Fecal Incontinence Evaluation and Treatments

INDEPENDENT CARE HEALTH PLAN

Effective Date: 01/01/2024
Revision Date: 01/01/2024
Review Date: Click or tap to enter a date.
Policy Number: WI.PA-1085-000
Line of Business: Medicare

Medicare Advantage Medical Coverage Policy

Table of Contents

Related Medicare Advantage Medical/Pharmacy Coverage Policies

None

Related Documents

Please refer to CMS website for the most current applicable National Coverage Determination (NCD)/ Local Coverage Determination (LCD)/Local Coverage Article (LCA)/CMS Online Manual System/Transmittals.

Type	Title	ID Number	Jurisdiction Medicare Administrative Contractors (MACs)	Applicable States/Territories
NCD	Electrical Continence Aid	230.15		

NCD	Durable Medical Equipment (DME)	280.1		
LCD LCA	Outpatient Physical and Occupational Therapy Services	L33631 A56566	J6 - National Government Services, Inc. (Part A/B MAC) IL, MN, WI JK - National Government Services, Inc. (Part A/B MAC) CT, NY, ME, MA, NH, RI, VT	
LCA	Billing and Coding: Sacral Nerve Stimulation for Urinary and Fecal Incontinence	A55835	J15 - CGS Administrators, LLC (Part A/B MAC)	KY, OH
LCD LCA	Outpatient Physical and Occupational Therapy Services	L34049 A57067	J15 - CGS Administrators, LLC (Part A/B MAC)	KY, OH
LCA	Billing and Coding: Sacral Nerve Stimulation for Urinary and Fecal Incontinence	A53359	JE - Noridian Healthcare Solutions, LLC	CA, HI, NV, American Samoa, Guam, Northern Mariana Islands
LCA	Billing and Coding: Sacral Nerve Stimulation for Urinary and Fecal Incontinence	A53017	JF - Noridian Healthcare Solutions, LLC	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY
LCD LCA	Outpatient Occupational Therapy	L34427 A53064	JJ - Palmetto GBA (Part A/B MAC) AL, GA, TN JM - Palmetto GBA (Part A/B MAC) NC, SC, VA, WV	
LCD LCA	Bowel Management Devices	L36267 A54516	DME A - Noridian Healthcare Solutions, LLC (DME MAC) CT, DE, DC, ME, MD, MA, NH, NJ, NY, PA, RI, VT DME B - CGS Administrators, LLC (DME MAC) IL, IN, KY, MI, MN, OH, WI DME C - CGS Administrators, LLC (DME MAC) AL, AR, CO, FL, GA, LA, MS, NM, NC, OK, SC, TN, TX, VA, WV, PR, U.S. VI DME D - Noridian Healthcare Solutions, LLC (DME MAC)	

			AK, AZ, CA, HI, ID, IA, KS, MO, MT, NE, NV, ND, OR, SD, UT, WA, WY, American Samoa, Guam, Northern Mariana Islands

Description

Fecal incontinence (FI), also known as bowel incontinence, is the loss of bowel control, which causes stool to leak involuntarily from the rectum. FI can range from the occasional leakage of stool to complete loss of bowel control. FI may also occur only occasionally (eg, with bouts of diarrhea) or it may be chronic or recurring.

Causes include, but may not be limited to:

- Damage to the anal sphincter (eg, childbirth, surgery)
- Damage to the pelvic diaphragm
- Diarrhea
- Fecal impaction
- Illnesses that cause the inability to expand and store fecal matter (eg, inflammatory bowel disease [IBD])
- Injury

Evaluation
Treatment for FI depends on the type of incontinence and the underlying cause; therefore, prior to treatment for FI, an evaluation must be performed. The initial assessment includes obtaining a history and physical, which may consist of an inspection of the perianal area and a digital rectal exam. Other tests include, but may not be limited to, anorectal manometry, endoscopy, endorectal ultrasound or rectal sensory testing.[36]

Treatment
Examples of **FI treatments** include, but may not be limited to:

Artificial anal sphincter (eg, **Acticon Neosphincter**) is an implantable, fluid filled device that consists of an inflatable silicon cuff, a pressure-regulating balloon and a control pump, which reportedly maintains continence by using the pressure of the fluid filled cuff to occlude the anal canal. When there is a need to defecate (bowel movement), the individual squeezes and releases the pump mechanism, which releases the compressive force around the anal canal.

