Fecal Incontinence Treatments

MEDICAL POLICY NUMBER: 103

Effective Date: 1/1/2024

Last Review Date: 11/2023

Next Annual Review: 8/2024

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 Company reserves the right to determine the application of medical policies and make revisions to medical policies at any time. 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. 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.

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

PLAN PRODUCT AND BENEFIT APPLICATION

☒ **Commercial** ☒ **Medicaid/OHP*** ☐ **Medicare****

*Medicaid/OHP 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.

**Medicare Members

This *Company* policy may be applied to Medicare Plan members only when directed by a separate *Medicare* policy. Note that investigational services are considered **"not medically necessary"** for Medicare members.

COVERAGE 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** 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 **not medically necessary** 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** 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 **not medically necessary** when criterion III. above is not met.

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

Removal of Implanted Sacral Nerve Stimulator

VI. Removal of an implanted sacral nerve stimulator may be considered **medically necessary** if it has been thoroughly evaluated and found to be no longer functional and was appropriately placed for medical necessity.

Manual Pump Enema Systems

VII. Manual pump enema systems (e.g., Peristeen anal irrigation system) are considered **not medically necessary** 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.

Other Treatments

VIII. Other treatments of fecal incontinence are considered **not medically necessary**, including but not limited to, the following:

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

Link to Evidence Summary

POLICY CROSS REFERENCES

None

The full Company portfolio of current Medical Policies is available online and can be accessed here.

POLICY GUIDELINES

BACKGROUND

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 eposiodes.[2] The majority of patients experiencing FI have previsously 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 embeeded in the subcutaneous pouch of the upper buttock.[1,2] Several devices have been approved by the United States Food & Drug Administration for the purpose of treating fecal incontinence. Product code: EZW. See the Regulatory section, below.

Biofeedback

Biofeedback is a treatment that attemps to increase patient awareness of phsyological 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 relxation of the external anal sphincter. Accompanying visual or audio feedback equipment aims to assist the patient in improving their ablity to both perceive rectal distentions, and to strengthen and coordinate abdominal wall and pelvic floor musculature in reponse to these distentions.[1,3]

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 enhaces 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 place 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 empy the lower bowel by introducing water into the bowel using a rectal catherter. Devices typically consist of an enema bag, a rectal catheter with an inflatable balloon and a pump.

REGULATORY STATUS

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

Approval or clearance by the Food and Drug Administration (FDA) does not in itself establish medical necessity or serve as a basis for coverage. Therefore, this section is provided for informational purposes only.

Table 1. US FDA Premarket Approval (PMA): Sacral Neuromodulation Systems for Fecal Incontinence

TRADE NAME (MANUFACTURER)	ORIGINAL PMA (APPROVAL FOR THE MANAGEMENT OF FECAL INCONTINENCE)	PRODUCT INFORMATION
AXONICS SACRAL NEUROMODULATION (AXONICS MODULATION TECHNOLOGIES INC.)	P190006 first approved 9/06/2019 (indicated for treatment of chronic fecal incontinence in first approval order)[5]	Charge weekly × 10 minutes Monthly × 1 hour or less If low energy setting may only need recharging every other month for ~1 hour Full body 1.5T and 3T MRI. No office visit required prior to MRI Titanium-ceramic neurostimulator case enables the miniaturized neurostimulator to deliver maximum performance for at least 15 years 42 × 22 × 6 mm (5.5cm3)
INTERSTIM MICRO (MEDTRONIC)	P970004/S302 First reference to the InterStim Micro System 7/30/2020[6] (First approval for InterStim SNS for use in the management of fecal incontinence 3/31/2011)[7]	Rechargeable, implantable SNM Treats device to treat patients affected by overactive bladder, urinary urge incontinence, unobstructed urinary retention and fecal incontinence. 17mm × 47mm (2.8cm3) Weight 7.3g Recharges in 20 minutes 1×/week Full Implant Components

		InterStim™ smart programmer and communicator Recharger kit InterStim™ SureScan MRI lead
INTERSTIM III (MEDTRONIC)	P970004 S050 First reference to the InteStim II on 8/18/2008 (P080025 First approval for InterStim SNS for use in the management of fecal incontinence 3/31/2011)[8]	The recharge-free InterStim™ – long-term therapy Connects directly to the lead, eliminating need for an extension Accommodates three lead sizes: 28 cm, 33 cm, and 41 cm Integrates strain relief in the header Incorporates radiopaque identification of manufacturer and model number Allows 1-screw implantation Allows full-body MRI scans for patients who need them* Weight 22g 44 mm × 51 mm

CLINICAL EVIDENCE AND LITERATURE REVIEW

EVIDENCE REVIEW

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 June 2023.

