

Medicare Medical Policy

Electrical Stimulation and Electromagnetic Therapies

MEDICARE MEDICAL POLICY NUMBER: 333

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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, Providence Plan Partners, and Ayin Health Solutions as applicable (referred to individually as “Company” and collectively as “Companies”).

PRODUCT AND BENEFIT APPLICATION

Medicare Only

MEDICARE COVERAGE CRITERIA

IMPORTANT NOTE: More than one Centers for Medicare and Medicaid Services (CMS) reference may apply to the same health care service, such as when more than one coverage policy is available (e.g., both an NCD and LCD exist). All references listed should be considered for coverage decision-making. The Company uses the most current version of a Medicare reference available at the time of publication; however, these websites are not maintained by the Company, so Medicare references and their corresponding hyperlinks may change at any time. If there is a conflict between the Company Medicare Medical Policy and CMS guidance, the CMS guidance will govern.

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 *Medical 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.).
 - **Oral appliance** nerve stimulation devices (K1029)
 - **Gastric electrical stimulation** (GES)

Service	Medicare Guidelines
Auricular Electrostimulation (0783U, A9270, E1399, S8930)	Under Medicare, auricular electrostimulation devices are not medically necessary .
	NOTES:

	<ul style="list-style-type: none"> • 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.
<i>Cefaly Device</i>	<i>See row for “Transcutaneous Electrical Nerve Stimulators (TENS) and Related Supplies”</i>
<i>Cranial Electrostimulation (Electrical Stimulation) Therapy (CES) (A4596, K1002, E1399)</i>	<ul style="list-style-type: none"> • Prior to 1/1/2021: NCD for Electrosleep Therapy (30.4) • On or after 1/1/2021: Cranial electrostimulation (or cranial electrical stimulation; CES) is considered not medically necessary for Medicare Plan members based on the Company medical policy for <i>Electrical Stimulation: Non-Covered Therapies (All Lines of Business Except Medicare)</i>. <u>Services deemed “investigational” when criteria are not met are considered not medically necessary for Medicare Plan members.</u>
<i>Deep Brain Stimulation (DBS) (Codes include but are not limited to, 61880, 61885, 61886, 61888)</i>	<ul style="list-style-type: none"> • Essential tremor (ET) and/or Parkinsonian tremor: NCD for Deep Brain Stimulation for Essential Tremor and Parkinson's Disease (160.24) • 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. <p>NOTE: For other indications not otherwise addressed (e.g., depression, obsessive compulsive disorder [OCD], etc.), DBS is not medically necessary.</p>
<i>Dorsal <u>Column</u> Stimulators (aka, Spinal Cord Stimulators or SCS) (Codes include, but are not limited to, 63650, 63655, 63661-63664, 63685, 63688)</i>	<ul style="list-style-type: none"> • NCD for Electrical Nerve Stimulators (160.7) • LCD for Spinal Cord Stimulators for Chronic Pain (L36204)
<i>Dorsal <u>Root Ganglion</u> (DRG) Stimulators (Codes include, but are not limited to, 63650, 63655, 63661-63664, 63685, 63688)</i>	DRG stimulation is considered not medically necessary for Medicare Plan members based on the Company medical policy for <i>Back: Implantable Spinal Cord and Dorsal Root Ganglion Stimulation (All Lines of Business Except Medicare)</i> . <u>Services deemed “investigational” when criteria are not met are considered not medically necessary for Medicare Plan members.</u>

