Medicare Medical Policy

Electrical Stimulation and Electromagnetic Therapies

MEDICARE MEDICAL POLICY NUMBER: 333

Effective Date: 10/1/2024	MEDICARE COVERAGE CRITERIA	2
Last Review Date: 9/2024	POLICY CROSS REFERENCES	
Next Annual Review: 6/2025	POLICY GUIDELINES	12
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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.

Notes:

- 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.
- The following electrical stimulation services are **not** included in this policy, but are addressed in separate medical policies (see *Policy Cross References* below):
 - Electrical stimulators used to treat **urinary or fecal incontinence** (e.g., pelvic floor electrical stimulator [E0740], sacral nerve stimulation, posterior tibial nerve stimulation [PTNS], etc.).
 - o Oral appliance nerve stimulation devices (K1029)

Service Medicare Guidelines

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 <u>Policy Guidelines</u> below)

Medicare Coverage Manuals, National Coverage Determination (NCD), and Noridian J-F or J-D Local Coverage Determination (LCD)/Local
Coverage Article (LCA): Medicare does have guidance for various electrical stimulation and electromagnetic therapies in either coverage
manuals, NCDs, LCDs or LCAs. Those are provided when available in the table below.

In the absence of established Medicare coverage criteria in a manual, NCD, LCD, or other regulatory guidance for the health plan's service area, Company criteria are applied for medical necessity decision-making for any electrical stimulation or electromagnetic therapy which doesn't have a relevant Medicare coverage policy. Auricular Electrostimulation (0783U, Under Medicare, auricular electrostimulation devices are not medically necessary. A9270, E1399, S8930) NOTES: These devices provide a variant of acupuncture known as "electro acupuncture." In January 2020, CMS determined coverage may be allowed for acupuncture services to treat cLBP when rendered by a qualified, Medicare eligible provider (see the Medicare National Coverage Determinations (NCDs) 30.3, 30.3.1, and 30.3.2, all of which deny acupuncture for any indication except cLBP); however, this coverage does not extend to electrostimulation of auricular points or electroacupuncture devices used in the home. (This non-coverage is consistent with non-coverage found by other Medicare contractors [MACs].) See Policy Guidelines below regarding appropriate coding, including the use of CPT 64555. Cefaly Device See row for "Transcutaneous Electrical Nerve Stimulators (TENS) and Related Supplies" Cranial Electrostimulation (Electrical • Prior to 1/1/2021: NCD for Electrosleep Therapy (30.4) Stimulation) Therapy (CES) (e.g., On or after 1/1/2021: Company medical policy for Electrical Stimulation: Non-Covered Therapies Alpha-Stim CES) (A4596, E0732, Cranial electrostimulation (or cranial electrical stimulation; CES) is considered not medically E1399) necessary for Medicare Plan members based on the Company medical policy. See Policy Guidelines below. Deep Brain Stimulation (DBS) (Codes • Essential tremor (ET) and/or Parkinsonian tremor: NCD for Deep Brain Stimulation for Essential Tremor include but are not limited to, and Parkinson's Disease (160.24) 61880, 61885, 61886, 61888, Chronic intractable pain: NCD for Electrical Nerve Stimulators (160.7) For other indications specified in a separate row (e.g., motor function disorders, etc.), see separate row. 61889, 61891, 61892) NOTE: For other indications not otherwise addressed (e.g., depression, obsessive compulsive disorder [OCD], etc.), DBS is **not medically necessary**. Dorsal Column Stimulators (aka, NCD for Electrical Nerve Stimulators (160.7) Spinal Cord Stimulators or SCS) LCD for Spinal Cord Stimulators for Chronic Pain (L36204) (Codes include, but are not limited to, 63650, 63655, 63661-63664, 63685, 63688)

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Dorsal <u>Root Ganglion</u> (DRG)	Company medical policy for <u>Implantable Spinal Cord and Dorsal Root Ganglion Stimulation</u>
Stimulators (Codes include, but are	
not limited to, 63650, 63655,	
63661-63664, 63685, 63688)	I. DRG stimulation may be considered medically necessary for Medicare when the Company medical policy
	criteria are met.
	II. DRG stimulation is considered not medically necessary for Medicare when the Company medical policy
	criteria are not met. <u>See Policy Guidelines below.</u>
Electrical Stimulation (any type) for	NCD for Treatment of Motor Function Disorders with Electric Stimulation (160.2)
the Treatment of Motor Function	
Disorders (e.g., multiple sclerosis	NOTE: This excludes the Cala Trio™ device, which is addressed separately below (see row for "External Upper
[MS], etc.)	Limb Tremor Stimulator).
Electrical Stimulation (any type) or	NCD for Electrical Stimulation (ES) and Electromagnetic Therapy for the Treatment of Wounds (270.1)
Electromagnetic Therapy for the	
Treatment of Wounds	NOTE: One covered ES therapy or one covered electromagnetic therapy is allowed for the treatment of
	wounds. ES and electromagnetic therapy services can only be covered when performed by a physician,
	physical therapist, or incident to a physician service. Unsupervised use of ES or electromagnetic therapy for
	wound therapy, including ES or electromagnetic therapy in the home, is not medically necessary.
Electrical Stimulation (any type) for	LCD for Nerve Blockade for Treatment of Chronic Pain and Neuropathy (<u>L35457</u>) (Coverage guidance specific
the Treatment of Peripheral	to electrical stimulation for peripheral neuropathy is found within the LCD)
Neuropathies	
Electrical Stimulation (any type) for	NCD for Electrotherapy for Treatment of Facial Nerve Paralysis (Bell's Palsy) (160.15)
the Treatment of Facial Nerve	
Paralysis	
External Upper Limb Tremor	As of April 7, 2024: Apply LCD for External Upper Limb Tremor Stimulator Therapy (<u>L39591</u>)
Stimulator (e.g., Cala Trio™ device)	Prior to April 7, 2024: Apply NCD Treatment for Motor Function Disorders with Electrical Stimulation
(HCPCS codes E0734, A4542)	(160.2)
Functional Electrical Stimulation	NCD for Neuromuscular Electrical Stimulation (160.12)
(FES) (HCPCS codes E0770, E0764)	
	NOTE: "Indications for FES other than to enable SCI patients to walk will be denied as not medically
	necessary." (Noridian web page for <u>Functional Electrical Stimulation (FES) – Coverage and HCPCS Coding –</u>
	Revised) Therefore, the use of FES for any condition or indication <u>not</u> noted as covered in the NCD is not
	medically necessary.