Sacral Nerve Stimulation (SNS)

In 2021 and 2022, ECRI published Clincial Evidence Assessments regarding the Axonics® Rechargeable Sacral Neuromodulation (r-SNM) System and the InterStim II Recharge-free Sacral Neurostimulation System (Medtronic plc.).[9,10] Both reports note that small sample sizes and limited follow-up time in the available evidence may bias study results, though practice guidelines state that sacroneuromodulation is generally safe and effective for certain patients with fecal incontinence.

In 2020, Hayes published an annual update of its 2016 evidence review (archived 2021) 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 improvments. 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).[11] 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.

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).[12] 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),[13] 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.[12]

Biofeedback

In 2016, the Agency for Healthcare Research and Quality (AHRQ) published a systematic review examining several treatment modalities for fecal incontinence (FI).[11] 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 insignicant 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).[14] 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."[14]

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.[15]

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,[11] rendering the safety and efficacy of the treatement 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.[11]

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.[16] 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.[17] 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.[18] Thirty-seven patients were randomized to TAI or supportive care and 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.[19-21] Conclusions were limited by small sample sizes and retrospective study design.

In 2023 Falletto and collegues published a multicenter observational study on (12 sites, n=369) on short-term results of transanal irrigation in functional bowel disorders and low anterior resection syndrome (LARS).[22] This Italian study evaluated the level of satisfaction regarding bowel control and quality of life (QoL) as well as measured bowel symptom severity and dropout frequenfcy and reason. Validated questionnaires were provided to the patients at baseline and after 6 months of transanal irrigation (TAI) treatment. At 6-months, there was a statistically significant ($p < 0.05$) improvement of QoL scores, satisfaction scores regarding bowel control, and severity indexes of disorder-related symptoms. A total of 8.0% of patients discontinued after 6 months as a result of occurrence of symptoms (2/4%) or other justificaitonas (3.8%) such as personal reasons. The authors concluded that the study results suggest

that short-term TAI treatment is beneficial for patients suffering from functional bowel disorders and LARS. Additional studies are needed to analyze the clinical outcomes associated with long-term use.

CLINICAL PRACTICE GUIDELINES

Sacral Nerve Stimulation (SNS)

American College of Obstetrics and Gynecology (ACOG)

In 2019, the ACOG published a clinical practice bulletin addressing fecal incontinence.[23] On the basis of limited evidence, the authors 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.[24] 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." [24]

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).[25]

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.[26]

Injectable Bulking Agents

American College of Obstetrics and Gynecology (ACOG)

In 2019, the ACOG published a clinical practice bulletin addressing fecal incontinence.[23] 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."[25] 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.[25]

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 contraindicates 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.[24] 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." [24]

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.[25] Given the comparative success of SNS, the ASCRS recommended artificial sphincter replacement only in patients for whom all other treatments have failed.[25]

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.[26]

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."[27]

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.[28] On the basis of low-quality evidence, investigators stated that the provedure "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)."[28]

Manual Pump Enema Systems

National Institute for Health and Care Excellence (NICE)

In 2018 and updated in 2022, NICE published a "medical technologies guidance" addressing the use of the Peristeen® transanal irrigation system.[29] Investigators concluded that evidence supported the use of Peristeen to reduce the severy 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.

EVIDENCE SUMMARY

Sacral Nerve Stimulation/Neuromodulation

The evidence for sacral nerve stimulation or sacral neuromodulcation as a treatment for fecal incontinence suggests that some individuals may have improved overall health outcomes if prior conservative treatments have failed to help symptoms. More research is still needed to know for sure, though practice guidelines recommend trial uses of sacral nerve stimulation (SNS) and permanatly implanted stimulators for those with chronic fecal incontinence when specific criteria are met. Therefore, sacral nerve stimulation or sacral neuromodulcation may be considered medically necessary and covered for the treatment of fecal incontinence when policy criteria are met. Removal or replacement of a sacral nerve stimulator is considered not medically necessary and not covered when the initial stimulator is still functional.

Due to a lack of evidence and clinical practice guidelines, a trial period of sacral nerve stimulation or permanent implantation of a sacral nerve stimulator is considered investigational when criteria are not met.

Manual Pump Enema Systems

There is enough research to show that manual pump enema systems (also known as transanal irrigation) (e.g. Peristeen irrigation system) do not have long term overall improved health outcomes for those with fecal incontinence. Therefore, manual pump enema systems (e.g., Peristeen anal irrigation system) are considered not medically necessary and not covered for the treatment of fecal incontinence.