<p><i>Electrical Stimulation (any type) for the Treatment of Motor Function Disorders (e.g., multiple sclerosis [MS], etc.)</i></p>	<p>NCD for Treatment of Motor Function Disorders with Electric Stimulation (160.2)</p> <p>NOTE: This includes the Cala Trio™ device (K1018, K1019), FDA-cleared for use to treat essential tremor (ET).</p>
<p><i>Electrical Stimulation (any type) or Electromagnetic Therapy for the Treatment of Wounds</i></p>	<p>NCD for Electrical Stimulation (ES) and Electromagnetic Therapy for the Treatment of Wounds (270.1)</p> <p>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.</p>
<p><i>Electrical Stimulation (any type) for the Treatment of Peripheral Neuropathies</i></p>	<p>LCD for Nerve Blockade for Treatment of Chronic Pain and Neuropathy (L35457) (<i>Coverage guidance specific to electrical stimulation for peripheral neuropathy is found within the LCD</i>)</p>
<p><i>Electrical Stimulation (any type) for the Treatment of Facial Nerve Paralysis</i></p>	<p>NCD for Electrotherapy for Treatment of Facial Nerve Paralysis (Bell's Palsy) (160.15)</p>
<p><i>Functional Electrical Stimulation (FES) (HCPCS codes E0770, E0764)</i></p>	<p>NCD for Neuromuscular Electrical Stimulation (160.12)</p> <p>NOTE: "Indications for FES other than to enable SCI patients to walk will be denied as not medically necessary." (Noridian web page for Functional Electrical Stimulation (FES) - Coverage and HCPCS Coding – Revised) Therefore, the use of FES for any condition or indication <u>not</u> noted as covered in the NCD is not medically necessary.</p>
<p><i>H-Wave Stimulation (E1399)</i></p>	<ul style="list-style-type: none"> • 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)"
<p><i>Implanted Peripheral Nerve Stimulators (CPT codes 64555, 64575, 64585, 64590, 64595)</i></p>	<ul style="list-style-type: none"> • NCD for Electrical Nerve Stimulators (160.7) • LCD for Peripheral Nerve Stimulation (L37360)
<p><i>Interferential Stimulation (IFS) or Interferential Current (IFC) Devices</i></p>	<p>Medicare considers IFC/IFS therapy devices to be forms of TENS or NMES, depending on the setting the device is configured to and used. These devices can be configured to either (1) provide pain relief like a TENS or (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}</p>

	<ul style="list-style-type: none"> • 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.
<i>Microcurrent Electrical Nerve Stimulation (MENS)</i>	<ul style="list-style-type: none"> • Wounds: See separate row for wound treatment above. • Peripheral neuropathy: See separate row for peripheral neuropathy above. • All other indications: MENS is considered not medically necessary for Medicare Plan members based on the Company medical policy for <i>Electrical Stimulation: Non-Covered Therapies (All Lines of Business Except Medicare)</i>. <u>Services deemed “investigational” when criteria are not met are considered not medically necessary for Medicare Plan members.</u>
<i>Monarch external Trigeminal Nerve Stimulation (eTNS) System for ADHD (Non-Implantable [External] Trigeminal Nerve Stimulation)</i>	See row for “Transcutaneous Electrical Nerve Stimulators (TENS) and Related Supplies”
<i>Neuromuscular Electrical Stimulator (NMES)</i>	<ul style="list-style-type: none"> • 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 (160.13) <p>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 Stimulation (FES) - Coverage and HCPCS Coding – Revised) Therefore, the use of NMES for any condition or indication <u>not</u> noted as covered in the NCD is not medically necessary.</p>
<i>Percutaneous Electrical Nerve Stimulation (PENS)</i>	<ul style="list-style-type: none"> • As a diagnostic procedure: NCD for Assessing Patient's Suitability for Electrical Nerve Stimulation Therapy (160.7.1) • All other indications: PENS is considered not medically necessary for Medicare Plan members based on the Company medical policy for <i>Electrical Stimulation: Non-Covered Therapies (All Lines of Business Except Medicare)</i>. <u>Services deemed “investigational” when criteria are not met are considered not medically necessary for Medicare Plan members.</u>
<i>Percutaneous Electrical Nerve Field Stimulation (PENFS) (0720T)</i>	PENFS is considered not medically necessary for Medicare Plan members based on the Company medical policy for Electrical Stimulation: Non-Covered Therapies (All Lines of Business Except Medicare). <u>Services deemed “investigational” when criteria are not met are considered not medically necessary for Medicare Plan members.</u>

