Medicare Medical Policy

Urinary Dysfunction Treatments

MEDICARE MEDICAL POLICY NUMBER: 231

Effective Date: 10/1/2024

Last Review Date: 9/2024

Next Annual Review: 7/2025

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
*Injectable **Collagen** Implants*	National Coverage Determination (NCD) for Incontinence Control Devices (230.10) **NOTE:** For mechanical/hydraulic incontinence control devices, see below.
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)
*Intraurethral Valve-Pump (e.g., InFlow Intraurethral device) and External Male Catheters or Female Urinary Collection Devices (**Excludes** PureWick)*	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)
Spinal Cord Electrical Stimulators and Bladder Wall Stimulators for Urinary Incontinence	NCD for Bladder Stimulators (Pacemakers) (230.16) **NOTE:** Bladder stimulators (pacemakers) directly stimulate the bladder muscles, while sacral nerve stimulators stimulate the sacral nerves.
*Revision, Replacement or Removal of **Implanted** Devices*	For **removal only**:

(e.g., electrical nerve stimulators, such as sacral nerve, PTNS, tibial nerve, etc., as well as other implanted continence therapy devices)	• 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 urinary incontinence treatments in a coverage manual.
- **National Coverage Determination (NCD):** The NCDs noted above are applied to their respective services or devices. For services not otherwise addressed above:
  - There is an NCD for **incontinence control devices** which addresses mechanical or hydraulic incontinence control devices. Specifically, Medicare states these devices are "covered when its use is reasonable and necessary for the individual patient." However, criteria to determine reasonable and necessary use for these devices are not provided within this NCD. Therefore, these coverage criteria are considered "not fully established" under CFR § 422.101(6)(i)(A) as additional criteria are needed to

interpret or supplement these general coverage provisions in order to determine medical necessity consistently.
    - There is an NCD for **electrical nerve stimulators**, but it only addresses electrical nerve stimulation when used to treat chronic intractable pain. Therefore, the coverage criteria in this electrical nerve stimulator NCD are considered "not fully established" under CFR § 422.101(6)(i)(C) as no coverage criteria exists for electrical nerve stimulation for the indication of urinary incontinence.
- **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 **injectable *non-collagen* bulking agents** used for urinary incontinence, **implantable adjustable continence therapy**, **transurethral radiofrequency therapy, artificial urinary sphincter, vaginal cones, endovaginal cryogen-cooled monopolar radiofrequency systems, implantable tibial nerve stimulators or transcutaneous (wearable) tibial nerve stimulators,** or the **Purewick system.** As of November 1, 2023, there is no longer a Noridian J-F LCD or LCA for **posterior tibial nerve stimulation (PTNS)**. Currently only one MAC maintains an LCD for PTNS, but it does not have jurisdiction over the plan service area.
- 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 service is being performed, Company criteria below are applied for medical necessity decision-making. One Medicare NCD provides implies coverage is available for incontinence control devices such as an artificial sphincter, but additional criteria to interpret or supplement the NCD criteria in order to determine medical necessity consistently. Some procedures or devices are only indicated for certain indications, and only if other treatments have failed. Thus, these additional criteria provide clinical benefits that are highly likely to outweigh any clinical harms, including from delayed or decreased access to items or services **because the use of this additional criteria is expected to improve diagnosis, improve patient management, and/or improve health outcomes**. Specifically, this literature review is used to evaluate whether or not each procedure has been directly compared to other urinary incontinence treatment options to establish each individual treatments' overall safety and efficacy, as well as the appropriateness of a given treatment for the individual patient and their clinical history.