Other Treatments of Fecal Incontinence

Other treatments, such as biofeedback therapy are commonly used for fecal incontinence even though there is not enough evidence to know if overall health outcomes are improved. Clinical practice guidelines state that there is not enough evidence to recommend use of other treatments such injectable bulking agents, transanal radiofrequency therapy (Secca procedure), anal sphincter replacement (i.e. Acticon Neosphincter), posterior tibial nerve stimulation (PTNS) and the Eclipse™ Vaginal Insert System). Therefore, these treatments are considered investigational and not covered for the treatment of fecal incontinence.

BILLING GUIDELINES AND CODING

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 not medically necessary.

CPT code 64566 will deny as not medically necessary when billed with ICD-10 codes F98.1, R151, R152, R150, R159 for fecal incontinence.

HCPCS code L9900 is not allowed separate reimbursement because it is considered a bundled item or service, even if billed alone.

CODES*		
CPT	0786T	Insertion or replacement of percutaneous electrode array, sacral, with integrated neurostimulator, including imaging guidance, when performed
	0787T	Revision or removal of neurostimulator electrode array, sacral, with integrated neurostimulator
	0788T	Electronic analysis with simple programming of implanted integrated neurostimulation system (eg, electrode array and receiver), including contact group(s), amplitude, pulse width, frequency (Hz), on/off cycling, burst, dose lockout, patient-selectable parameters, responsive neurostimulation, detection algorithms, closed-loop parameters, and passive parameters, when performed by physician or other qualified health care professional, spinal cord or sacral nerve, 1-3 parameters
	0789T	Electronic analysis with complex programming of implanted integrated neurostimulation system (eg, electrode array and receiver), including contact group(s), amplitude, pulse width, frequency (Hz), on/off cycling, burst, dose lockout, patient-selectable parameters, responsive neurostimulation, detection algorithms, closed-loop parameters, and passive parameters, when performed by physician or other qualified health care professional, spinal cord or sacral nerve, 4 or more parameters
	46999	Unlisted procedure, anus

	64561	Percutaneous implantation of neurostimulator electrode array; sacral nerve (transforaminal placement) including image guidance, if performed
	64566	Posterior tibial neurostimulation, percutaneous needle electrode, single treatment, includes programming
	64581	Open implantation of neurostimulator electrode array; sacral nerve (transforaminal placement)
	64585	Revision or removal of peripheral neurostimulator electrode array
	64590	Insertion or replacement of peripheral, sacral, or gastric neurostimulator pulse generator or receiver, requiring pocket creation and connection between electrode array and pulse generator or receiver
	64595	Revision or removal of peripheral, sacral, or gastric neurostimulator pulse generator or receiver, with detachable connection to electrode array
	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)
HCPCS	A4290	Sacral nerve stimulation test lead, each
	A4453	Rectal catheter for use with the manual pump-operated enema system, replacement only
	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
	C1767	Generator, neurostimulator (implantable), non-rechargeable
	C1778	Lead, neurostimulator (implantable)
	C1787	Patient programmer, neurostimulator
	C1823	Generator, neurostimulator (implantable), non-rechargeable, with transvenous sensing and stimulation leads
	C1827	Generator, neurostimulator (implantable), non-rechargeable, with implantable stimulation lead and external paired stimulation controller
	C1897	Lead, neurostimulator test kit (implantable)
	L8605	Injectable bulking agent, dextranomer/hyaluronic acid copolymer implant, anal canal, 1 ml, includes shipping and necessary supplies.
	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
	L9900	Orthotic and prosthetic supply, accessory, and/or service component of another HCPCS "L"; code

***Coding Notes:**

- The above code list is provided as a courtesy and may not be all-inclusive. Inclusion or omission of a code from this policy neither implies nor guarantees reimbursement or coverage. Some codes may not require routine review for medical necessity, but they are subject to provider contracts, as well as member benefits, eligibility and potential utilization audit.
- All unlisted codes are reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is submitted for non-covered services addressed in this policy then it will be **denied as not covered**. If an unlisted code is submitted for potentially covered services addressed in this policy, to avoid post-service denial, **prior authorization is recommended**.
- **See the non-covered and prior authorization lists on the Company Medical Policy, Reimbursement Policy, Pharmacy Policy and Provider Information website for additional information.**
- HCPCS/CPT code(s) may be subject to National Correct Coding Initiative (NCCI) procedure-to-procedure (PTP) bundling edits and daily maximum edits known as "medically unlikely edits" (MUEs) published by the Centers for Medicare and Medicaid Services (CMS). This policy does not take precedence over NCCI edits or MUEs. Please refer to the CMS website for coding guidelines and applicable code combinations.

