Medicare Medical Policy

Fecal Incontinence Treatments

MEDICARE MEDICAL POLICY NUMBER: 228

Effective Date: 8/1/2025

Last Review Date: 7/2025

Next Annual Review: 7/2026

INSTRUCTIONS FOR USE: Company Medicare Medical Policies serve as guidance for the administration of plan benefits and do not constitute medical advice nor a guarantee of coverage. Company Medicare Medical Policies are reviewed annually to guide the coverage or non-coverage decision-making process for services or procedures in accordance with member benefit contracts (otherwise known as Evidence of Coverage or EOCs) and Centers of Medicare and Medicaid Services (CMS) policies, manuals, and other CMS rules and regulations. In the absence of a CMS coverage determination or specific regulation for a requested service, item or procedure, Company policy criteria or applicable utilization management vendor criteria may be applied. These are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. 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.

The Company reserves the right to determine the application of Medicare Medical Policies and make revisions to these policies at any time. Any conflict or variance between the EOC and Company Medical Policy will be resolved in favor of the EOC.

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

PRODUCT AND BENEFIT APPLICATION

☒ Medicare Only

MEDICARE COVERAGE CRITERIA

IMPORTANT NOTE: More than one Centers for Medicare and Medicaid Services (CMS) reference may apply to the same health care service, such as when more than one coverage policy is available (e.g., both an NCD and LCD exist). All references listed should be considered for coverage decision-making. The Company uses the most current version of a Medicare reference available at the time of publication; however, these websites are not maintained by the Company, so Medicare references and their corresponding hyperlinks may change at any time. If there is a conflict between the Company Medicare Medical Policy and CMS guidance, the CMS guidance will govern.

Service	Medicare Guidelines
Sacral Nerve Stimulation for Fecal Incontinence	Local Coverage Article (LCA): Billing and Coding: Sacral Nerve Stimulation for Urinary and Fecal Incontinence (~~A53017~~) ***(As of 10/2/2025, use LCA A53359)***
Manual Pump Enema Systems (e.g., Peristeen® Anal Irrigation System) and Other Enema Supplies/Products (HCPCS A4453, A4459)	Local Coverage Determination (LCD): Bowel Management Devices (L36267)
Spinal Cord Electrical Stimulators and Rectal Electrical Stimulators	NCD for Bladder Stimulators (Pacemakers) (230.16) **NOTE:** Rectal electrical stimulators directly stimulate the rectal muscles, while sacral nerve stimulators stimulate the sacral nerves.
*Revision, Replacement or Removal of **Implanted** Nerve Stimulator Devices (e.g., sacral nerve, PTNS, etc.)*	For **removal only**: • Medicare Benefit Policy Manual, Chapter 16 – General Exclusions From Coverage, §180 - Services Related to and Required as a Result of Services Which Are Not Covered Under Medicare **NOTE:** Even if initial placement of a device did not meet medical necessity coverage criteria and the complication or subsequent medical condition is the result of a prior non-covered service, coverage may be allowed in certain circumstances for the removal of the device. For **revision/replacement**: • Medicare Benefit Policy Manual, Chapter 15 – Covered Medical and Other Health Services, §120 - Prosthetic

	Devices, D. Supplies, Repairs, Adjustments, and Replacement **NOTE:** Device replacement may be medically necessary if it is required due to the end of battery life, or any other device-related malfunction. However, a device that did not meet medical necessity criteria when initially placed would have been non-covered, thus any revision or replacement to allow for the *continued* use of the non-covered device would not meet Medicare's general requirements for coverage. Replacement of previously placed medically necessary devices or their components that are nonfunctioning and irreparable (e.g., device malfunction, etc.) may be considered medically necessary in accordance with the above Medicare reference if the stimulator continues to be medically indicated and is no longer under manufacturer warranty or if the component is not included under the warranty. *(See "Policy Guidelines" below)*

Medicare Coverage Criteria: "MA organizations may create publicly accessible internal coverage criteria… when coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs." *(§ 422.101(b)(6) – see Policy Guidelines below*)