Biofeedback is therapy that utilizes sensors to help the individual identify and contract the anal sphincter muscles, which help maintain continence.

Defecation programs (bowel training) are designed to help the individual who has difficulties setting a schedule for sitting on the toilet at a regular time every day after a meal. This training is designed to help incontinence by regularly emptying the bowels.

Injectable bulking agents (eg, **Solesta**) involves the injection of collagen, autologous fat or other materials into the anal sphincter area to increase the surface area, which purportedly provides a better seal for the anal canal.

Nonimplantable muscle stimulators (eg, **Ieva Digital Therapeutic System**) are devices that reportedly provide pelvic muscle stimulation and biofeedback without implantation of electrodes to aid in the treatment of fecal incontinence. These devices may be combined with a smartphone app that reportedly transmits real-time data of pelvic floor muscle training.

Percutaneous tibial nerve stimulation (PTNS) (eg, **Urgent PC, Nuro Percutaneous Neuromodulation System** [PTNM]), also known as posterior tibial nerve stimulation, involves the use of nonimplanted electrodes which produce stimulation to the tibial nerve that purportedly travels to the sacral nerve plexus to control FI.

Radiofrequency ablation (eg, **Secca System**) is a minimally invasive procedure that uses alternating electrical current to cause controlled heating of the tissue in the anal sphincter, which reportedly remodels the treated tissue by stimulating the formation of connective tissue.

Rectal catheters and rectal inserts are being investigated for use in a bedridden, immobilized or incontinent individual. Examples of the systems includes, but may not be limited to, include the **Qora Stool Management System**, which is comprised of a self-expanding indwelling diverter that anchors in the anorectal junction (without a balloon). It is designed to collapse and expand during peristaltic rectal contractions.[46] The **Renew Anal Insert** is a self-inserted silicone insert that purportedly prevents bowel leakage by resting against the rectum. Another system under study (eg, **Contix Fecal Incontinence Management System**) is a disposable catheter device that utilizes a balloon that is placed via an injector into the anorectal junction and filled with air. The air is deflated for removal. This device is not currently approved by the US Food & Drug Administration (FDA).

Rectal control system for vaginal insertion (eg, **Eclipse system**) is a device that includes an inflatable balloon that is placed in the vagina, which upon inflation exerts pressure on the vaginal wall supposedly closing off the rectum. Reportedly, bowel evacuation is completed by deflating the device and re-inflating using an external pump.

Sacral nerve stimulation (eg, **Axonics Sacral Neuromodulation System**, **InterStim II**, **InterStim Micro, InterStimX**) involves the implantation of electrodes at the sacral nerve to improve rectal sensation and anal sphincter muscle control.

Stem cells, specifically adipose tissue-derived stem cells, autologous myoblasts, mesenchymal stem cells are being investigated for the treatment of FI. Purportedly, the injection of stem cells during surgical repair of FI stimulates the formation of granulation tissue, leading to regeneration of the anal sphincter muscles.

Surgical treatment may be performed if there is pelvic floor or anal sphincter muscle injuries. Procedures include, but may not be limited to:

- **Colostomy** is the construction of an artificial opening from the colon through the abdominal wall, which bypasses a diseased portion of the lower intestine and permits the passage of stool to a bag outside of the body; typically used as the last attempt to correct FI.

- **Muscle transposition** is a surgical procedure that uses muscles from another area of the body to encircle and strengthen the anal canal (eg, gluteal or gracilis muscles [dynamic graciloplasty]).

- **Sphincteroplasty** is utilized to repair a defect in the sphincter muscle in which the two ends of the muscle are cut and overlapped onto one another and then sutured into place to restore the complete circle of muscle.

Transanal electrical stimulation utilizes electrical stimulation that is applied to the anal canal to supposedly stimulate muscle contraction.