Gastric Electrical Stimulation	Company medical policy for Gastric Electrical Stimulation
(43647, 43648, 43881, 43882)	Company medical policy for dastric Electrical Stimulation
(43047, 43040, 43001, 43002)	III. These services may be considered medically necessary for Medicare when the Company medical policy
	criteria are met.
	IV. These services are considered not medically necessary for Medicare when the Company medical policy
	criteria are not met. <u>See Policy Guidelines below.</u>
H-Wave Stimulation (E1399)	Wounds: See separate row for wound treatment above.
	Peripheral neuropathy: See separate row for peripheral neuropathy above.
	All other indications: See row for "Neuromuscular Electrical Stimulation (NMES)"
Implanted Peripheral Nerve	NCD for Electrical Nerve Stimulators (160.7)
Stimulators (PNS) (CPT codes 64555,	,
64575, 64585, 64590, 64595,	
64596, 64597, 64598, A4438)	NOTES:
	Includes devices such as the Nalu™ Neurostimulation System, StimRouter System, Sprint PNS, and restarative neuromodulation therapy devices such as the PoAstiv® Implantable Neurostimulation System.
	 restorative neuromodulation therapy devices such as the ReActiv8 Implantable Neurostimulation System. According to the companion billing and coding LCA for PNS (A55531), a temporary trial or psychological evaluation may not be required for all indications. See the LCA for full details. Also according to the LCA A55531, when a restorative neuromodulation therapy device is used for the treatment of multifidus muscle dysfunction, the device implanted must be a Class III medical device with product classification QLK as defined by the FDA. As of the date of the most recent policy review, ReActiv8 is the only product listed under Product Code QLK.
Interferential Stimulation (IFS) or	Medicare considers IFC/IFS therapy devices to be forms of TENS or NMES, depending on the setting the
Interferential Current (IFC) Devices	device is configured to and used. These devices can be configured to either (1) provide pain relief like a TENS
	<u>or</u> (2) treat disuse atrophy like NMES. Therefore, Medicare coverage criteria for TENS or NMES are applied to
	 IFC therapy devices based on how the device is used.^{1,2} IFS or IFC therapy devices used on TENS setting (e.g., for treatment of pain): See row for TENS. IFS/IFC therapy devices used on NMES setting (e.g., for treatment of disuse atrophy): See row for NMES.
Microcurrent Electrical Nerve	Wounds: See separate row for wound treatment above.
Stimulation (MENS)	Peripheral neuropathy: See separate row for peripheral neuropathy above.
	All other indications: Company medical policy for <u>Electrical Stimulation: Non-Covered Therapies</u>

	o MENS is considered not medically necessary for Medicare Plan members based on the Company
	medical policy. <u>See Policy Guidelines below.</u>
	See row for "Transcutaneous Electrical Nerve Stimulators (TENS) and Related Supplies"
Stimulation (eTNS) System for ADHD	
(Non-Implantable [External]	
Trigeminal Nerve Stimulation)	
Neuromuscular Electrical Stimulator (NMES)	 General coverage for NMES: National Coverage Determination (NCD) for Neuromuscular Electrical Stimulation (160.12)
	• Supplies necessary for NMES: NCD for Supplies Used in the Delivery of Transcutaneous Electrical Nerve Stimulation (TENS) and Neuromuscular Electrical Stimulation NMES (<u>160.13</u>)
	NOTE: "Coverage of NMES (other than FES) to treat muscle atrophy is limited to the treatment of patients
	with disuse atrophy" and when the NMES NCD criteria are met. (Noridian web page for Functional Electrical
	<u>Stimulation (FES) – Coverage and HCPCS Coding – Revised</u>) Therefore, the use of NMES for any condition or
	indication <u>not</u> noted as covered in the NCD is not medically necessary.
Percutaneous Electrical Nerve Stimulation (PENS)	• As a diagnostic procedure: NCD for Assessing Patient's Suitability for Electrical Nerve Stimulation Therapy (160.7.1)
	 All other indications: Company medical policy for <u>Electrical Stimulation: Non-Covered Therapies</u> PENS is considered not medically necessary for Medicare Plan members based on the Company medical policy. <u>See Policy Guidelines below.</u>
Percutaneous Electrical Nerve Field Stimulation (PENFS) (0720T)	Company medical policy for <u>Electrical Stimulation: Non-Covered Therapies</u>
	I. PENFS is considered not medically necessary for Medicare Plan members based on the Company medical policy. <u>See Policy Guidelines below.</u>
Percutaneous Neuromodulation	Company medical policy for Electrical Stimulation: Non-Covered Therapies
Therapy (PNT) (Codes include, but	
are not limited to, A4593, A4594)	I. PNT is considered not medically necessary for Medicare Plan members based on the Company medical policy. <u>See Policy Guidelines below.</u>
	NOTE: Thee include, but may not be limited to, devices such as the Portable Neuromodulation Stimulator or PoNS™, and all related components and accessories.

Peripheral Nerve Field Stimulation (PNFS)	LCA for Billing and Coding: Peripheral Nerve Stimulation (A55531) and LCD L37360
Phrenic Nerve Stimulators	NCD for Phrenic Nerve Stimulatory (<u>160.19</u>)
Peripheral Nerve Stimulation (Implantable)	See row for "Implanted Peripheral Nerve Stimulators"
Peripheral Nerve Stimulation (Intraoperative) for Nerve Regeneration (0882T, 0883T)	Company medical policy for Electrical Stimulation: Non-Covered Therapies • Peripheral nerve stimulation to promote nerve regeneration is considered not medically necessary for
Occipital Nerve Stimulation	Medicare Plan members based on the Company medical policy. <u>See Policy Guidelines below.</u> See row for "Implanted Peripheral Nerve Stimulators"
occipital Nerve Stillandion	NOTE: For occipital nerve <u>ablative procedures</u> (e.g., radiofrequency, cryoablation, chemical ablation, etc.), see the separate Medicare medical policy for "Ablative Procedures to Treat Back and Neck Pain"
Responsive Cortical Stimulation or Responsive Neurostimulation (RNS)	 I. RNS may be considered medically necessary for Medicare Plan members when criteria from the Company medical policy are met. II. RNS is considered not medically necessary for Medicare when criteria from the Company medical policy are not medically necessary for Medicare when criteria from the Company medical policy are not met. See Policy Guidelines below.
Spinal Cord Stimulators (SCS; e.g.,	NCD for Electrical Nerve Stimulators (<u>160.7</u>)
Dorsal <u>Column</u> Stimulators)	LCD for Spinal Cord Stimulators for Chronic Pain (<u>L36204</u>)
Transcutaneous Electrical Acupoint Stimulation (TEAS) for Treatment of Nausea and Vomiting (aka, electrical acustimulation; E0765)	Noridian web page for Transcutaneous Electrical Nerve Stimulators (TENS) Sold Over-the-Counter – Coding Guidelines NOTES:
c.cca. acasa.maration, 20703)	 According to the FDA Summary (K191547), ReliefBand® 1.5 and 2.0 have been classified as transcutaneous electrical nerve stimulator for pain relief and are approved for over-the-counter (OTC) use. These devices are indicated for "use in the relief of mild to moderate nausea and retching associated with physician-diagnosed migraine, hangover, anxiety, motion sickness, chemotherapy and morning sickness associated with pregnancy as an adjunct to antiemetics in reducing mild to moderate postoperative nausea." OTC

