

UnitedHealthcare® Medicare Advantage Coverage Summary

Electrical and Ultrasonic Stimulators

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Instructions for Use

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Related Medicare Advantage Policy Guideline

Transcutaneous Electrical Nerve Stimulation (TENS)

Coverage Guidelines

Electrical and spinal cord stimulators are covered in accordance with Medicare coverage criteria.

Note: The guidelines in this Coverage Summary are for specific procedures only. For procedures not addressed in this Coverage Summary, refer to the <u>Medicare Coverage Database</u> to search for applicable coverage policies (National Coverage Determinations, Local Coverage Determinations and Local Coverage Articles).

Notes:

• DME Face to Face Requirement: Section 6407 of the Affordable Care Act (ACA) established a face-to-face encounter requirement for certain items of DME (including transcutaneous electrical nerve stimulation; form fitting conductive garments for delivery of TENS or NMES; pelvic floor stimulator; neuromuscular stimulator electric shock unit; transcutaneous electrical joint stimulation system; functional neuromuscular stimulator; and FDA approved nerve stimulator for treatment of nausea and vomiting). For DME Face to Face Requirement information, refer to the Coverage Summary titled <u>Durable Medical Equipment (DME)</u>, <u>Prosthetics</u>, <u>Corrective Appliances/Orthotics</u> (<u>Non-Foot Orthotics</u>), <u>Nutritional Therapy</u>, and <u>Medical Supplies Grid</u>.

Specific Coding and Pricing Issues for HCPCS code L8680 and CPT code 63650: For neurostimulator devices, HCPCS code L8680 is no longer separately billable for Medicare because payment for electrodes has been incorporated in CPT code 63650. For additional information, refer to the MLN Matters® Article MM8645 dated March 11, 2014 at https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R2902CP.pdf.
 (Accessed January 10, 2024)

Neuromuscular Electrical Stimulator (NMES)

NMES is covered when criteria are met. Refer to the <u>National Coverage Determination (NCD) for Neuromuscular Electrical</u> Stimulation (NMES) (160.12).

For coverage of supplies necessary for NMES; refer to the NCD for Supplies Used in the Delivery of Transcutaneous Electrical Nerve Stimulation (TENS) and Neuromuscular Electrical Stimulation (NMES) (160.13). (Accessed January 10, 2024)

Functional Electrical Stimulation (FES) (HCPCS Codes E0770 and E0764)

FES is covered when criteria are met. Refer to the <u>National Coverage Determination (NCD) for Neuromuscular Electrical Stimulation (NMES) (160.12).</u>

Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) exist and compliance with these policies is required where applicable. These LCDs/ LCAs are available at https://www.cms.gov/medicare-coverage-database/search.aspx. (Accessed January 10, 2024)

Vagus Nerve Stimulation for Treatment of Chronic Pain Syndrome

Medicare does not have a National Coverage Determination (NCD) for implantable vagus nerve stimulation for the treatment of chronic pain syndrome. Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) do not exist at this time.

For coverage guidelines, refer to the UnitedHealthcare Commercial Medical Policy titled <u>Vagus and External Trigeminal Nerve</u> Stimulation.

Note: After searching the <u>Medicare Coverage Database</u>, if no LCD/LCA is found, then use the policy referenced above for coverage guidelines. (Accessed December 18, 2023)

Spinal Cord Stimulators (i.e., Dorsal Column Stimulators and Depth Brain Stimulators)

Spinal cord stimulators are covered when criteria are met. Refer to the NCD for Electrical Nerve Stimulators (160.7).

Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) exist and compliance with these policies is required where applicable. These LCDs/ LCAs are available at https://www.cms.gov/medicare-coverage-database/search.aspx. (Accessed January 10, 2024)

Dorsal Root Ganglion (DRG) Stimulators (CPT Code 63650)

DRG stimulators may be covered when coverage criteria for spinal cord stimulation are met. Refer to the NCD for Electrical Nerve Stimulators (160.7).

Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) exist and compliance with these policies is required where applicable. These LCDs/ LCAs are available at https://www.cms.gov/medicare-coverage-database/new-search/search.aspx. (Accessed January 10, 2024)

Deep Brain Stimulation for Essential Tremor and Parkinson's Disease

Deep brain stimulation for essential tremor and Parkinson's Disease is covered when Medicare criteria are met. Refer to the National Coverage Determination (NCD) for Deep Brain Stimulation for Essential Tremor and Parkinson's Disease (160.24). (Accessed January 10, 2024)

Implanted Peripheral Nerve Stimulators

Electrical nerve stimulators are covered when criteria are met. Refer to the NCD for Electrical Nerve Stimulators (160.7).

Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) exist and compliance with these policies is required where applicable. These LCDs/ LCAs are available at https://www.cms.gov/medicare-coverage-database/new-search/search.aspx.

Notes:

- When CPT code 64590 is used for gastric electrical stimulation therapy, refer to the Coverage Summary titled
 Gastroesophageal and Gastrointestinal (GI) Services and Procedures.
- For sacral nerve stimulation for incontinence, refer to the Coverage Summary titled <u>Urinary and Fecal Incontinence</u>, <u>Diagnosis</u>, and <u>Treatments</u>.

(Accessed January 10, 2024)

Percutaneous Peripheral Nerve Stimulation (PNS) (SPRINT endura® and SPRINT extensa®) Systems (CPT Code 64555)

Medicare does not have an NCD that specifically address these types of percutaneous peripheral nerve stimulators. Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) exist and compliance with these policies is required where applicable. For state specific LCDs/LCAs, refer to the table for <u>Percutaneous Peripheral Nerve Stimulation (PNS)</u>.

For coverage guidelines for states/territories with no LCDs/LCAs, refer to the UnitedHealthcare Commercial Medical Policy titled <u>Electrical Stimulation for the Treatment of Pain and Muscle Rehabilitation</u>.

Note: After checking the <u>Percutaneous Peripheral Nerve Stimulation (PNS)</u> table and searching the <u>Medicare Coverage Database</u>, if no LCD/LCA is found, then use the policy referenced above for coverage guidelines.

Electrical Osteogenic Stimulator

Invasive (Implantable) Stimulator (HCPCS Code E0749)

The invasive stimulator device is covered only for the following indications:

- Nonunion of long bone fractures;
- As an adjunct to spinal fusion surgery for patients at high risk of pseudarthrosis due to previously failed spinal fusion at the same site or for those undergoing multiple level fusions. A multiple level fusion involves 3 or more vertebrae (e.g., L3-L5, L4-S1, etc.).
- Effective April 1, 2000, nonunion of long bone fractures is considered to exist only when serial radiographs have confirmed that fracture healing has ceased for 3 or more months prior to starting treatment with the electrical osteogenic stimulator. Serial radiographs must include a minimum of 2 sets of radiographs, each including multiple views of the fracture site, separated by a minimum of 90 days.

Noninvasive Stimulator (HCPCS Codes E0747 and E0748)

The noninvasive stimulator device is covered only for the following indications:

- Nonunion of long bone fractures;
- Failed fusion, where a minimum of 9 months has elapsed since the last surgery;
- Congenital pseudarthroses;
- As an adjunct to spinal fusion surgery for patients at high risk of pseudarthrosis due to previously failed spinal fusion at the same site or for those undergoing multiple level fusions. A multiple level fusion involves 3 or more vertebrae (e.g., L3-L5, L4-S1, etc.);
- Effective April 1, 2000, nonunion of long bone fractures is considered to exist only when serial radiographs have confirmed that fracture healing has ceased for 3 or more months prior to starting treatment with the electrical osteogenic stimulator. Serial radiographs must include a minimum of 2 sets of radiographs, each including multiple views of the fracture site, separated by a minimum of 90 days.

Ultrasonic Osteogenic Stimulator (HCPCS Code E0760)

Effective April 27, 2005, noninvasive ultrasound stimulators are covered as medically reasonable and necessary for the treatment of nonunion bone fractures prior to surgical intervention. In demonstrating non-union fractures, the following must be met.

A minimum of 2 sets of radiographs, obtained prior to starting treatment with the osteogenic stimulator, separated by a minimum of 90 days. Each radiograph set must include multiple views of the fracture site accompanied with a written interpretation by a physician stating that there has been no clinically significant evidence of fracture healing between the 2 sets of radiographs.

Non-invasive ultrasonic stimulator is not covered for any of the following:

- Nonunion fractures of the skull, vertebrae and those that are tumor related.
- Fresh fractures and delayed unions.
- For use concurrently with other non-invasive osteogenic devices.

Refer the National Coverage Determination (NCD) for Osteogenic Stimulators (150.2).

Local Coverage Determination (LCDs)/Local Coverage Articles (LCAs) exist and compliance with these policies is required where applicable. Refer the DME MAC <u>LCD for Osteogenesis Stimulators (L33796)</u> (Accessed January 10, 2024)

Electrical Stimulation for the Treatment of Dysphagia

Medicare does not have a National Coverage Determination (NCD) specifically for the use electrical stimulation for the treatment of dysphagia. Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) exist and compliance with these policies is required where applicable. For specific LCDs/LCAs, refer to the table for <u>Electrical Stimulation for the Treatment of Dysphagia</u>.