Incontinence Control Devices such as The Artificial Urinary Sphincter and the AMS 800 Artificial Urinary Sphincter / Urinary Control System *Injectable **non-collagen** bulking agents* *Transurethral radiofrequency therapy (Renessa procedure)* *Vaginal conesImplanted adjustable continence therapy (e.g., ProAct Therapy System)*	Company medical policy for Urinary Dysfunction 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 when Company medical policy criteria are not met. *See Policy Guidelines below.*

External female catheters (e.g., PureWick Urine Collection System) (HCPCS E2001) *Endovaginal cryogen-cooled monopolar radiofrequency systems (e.g., Viveve System) (CPT 0672T)* *Posterior Tibial Nerve Stimulation (PTNS) for Urinary Incontinence (CPTs 0587T-0590T, 64566)* *Implantable tibial nerve stimulator (e.g., eCOIN Peripheral Neurostimulator System)* *Transcutaneous (wearable) tibial nerve stimulators (e.g., ZIDA Wearable neuromodulation system [E0736] and Vivally® System [E0737, A4545])* *Transvaginal Mechanotherapy (e.g., The Flyte® System; E0715, E0716)*	

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 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. 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 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. Effective November 1, 2023, Noridian retired this LCA, and Company criteria now applies. The Company position regarding the medical necessity of a 12-week course of therapy using PTNS as a treatment of urinary urge incontinence is consistent with the Medicare LCA.

Implantable Tibial Nerve Stimulators

- Implantable tibial nerve stimulators (*e.g., eCOIN Peripheral Neurostimulator System*) are different from *sacral* nerve stimulation, so Medicare references for sacral nerve stimulation to treat urge incontinence (NCD 230.18 and LCA A53017) are not applicable.
- The Medicare noted NCD and LCD for *peripheral* nerve stimulation (160.7 and L37360, respectively) are specific to the use of peripheral nerve stimulation for the treatment of pain. Urge urinary

incontinence is **not** included in the scope of these Medicare guidelines and thus, they are not applicable.
- The now-retired Medicare LCA for posterior tibial nerve stimulation (A52965) referred to a technique that is **percutaneous** in nature, rather than **implanted**. In addition, CPT code 64590 wasn't included in the PTNS LCA, which is reasonable since they are for different stimulation techniques.

Thus, **no current Medicare guideline** is available for this medical technology and Company coverage criteria are applied.

Transcutaneous Tibial Nerve Stimulators

The ZIDA Wearable Neuromodulation System received the Food and Drug Administration's (FDA's) 510(k) clearance on March 19, 2021. It is indicated for the treatment of overactive bladder (OAB) and the associated symptoms of urinary urgency, urinary frequency, and urge incontinence.

The Vivally® System received the Food and Drug Administration's (FDA's) 510(k) clearance on April 3, 2023. The Vivally® System is a wearable neuromodulation system for home use to treat patients with urge urinary incontinence and urinary urgency caused by overactive bladder (OAB) syndrome.

There is **no current Medicare coverage guideline** available for this medical technology and Company coverage criteria are applied for these items as well.

Transvaginal Mechanotherapy

The Flyte® System received the Food and Drug Administration's (FDA's) 510(k) clearance on December 29, 2023. It is indicated for the treatment of stress urinary incontinence. This vaginal device is intended to strengthen the pelvic floor muscles during normal Kegel exercises.

There is **no current Medicare coverage guideline** available for this medical technology and Company coverage criteria are applied for these items as well.

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.

The following are examples of devices that have received FDA clearance (not all inclusive):

- **Artificial Urinary Sphincter**: The AMS 800™ artificial urinary sphincter, the Artificial Urinary Sphincter

- **Bulking Agents:** Contigen, Coaptite, Durasphere, Macroplastique, URYX
- **Percutaneous Tibial Nerve Stimulation:** Urgent PC Neuromodulation System
- **Sacral Nerve Stimulation:** Axonics Sacral Neuruomodulation System, Medtronic Interstim® Sacral Nerve Stimulation™ System
- **Pelvic Floor Electrical Stimulation:** NeoControl® Pelvic Floor Therapy System; MyoTrac Infiniti; ApexM; In Tone®MV.
- **Adjustable Continence Therapy:** ProACT™ Adjustable Continence Therapy for Men
- **Intraurethral valve-pump:** InFlow™ Intraurethral Valve-Pump (Vesiflo, Inc.)
- **Implantable Tibial Nerve Stimulator:** eCoin Peripheral Neurostimulator, Valencia Technologies Corporation
- **Transcutaneous (Wearable) Tibial Nerve Stimulators:** Vivally® System and ZIDA Wearable Neuromodulation System
- **Transvaginal Mechanotherapy:** Flyte® System Controller and Wand

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.