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	devices are not eligible for Medicare coverage (some Medicare Advantage members may have OTC
	benefits, but these are generally limited benefits).
	• In addition, stimulation devices (E0755-E0770) fall under the durable medical equipment Medicare
	contractor (DME MAC) jurisdiction. In order to be considered for coverage as DME, all Medicare DME
	elements are required to be met, including but not limited to, that the device must be used to serve a
	medical purpose and last a minimum of 3 years.
	Claims for E0765 will be denied not medically necessary. Denials may be appealed for reconsideration if
	the device in question can be shown to meet Medicare coverage requirements (i.e., not an OTC device,
	meets all of Medicare's DME requirements, etc.)
Transcutaneous Electrical Joint	Transcutaneous Electrical Joint Stimulation Devices (TEJSD) (<u>L34821</u>)
Stimulation Devices (TEJSD) (E0762)	
Transcutaneous Electrical	Company medical policy for Electrical Stimulation: Non-Covered Therapies
Modulation Pain Reprocessing (e.g.,	
scrambler therapy; TEMPR) (0278T)	I. TEMPR is considered not medically necessary for Medicare Plan members based on the Company
	medical policy. See Policy Guidelines below.
Transcutaneous Electrical Nerve	After review of this device, Medicare has determined this device does not meet the Medicare requirements
Stimulator, Distal (A4540) (Nerivio™	to be considered DME. Therefore, this device is considered not medically necessary . (Medicare Benefit Policy
device)	Manual, Chapter 15, §110.8 – DMEPOS Benefit Category Determinations, specifically the "Distal
	Transcutaneous Electrical Nerve Stimulator, Stimulates Peripheral Nerves of the Upper Arm" entry in the
See the next row for other TENS	Benefit Category Determination table)
devices	
Transcutaneous Electrical Nerve	TENS used for assessing suitability for electrical nerve stimulation:
Stimulators (TENS) and Related	 NCD for Assessing Patient's Suitability for Electrical Nerve Stimulation Therapy (<u>160.7.1</u>)
Supplies	
	TENS used for acute post-operative pain:
	• NCD: Transcutaneous Electrical Nerve Stimulation (TENS) for Acute Post-Operative Pain (10.2)
	LCD: Transcutaneous Electrical Nerve Stimulators (TENS) (<u>L33802</u>)
	TENS used for chronic low back pain (CLBP):
	NCD: Transcutaneous Electrical Nerve Stimulation (TENS) for Chronic Low Back Pain (CLBP) (160.27)
	LCD: Transcutaneous Electrical Nerve Stimulators (TENS) (<u>L33802</u>)

TENS used for all other indications (e.g., headaches, TMJ, chronic pain other than CLBP, ADHD, etc. – See "Important Notes" below): LCD: Transcutaneous Electrical Nerve Stimulators (TENS) (L33802) LCA: Transcutaneous Electrical Nerve Stimulators (TENS) – Policy Article (A52520) Form-fitting conductive garment used with TENS devices: • NCD: Supplies Used in the Delivery of Transcutaneous Electrical Nerve Stimulation (TENS) and Neuromuscular Electrical Stimulation (NMES) (160.13) **IMPORTANT NOTES:** 1. For documentation requirements, see the Documentation Checklist for TENS. 2. TENS devices used to treat headaches (e.g., Cefaly device; E0733, E0720): TENS used to treat headaches is addressed by the list of "Examples of conditions for which TENS therapy is not considered to be reasonable and necessary" within the LCD L33802. 3. TENS devices used to treat indications other than pain (e.g., attention deficit hyperactivity disorder [ADHD]; e.g., Monarch external Trigeminal Nerve Stimulation (eTNS) System; E0733, A4541), opioid withdrawal; e.g., Sparrow Ascent®; E0721, A4543): Medicare coverage of TENS found in the above NCDs and LCDs is limited to pain-related conditions. Therefore, TENS devices used to treat indications other than pain do not meet Medicare's criteria and are not medically necessary. 4. TENS devices sold over-the-counter (OTC) must be reported using HCPCS code A9270. These items are not considered "durable medical equipment" under Medicare and are non-covered. (See the Medicare Pricing, Data Analysis and Coding (PDAC) contractor Web page for Transcutaneous Electrical Nerve Stimulators (TENS) Sold Over-The-Counter – Coding Guidelines.) Company medical policy for Electrical Stimulation: Non-covered Therapies Transcutaneous Magnetic Stimulation with Focused Low-Frequency Electromagnetic Pulse This service is considered **not medically necessary** for Medicare based on the Company medical ١. (Codes 0766T, 0767T, 0768T, 0769T) policy. See Policy Guidelines below. Vagus (vagal) nerve stimulation Implantable VNS: National Coverage Determination (NCD): Vagus Nerve Stimulation (VNS) (160.18) (VNS) All other VNS not addressed above: Company medical policy for Vagus Nerve Stimulation

	 I following services are considered not medically necessary for Medicare, based on the Company medical policy:
	 Noninvasive or non-implantable VNS (HCPCS E0735)
	Transcutaneous vagus nerve stimulation
	Percutaneous vagus nerve stimulation (CPT 64553)
Revision, Replacement or Removal	For removal only :
of Implanted Nerve Stimulator	• Medicare Benefit Policy Manual, Chapter 16 – General Exclusions From Coverage, §1–0 - Services Related
Devices (e.g., deep brain, spinal cord, vagus nerve, etc.)	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, §1–0 -
	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 <i>continued</i> 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)
Replacement of Nonimplanted	 Replacement of TENS units and/or supplies: LCD: Transcutaneous Electrical Nerve Stimulators (TENS)
Nerve Stimulator Devices,	(L33802) and related LCA (A52520)
Components, and Accessories (e.g.,	 Replacement of all other non-implanted electrical nerve stimulator devices: Medicare Benefit Policy
TENS, NMES, FES, IFC, etc.)	Manual, Chapter 15 – Covered Medical and Other Health Services, §1–0 - Prosthetic Devices, A. General

NOTE:

- I. Replacement of **non**-functioning medically necessary electrical stimulation devices (those which met criteria for coverage) or their components may be **medically necessary** when Medicare's replacement requirements in the above manual are met (e.g., irreparable change in condition of device or component, etc.), the device is still providing therapeutic benefit to the patient, and the device or required component are not under manufacturer warranty.
- II. Replacement or upgrades of functioning electrical stimulation devices or components may be medically necessary if the device is no longer providing therapeutic benefit due to a change in the physiological condition of the member.
- III. Replacement or upgrades of **functioning** electrical stimulation devices or components are **not medically necessary** when Medicare's replacement criteria are not met. This includes upgrading to a new version when existing the existing device is still functioning and providing therapeutic benefit. These replacement or upgrade situations would be considered a "convenience."
- IV. Replacement of non-functioning not medically necessary electrical stimulation devices (those which did not meet criteria for coverage) or their components are also considered not medically necessary.

