


MEDICAL POLICY	Urinary Incontinence Treatments (Medicare Only)
Effective Date: 9/1/2022  9/1/2022	Medical Policy Number: 231 Medical Policy Committee Approved Date: 5/19; 11/19; 06/2020; 10/2020; 4/2021; 07/2021; 11/2021; 5/2022; 7/2022
Medical Officer	Date

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	
<p>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.</p>	
Service	Medicare Guidelines
<i>Incontinence Control Devices (includes mechanical/hydraulic incontinence control devices and injectable collagen implants)</i>	National Coverage Determination (NCD) for Incontinence Control Devices (230.10)
<i>Sacral Nerve Stimulation for Urinary Incontinence</i>	NCD for Sacral Nerve Stimulation for Urinary Incontinence (230.18) (<i>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.</i>)
<i>Non-Implantable Pelvic Floor Electrical Stimulator (HCPCS E0740)</i>	NCD for Non-Implantable Pelvic Floor Electrical Stimulator (230.8)
<i>Posterior Tibial Nerve Stimulation (PTNS) for Urinary Incontinence (CPTs 0587T-0590T, 64566)</i>	LCA: Posterior Tibial Nerve Stimulation Coverage (A52965)
<i>Intraurethral Valve-Pump (e.g., InFlow Intraurethral device) and External Male</i>	Local Coverage Determination (LCD): Urological Supplies (L33803)

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<p><i>Catheters or Female Urinary Collection Devices</i></p> <p><i>Biofeedback for Urinary Incontinence (CPTs 90912, 90913)</i></p> <p><i>Artificial urinary sphincter</i></p> <p><i>Injectable non-collagen bulking agents</i></p> <p><i>Transurethral radiofrequency therapy (Renessa procedure)</i></p> <p><i>Vaginal cones</i></p> <p><i>Implanted adjustable continence therapy (e.g., ProAct Therapy System)</i></p> <p><i>External female catheters (e.g., PureWick Urine Collection System) (HCPCS K1006)</i></p> <p><i>Endovaginal cryogen-cooled monopolar radiofrequency systems (e.g., Viveve System) (CPT 0672T)</i></p>	<p>NCD for Biofeedback Therapy for the Treatment of Urinary Incontinence (30.1.1)</p> <p>Company medical policy for Urinary Incontinence Treatments (All Lines of Business Except Medicare)</p> <p>I. These procedures may be considered medically necessary when Company medical policy criteria are met.</p> <p>II. These procedures are considered not medically necessary for Medicare Plan members either when Company medical policy criteria are not met <u>or</u> when a service is always deemed to be “investigational” by the Company medical policy. <u>“Investigational” services are considered not medically necessary for Medicare Plan members. See Policy Guidelines below.</u></p>
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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) 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

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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.

CPT/HCPCS CODES

Medicare Only	
Prior Authorization Required	
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
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)
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
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

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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
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
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

No Prior Authorization 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)
97014	Application of a modality to 1 or more areas; electrical stimulation (unattended)

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97032	Application of a modality to 1 or more areas; electrical stimulation (manual), each 15 minutes
A4335	Incontinence supply; miscellaneous
E0745	Neuromuscular stimulator, electronic shock unit
Not Covered	
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
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
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
K1006	Suction pump, home model portable or stationary, electric, any type, for use with external urine management system
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

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>