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.

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	0587T	Percutaneous implantation or replacement of integrated single device neurostimulation system for bladder dysfunction including electrode array and receiver or pulse generator, including analysis, programming, and imaging guidance when performed, posterior tibial nerve
	0588T	Revision or removal of percutaneously placed integrated single device neurostimulation system for bladder dysfunction 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 for bladder dysfunction (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 for bladder dysfunction (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
	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
	0816T	Open insertion or replacement of integrated neurostimulation system for bladder dysfunction including electrode(s) (eg, array or leadless), and pulse generator or receiver, including analysis, programming, and imaging guidance, when performed, posterior tibial nerve; subcutaneous
	0817T	Open insertion or replacement of integrated neurostimulation system for bladder dysfunction including electrode(s) (eg, array or leadless), and pulse generator or receiver, including analysis, programming, and imaging guidance, when performed, posterior tibial nerve; subfascial
	0818T	Revision or removal of integrated neurostimulation system for bladder dysfunction, including analysis, programming, and imaging, when performed, posterior tibial nerve; subcutaneous
	0819T	Revision or removal of integrated neurostimulation system for bladder dysfunction, including analysis, programming, and imaging, when performed, posterior tibial nerve; subfascial
	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, sacral, or gastric neurostimulator pulse generator or receiver, 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)
	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
	A4545	Supplies and accessories for external tibial nerve stimulator (e.g., socks, gel pads, electrodes, etc.), needed for one month
	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)
	E0715	Intravaginal device intended to strengthen pelvic floor muscles during kegel exercises
	E0716	Supplies and accessories for intravaginal device intended to strengthen pelvic floor muscles during kegel exercises
	E0736	Transcutaneous tibial nerve stimulator
	E0737	Transcutaneous tibial nerve stimulator, controlled by phone application
	E0740	Non-implanted pelvic floor electrical stimulator, complete system
	E0745	Neuromuscular stimulator, electronic shock unit
	E2001	Suction pump, home model, portable or stationary, electric, any type, for use with external urine and/or fecal management system
	~~K1006~~	**TERMED 12/31/2023**

		~~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
	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. Medicare Change Request 8645, Transmittal 2902; Dated 03/11/2014; Available at: https://www.cms.gov/regulations-and-guidance/guidance/transmittals/downloads/r2902cp.pdf. Last Cited 06/12/2023.
2. MLN Matters® Article SE20001 January 2020; Incorrect Billing of HCPCS L8679 – Implantable Neurostimulator, Pulse Generator, Any Type; Available at: https://www.cms.gov/files/document/se20001.pdf. Last Cited 06/12/2023.
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. Last Cited 06/12/2023.

POLICY REVISION HISTORY

DATE	REVISION SUMMARY
9/2022	Annual review (converted to new format 2/2023)
5/2023	Interim update; added device removal, revision, replacement criteria and implantable tibial nerve stimulation to the policy
10/2023	Annual review; no criteria changes but language revision due to Company policy change from "investigational" to "not medically necessary," add L9900
12/2023	Interim update due to retirement of LCA for PTNS
1/2024	Q1 2024 code updates
4/2024	Q2 2024 code updates
8/2024	Annual review; update language for criteria for mechanical or hydraulic incontinence control devices, such as artificial urinary sphincters; add NCD 230.16
10/2024	Q4 2024 code updates