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

- Fecal Incontinence Treatments, MP228
- Sleep Disorder Treatment: Oral and Sleep Position Appliances, MP45
- Urinary Incontinence Treatments, MP231

The full Company portfolio of Medicare Medical Policies is available online and can be accessed here.

POLICY GUIDELINES

DOCUMENTATION REQUIREMENTS

In order to determine the medical necessity of the request, the following documentation must be provided at the time of the request. Medical records to include documentation of all of the following:

- Type of electrical stimulation (the CPT/HCPCS code(s) will **not** be considered sufficient).
- · Name of device.
- Indication being treated, including location, severity and duration of symptoms.
- All medical records and clinical documentation pertinent to the request, including history, physical examination and treatment plan, as well as documentation of prior therapies or treatments (e.g., procedural or surgical interventions, medications, physical therapy, etc.) attempted and the results of those treatments.

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 all types of electrical stimulation systems available in applicable Medicare statutes, regulations, NCDs or LCDs, then Company medical policy criteria for electrical stimulations will be applied when Medicare guidance is not available.

GENERAL

The main types of e-stim are:

- electrical nerve stimulation and
- electrical muscle stimulation and
- electrical nerve field stimulation.

The primary distinction between <u>nerve</u> stimulation and nerve <u>field</u> stimulation is that for nerve field stimulation, a "field" of pain is targeted, as opposed to targeting a specific nerve.

The stimulation approach can be transcutaneous, percutaneous, or implantable. Examples of each category are below (this is not an all-inclusive list).

Table 1. Electrical stimulation approach

Transcutaneous	Percutaneous	Implantable
 Transcutaneous electrical nerve stimulators (TENS) Neuromuscular electrical stimulation (NMES) Transcutaneous electronic modulation pain reprocessing (TEMPR), aka scrambler therapy Transcutaneous Electrical Acupoint Stimulation (TEAS) (aka, electrical acustimulation (e.g., ReliefBand®, PrimaBella™) 	 Percutaneous electrical nerve stimulation (PENS) Percutaneous electrical nerve field stimulation (PENFS) Percutaneous neuromodulation therapy (PNT) 	 Peripheral nerve stimulation (PNS) Peripheral nerve field stimulation (PNFS), aka peripheral subcutaneous field stimulation (PSFS) Spinal cord stimulation (SCS) Deep brain stimulation (DBS) Vagus nerve stimulation (VNS) Dorsal root ganglion (DRG) stimulator Gastric electrical stimulation (GES)

Some electrical stimulation and electromagnetic systems have been reviewed by the Medicare Pricing, Data Analysis and Coding (PDAC) contractor and assigned to a specific HCPCS code, but not all. Table 2 provides examples of electrical stimulation and electromagnetic devices (this is not an all-inclusive list).

Table 2: Examples of Electrical Stimulation and Electromagnetic Devices

Device	Manufacturer	PDAC Assigned Code (if applicable)
Auricular Electrostimulation		(i) applicable)
AcuStim	S.H.P. International	
P-Stim™ System	DyAnsys	A9270
E-pulse®	AMM Marketing	A9270
Electro Auricular Device (EAD)	Key Electronics	
P-Stim	Biegler Gmbh	
ANSiStim [®]	DyAnsys	
Stivax System	Biegler Gmbh	
Transcutaneous nerve stimula	tor (TENS) (supraorbital)	
Cefaly Dual	Cefaly Technology/STX-Med	Prior to 1/1/2024: K1016 As of 1/1/2024: E0733
Cranial Electrical Stimulation (CES)	1.00.2/2/2021.2000
Alpha-Stim [®] Cs	Electromedical Products, Inc.	Prior to 1/1/2024: K1002 As of 1/1/2024: E0732
BR-2 Biorest	Biorest, Inc.	
Biotron18	Biotronics Corp.	
CES Ultra ™	Neuro-Fitness, LLC.	
Elexoma Medic	Redplane AG	
FM 10/C	Johari Digital Healthcare, Ltd	
HP-1 Healthpax or Nurtipax	Health Directions, Inc	
LB-2000	Life Balance Intl., Inc.	
LISS SBI202-B and SBI201-M	Medical Consultants Intl., Ltd	
NET-2000 Microcurrent Stimulator	Auri-Stim Medical, Inc.	
NF-1 Mindpeace	NeuroFitness	
NH 2002	Life Balance Intl., Inc.	
NTI-1000	Neurotek, Inc.	
TESA-1	Kalaco Scientific, Inc.	
Interferential Stimulation (IFS)	*	
BMLS02-6 and BMLS03-6	Biomedical Life Systems, Inc.	
IF-4000	Apex Medical Corporation	
IF-100507	Everlife Medical Equipment Co., Ltd.	
Medstar™ 100	MedNet Services. Inc.	
Netwave and RTM1000	Ryan Telemedicine	
RS-4i®	RS Medical	
Microcurrent Electrical Nerve		<u> </u>
Alpha-Stim PPM (personal pain manager)		
Inspirstar ISO2 Microcurrent Stimulator	Inspirstar Inc.	
Promax-MC, Microcurrent Device, Model MC-4440	Rehabilicare, Inc.	
H-Wave		
H-Wave		
Functional Electrical Stimulation	on (FES)/Neuromuscular Electrical Stimu	lator (NMES)