<i>Percutaneous Neuromodulation Therapy (PNT)</i>	All indications: PNT is considered not medically necessary for Medicare Plan members based on the Company medical policy for <i>Electrical Stimulation: Non-Covered Therapies (All Lines of Business Except Medicare)</i> . <u>Services deemed “investigational” when criteria are not met are considered not medically necessary for Medicare Plan members.</u>
<i>Peripheral Nerve Field Stimulation (PNFS)</i>	LCA for Billing and Coding: Peripheral Nerve Stimulation (A55531)
<i>Phrenic Nerve Stimulators</i>	NCD for Phrenic Nerve Stimulatory (160.19)
<i>Peripheral Nerve Stimulation (Implantable)</i>	See row for “Implanted Peripheral Nerve Stimulators”
<i>Occipital Nerve Stimulation</i>	See row for “Implanted Peripheral Nerve Stimulators” NOTE: For occipital nerve ablation , see the separate medical policy for “ <i>Back: Facet Joint Interventions for Pain Management (Medicare Only)</i> ”
<i>Responsive Cortical Stimulation or Responsive Neurostimulation (RNS)</i>	I. RNS may be considered medically necessary for Medicare Plan members when criteria from the Company medical policy for <i>Deep Brain and Responsive Cortical Stimulation (All Lines of Business Except Medicare)</i> are met. II. RNS is considered not medically necessary for Medicare when criteria from the Company medical policy for <i>Deep Brain and Responsive Cortical Stimulation (All Lines of Business Except Medicare)</i> are not met. <u>Services deemed “investigational” when criteria are not met are considered not medically necessary for Medicare Plan members.</u>
<i>Spinal Cord Stimulators (SCS; e.g., Dorsal <u>Column</u> Stimulators)</i>	<ul style="list-style-type: none"> • NCD for Electrical Nerve Stimulators (160.7) • LCD for Spinal Cord Stimulators for Chronic Pain (L36204)
<i>Transcutaneous Electrical Joint Stimulation Devices (TEJSD) (E0762)</i>	Transcutaneous Electrical Joint Stimulation Devices (TEJSD) (L34821)
<i>Transcutaneous electrical modulation pain reprocessing (e.g., scrambler therapy; TEMPR) (O278T)</i>	TEMPR is considered not medically necessary for Medicare Plan members based on the Company medical policy for <i>Electrical Stimulation: Non-Covered Therapies (All Lines of Business Except Medicare)</i> . <u>Services deemed “investigational” when criteria are not met are considered not medically necessary for Medicare Plan members.</u>

Transcutaneous Electrical Nerve Stimulators (TENS) and Related Supplies

TENS used for **assessing suitability for electrical nerve stimulation:**

- NCD for Assessing Patient's Suitability for Electrical Nerve Stimulation Therapy ([160.7.1](#))

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) ([L33802](#))

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) ([L33802](#))

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; A9270, A9999, 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; K1016, K1017**): 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**.

	<p>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 PDAC Web page for Transcutaneous Electrical Nerve Stimulators (TENS) Sold Over-The-Counter – Coding Guidelines.)</p>
<p><i>Transcutaneous Magnetic Stimulation with Focused Low-Frequency Electromagnetic Pulse (Codes 0766T, 0767T, 0768T, 0769T)</i></p>	<p>Company medical policy for Electrical Stimulation: Non-covered Therapies (All LOB except Medicare)</p> <p>This service is considered not medically necessary for Medicare based on the Company medical policy. <u>Services deemed “investigational” are considered not medically necessary for Medicare Plan members. See Policy Guidelines below.</u></p>
<p><i>Vagus (vagal) nerve stimulation (VNS)</i></p>	<ul style="list-style-type: none"> • Implantable VNS: National Coverage Determination (NCD): Vagus Nerve Stimulation (VNS) (160.18) • All other VNS not addressed above: <u>Services deemed “investigational” are considered not medically necessary for Medicare Plan members.</u> Therefore, the following services are considered not medically necessary for Medicare, based on the Company medical policy for <i>Vagus Nerve Stimulation (All Lines of Business Except Medicare)</i>: <ul style="list-style-type: none"> ○ Noninvasive or non-implantable VNS (HCPCS K1020) ○ Transcutaneous vagus nerve stimulation ○ Percutaneous vagus nerve stimulation (CPT 64553)
<p><i>Revision, Replacement or Removal of Implanted Nerve Stimulator Devices (e.g., deep brain, spinal cord, vagus nerve, etc.)</i></p>	<p>For removal only:</p> <ul style="list-style-type: none"> • 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 <p>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.</p> <p>For revision/replacement:</p> <ul style="list-style-type: none"> • Medicare Benefit Policy Manual, Chapter 15 – Covered Medical and Other Health Services, §120 - Prosthetic Devices, D. Supplies, Repairs, Adjustments, and Replacement