Coverage Determination

iCare follows the CMS requirements that only allows coverage and payment for services that are reasonable and necessary for the diagnosis and treatment of illness or injury or to improve the functioning of a malformed body member except as specifically allowed by Medicare.

In interpreting or supplementing the criteria above and in order to determine medical necessity consistently, iCare may consider the criteria contained in the following:

Diagnostic testing for fecal incontinence will be considered medically reasonable and necessary for the following:

- Anorectal manometry; **OR**
- Anorectal ultrasonography; **OR**
- Rectal sensory testing

Conservative management will be considered medically reasonable and necessary, which includes, but may not be limited to:

- Biofeedback; **OR**

- Defecation programs/bowel training; **OR**

- Diet modification; **OR**

- Pelvic floor physical therapy; **OR**
- Pharmacotherapy

Sacral nerve stimulation (eg, Axonics Sacral Neuromodulation System, InterStim II, InterStim Micro and InterStimX) will be considered medically reasonable and necessary when the following requirements are met:

- Absence of contraindications; **AND**
- Testing confirms a diagnosis of FI; **AND**
- Failure of, contraindication to or intolerance of conservative management; **AND**
- Trial test stimulation that demonstrates 50% or greater improvement in incontinence symptoms during a 14-day trial period.[1,4]

Removal of a SNS device will be considered medically reasonable and necessary when the following requirements are met:

- A previously implanted device and/or its associated components cause complications or unintended negative outcomes (eg, adverse change in bowel function, infection, new pain, undesirable stimulation) for the individual

SNS replacement will be considered medically reasonable and necessary when the following requirements are met:

- Previously implanted device and/or its associated components are no longer functioning appropriately (eg, defective pulse generator, lead migration) and are no longer under warranty; **AND**
- Absence of contraindications; **AND**
- FDA-approved device is being utilized as the replacement

Surgical treatments for FI will be considered medically reasonable and necessary when the following requirements are met:

- Anal sphincter repair (eg, sphincteroplasty) for the following indications:
    - Anal sphincter injury; **AND**

- Failure of, contraindication to or intolerance of conservative management; **OR**

- Colostomy for the following indications:

  - Failure of, contraindication to or intolerance of conservative management of a minimum of 2 therapies; **AND**

  - Failure of or not a candidate for minimally invasive surgical interventions (eg, sacral nerve stimulation) or sphincteroplasty

The use of the criteria in this Medicare Advantage Medical Coverage Policy provides clinical benefits highly likely to outweigh any clinical harms. Services that do not meet the criteria above are not medically necessary and thus do not provide a clinical benefit. Medically unnecessary services carry risks of adverse outcomes and may interfere with the pursuit of other treatments which have demonstrated efficacy.

Coverage Limitations

US Government Publishing Office. Electronic code of federal regulations: part 411 – 42 CFR § 411.15 - Particular services excluded from coverage

The following **incontinence items** will not be considered a benefit (statutory exclusion):

- Incontinence collection systems (eg, perianal fecal collection pouches);
- Incontinence undergarments (eg, briefs, diapers);
- Rectal catheters (eg, Contix Fecal Incontinence Management System, Qora Stool Management Kit);
- Rectal inserts (eg, Renew Insert)

These treatments and services fall within the Medicare program's statutory exclusion that prohibits payment for items and services that have not been demonstrated to be reasonable and necessary for the diagnosis and treatment of illness or injury (§1862(a)(1) of the Act).

The following **fecal incontinence treatments** will not be considered medically reasonable and necessary:

- Adipose tissue-derived stem cells
- Autologous myoblasts or mesenchymal stem cell injections
- Nonimplantable muscle stimulators
- Transanal electrical stimulation

A review of the current medical literature shows that there is no evidence to determine that these services are standard medical treatments. There is an absence of randomized, blinded clinical studies examining benefit and long-term clinical outcomes establishing the value of these services in clinical management.

