transanal irrigation for the treatment of neuropathic bowel dysfunction. *J Pediatr Urol*. 2010;6(2):134-138.
 16. American College of Obstetrics and Gynecology. ACOG Practice Bulletin No. 210: Fecal Incontinence. *Obstetrics & Gynecology*. 2019;133(4):e260-e273.
https://journals.lww.com/greenjournal/Fulltext/2019/04000/ACOG_Practice_Bulletin_No_210_Fecal_Incontinence.57.aspx
 17. National Institute for Health and Care Excellence. Faecal incontinence in adults: management. <https://www.nice.org.uk/guidance/CG49>. Published 2007. Accessed 6/3/2020.
 18. Paquette IM, Varma MG, Kaiser AM, Steele SR, Rafferty JF. The American Society of Colon and Rectal Surgeons' clinical practice guideline for the treatment of fecal incontinence. *Diseases of the Colon & Rectum*. 2015;58(7):623-636.
https://journals.lww.com/dcrjournal/Fulltext/2015/07000/The_American_Society_of_Colon_and_Rectal_Surgeons_.2.aspx?WT.mc_id=HPxADx20100319xMP&utm_source=TrendMD&utm_medium=cpc&utm_campaign=Diseases_of_The_Colon_%2526_Rectum_TrendMD_0
 19. Wald A, Bharucha AE, Cosman BC, Whitehead WE. ACG clinical guideline: management of benign anorectal disorders. *The American journal of gastroenterology*. 2014;109(8):1141.
https://www.researchgate.net/profile/Arnold_Wald/publication/263934712_ACG_Clinical_Guideline_Management_of_Benign_Anorectal_Disorders/links/541b1d160cf203f155ae924e/ACG-Clinical-Guideline-Management-of-Benign-Anorectal-Disorders.pdf
 20. National Institute for Health and Care Excellence. Percutaneous tibial nerve stimulation for faecal incontinence <https://www.nice.org.uk/guidance/ipg395/resources/percutaneous-tibial-nerve-stimulation-for-faecal-incontinence-pdf-1899867877238725>. Published 2011. Accessed 6/4/2020.
 21. National Institute for Health and Care Excellence. Secca System for faecal incontinence. <https://www.nice.org.uk/advice/mib66/resources/secca-system-for-faecal-incontinence-pdf-63499290352837>. Published 2016. Accessed 6/4/2020.

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- 22. National Institute for Health and Care Excellence. Peristeen transanal irrigation system for managing bowel dysfunction. <https://www.nice.org.uk/guidance/mtg36>. Published 2018. Accessed 6/4/2020.
- 23. U.S. Food and Drug Administration. Premarket Approval (PMA) - Interstim Therapy System, Verify Evaluation System (SNS Bowel). <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P080025S205>. Published 2011. Accessed 6/3/2020.