	<p>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)</p>
<p>Replacement of <i>Nonimplanted Nerve Stimulator Devices, Components, and Accessories</i> (e.g., TENS, NMES, FES, IFC, etc.)</p>	<ul style="list-style-type: none"> • Replacement of TENS units and/or supplies: LCD: Transcutaneous Electrical Nerve Stimulators (TENS) (L33802) and related LCA (A52520) • Replacement of all other non-implanted electrical nerve stimulator devices: Medicare Benefit Policy Manual, Chapter 15 – Covered Medical and Other Health Services, §120 - Prosthetic Devices, A. General <p>NOTE:</p> <ol style="list-style-type: none"> 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
- Gastric Electrical Stimulation, MP107
- 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

The Company policy for *PHA Medicare Medical Policy Development and Application* (MP50) provides details regarding Medicare's definition of medical necessity and the hierarchy of Medicare references and resources during the development of medical policies, as well as the Plan's use of evidence-based processes for policy development. In the absence of Medicare coverage policies (e.g., manual, national coverage determination [NCD], local coverage determination [LCD], article [LCA], etc.), Medicare regulatory guidelines do allow Medicare Advantage Organizations (MAOs) to make their own coverage determinations, as long as the MAO applies an objective, evidence-based process, based on authoritative evidence. (*Medicare Managed Care Manual, Ch. 4, §90.5*)

Following an evidence-based assessment of current peer-reviewed medical literature, the Company may consider certain medical services or technologies to be "investigational." The term "investigational" is not limited to devices or technologies which have not received the appropriate governmental regulatory approval (e.g., U.S. Food and Drug Administration [FDA]), but rather may also mean the procedure, device, or technology does not meet all of the Company's technology assessment criteria, as detailed within the Company policy for *Definition: Experimental/Investigational* (MP5).

For Medicare, only medically reasonable and necessary services or items which treat illness or injury are eligible for Medicare coverage, as outlined in *Title XVIII of the Social Security Act, §1862(a)(1)(A)*. Thus,

services which lack scientific evidence regarding safety and efficacy because they are investigational are “not medically reasonable or necessary” for Medicare Plan members. (*Medicare Claims Processing Manual, Ch. 23, §30 A*)

GENERAL

The main types of e-stim are:

- electrical **nerve** stimulation and
- electrical **muscle** stimulation.

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
<ul style="list-style-type: none"> • Transcutaneous electrical nerve stimulators (TENS) • Neuromuscular electrical stimulation (NMES) • Transcutaneous electronic modulation pain reprocessing (TEMPR), aka scrambler therapy 	<ul style="list-style-type: none"> • Percutaneous electrical nerve stimulation (PENS) • Percutaneous electrical nerve field stimulation (PENFS) • Percutaneous neuromodulation therapy (PNT) 	<ul style="list-style-type: none"> • 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

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](#))

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.”⁶

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, this device and all components (pulse generator and electrodes) are reported with HCPCS code E0720, which is the HCPCS code used for TENS.

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).¹⁰ 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 [Medicare HCPCS Quarterly Updates website](#).

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).¹² Therefore, these codes (E0761, E0769) will be denied as not medically necessary.