The following **fecal incontinence treatments** will not be considered medically reasonable and necessary:

- Artificial anal sphincter (eg, Acticon Neosphincter); **OR**
- Injectable bulking agents (eg, Solesta); **OR**
- Percutaneous tibial nerve stimulation (eg, Urgent PC); **OR**
- Rectal control system for vaginal insertion (eg, Eclipse system); **OR**
- Sacral nerve stimulation (eg, Axonics Sacral Neuromodulation System, InterStim II, InterStim Micro and InterStimX) if the following contraindications are present:
  - 17 years of age or younger; **OR**
  - Presence of anorectal malformation (eg, congenital anorectal malformation; defects of the external anal sphincter over 60 degrees; visible sequelae of pelvic radiation; active anal abscesses and fistulae and/or chronic inflammatory bowel disease); **OR**
  - Bilateral stimulation; **OR**
  - Individual not capable of operating the device: **OR**
  - Pregnancy; **OR**
  - Presence of progressive, systemic neurologic diseases (eg, multiple sclerosis, Parkinson's disease)[51,52]; **OR**
- Transanal radiofrequency therapy (eg, Secca System)

A review of the current medical literature shows that the evidence is insufficient to determine that this service is standard medical treatment. There remains an absence of randomized, blinded clinical studies examining benefit and long-term clinical outcomes establishing the value of this service in clinical management.

Summary of Evidence

Artificial Anal Sphincter

Even though the use of an artificial sphincter device has been correlated with clinical improvements for the treatment of FI, its use is limited by complications, which include explantation in up to one-third of individuals.[37] Many of these devices have shown unacceptable complication or explantation rates and have only been evaluated in small numbers of individuals.[1]

Injectable Bulking Agents

Data regarding the long-term effects of sphincter bulking injections are lacking.[2] A total of 24 studies have been published that describe a variation of injection sites, the implanted materials and techniques. However, the results have been inconsistent, and interpretation was challenging due to the multiple compounds and injection techniques that were utilized.[6]

Percutaneous Tibial Nerve Stimulation (PTNS)
Evidence is insufficient, conflicting or poor and there is insufficient evidence to determine net benefit versus harms; additional research is recommended.[29] Until further evidence is available, PTNS should not be used for the treatment of fecal incontinence in clinical practice.[4] PTNS is not approved for the treatment of fecal incontinence.[2]

Rectal Control System for Vaginal Insertion
In a study of 61 women who were fitted with the Eclipse device, an 85% success rate was reported at a three-month follow-up. However, limited studies prevent determination of efficacy in the long-term.[37]

Sacral Nerve Stimulation
According to the manufacturer of the device listed above, the indications are considered either contraindications or warnings.[30]

Transanal Radiofrequency Therapy
Due to the limited available data, alternative methods should be pursued before considering radiofrequency delivery.[6] Radiofrequency should not be offered routinely as there is a lack of high-quality studies to support its use.[2]

Coding Information

Any codes listed on this policy are for informational purposes only. Do not rely on the accuracy and inclusion of specific codes. Inclusion of a code does not guarantee coverage and/or reimbursement for a service or procedure.

CPT® Code(s)	Description	Comments
38240	Hematopoietic progenitor cell (HPC); allogeneic transplantation per donor	
38241	Hematopoietic progenitor cell (HPC); autologous transplantation	
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	
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)	
CPT® Category III Code(s)	**Description**	**Comments**
No code(s) identified		
HCPCS Code(s)	**Description**	**Comments**
A4290	Sacral nerve stimulation test lead, each	
A4330	Perianal fecal collection pouch with adhesive, each	
A4335	Incontinence supply; miscellaneous	
A4337	Incontinence supply, rectal insert, any type, each	
A4520	Incontinence garment, any type, (eg, brief, diaper), each	**Not Covered**
A4553	Nondisposable underpads, all sizes	**Not Covered**
A4554	Disposable underpads, all sizes	**Not Covered**
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), nonrechargeable	
C1778	Lead, neurostimulator (implantable)	
C1883	Adaptor/extension, pacing lead or neurostimulator lead (implantable)	
C1897	Lead, neurostimulator test kit (implantable)	
G0283	Electrical stimulation (unattended), to one or more areas for indication(s) other than wound care, as part of a therapy plan of care	
L8680	Implantable neurostimulator electrode, each	
L8681	Patient programmer (external) for use with implantable programmable neurostimulator pulse generator, replacement only	
L8682	Implantable neurostimulator radiofrequency receiver	
L8683	Radiofrequency transmitter (external) for use with implantable neurostimulator radiofrequency receiver	