Parastep® Ambulation System	Sigmedics	
ReWalk™	ReWalk™ Bionics Research Inc.	
NESS H200® (previously the	Nevvanc Biornes nesearch me.	
Handmaster		
NMS I system)		
Table 1 by County	Innovative Neurotronics (formerly	
WalkAide®	NeuroMotion,	
	Inc.)	
Radio-frequency controlled NESS L300™	Bioness	
MyGait	Otto Bock HealthCare	
Foot Drop Stimulator	Odstock Medical Limited	
RT300	Restorative Therapies, Inc.	
Transcutaneous Electrical Modu	lation Pain Reprocessing (TEMPR)	'
Calmare® Pain Therapy device	Competitive Technologies, Inc.	
External Trigeminal Nerve Stim		
Monarch external Trigeminal		Prior to 1/1/2024: K1016
Nerve Stimulation (eTNS)	NeuroSigma	As of 1/1/2024: E0733
External Upper Limb Tremor Sti	mulator	
Cala ONE and Cala Trio	Cala Health, Inc.	
	Cala Fleatti, IIIC. S) and Peripheral Nerve Field Stimulation	on (DNES)
I	e not billable to DME MACs, and thus, a	
Bioness® StimRouter™	Bioness	N/A
	Dioliess	N/A
StimQ Peripheral Nerve Stimulator (PNS)		N/A
SPRINT® Peripheral Nerve		N/A
Stimulation System (SPRINT®	SPR Therapeutics, Inc.	IN/A
PNS)	3FN Merapeutics, Inc.	
1 143)		L8683 (Neither the system
		nor the adhesive clips
Nalu™ Neurostimulation		[reported with A4438 as of
System		4/1/2024] are billable to
System		DME MACs, but may be
		reported to Part B MACs)
StimRouter System		N/A
ReActiv8 Implantable		N/A
Neurostimulation System		N/A
-	│ Therapy (PNT) and Percutaneous Electri	ical Nanya Stimulation
(PENS)	Therapy (FIVI) and Fercutarieous Liectif	Tai Nerve Stillidiation
Percutaneous Neuromodulation Therapy™	Vertis Neurosciences	
Deepwave® Percutaneous		
Neuromodulation Pain Therapy System	Biowave Corp.	
Percutaneous Electrical Nerve Fig	eld Stimulation (PENFS)	
IB-Stim (formerly Neruo-Stim)	Innovative Health Solutions	
	(TENS) (Not otherwise specified)	
A large number of TENS devices	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	As of the date of the most
have received marketing		recent policy review,
		Page 15 of 27

clearance through the U.S. Food and Drug Administration over the past several decades; therefore, marketing clearance via the 510(k) process for new devices does not require data collection regarding clinical efficacy because these devices are considered substantially equivalent to predicate devices marketed to date.		around 30 products have been assigned to HCPCS code E0720 by the Medicare PDAC contractor
Electromagnetic Therapy		
Active Knee Systems (any size)	Orthocor Medical, Inc.	E0761
Diapulse Wound Treatment System	Diapulse Corp. of America	E0761
Roma Pulsed Electromagnetic Field (PEMF) Therapy	IVIVI Technologies, Inc.	E0761
Provant	Regenesis Biomedical, Inc.	E0769

REPLACEMENT

Replacement of **implanted** electrical stimulation devices are subject to Medicare rules for *prosthetic* device replacement. Specifically, documentation must demonstrate both of the following (1 and 2):

- 1) One of the following (a or b):
 - a) A change in physiological condition of the member and their current device does not adequately provide the necessary therapeutic benefit; or
 - b) There is an irreparable change in the condition of the device or part of the device.
- 2) There is no warranty provision provided by the manufacturer to either replace or repair the current device.³

Replacement of **non-implanted** electrical stimulation devices are subject to Medicare rules for *DME* replacement. To be eligible for replacement, items must continue to be medically necessary (providing therapeutic benefit), be irreparably worn or damaged, and no longer under any manufacturer warranty that would cover the cost of the repair or replacement. Replacement of an entire device may also be allowed if a *component* is non-functional but is no longer available and cannot be replaced with comparable part.

If an electrical stimulation device is still functioning and providing therapeutic benefit, the clinical documentation must support the need for a new device, other than being a request for an upgrade. Replacement of supplies or components (e.g., leads, lead wires, etc.) is also allowed for electrical stimulation devices that continue to be medically necessary. Note that some supplies may have frequency and utilization limitations established by Medicare (e.g., TENS replacement supplies noted in LCD L33802, etc.).

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 associated local coverage articles (LCAs) for related billing and coding guidance, as well as additional coverage and non-coverage scenarios and frequency utilization allowances and limitations:

- LCA: Transcutaneous Electrical Nerve Stimulators (TENS) Policy Article (A52520)
- LCA: External Upper Limb Tremor Stimulator Therapy Policy Article (A59680)

AURICULAR ELECTROSTIMULATION

According to both Noridian and the Palmetto GBA PDAC Contractor websites^{4,5}, the P-Stim® and E-Pulse are to be reported with HCPCS code A9270 (Non-covered item or service). HCPCS code S8930 is also available, but S-codes are not payable by Medicare. In January 2020, Medicare released an article (SE20001) that advises providers to not use HCPCS code L8679 (*Implantable neurostimulator, pulse generator, any type*) for electroacupuncture devices because "Electro-acupuncture devices and implantable neurostimulators are two separate devices, and coding electro-acupuncture devices as implantable neurostimulators is incorrect."

If a specific CPT code (e.g., 64555) is used incorrectly, or an unlisted code (e.g., 64999) is used instead of A9270 or S8930, the service is non-covered per the Medicare reference noted in the "Medicare Policy Criteria" section of the policy. CPT codes 97813 or 97814 are not specific to auricular electrostimulation, therefore, if they are billed for this service they will also be denied.

This coding and non-coverage rationale is applicable to all electro-acupuncture or auricular electrostimulation devices and is consistent with other Medicare contractors with published policies.^{7,8}

CEFALY DEVICE

According to the Medicare Pricing, Data Analysis and Coding (PDAC) contractor, the Cefaly electrical pulse generator (EPG) and electrodes kit are reported with HCPCS code E0720, which is the HCPCS code used for TENS.

Between October 1, 2023 and December 31, 2023, the PDAC determined the **Cefaly Dual** system was to be reported with HCPCS code K1016. As of January 1, 2024, this device has been assigned to HCPCS code E0733.

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")⁹ 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.⁶

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). Therefore, HCPCS codes L8680 will also be denied as not separately billable for Medicare or Medicare Advantage.

General

Coverage indicators assigned by Medicare to HCPCS codes can be found on the <u>Medicare HCPCS</u> <u>Quarterly Updates website</u>.

