Medicare Medical Policy

Fecal Incontinence Treatments

MEDICARE MEDICAL POLICY NUMBER: 228

Effective Date: 5/1/2023

Last Review Date: 2/2023

Next Annual Review: 7/2023

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, Providence Plan Partners, and Ayin Health Solutions 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)
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)
Posterior Tibial Nerve Stimulation (PTNS) for Fecal Incontinence (CPTs 0587T-0590T, 64566)	LCA for Billing and Coding: Posterior Tibial Nerve Stimulation Coverage (A52965)
*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)*
Biofeedback *Injectable bulking agents* *Transanal radiofrequency therapy (Secca procedure)* *Anal sphincter replacement (i.e., Acticon Neosphincter)* *Eclipse™ Vaginal Insert System*	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. *"Investigational" services are considered not medically necessary for Medicare Plan members. 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

The Company 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. In the absence of Medicare coverage policies (e.g., manual, national coverage determination [NCD], local coverage determination [LCD], article [LCA], etc.), Medicare regulatory guidelines do allow Medicare Advantage Organizations (MAOs) to make their own coverage determinations, as long as the MAO applies an objective, evidence-based process, based on authoritative evidence. *(Medicare Managed Care Manual, Ch. 4, §90.5)*

Following an evidence-based assessment of current peer-reviewed medical literature, the Company may consider certain medical services or technologies to be "investigational." The term "investigational" is not limited to devices or technologies which have not received the appropriate governmental regulatory approval (e.g., U.S. Food and Drug Administration [FDA]), but rather may also mean the procedure, device, or technology does not meet all of the Company's technology assessment criteria, as detailed within the Company policy for *Definition: Experimental/Investigational* (MP5).

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)*. Thus, services which lack scientific evidence regarding safety and efficacy because they are investigational are "not medically reasonable or necessary" for Medicare Plan members. *(Medicare Claims Processing Manual, Ch. 23, §30 A)*

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)

POSTERIOR TIBIAL NERVE STIMULATION (PTNS)

CPT codes 0587T-0590T and 64566 will deny as not medically necessary when **not** reported with ICD-10 codes that support medical necessity, as determined by the relevant PTNS LCA A52965.

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 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 and is reported under a CPT code that is all-inclusive. Services rendered in a physician office and billed under a CPT code are 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 Commercial policy criteria are applied.

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.

CODES*		
CPT	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 (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, posterior tibial nerve, 1-3 parameters
	0590T	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, posterior tibial nerve, 4 or more parameters
	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 or gastric neurostimulator pulse generator or receiver, direct or inductive coupling
	64595	Revision or removal of peripheral or gastric neurostimulator pulse generator or receiver

	90912	Biofeedback training, perineal muscles, anorectal or urethral sphincter, including EMG and/or manometry, when performed; initial 15 minutes of one-on-one physician or other qualified health care professional contact with the patient
	90913	Biofeedback training, perineal muscles, anorectal or urethral sphincter, including EMG and/or manometry, when performed; each additional 15 minutes of one-on-one physician or other qualified health care professional contact with the patient (List separately in addition to code for primary procedure)
HCPCS	A4290	Sacral nerve stimulation test lead, each
	A4453	Rectal catheter for use with the manual pump-operated enema system, replacement only
	A4459	Manual pump enema system, includes balloon, catheter and all accessories, reusable, any type
	A4563	Rectal control system for vaginal insertion, for long term use, includes pump and all supplies and accessories, any type each
	C1767	Generator, neurostimulator (implantable), non-rechargeable
	C1778	Lead, neurostimulator (implantable)
	C1787	Patient programmer, neurostimulator
	C1823	Generator, neurostimulator (implantable), non-rechargeable, with transvenous sensing and stimulation leads
	C1827	Generator, neurostimulator (implantable), non-rechargeable, with implantable stimulation lead and external paired stimulation controller
	C1897	Lead, neurostimulator test kit (implantable)
	L8605	Injectable bulking agent, dextranomer/hyaluronic acid copolymer implant, anal canal, 1 ml, includes shipping and necessary supplies.
	L8679	Implantable neurostimulator, pulse generator, any type
	L8680	Implantable neurostimulator electrode, each
	L8685	Implantable neurostimulator pulse generator, single array, rechargeable, includes extension
	L8686	Implantable neurostimulator pulse generator, single array, non-rechargeable, includes extension
	L8687	Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension
	L8688	Implantable neurostimulator pulse generator, dual array, non-rechargeable, includes extension

***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. Medicare Change Request 8645, Transmittal 2902; Dated 03/11/2014; Available at: https://www.cms.gov/regulations-and-guidance/guidance/transmittals/downloads/r2902cp.pdf
2. MLN Matters® Article SE20001 January 2020; Incorrect Billing of HCPCS L8679 - Implantable Neurostimulator, Pulse Generator, Any Type; Last Cited 01/24/2022
3. Medicare Change Request 8531, Transmittal 2836; Dated 12/13/2013; Available at: https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R2836CP.pdf.

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