L8684	Radiofrequency transmitter (external) for use with implantable sacral root neurostimulator receiver for bowel and bladder management, replacement	
L8685	Implantable neurostimulator pulse generator, single array, rechargeable, includes extension	**Not Covered**
L8686	Implantable neurostimulator pulse generator, single array, nonrechargeable, includes extension	**Not Covered**
L8687	Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension	**Not Covered**
L8688	Implantable neurostimulator pulse generator, dual array, nonrechargeable, includes extension	**Not Covered**
L8689	External recharging system for battery (internal) for use with implantable neurostimulator, replacement only	
L8695	External recharging system for battery (external) for use with implantable neurostimulator, replacement only	

References

1. American College of Gastroenterology (ACG). ACG clinical guideline: management of benign anorectal disorders. https://www.gi.org. Published October 2021. Accessed November 11, 2022.

2. American College of Obstetricians and Gynecologists (ACOG). Practice Bulletin. Fecal incontinence. https://www.acog.org. Published April 2019. Accessed October 21, 2022.

3. American College of Radiology (ACR). ACR Appropriateness Criteria. Pelvic floor dysfunction in females. https://www.acr.org. Published 2021. Accessed November 11, 2022.

4. American Gastroenterological Association (AGA). AGA clinical practice guideline update: expert review – surgical interventions and the use of device-aided therapy for the treatment of fecal incontinence and defecatory disorders. https://www.gastro.org. Published December 2017. Accessed November 11, 2022.

5. American Society for Gastrointestinal Endoscopy (ASGE). Standards of Practice. The role of endoscopy in patients with anorectal disorders. https://www.asge.org. Published 2010. Accessed November 11, 2022.

6. American Society of Colon and Rectal Surgeons (ASCRS). The American Society of Colon and Rectal Surgeons' clinical practice guideline for the treatment of fecal incontinence. https://www.fascrs.org. Published 2015. Accessed November 11, 2022.

7. Centers for Medicare & Medicaid Services (CMS). Local Coverage Article (LCA) Billing and Coding. Sacral nerve stimulation for urinary and fecal incontinence (A53017). https://cms.gov. Published October 1, 2015. Updated January 1, 2020. Accessed August 29, 2023.

8. Centers for Medicare & Medicaid Services (CMS). Local Coverage Article (LCA) Billing and Coding. Sacral nerve stimulation for urinary and fecal incontinence (A53359). https://cms.gov. Published October 1, 2015. Updated January 1, 2020. Accessed August 29, 2023.

9. Centers for Medicare & Medicaid Services (CMS). Local Coverage Article (LCA) Billing and Coding. Sacral nerve stimulation for urinary and fecal incontinence (A55835). https://cms.gov. Published February 1, 2018. Updated March 2, 2023. Accessed August 29, 2023.

10. Centers for Medicare & Medicaid Services (CMS). Local Coverage Determination (LCD) Bowel management devices (L36267). https://cms.gov. Published December 1, 2015. Updated October 1, 2021. Accessed August 30, 2023.

11. Centers for Medicare & Medicaid Services (CMS). Local Coverage Determination (LCD) Outpatient occupational therapy (L34427). https://cms.gov. Published October 1, 2015. Updated April 13, 2023. Accessed August 30, 2023.

12. Centers for Centers for Medicare & Medicaid Services (CMS). Local Coverage Determination (LCD) Outpatient physical and occupational therapy Services (L33631). https://cms.gov. Published October 1, 2015. Updated January 1, 2020. Accessed August 31, 2023.

13. Centers for Medicare & Medicaid Services (CMS). Local Coverage Determination (LCD) Outpatient physical and occupational therapy services (L34049). https://cms.gov. Published October 1, 2015. Updated May 25, 2023. Accessed August 30, 2023.