HCPCS CODE A9900

While HCPCS code A9900 is a miscellaneous code (i.e., it does not represent a single device or type of device), Medicare considers this code to be non-covered regardless of what it is used for. Therefore, this code will deny as not separately reimbursable.¹¹

ELECTRICAL STIMULATION OR ELECTROMAGNETIC THERAPY DEVICES

According to NCD 270.1 and NCD 280.1, unsupervised use of ES or electromagnetic therapy for wound therapy will not be covered, including the use of these devices in the home setting. In addition, while Medicare allows coverage of the application of electrical stimulation or electromagnetic therapy for the treatment of wounds (G0281, G0329), separate reimbursement is not made for the device itself (E0761, E0769). Therefore, these codes (E0761, E0769) will be denied as not medically necessary.

CODE	CODES*				
СРТ	0278T	Transcutaneous electrical modulation pain reprocessing (eg, scrambler therapy), each treatment session (includes placement of electrodes)			
	0720T	Percutaneous electrical nerve field stimulation, cranial nerves, without implantation			
	0766T	Transcutaneous magnetic stimulation by focused low-frequency electromagnetic pulse, peripheral nerve, with identification and marking of the treatment location, including noninvasive electroneurographic localization (nerve conduction localization), when performed; first nerve			
	0767T	Transcutaneous magnetic stimulation by focused low-frequency electromagnetic pulse, peripheral nerve, with identification and marking of the treatment location, including noninvasive electroneurographic localization (nerve conduction localization), when performed; each additional nerve (List separately in addition to code for primary procedure)			
	0768T	TERMED 12/31/2023 Transcutaneous magnetic stimulation by focused low-frequency electromagnetic pulse, peripheral nerve, subsequent treatment, including noninvasive electroneurographic localization (nerve conduction localization), when performed; first nerve			
	0769T	TERMED 12/31/2023 Transcutaneous magnetic stimulation by focused low-frequency electromagnetic pulse, peripheral nerve, subsequent treatment, including noninvasive electroneurographic localization (nerve conduction localization), when performed; each additional nerve (List separately in addition to code for primary procedure)			
	0783T	Transcutaneous auricular neurostimulation, set-up, calibration, and patient education on use of equipment			
	0784T	Insertion or replacement of percutaneous electrode array, spinal, with integrated neurostimulator, including imaging guidance, when performed			
	0785T	Revision or removal of neurostimulator electrode array, spinal, 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			
	0882T	Intraoperative therapeutic electrical stimulation of peripheral nerve to promote nerve regeneration, including lead placement and removal, upper extremity, minimum of 10 minutes; initial nerve (List separately in addition to code for primary procedure)			

0883T	Intraoperative therapeutic electrical stimulation of peripheral nerve to promote nerve regeneration, including lead placement and removal, upper extremity,
	minimum of 10 minutes; each additional nerve (List separately in addition to code for primary procedure)
43647	Laparoscopy, surgical; implantation or replacement of gastric neurostimulator
43047	electrodes, antrum
43648	Laparoscopy, surgical; revision or removal of gastric neurostimulator electrodes, antrum
43659	Unlisted laparoscopy procedure, stomach
43881	Implantation or replacement of gastric neurostimulator electrodes, antrum, open
43882	Revision or removal of gastric neurostimulator electrodes, antrum, open
43999	Unlisted procedure, stomach
61850	Twist drill or burr hole(s) for implantation of neurostimulator electrodes, cortical
61860	Craniectomy or craniotomy for implantation of neurostimulator electrodes, cerebral, cortical
61863	Twist drill, burr hole, craniotomy, or craniectomy with stereotactic implantation of neurostimulator electrode array in subcortical site (eg, thalamus, globus pallidus, subthalamic nucleus, periventricular, periaqueductal gray), without use of intraoperative microelectrode recording; first array
61864	Twist drill, burr hole, craniotomy, or craniectomy with stereotactic implantation of neurostimulator electrode array in subcortical site (eg, thalamus, globus pallidus, subthalamic nucleus, periventricular, periaqueductal gray), without use of intraoperative microelectrode recording; each additional array (List separately in addition to primary procedure)
61867	Twist drill, burr hole, craniotomy, or craniectomy with stereotactic implantation of
01007	neurostimulator electrode array in subcortical site (eg, thalamus, globus pallidus, subthalamic nucleus, periventricular, periaqueductal gray), with use of intraoperative microelectrode recording; first array
61868	Twist drill, burr hole, craniotomy, or craniectomy with stereotactic implantation of
01000	neurostimulator electrode array in subcortical site (eg, thalamus, globus pallidus, subthalamic nucleus, periventricular, periaqueductal gray), with use of intraoperative microelectrode recording; each additional array (List separately in addition to primary procedure)
61880	Revision or removal of intracranial neurostimulator electrodes
61885	Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to a single electrode array
61886	Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to 2 or more electrode arrays
61888	Revision or removal of cranial neurostimulator pulse generator or receiver
61889	Insertion of skull-mounted cranial neurostimulator pulse generator or receiver, including craniectomy or craniotomy, when performed, with direct or inductive coupling, with connection to depth and/or cortical strip electrode array(s)
61891	Revision or replacement of skull-mounted cranial neurostimulator pulse generator or receiver with connection to depth and/or cortical strip electrode array(s)
61892	Removal of skull-mounted cranial neurostimulator pulse generator or receiver with cranioplasty, when performed
63650	Percutaneous implantation of neurostimulator electrode array, epidural
63655	Laminectomy for implantation of neurostimulator electrodes, plate/paddle, epidural

63661	Removal of spinal neurostimulator electrode percutaneous array(s), including fluoroscopy, when performed
63662	Removal of spinal neurostimulator electrode plate/paddle(s) placed via
	laminotomy or laminectomy, including fluoroscopy, when performed
63663	Revision including replacement, when performed, of spinal neurostimulator
	electrode percutaneous array(s), including fluoroscopy, when performed
63664	Revision including replacement, when performed, of spinal neurostimulator
	electrode plate/paddle(s) placed via laminotomy or laminectomy, including fluoroscopy, when performed
63685	Insertion or replacement of spinal neurostimulator pulse generator or receiver,
	requiring pocket creation and connection between electrode array and pulse
	generator or receiver
63688	Revision or removal of implanted spinal neurostimulator pulse generator or
	receiver, with detachable connection to electrode array
64553	Percutaneous implantation of neurostimulator electrode array; cranial nerve
64555	Percutaneous implantation of neurostimulator electrode array; peripheral nerve (excludes sacral nerve)
64568	Open implantation of cranial nerve (eg, vagus nerve) neurostimulator electrode
6.45.60	array and pulse generator
64569	Revision or replacement of cranial nerve (eg, vagus nerve) neurostimulator
64570	electrode array, including connection to existing pulse generator Removal of cranial nerve (eg, vagus nerve) neurostimulator electrode array and
04370	pulse generator
64575	Open implantation of neurostimulator electrode array; peripheral nerve (excludes
	sacral nerve)
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
04333	generator or receiver, with detachable connection to electrode array
64596	Insertion or replacement of percutaneous electrode array, peripheral nerve, with
	integrated neurostimulator, including imaging guidance, when performed; initial
	electrode array
64597	Insertion or replacement of percutaneous electrode array, peripheral nerve, with
	integrated neurostimulator, including imaging guidance, when performed; each
	additional electrode array (List separately in addition to code for primary
	procedure)
64598	Revision or removal of neurostimulator electrode array, peripheral nerve, with
64000	integrated neurostimulator
64999	Unlisted procedure, nervous system
95836	Electrocorticogram from an implanted brain neurostimulator pulse
	generator/transmitter, including recording, with interpretation and written report, up to 30 days
95970	Electronic analysis of implanted neurostimulator pulse generator system (eg, rate,
33370	pulse amplitude, pulse duration, configuration of wave form, battery status,
	electrode selectability, output modulation, cycling, impedance and patient
	compliance measurements); simple or complex brain, spinal cord, or peripheral (ie,
	cranial nerve, peripheral nerve, sacral nerve, neuromuscular) neurostimulator
	pulse generator/transmitter, without reprogramming