REFERENCES

1. UpToDate | Fecal incontinence in adults: Management. Literature review current through: May 2023. | This topic last updated: Nov 2, 2021. https://www.uptodate.com/contents/fecal-incontinence-in-adults-management. Accessed 6/23/2023.
2. Hayes Inc., Staged Approach to Sacral Nerve Stimulation for Treatment of Fecal Incontinence | 2015 (ARCHIVED Jan 28, 2021. Report outdated.). https://evidence.hayesinc.com/report/dir.staged3295. Accessed 6/23/2023.
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.
4. Pelvalon Inc. | Eclipse System. http://eclipsesystem.com/. Accessed 6/23/2023.
5. U.S. Food and Drug Administration. Premarket Approval (PMA) - Axonics Sacral Neuromodulation System, PMA Number: P190006. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P190006. Accessed 6/23/2023.
6. U.S. Food and Drug Administration. Premarket Approval (PMA) - Interstim Therapy System And Verify Evaluation System (SNS Urinary Programming Systems), PMA Number: P970004, Supplement: 302. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P970004S302. Accessed 6/23/2023.
7. U.S. Food and Drug Administration. Premarket Approval (PMA) - Interstim Therapy System, Original PMA Number: P970004. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P970004. Accessed 6/23/2023.
8. U.S. Food and Drug Administration. Premarket Approval (PMA) - Interstim Therapy System, Verify Evaluation System (SNS Bowel). PMA Number: P080025.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P080025. Accessed 6/23/2023.
9. ECRI | Clinical Evidence Assessment - Products - Guidance | Axonics Rechargeable Sacral Neuromodulation System (Axonics Modulation Technologies, Inc.) for Treating Fecal Incontinence. Published 04/13/2021. https://www.ecri.org/components/ProductBriefs/Pages/210125.aspx. Accessed 6/23/2023.
10. ECRI | Clinical Evidence Assessment - Products - Guidance | InterStim II Recharge-free Sacral Neurostimulation System (Medtronic plc.) for Restoring Bowel Control. Published 2020 & updated 2022. https://www.ecri.org/components/ProductBriefs/Pages/29236.aspx. Accessed 6/23/2023.
11. Forte ML, Andrade KE, Butler M, et al. Treatments for Fecal Incontinence. Agency for Healthcare Research and Quality. U.S. Department of Health and Human Services. Comparative Effectiveness Review No. 165. Web site. https://effectivehealthcare.ahrq.gov/sites/default/files/pdf/fecal-incontinence_research.pdf. Published 2016. AccessedAHRQ Publication NO. 15 (16)-EHC037-EF.
12. 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.
13. 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.
14. Norton C, Cody JD. Biofeedback and/or sphincter exercises for the treatment of faecal incontinence in adults. *Cochrane Database of Systematic Reviews.* 2012(7).
15. Hayes Inc., Solesta (NASHA Dx; Q-Med AB) For Treatment Of Fecal Incontinence 2014 (reviewed 2016; archived 2017). https://evidence.hayesinc.com/report/htb.solesta2617. Accessed 6/23/2023.
16. 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.
17. 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.
18. 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.
19. 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.
20. 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.
21. 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.
22. Falletto E, Martellucci J, Rossitti P, et al. Transanal irrigation in functional bowel disorders and LARS: short-term results from an Italian national study. *Tech Coloproctol.* 2023;27(6):481-490.
23. American College of Obstetrics and Gynecology. ACOG Practice Bulletin No. 210: Fecal Incontinence. *Obstetrics & Gynecology.* 2019;133(4):e260-e273.
24. National Institute for Health and Care Excellence | Faecal incontinence in adults: management. Clinical guideline [CG49]Published: 27 June 2007. https://www.nice.org.uk/guidance/CG49. Accessed 6/23/2023.

25. 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.
26. 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.
27. National Institute for Health and Care Excellence | Percutaneous tibial nerve stimulation for faecal incontinence, Interventional procedures guidance, Published: 25 May 2011. https://www.nice.org.uk/guidance/ipg395/resources/percutaneous-tibial-nerve-stimulation-for-faecal-incontinence-pdf-1899867877238725. Accessed 6/23/2023.
28. National Institute for Health and Care Excellence | Secca System for faecal incontinence, Medtech innovation briefing, Published: 24 May 2016. https://www.nice.org.uk/advice/mib66/resources/secca-system-for-faecal-incontinence-pdf-63499290352837. Accessed 6/23/2023.
29. National Institute for Health and Care Excellence | Peristeen transanal irrigation system for managing bowel dysfunction | Medical technologies guidance [MTG36], Published: 23 February 2018 . 06 Updated 2022. https://www.nice.org.uk/guidance/mtg36. Accessed 6/23/2023.

POLICY REVISION HISTORY

DATE	REVISION SUMMARY
2/2023	Converted to new policy template.
5/2023	Added device removal criteria.
8/2023	Annual review. Added to non-covered treatments criteria. Billing guideline updated on unbundling.
1/2024	Code set update, added, revised, and removed codes for 1/1/2024.