14. Centers for Medicare & Medicaid Services (CMS). National Coverage Determination (NCD). Electrical continence aid (230.15). https://cms.gov. Accessed August 29, 2023.

15. ClinicalKey. Clinical Overview. Incontinence, bowel, elderly patient. https://www.clinicalkey.com. Accessed November 11, 2022.

16. ECRI Institute. Clinical Evidence Assessment. Axonics rechargeable sacral neuromodulation system (Axonics Modulation Technologies, Inc.) for treating fecal incontinence. https://www.ecri.org. Published April 13, 2021. Accessed November 2, 2022.

17. ECRI Institute. Clinical Evidence Assessment. DigniShield stool management system (C.R. Bard, Inc.) for diverting and collecting stool. https://www.ecri.org. Published July 5, 2016. Updated March 3, 2021. Accessed November 2, 2022.

18. ECRI Institute. Clinical Evidence Assessment. Flexi-seal fecal management system (ConvaTec, Inc.) for diverting and collecting stool. https://www.ecri.org. Published July 5, 2016. Updated March 3, 2021. Accessed November 2, 2022.

19. ECRI Institute. Clinical Evidence Assessment. InterStim II system (Medtronic plc.) for restoring bowel control in patients with chronic fecal incontinence. https://www.ecri.org. Published September 24, 2020. Updated November 28, 2022. Accessed November 2, 2022.

20. ECRI Institute. Clinical Evidence Assessment. Leva pelvic health system (Renovia, Inc.) for improving pelvic floor muscle strength. https://www.ecri.org. Published October 22, 2022. Accessed November 2, 2022.

21. Hayes, Inc. Clinical Research Response (ARCHIVED). Axonics (Axonics Neuromodulation Technologies Inc.) versus InterStim (Medtronic) sacral neuromodulation systems for urinary or fecal incontinence. https://evidence.hayesinc.com. Published October 16, 2020. Accessed November 2, 2022.

22. Hayes, Inc. Health Technology Brief (ARCHIVED). Cecostomy for treatment of fecal incontinence in adults. https://evidence.hayesinc.com. Published November 18, 2011. Updated November 12, 2012. Accessed November 2, 2022.

23. Hayes, Inc. Health Technology Brief (ARCHIVED). Secca (Mederi Therapeutics Inc.) procedure for fecal incontinence. https://evidence.hayesinc.com. Published December 27, 2010. Updated November 21, 2012. Accessed November 2, 2022.

24. Hayes, Inc. Health Technology Brief (ARCHIVED). Solesta (NASHA Dx: Q-Med AB) for treatment of fecal incontinence. https://evidence.hayesinc.com. Published October 16, 2014. Updated August 18, 2016. Accessed November 2, 2022.

25. Hayes, Inc. Medical Technology Directory (ARCHIVED). Artificial anal sphincter for fecal incontinence. https://evidence.hayesinc.com. Published August 5, 2008. Updated August 2, 2012. Accessed November 2, 2022.

26. Hayes, Inc. Medical Technology Directory (ARCHIVED). Staged approach to sacral nerve stimulation for treatment of fecal incontinence. https://evidence.hayesinc.com. Published December 29, 2015. Updated April 29, 2020. Accessed November 2, 2022.

27. MCG Health. Implanted electrical stimulator, sacral nerve. 26th edition. https://www.mcg.com. Accessed September 28, 2022.

28. MCG Health. Pelvic floor rehabilitation. 26th edition. https://www.mcg.com. Accessed September 28, 2022.

29. MCG Health. Percutaneous tibial nerve stimulation (PTNS). 26th edition. https://www.mcg.com. Accessed September 28, 2022.

30. Medtronic Product Brochure. Introducing the InterStimX system. https://www.medtronic.com. 2022. Accessed October 5, 2023.

31. Merck Manual: Professional Version. Fecal incontinence. https://www.merckmanuals.com. Updated September 2022. Accessed November 9, 2022.