95971	Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with simple spinal cord or peripheral nerve (eg, sacral nerve) neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional
95972	Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with complex spinal cord or peripheral nerve (eg, sacral nerve) neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional
95974	Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude, pulse duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); complex cranial nerve neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming, with or without nerve interface testing, first hour
95975	Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude, pulse duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); complex cranial nerve neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming, each additional 30 minutes after first hour (List separately in addition to code for primary procedure)
95976	Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with simple cranial nerve neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional
95977	Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with complex cranial nerve neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional
95980	Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient measurements) gastric neurostimulator pulse generator/transmitter; intraoperative, with programming
95981	Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude and duration, configuration of wave form, battery status,

	electrode selectability, output modulation, cycling, impedance and patient measurements) gastric neurostimulator pulse generator/transmitter; subsequent, without reprogramming
95982	Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient measurements) gastric neurostimulator pulse generator/transmitter; subsequent, with reprogramming
95983	Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with brain neurostimulator pulse generator/transmitter programming, first 15 minutes face-to-face time with physician or other qualified health care professional
95984	Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with brain neurostimulator pulse generator/transmitter programming, each additional 15 minutes face-to-face time with physician or other qualified health care professional (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
97110	Therapeutic procedure, 1 or more areas, each 15 minutes; therapeutic exercises to develop strength and endurance, range of motion and flexibility
97535	Self-care/home management training (eg, activities of daily living (ADL) and compensatory training, meal preparation, safety procedures, and instructions in use of assistive technology devices/adaptive equipment) direct one-on-one contact, each 15 minutes
A4438	Adhesive clip applied to the skin to secure external electrical nerve stimulator controller, each
A4540	Distal transcutaneous electrical nerve stimulator, stimulates peripheral nerves of the upper arm
A4541	Monthly supplies for use of device coded at E0733
A4542	Supplies and accessories for external upper limb tremor stimulator of the
	peripheral nerves of the wrist
A4543	Supplies for transcutaneous electrical nerve stimulator, for nerves in the auricular region, per month
A4556	Electrodes, (e.g., apnea monitor), per pair
A4557	Lead wires, (e.g., apnea monitor), per pair
A4558	Conductive gel or paste, for use with electrical device (e.g., TENS, NMES), per oz
A4593	Neuromodulation stimulator system, adjunct to rehabilitation therapy regime
A4594	Neuromodulation stimulator system, adjunct to rehabilitation therapy regime, mouthpiece each
A4595	Electrical stimulator supplies, 2 lead, per month, (e.g., TENS, NMES)
A4596	Cranial electrotherapy stimulation (CES) system supplies and accessories, per month
	95983 95984 97014 97032 97110 97535 A4438 A4540 A4541 A4542 A4543 A456 A457 A456 A457 A458 A4593 A4594 A4595

A4630	Replacement batteries, medically necessary, transcutaneous electrical stimulator,
	owned by patient
A9270	Non-covered item or service
A9900	Miscellaneous DME supply, accessory, and/or service component of another HCPCS code
A9999	Miscellaneous DME supply or accessory, not otherwise specified
C1767	Generator, neurostimulator (implantable), non-rechargeable
C1778	Lead, neurostimulator (implantable)
C1787	Patient programmer, neurostimulator
C1816	Receiver and/or transmitter, neurostimulator (implantable)
C1820	Generator, neurostimulator (implantable), with rechargeable battery and charging system
C1822	Generator, neurostimulator (implantable), high frequency, with rechargeable battery and charging system
C1823	Generator, neurostimulator (implantable), non-rechargeable, with transvenous sensing and stimulation leads
C1826	Generator, neurostimulator (implantable), includes closed feedback loop leads and all implantable components, with rechargeable battery and charging system
C1827	Generator, neurostimulator (implantable), non-rechargeable, with implantable stimulation lead and external paired stimulation controller
C1883	Adapter/extension, pacing lead or neurostimulator lead (implantable)
C1897	Lead, neurostimulator test kit (implantable)
E0720	Transcutaneous electrical nerve stimulation (TENS) device, 2 lead, localized stimulation
E0721	Transcutaneous electrical nerve stimulatory, stimulates nerves in the auricular
	region
E0730	Transcutaneous electrical nerve stimulation (TENS) device, 4 or more leads, for
	multiple nerve stimulation
E0731	Form fitting conductive garment for delivery of TENS or NMES (with conductive
	fibers separated from the patient's skin by layers of fabric)
E0732	Cranial electrotherapy stimulation (CES) system, any type
E0733	Transcutaneous electrical nerve stimulator for electrical stimulation of the trigeminal nerve
E0734	External upper limb tremor stimulator of the peripheral nerves of the wrist
E0735	Non-invasive vagus nerve stimulator
E0744	Neuromuscular stimulator for scoliosis
E0745	Neuromuscular stimulator, electronic shock unit
E0761	Non-thermal pulsed high frequency radiowaves, high peak power electromagnetic energy treatment device
E0762	Transcutaneous electrical joint stimulation device system, includes all accessories
E0764	Functional neuromuscular stimulation, transcutaneous stimulation of sequential
20701	muscle groups of ambulation with computer control, used for walking by spinal cord injured, entire system, after completion of training program
E0765	FDA approved nerve stimulator, with replaceable batteries, for treatment of
20.00	nausea and vomiting
E0769	Electrical stimulation or electromagnetic wound treatment device, not otherwise classified
E0770	Functional electrical stimulator, transcutaneous stimulation of nerve and/or
	muscle groups, any type, complete system, not otherwise specified