- **Medicare Coverage Manuals:** Other than the services mentioned above, Medicare does not have coverage criteria for fecal incontinence treatments in a coverage manual.
- **National Coverage Determination (NCD):** While there is an NCD for biofeedback of *urinary* incontinence, no NCD exists for *fecal* incontinence. There is no NCD for fecal incontinence treatment available.
- **Noridian J-F Local Coverage Determination (LCD)/Local Coverage Article (LCA):** As of the most recent policy review:
    - No Medicare Administrative Contractors (MACs) have LCDs for **transanal radiofrequency therapy, anal sphincter replacement, biofeedback** for fecal incontinence, **or the Eclipse™ Vaginal Insert System.**
    - As of November 1, 2023, there is no longer a Noridian J-F LCD or LCA for **posterior tibial nerve stimulation (PTNS)**.
    - As of December 4, 2017, there is no longer a Noridian LCD or LCA for **injectable bulking agents** for fecal incontinence.
    - The Noridian LCA for **biofeedback** (A53352) is for coding instruction only, and it does not provide coverage criteria.
    - As of July 1, 2020, there is no longer a Noridian LCD or LCA for the **Secca procedure (transanal radiofrequency therapy)** for fecal incontinence.
- Therefore, in the absence of established Medicare coverage criteria in a manual, NCD, LCD, or other regulatory guidance for the service area in which the testing is being performed, Company criteria below are applied for medical necessity decision-making. In this case, Medicare coverage criteria are considered "not fully established" as defined under CFR § 422.101(6)(i)(C) as there are no Medicare coverage criteria available.

• ***NOTE:*** *The summary of evidence, as well as the list of citations/references used in the development of the Company's internal coverage criteria, are publicly available and can be found using the Company medical policy link below [CFR § 422.101(6)(ii)(A) and (B)].*	
• *Services without fully established Medicare coverage criteria include the following: Biofeedback* • *Injectable bulking agents (e.g., Solesta)* • *Transanal radiofrequency therapy (Secca procedure)* • *Anal sphincter replacement (i.e., Acticon Neosphincter)* • *Eclipse™ Vaginal Insert System* • *Posterior Tibial Nerve Stimulation (PTNS) for Fecal Incontinence*	Company medical policy for Fecal Incontinence Treatments I. These procedures are considered **not medically necessary** for Medicare Plan members based on the Company medical policy. *See Policy Guidelines below.*

IMPORTANT NOTICE: While some services or items may appear medically indicated for an individual, they may also be a direct exclusion of Medicare or the member's benefit plan. Such excluded services or items by Medicare and member EOCs include, but are not limited to, services or procedures considered to be cosmetic, not medical in nature, or those considered not medically reasonable or necessary under *Title XVIII of the Social Security Act, §1862(a)(1)(A).* If there is uncertainty regarding coverage of a service or item, please review the member EOC or submit a pre-service organization determination request. Note that the Medicare Advance Beneficiary Notice of Noncoverage (ABN) form **cannot** be used for Medicare Advantage members. *(Medicare Advance Written Notices of Non-coverage. MLN006266 May 2021)*

POLICY CROSS REFERENCES

None

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

POLICY GUIDELINES

MEDICARE AND MEDICAL NECESSITY

For Medicare, only medically reasonable and necessary services or items which treat illness or injury are eligible for Medicare coverage, as outlined in *Title XVIII of the Social Security Act, §1862(a)(1)(A)*. MA organizations (MAOs) make medical necessity determinations based on coverage and benefit criteria, current standards of care, the member's unique personal medical history (e.g., diagnoses, conditions, functional status, co-morbidities, etc.), physician recommendations, and clinical notes, as well as involvement of a plan medical director, where appropriate. *(§ 422.101(c)(1))*

In addition:

> "MA organizations may create publicly accessible internal coverage criteria that are based on current evidence in widely used treatment guidelines or clinical literature when coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs. Current, widely-used treatment guidelines are those developed by organizations representing clinical medical specialties, and refers to guidelines for the treatment of specific diseases or conditions. Acceptable clinical literature includes large, randomized controlled trials or prospective cohort studies with clear results, published in a peer-reviewed journal, and specifically designed to answer the relevant clinical question, or large systematic reviews or meta-analyses summarizing the literature of the specific clinical question." *(§ 422.101(b)(6) and Medicare Managed Care Manual, Ch. 4, §90.5)*

The Plan's Medicare policy for *PHA Medicare Medical Policy Development and Application* (MP50) provides details regarding Medicare's definition of medical necessity and the hierarchy of Medicare references and resources during the development of medical policies, as well as the Plan's use of evidence-based processes for policy development.

