MEDICAL POLICY	Fecal Incontinence Treatments (Medicare Only)
Effective Date: 9/1/2022  9/1/2022 Medical Officer Date	Medical Policy Number: 228 Medical Policy Committee Approved Date: 2/19; 11/19; 8/2020; 08/2021; 11/2021; 5/2022; 7/2022

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:

Medicare only

MEDICARE POLICY CRITERIA

The following Centers for Medicare & Medicaid Service (CMS) guidelines should be utilized for medical necessity coverage determinations. Click the link provided in the table below to access applicable medical necessity criteria. All listed guidelines apply.

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)

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 (All Lines of Business Except Medicare) 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.*

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)*

BILLING GUIDELINES

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.

CPT/HCPCS CODES

Medicare Only	
Prior Authorization Required	
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
C1897	Lead, neurostimulator test kit (implantable)
L8679	Implantable neurostimulator, pulse generator, any type
No PA 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 (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
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
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)
Not Covered	
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.
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
Unlisted Codes 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 **prior-authorization is required.**	
46999	Unlisted procedure, anus
58999	Unlisted procedure, female genital system (nonobstetrical)

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

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.

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