32. UpToDate, Inc. Chronic functional constipation and fecal incontinence in infants, children and adolescents: treatment. https://www.uptodate.com. Updated October 2022. Accessed November 7, 2022.

33. UpToDate, Inc. Delayed surgical management of the disrupted anal sphincter. https://www.uptodate.com. Updated October 2022. Accessed November 8, 2022.

34. UpToDate, Inc. Endorectal endoscopic ultrasound (EUS) in the evaluation of fecal incontinence. https://www.uptodate.com. Updated October 2022. Accessed November 16, 2022.

35. UpToDate, Inc. Fecal and anal incontinence associated with pregnancy and childbirth: counseling, evaluation and management. https://www.uptodate.com. Updated October 2022. Accessed November 8, 2022.

36. UpToDate, Inc. Fecal incontinence in adults: etiology and evaluation. https://www.uptodate.com. Updated October 2022. Accessed November 2, 2022.

37. UpToDate, Inc. Fecal incontinence in adults: management. https://www.uptodate.com. Updated October 2022. Accessed November 7, 2022.

38. UpToDate, Inc. Functional fecal incontinence in infants and children: definition, clinical manifestations and evaluation. https://www.uptodate.com. Updated October 2022. Accessed November 16, 2022.

39. UpToDate, Inc. Low anterior resection syndrome (LARS). https://www.uptodate.com. Updated October 2022. Accessed November 8, 2022.

40. UpToDate, Inc. Obstetric anal sphincter injury (OASIS). https://www.uptodate.com. Updated October 2022. Accessed November 16, 2022.

41. UpToDate, Inc. Overview of rectal procidentia (rectal prolapse). https://www.uptodate.com. Updated October 2022. Accessed November 16, 2022.

42. UpToDate, Inc. Posterior vaginal defects (eg, rectocele): clinical manifestations, diagnosis and nonsurgical management. https://www.uptodate.com. Updated October 2022. Accessed November 16, 2022.

43. UpToDate, Inc. Treatment of gastrointestinal disease in systemic sclerosis. https://www.uptodate.com. Updated November 4, 2022. Accessed November 16, 2022.

44. US Food & Drug Administration (FDA). 510(k) summary: leva Pelvic Health System. https://www.fda.gov. Published June 30, 2022. Accessed November 10, 2022.

45. US Food & Drug Administration (FDA). 510(k) summary: Nuro neuromodulation system. https://www.fda.gov. Published November 5, 2013. Accessed November 17, 2015.

46. US Food & Drug Administration (FDA). 510(k) summary: Qora AIM stool management kit. https://www.fda.gov. Published May 6, 2016. Accessed October 14, 2014.

47. US Food & Drug Administration (FDA). 510(k) summary: Secca system. https://www.fda.gov. Published March 21, 2002. Accessed October 28, 2014.

48. US Food & Drug Administration (FDA). 510(k) summary: Urgent PC neuromodulation system. https://www.fda.gov. Published October 17, 2005. Accessed October 8, 2012.

49. US Food & Drug Administration (FDA). De novo summary: Eclipse system. https://www.fda.gov. Published June 25, 2014. Accessed October 25, 2017.

50. US Food & Drug Administration (FDA). Summary of safety and effectiveness data: Acticon Neosphincter. https://www.fda.gov. Published December 18, 2001. Accessed October 8, 2012.

51. US Food & Drug Administration (FDA). Summary of safety and effectiveness data: Axonics sacral neuromodulation system. https://www.fda.gov. Published September 6, 2019. Accessed November 8, 2019.

52. US Food & Drug Administration (FDA). Summary of safety and effectiveness data: Medtronic InterStim therapy system. https://www.fda.gov. Published March 14, 2011. Accessed October 8, 2012.

53. US Food & Drug Administration (FDA). Summary of safety and effectiveness data: NeoControl pelvic floor therapy system. https://www.fda.gov. Published August 29, 2000. Accessed October 8, 2012.

54. US Food & Drug Administration (FDA). Summary of safety and effectiveness data: Solesta. https://www.fda.gov. Published May 27, 2011. Accessed October 28, 2014.

Change Summary

- Click or tap to enter a date. New Policy.
-