Since there are not fully established coverage criteria for certain fecal incontinence treatments available in applicable Medicare statutes, regulations, NCDs or LCDs, then Company medical policy criteria for select treatments will be applied. See the Medicare Coverage Criteria table above, as well as the service-specific coverage information below, for more information regarding the use of internal coverage criteria when Medicare coverage criteria are not fully established.

Posterior Tibial Nerve Stimulation (PTNS) for Fecal Incontinence

Prior to November 1, 2023, the Noridian LCA for *Billing and Coding: Posterior Tibial Nerve Stimulation Coverage* (A52965) provided billing and coverage guidance for PTNS for urinary urgency, urinary frequency, and urge incontinence. It did **not** provide coverage of PTNS for fecal incontinence and considered the use of PTNS for fecal incontinence to be a non-covered indication. Effective November 1, 2023, Noridian retired this LCA, and Company criteria now apply. The Company position of non-coverage of PTNS for fecal incontinence is consistent with the Medicare LCA.

Injectable Bulking Agents for Fecal Incontinence

Prior to December 4, 2017, the Noridian LCA for *Injectable Bulking Agents for the Treatment of Fecal Incontinence* (A52923) provided billing guidance for injectable bulking agents used in the treatment of fecal incontinence. Effective December 4, 2017, Noridian retired this LCA, and Company criteria now apply.

Transanal Radiofrequency Therapy (Secca Procedure)

Prior to July 1, 2020, the Noridian LCA for Billing and Coding: Non-Covered Services (A57642) provided non-coverage guidance for the Secca® procedure. Effective July 1, 2020, Noridian retired this LCA, as well as the companion LCD (L35008) "to better align with Chapter 13 of the Program Integrity Manual (PIM)." In the absence of new instruction from Noridian, Company criteria now apply. The Company position of non-coverage of the Secca® procedure for fecal incontinence is consistent with the Medicare LCA.

The Eclipse™ Vaginal Insert system (Pelvalon, Inc.)

The Eclipse™ Vaginal Insert system (Pelvalon, Inc.) is an inflatable vaginal insert designed to exert pressure on the rectal vault to treat fecal incontinence. The Eclipse™ system consists of a vaginal insert and a pressure-regulated pump. The insert, consisting of a silicone-covered stainless-steel base and a posteriorly directed balloon, is placed in the vaginal vault and inflated. The balloon is deflated via the pump when the user needs to have a bowel movement. However, the insert must first be fitted in the physician's office. The Eclipse™ Vaginal Insert system (Pelvalon, Inc.) is not within the jurisdiction of the DME MACs and therefore, the above noted DME LCD and LCA do not address coverage for this device and our internal Company policy coverage criteria are applied.

REGULATORY STATUS

U.S. FOOD & DRUG ADMINISTRATION (FDA)

While clearance by the Food and Drug Administration (FDA) is a prerequisite for Medicare coverage, the 510(k) premarket clearance process does not in itself establish medical necessity. Medicare payment policy is determined by the interaction of numerous requirements, including but not limited to, the availability of a Medicare benefit category and other statutory requirements, coding and pricing guidelines, as well as national and local coverage determinations and clinical evidence.

BILLING GUIDELINES AND CODING

GENERAL

See related local coverage articles (LCAs) for billing assistance:

- Local Coverage Article: Bowel Management Devices - Policy Article (A54516)

IMPLANTABLE NEUROSTIMULATOR DEVICES

Pulse Generator HCPCS Codes

Effective January 1, 2014, HCPCS codes L8685, L8686, L8687, and L8688 (Implantable neurostimulator pulse generator codes) were removed from the 2014 DMEPOS fee schedule file to reflect the change in the coverage indicator to "invalid" for Medicare (Coverage indicator of "I")[1] and thus, these HCPCS codes are considered invalid for Medicare Advantage use as well. However, HCPCS code L8679 *(Implantable neurostimulator, pulse generator, any type)* was added to the HCPCS and DMEPOS fee schedule file effective January 1, 2014 to use for billing Medicare claims that were previously submitted under L8685, L8686, L8687 and L8688. While HCPCS codes L8685, L8686, L8687 and L8688 will be denied as not separately billable for Medicare or Medicare Advantage, HCPCS code L8679 can be used instead.

