Medicare Medical Policy

Urinary Incontinence Treatments

MEDICARE MEDICAL POLICY NUMBER: 231

Effective Date: 9/1/2022

Last Review Date: 7/2022

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
*Incontinence Control Devices (includes mechanical/hydraulic incontinence control devices and injectable **collagen** implants)*	National Coverage Determination (NCD) for Incontinence Control Devices (230.10)
Sacral Nerve Stimulation for Urinary Incontinence	NCD for Sacral Nerve Stimulation for Urinary Incontinence (230.18) *(The Noridian Local Coverage Article [LCA] for Sacral Nerve Stimulation for Urinary and Fecal Incontinence [A53017] includes the same coverage for urinary incontinence that is found in the NCD).*
Non-Implantable Pelvic Floor Electrical Stimulator (HCPCS E0740)	NCD for Non-Implantable Pelvic Floor Electrical Stimulator (230.8)
Posterior Tibial Nerve Stimulation (PTNS) for Urinary Incontinence (CPTs 0587T-0590T, 64566)	LCA: Posterior Tibial Nerve Stimulation Coverage (A52965)
Intraurethral Valve-Pump (e.g., InFlow Intraurethral device) and External Male Catheters or Female Urinary Collection Devices	Local Coverage Determination (LCD): Urological Supplies (L33803)
Biofeedback for Urinary Incontinence (CPTs 90912, 90913)	NCD for Biofeedback Therapy for the Treatment of Urinary Incontinence (30.1.1)
Artificial urinary sphincter *Injectable **non-collagen** bulking agents* *Transurethral radiofrequency therapy (Renessa procedure)* *Vaginal cones*	Company medical policy for Urinary Incontinence Treatments I. These procedures may be considered **medically necessary** when Company medical policy criteria are met. II. These procedures are considered **not medically necessary** for Medicare Plan members either when Company medical policy criteria are **not** met ***or*** when a service is always deemed to be

Implanted adjustable continence therapy (e.g., ProAct Therapy System) *External female catheters (e.g., PureWick Urine Collection System) (HCPCS K1006)* *Endovaginal cryogen-cooled monopolar radiofrequency systems (e.g., Viveve System) (CPT 0672T)*	"investigational" by 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) and other Medicare references for billing assistance:

- LCA: Urological Supplies - Policy Article (A52521)
- Medicare Claims Processing Manual, Chapter 32 - Billing Requirements for Special Services, §40 – Sacral Nerve Stimulation and the related subsections for additional information.

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.

CODES*		
CPT	~~0548T~~	**TERMED 12/31/2021** ~~Transperineal periurethral balloon continence device; bilateral placement, including cystoscopy and fluoroscopy~~
	~~0549T~~	**TERMED 12/31/2021** ~~Transperineal periurethral balloon continence device; unilateral placement, including cystoscopy and fluoroscopy~~
	~~0550T~~	**TERMED 12/31/2021** ~~Transperineal periurethral balloon continence device; removal, each balloon~~
	~~0551T~~	**TERMED 12/31/2021** ~~Transperineal periurethral balloon continence device; adjustment of balloon(s) fluid volume~~
	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
	0596T	Temporary female intraurethral valve-pump (ie, voiding prosthesis); initial insertion, including urethral measurement

	0597T	Temporary female intraurethral valve-pump (ie, voiding prosthesis); replacement
	0672T	Endovaginal cryogen-cooled, monopolar radiofrequency remodeling of the tissues surrounding the female bladder neck and proximal urethra for urinary incontinence
	51715	Endoscopic injection of implant material into the submucosal tissues of the urethra and/or bladder neck
	52327	Cystourethroscopy (including ureteral catheterization); with subureteric injection of implant material
	53444	Insertion of tandem cuff (dual cuff)
	53445	Insertion of inflatable urethral/bladder neck sphincter, including placement of pump, reservoir, and cuff
	53446	Removal of inflatable urethral/bladder neck sphincter, including pump, reservoir, and cuff
	53447	Removal and replacement of inflatable urethral/bladder neck sphincter including pump, reservoir, and cuff at the same operative session
	53449	Repair of inflatable urethral/bladder neck sphincter, including pump, reservoir, and cuff
	53451	Periurethral transperineal adjustable balloon continence device; bilateral insertion, including cystourethroscopy and imaging guidance
	53452	Periurethral transperineal adjustable balloon continence device; unilateral insertion, including cystourethroscopy and imaging guidance
	53453	Periurethral transperineal adjustable balloon continence device; removal, each balloon
	53454	Periurethral transperineal adjustable balloon continence device; percutaneous adjustment of balloon(s) fluid volume
	53860	Transurethral radiofrequency micro-remodeling of the female bladder neck and proximal urethra for stress urinary incontinence
	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)
	97014	Application of a modality to 1 or more areas; electrical stimulation (unattended)
	97032	Application of a modality to 1 or more areas; electrical stimulation (manual), each 15 minutes
HCPCS	A4290	Sacral nerve stimulation test lead, each

	A4335	Incontinence supply; miscellaneous
	C1767	Generator, neurostimulator (implantable), non-rechargeable
	C1778	Lead, neurostimulator (implantable)
	C1815	Prosthesis, urinary sphincter (implantable)
	C1816	Receiver and/or transmitter, neurostimulator (implantable)
	C1883	Adapter/extension, pacing lead or neurostimulator lead (implantable)
	C1897	Lead, neurostimulator test kit (implantable)
	E0740	Non-implanted pelvic floor electrical stimulator, complete system
	E0745	Neuromuscular stimulator, electronic shock unit
	K1006	Suction pump, home model portable or stationary, electric, any type, for use with external urine management system
	K1010	Indwelling intraurethral drainage device with valve, patient inserted, replacement only, each
	K1011	Activation device for intraurethral drainage device with valve, replacement only, each
	K1012	Charger and base station for intraurethral activation device, replacement only
	L8603	Injectable bulking agent, collagen implant, urinary tract, 2.5 ml syringe, includes shipping and necessary supplies
	L8604	Injectable bulking agent, dextranomer/hyaluronic acid copolymer implant, urinary tract, 1 ml, includes shipping and necessary supplies
	L8606	Injectable bulking agent, synthetic implant, urinary tract, 1 ml syringe, includes shipping and necessary supplies
	L8679	Implantable neurostimulator, pulse generator, any type
	L8680	Implantable neurostimulator electrode, each
	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
	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
	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

***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
9/2022	Annual review (converted to new format 2/2023)