E1399	Durable medical equipment, miscellaneous
G0281	Electrical stimulation, (unattended), to one or more areas, for chronic stage III and
	stage IV pressure ulcers, arterial ulcers, diabetic ulcers, and venous stasis ulcers
	not demonstrating measurable signs of healing after 30 days of conventional care,
	as part of a therapy plan of care
G0282	Electrical stimulation, (unattended), to one or more areas, for wound care other
	than described in G0281 (Medicare Status "N" code)
G0283	Therapeutic procedures to improve respiratory function, other than described by
00283	G0237, one on one, face to face, per 15 minutes (includes monitoring)
G0295	Electromagnetic therapy, to one or more areas, for wound care other than
	described in G0329 or for other uses (Medicare Status "N" code)
G0329	Electromagnetic therapy, to one or more areas for chronic stage III and stage IV
	pressure ulcers, arterial ulcers, diabetic ulcers and venous stasis ulcers not
	demonstrating measurable signs of healing after 30 days of conventional care as
	part of a therapy plan of care
K1002	TERMED 12/31/2023
	Cranial electrotherapy stimulation (CES) system, any type
K1016	TERMED 12/31/2023
	Transcutaneous electrical nerve stimulator for electrical stimulation of the
1/4047	trigeminal nerve
K1017	TERMED 12/31/2023
1/4.04.0	Monthly supplies for use of device coded at K1016
K1018	TERMED 12/31/2023
1/4.04.0	External upper limb tremor stimulator of the peripheral nerves of the wrist
K1019	TERMED 12/31/2023
	Replacement supplies and accessories for external upper limb tremor stimulator of
1/4020	the peripheral nerves of the wrist
K1020	TERMED 12/31/2023
K1023	Non-invasive vagus nerve stimulator TERMED 12/31/2023
N1UZ3	Distal transcutaneous electrical nerve stimulator, stimulates peripheral nerves of
	the upper arm
L8679	Implantable neurostimulator, pulse generator, any type
L8680	Implantable neurostimulator, puise generator, any type Implantable neurostimulator electrode, each (Medicare HCPCS Coverage indicator
LOUGU	"I" – Use L8679)
L8681	Patient programmer (external) for use with implantable programmable
10001	neurostimulator pulse generator, replacement only
L8682	Implantable neurostimulator radiofrequency receiver
L8683	Radiofrequency transmitter (external) for use with implantable neurostimulator
10003	radiofrequency receiver
L8685	Implantable neurostimulator pulse generator, single array, rechargeable, includes
10003	extension (Medicare HCPCS Coverage indicator "I" – Use L8679)
L8686	Implantable neurostimulator pulse generator, single array, non-rechargeable,
20000	includes (Medicare HCPCS Coverage indicator "1" – Use L8679)
L8687	Implantable neurostimulator pulse generator, dual array, rechargeable, includes
	extension (<i>Medicare HCPCS Coverage indicator "I" – Use L8679</i>)
L8688	Implantable neurostimulator pulse generator, dual array, non-rechargeable,
20000	includes extension (<i>Medicare HCPCS Coverage indicator "I" – Use L8679</i>)
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
S8130	Interferential current stimulator, 2 channel (Medicare Status "I" code)
S8131	Interferential current stimulator, 4 channel (Medicare Status "I" code)
S8930	Electrical stimulation of auricular acupuncture points; each 15 minutes of personal
	one-on-one contact with patient (Medicare Status "I" 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 <u>not</u> 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 <u>Medical Policy, Reimbursement Policy, Pharmacy Policy and Provider Information website</u> 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. Noridian web page for <u>Correct Coding Interferential Current (IFC) Therapy Devices</u>; Last Updated: July 27, 2018. Accessed 5/8/2024.
- 2. Palmetto GBA Pricing, Data Analysis and Coding (PDAC) Contractor web page for <u>CORRECT CODING INTERFERENTIAL CURRENT (IFC) THERAPY DEVICES</u>; Last Updated: April 5, 2017. Accessed 5/8/2024.
- 3. Medicare Benefit Policy Manual, Chapter 16 General Exclusions From Coverage, §40.4 Items Covered Under Warranty
- 4. Noridian web page for <u>Correct Coding P-stim Device</u>; Last Updated: 6/26/2018. Accessed 05/8/2024.
- 5. Medicare Pricing, Data Analysis and Coding (PDAC) Contractor Palmetto GBA <u>website and Product</u> Classification List
- 6. MLN Matters® Article SE20001 January 2020; <u>Incorrect Billing of HCPCS L8679 Implantable Neurostimulator</u>, <u>Pulse Generator</u>, <u>Any Type</u>; Accessed 5/8/2024.
- 7. Novitas Solutions, Inc. LCA for *Billing and Coding: Auricular Peripheral Nerve Stimulation (Electro-Acupuncture Device)* (A55240); Last Cited 5/8/2024.
- 8. Wisconsin Retired LCA for *Billing and Coding: Percutaneous Electrical Nerve Stimulation (PENS) and Percutaneous Neuromodulation Therapy (PNT)* (A56062); Last Cited 5/8/2024.
- Medicare Change Request 8645, Transmittal 2902; Dated 03/11/2014; Available at: https://www.cms.gov/regulations-and-guidance/guidance/transmittals/downloads/r2902cp.pdf. Accessed 5/8/2024.
- 10. Medicare Change Request 8531, Transmittal 2836; Dated 12/13/2013; Available at: https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R2836CP.pdf. Accessed 5/8/2024.

- 11. Noridian web page for <u>Two New Codes Established for Miscellaneous Supplies</u>. Last Updated: 5/1/2017. Accessed 5/8/2024.
- 12. Medicare Claims Processing Manual, Chapter 32 Billing Requirements for Special Services, §11.1 Electrical Stimulation and §11.2 Electromagnetic Therapy

POLICY REVISION HISTORY

DATE	REVISION SUMMARY
1/2023	Q1 2023 code updates (converted to new format 2/2023)
5/2023	Interim update
10/2023	Annual review; Language revision due to policy changes from "Investigational" to "not
	medically necessary" for the Company Electrical Stimulation: Non-Covered Therapies and
	Gastric Electrical Stimulation policies, added codes for gastric electrical stimulation.
1/2024	Q1 2024 code updates and interim update; update title for Company spinal cord and
	dorsal root ganglion stimulation policy
4/2024	Interim update; add LCD for external upper limb tremor stimulator therapy
7/2024	Annual review and Q3 2024 code updates. Add table of example products.
10/2024	Q4 2024 code updates