With respect to HCPCS code L8679, this code is specific to **implantable** devices. These neurostimulator devices are surgically implanted in the central nervous system (CNS) or targeted peripheral nerve. The use of L8679 for any type of **non-implantable** electrical stimulation device is incorrect coding.[2]

Electrode HCPCS Code

Effective April 1, 2014, HCPCS code L8680 *(Implantable neurostimulator electrode, each)* was also removed from the 2014 DMEPOS fee schedule file and the coverage indicator revised to not payable by Medicare (Coverage indicator of "I"). According to Medicare, practitioners (physicians) should not report for electrode(s) in conjunction with a lead implantation procedure furnished in any setting because Medicare considers payment for electrodes to be incorporated in the allowance for the surgical procedure (i.e., CPT code 63650).[3] Therefore, HCPCS codes L8680 will also be denied as not separately billable for Medicare or Medicare Advantage.

ADDITIONAL BILLING GUIDELINES

The Eclipse™ Vaginal Insert system (Pelvalon, Inc.)

The Eclipse™ Vaginal Insert system (Pelvalon, Inc.) is an inflatable vaginal insert designed to exert pressure on the rectal vault to treat fecal incontinence. The insert must first be fitted in the physician's office and is reported under a **CPT** code, which is all-inclusive of all components to the procedure.

C-HCPCS Codes

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.

Biofeedback

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 and not covered.

CPT codes 90912 and 90913 will deny as not medically necessary when billed with ICD-10 codes F98.1, R151, R152, R150, R159 for fecal incontinence.

Unbundling

Code A4459 is an all-inclusive code. Separate billing of any of the individual components is not allowed.

HCPCS Code L9900

HCPCS code L9900 is never allowed separate reimbursement because Medicare considers this code to be a bundled item or service, no matter what it is used to represent, and even if billed alone. While several LCAs and LCDs specifically call out this code as non-covered when used for specific types of devices, not all possible scenarios where this code may be used are addressed in LCDs or LCAs; however,

the Noridian webpage for *Two New Codes Established for Miscellaneous Supplies* provides general non-coverage information, for any use not found in an LCD or LCA.

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
	0963T	Anoscopy with directed submucosal injection of bulking agent into anal canal
	46999	Unlisted procedure, anus
	58999	Unlisted procedure, female genital system (nonobstetrical)
	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, direct or inductive coupling, 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 with or without balloon, for use with any type transanal irrigation system, each

	A4459	Manual transanal irrigation 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 code list above 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. According to Medicare, "presence of a payment amount in the MPFS and the Medicare physician fee schedule database (MPFSDB) does not imply that CMS has determined that the service may be covered by Medicare." The issuance of a CPT or HCPCS code or the provision of a payment or fee amount by Medicare does **not** make a procedure medically reasonable or necessary or a covered benefit by Medicare. *(Medicare Claims Processing Manual, Chapter 23 - Fee Schedule Administration and Coding Requirements, §30 - Services Paid Under the Medicare Physician's Fee Schedule, A. Physician's Services)*
- 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. Centers for Medicare and Medicaid Services (CMS). Medicare Change Request 8645, Transmittal 2902. Dated 03/11/2014. Available at: https://www.cms.gov/regulations-and-guidance/guidance/transmittals/downloads/r2902cp.pdf. Accessed 6/17/2025.
2. CMS. MLN Matters® Article SE20001 January 2020. Incorrect Billing of HCPCS L8679 – Implantable Neurostimulation, Pulse Generator, Any Type. Available at: https://www.cms.gov/files/document/se20001.pdf. Accessed 6/17/2025.
3. CMS. Medicare Change Request 8531, Transmittal 2836. Dated 12/13/2013. Available at: https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R2836CP.pdf. Last Cited 6/17/2025.

POLICY REVISION HISTORY

DATE	REVISION SUMMARY
1/2023	Q1 2023 code updates (converted to new format 2/2023)
5/2023	Interim update, added device removal, revision, replacement criteria
8/2023	Annual review; no changes to criteria but language revision due to Company policy change from “investigational” to “not medically necessary,” add L9900
1/2024	Interim update to remove Noridian LCA for PTNS (retired 11/1/2023) and Q1 2024 code updates
4/2024	Q2 2024 code updates
8/2024	Annual review; remove Carebidet from policy, add NCD 230.16, no other changes to criteria
4/2025	Q2 2025 code updates
7/2025	Q3 2025 code updates
8/2025	Annual review; no change to criteria (10/3/2025: Replaced A53017 with A53359 due to Noridian JF consolidation with JE LCD policies)