CODES*		
CPT	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, initial treatment, 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, initial treatment, 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	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	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
	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 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 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
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, direct or inductive coupling
63688		Revision or removal of implanted spinal neurostimulator pulse generator or receiver
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 array and pulse generator
64569		Revision or replacement of cranial nerve (eg, vagus nerve) neurostimulator electrode array, including connection to existing pulse generator
64570		Removal of cranial nerve (eg, vagus nerve) neurostimulator electrode array and 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 or gastric neurostimulator pulse generator or receiver, direct or inductive coupling
64595		Revision or removal of peripheral or gastric neurostimulator pulse generator or receiver
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, 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
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
HCPCS	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
	A4595	Electrical stimulator supplies, 2 lead, per month, (e.g., TENS, NMES)
	A4596	Cranial electrotherapy stimulation (CES) system supplies and accessories, per month
	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
	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)
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 muscle groups of ambulation with computer control, used for walking by spinal cord injured, entire system, after completion of training program
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 (<i>Medicare Status "N" code</i>)
G0283	Therapeutic procedures to improve respiratory function, other than described by 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 (<i>Medicare Status "N" code</i>)
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	Cranial electrotherapy stimulation (CES) system, any type
K1016	Transcutaneous electrical nerve stimulator for electrical stimulation of the trigeminal nerve
K1017	Monthly supplies for use of device coded at K1016
K1018	External upper limb tremor stimulator of the peripheral nerves of the wrist
K1019	Replacement supplies and accessories for external upper limb tremor stimulator of the peripheral nerves of the wrist
K1020	Non-invasive vagus nerve stimulator
K1023	Distal transcutaneous electrical nerve stimulator, stimulates peripheral nerves of the upper arm
L8679	Implantable neurostimulator, pulse generator, any type
L8680	Implantable neurostimulator electrode, each (<i>Medicare HCPCS Coverage indicator "I" – Use L8679</i>)
L8681	Patient programmer (external) for use with implantable programmable neurostimulator pulse generator, replacement only
L8682	Implantable neurostimulator radiofrequency receiver
L8683	Radiofrequency transmitter (external) for use with implantable neurostimulator radiofrequency receiver
L8685	Implantable neurostimulator pulse generator, single array, rechargeable, includes extension (<i>Medicare HCPCS Coverage indicator "I" – Use L8679</i>)

L8686	Implantable neurostimulator pulse generator, single array, non-rechargeable, includes (Medicare HCPCS Coverage indicator "I" – Use L8679)
L8687	Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension (Medicare HCPCS Coverage indicator "I" – Use L8679)
L8688	Implantable neurostimulator pulse generator, dual array, non-rechargeable, includes extension (Medicare HCPCS Coverage indicator "I" – Use L8679)
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 **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. Noridian web page for [Correct Coding - Interferential Current \(IFC\) Therapy Devices](#); Last Updated: July 27, 2018
2. Palmetto GBA Pricing, Data Analysis and Coding (PDAC) Contractor web page for [CORRECT CODING – INTERFERENTIAL CURRENT \(IFC\) THERAPY DEVICES](#); Last Updated: April 5, 2017
3. Medicare Benefit Policy Manual, Chapter 16 - General Exclusions From Coverage, [§40.4 - Items Covered Under Warranty](#)
4. Noridian web page for [Correct Coding - P-stim Device](#); Last Cited 01/24/2022
5. Medicare Pricing, Data Analysis and Coding (PDAC) Contractor Palmetto GBA [website and Product Classification List](#);
6. MLN Matters® Article SE20001 January 2020; [Incorrect Billing of HCPCS L8679 - Implantable Neurostimulator, Pulse Generator, Any Type](#); Last Cited 01/24/2022
7. Novitas Solutions, Inc. LCA for Billing and Coding: Auricular Peripheral Nerve Stimulation (Electro-Acupuncture Device) ([A55240](#)); Last Cited 01/24/2022
8. Wisconsin LCA for Billing and Coding: Percutaneous Electrical Nerve Stimulation (PENS) and Percutaneous Neuromodulation Therapy (PNT) ([A56062](#)); Last Cited 01/24/2022

9. Medicare Change Request 8645, Transmittal 2902; Dated 03/11/2014; Available at: <https://www.cms.gov/regulations-and-guidance/guidance/transmittals/downloads/r2902cp.pdf>
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>
11. Noridian web page for [Two New Codes Established for Miscellaneous Supplies](#)
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)