


<b>MEDICAL POLICY</b>	<b>Fecal Incontinence Treatments (All Lines of Business Except Medicare)</b>
<b>Effective Date: 1/1/2023</b>	Medical Policy Number: 103
 1/1/2023	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; 08/2021; 9/2021; 11/2021; 8/2022; 12/2022
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 except Medicare (*unless otherwise directed by a Medicare medical policy. Note that investigational services are considered “not medically necessary” for Medicare members.*)

**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** 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:

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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** 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 scaral nerve stimulator is considered **not medically necessary and not covered** if the initial device remains functional.

*Manual Pump Enema Systems*

- VI. Manual pump enema systems (e.g., Peristeen anal irrigation system) are 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.

*Other Treatments*

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

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- 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 [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	
0587T	Percutaneous implantation or replacement of integrated single device neurostimulation system including electrode array and receiver or pulse generator, including analysis, programming, and imaging guidance when performed, posterior tibial nerve
0588T	Revision or removal of integrated single device neurostimulation system including electrode array and receiver or pulse generator, including analysis, programming, and imaging guidance when performed, posterior tibial nerve
0589T	Electronic analysis with simple programming of implanted integrated neurostimulation system (e.g., 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, posterior tibial nerve, 1-3 parameters
0590T	Electronic analysis with complex programming of implanted integrated neurostimulation system (eg, electrode array and receiver), including contact

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	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, posterior tibial nerve, 4 or more parameters
64561	Percutaneous implantation of neurostimulator electrode array; sacral nerve (transforaminal placement) including image guidance, if performed
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 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
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)
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

**No PA Required**

Note: The following codes will deny as investigational when billed with a fecal incontinence diagnosis code.

64566	Posterior tibial neurostimulation, percutaneous needle electrode, single treatment, includes programming
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

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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)
<b>Not Covered</b>	
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
L8605	Injectable bulking agent, dextranomer/hyaluronic acid copolymer implant, anal canal, 1 ml, includes shipping and necessary supplies.
<b>Unlisted Codes</b> 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 <b>prior-authorization is required.</b>	
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.<sup>1</sup> FI may occur passively without the patient’s awareness, with an urgent need to defecate, or with some combination of both.<sup>2</sup> Among noninstitutionalized U.S. adults, prevalence is estimated at 8.3%, with 0.9% reporting daily FI episodes.<sup>2</sup> 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.<sup>1,2</sup> 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.<sup>1,2</sup>

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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 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.<sup>1,3</sup>

*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.<sup>1</sup>

*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.<sup>1</sup>

*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.<sup>1</sup>

*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.<sup>1</sup>

*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.<sup>4</sup>

### *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 July 2022.

### Systematic Reviews

#### *Sacral Nerve Stimulation (SNS)*

In 2021 and 2020, ECRI published Clinical Evidence Assessments regarding the Axonics® Rechargeable Sacral Neuromodulation (r-SNM) System and the InterStim II Recharge-free Sacral Neurostimulation System (Medtronic plc.).<sup>5,6</sup> 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 sacral neuromodulation 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).<sup>2</sup> 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).<sup>7</sup> 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).<sup>8</sup> 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),<sup>9</sup> 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.<sup>8</sup>

### *Biofeedback*

In 2016, the Agency for Healthcare Research and Quality (AHRQ) published a systematic review examining several treatment modalities for fecal incontinence (FI).<sup>7</sup> 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).<sup>10</sup> 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



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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.”<sup>10</sup>

#### *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.<sup>11</sup>

#### *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,<sup>7</sup> 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.<sup>7</sup>

#### *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.<sup>12</sup> 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.<sup>13</sup> 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

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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.<sup>14</sup> 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.<sup>15-17</sup> Conclusions were limited by small sample sizes 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 bulletin addressing fecal incontinence.<sup>18</sup> 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.<sup>19</sup> 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.”<sup>19</sup>

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*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).<sup>20</sup>

*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.<sup>21</sup>

Injectable Bulking Agents

*American College of Obstetrics and Gynecology (ACOG)*

In 2019, the ACOG published a clinical practice bulletin addressing fecal incontinence.<sup>18</sup> 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.”<sup>20</sup> 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.<sup>20</sup>

*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.<sup>3</sup> 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.<sup>3</sup>

*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.<sup>19</sup> 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

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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."<sup>19</sup>

#### 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.<sup>20</sup> Given the comparative success of SNS, the ASCRS recommended artificial sphincter replacement only in patients for whom all other treatments have failed.<sup>20</sup>

##### *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.<sup>21</sup>

#### 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."<sup>22</sup>

#### 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.<sup>23</sup> 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)."<sup>23</sup>

#### Manual Pump Enema Systems

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

In 2018, NICE published a "medical technologies guidance" addressing the use of the Peristeen<sup>®</sup> transanal irrigation system.<sup>24</sup> 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

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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**

*Sacral Nerve Stimulation/Neuromodulation*

The evidence for sacral nerve stimulation or sacral neuromodulation 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 permanently implanted stimulators for those with chronic fecal incontinence when specific criteria are met. Therefore, sacral nerve stimulation or sacral neuromodulation 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 as 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.

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**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)

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

<b>TRADE NAME (MANUFACTURER)</b>	<b>ORIGINAL PMA (APPROVAL FOR THE MANAGEMENT OF FECAL INCONTINENCE)</b>	<b>PRODUCT INFORMATION</b>
AXONICS SACRAL NEUROMODULATION (AXONICS MODULATION TECHNOLOGIES INC.)	P190006 first approved 9/06/2019 (indicated for treatment of chronic fecal incontinence in first approval order) <sup>25</sup>	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 <sup>26</sup> (First approval for InterStim SNS for use in the	Rechargeable, implantable SNM  Treats device to treat patients affected by overactive bladder, urinary urge incontinence,

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	management of fecal incontinence 3/31/2011) <sup>27</sup>	<p>unobstructed urinary retention and fecal incontinence.</p> <p>17mm × 47mm (2.8cm3)</p> <p>Weight 7.3g</p> <p>Recharges in 20 minutes 1×/week</p> <p>Full Implant Components</p> <p>InterStim™ smart programmer and communicator</p> <p>Recharger kit</p> <p>InterStim™ SureScan MRI lead</p>
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) <sup>28</sup>	<p>The recharge-free InterStim™ – long-term therapy</p> <p>Connects directly to the lead, eliminating need for an extension</p> <p>Accommodates three lead sizes: 28 cm, 33 cm, and 41 cm</p> <p>Integrates strain relief in the header</p> <p>Incorporates radiopaque identification of manufacturer and model number</p> <p>Allows 1-screw implantation</p> <p>Allows full-body MRI scans for patients who need them*</p> <p>Weight 22g</p> <p>44 mm × 51 mm</p>

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.

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