For coverage guidelines for states/territories with no LCDs/LCAs, refer to the UnitedHealthcare Commercial Medical Policy titled Electrical Stimulation for the Treatment of Pain and Muscle Rehabilitation.

Note: After checking the <u>Electrical Stimulation for the Treatment of Dysphagia</u> table and searching the <u>Medicare Coverage Database</u>, if no LCD/LCA is found, then use the policy referenced above for coverage guidelines.

For speech-language pathology services for the treatment of dysphagia, refer the Coverage Summary titled <u>Skilled Nursing</u> <u>Facility</u>, <u>Rehabilitation</u>, <u>and Long-Term Acute Care Hospitalization</u>.

Percutaneous Electrical Nerve Stimulation (PENS)/Percutaneous Neuromodulation Therapy (PNT) for Pain Therapy

Medicare does not have a National Coverage Determination (NCD) for PENS and PNT for pain therapy. Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) do not exist.

For coverage guidelines, refer to the UnitedHealthcare Commercial Medical Policy titled <u>Electrical Stimulation for the Treatment of Pain and Muscle Rehabilitation</u>.

Note: After searching the <u>Medicare Coverage Database</u>, if no LCD/LCA is found, then use the policy referenced above for coverage guidelines. (Accessed January 10, 2024)

Occipital Nerve Stimulation for the Treatment of Occipital Neuralgia or Headaches (CPT 64590)

Medicare does not have an NCD that specifically address occipital nerve stimulation for the treatment of occipital neuralgia or headaches. Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) exist and compliance with these policies is required where applicable. For specific LCDs/LCAs, refer to the table for Occipital Nerve Stimulation.

For coverage guidelines for states/territories with no LCDs/LCAs, refer to the UnitedHealthcare Commercial Medical Policy titled Occipital Nerve Injections and Ablation (Including Occipital Neuralgia and Headache).

Note: After checking the <u>Percutaneous Peripheral Nerve Stimulation (PNS)</u> table and searching the <u>Medicare Coverage</u> <u>Database</u>, if no LCD/LCA is found, then use the policy referenced above for coverage guidelines.

Definitions

Neuromuscular Electrical Stimulation (NMES): NMES involves the use of a device which transmits an electrical impulse to the skin over selected muscle groups by way of electrodes. There are two broad categories of NMES. One type of device stimulates the muscle when the patient is in a resting state to treat muscle atrophy. The second type is used to enhance functional activity of neurologically impaired patients. NCD for Neuromuscular Electrical Stimulation (NMES) (160.12). (Accessed January 10, 2024)

Supporting Information

Electrical Stimulation for the Treatment of Dysphagia Accessed January 10, 2024				
LCD/LCA ID	LCD/LCA Title	Contractor Type	Contractor Name	Applicable States/Territories
L34578 (A56584)	Surface Electrical Stimulation in the Treatment of Dysphagia	Part A and B MAC	Palmetto GBA	AL, GA, NC, SC, TN, VA, WV
L34565 (A56648)	Home Health-Surface Electrical Stimulation in the Treatment of Dysphagia	Part A and B MAC	Palmetto GBA	AL, AR, FL, GA, IL, IN, KY, LA, MS, NC, NM, OH, OK, SC, TN, TX
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Percutaneous Peripheral Nerve Stimulation (PNS) (SPRINT endura® and SPRINT extensa® Systems) Accessed January 10, 2024				
LCD/LCA ID	LCD/LCA Title	Contractor Type	Contractor Name	Applicable States/Territories
L34328 (A55530)	Peripheral Nerve Stimulation	Part A and B MAC	Noridian Healthcare Solutions, LLC	AS, CA, GU, HI, MP, NV
L37360 (A55531)	Peripheral Nerve Stimulation	Part A and B MAC	Noridian Healthcare Solutions, LLC	AK, AZ, ID, MT, ND, OR, SD, WA, UT, WY
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Occipital Nerve Stimulation Accessed January 10, 2024				
LCD/LCA ID	LCD/LCA Title	Contractor Type	Contractor Name	Applicable States/Territories
L34328 (A55530)	Peripheral Nerve Stimulation	Part A and B MAC	Noridian Healthcare Solutions, LLC	AS, CA, GU, HI, MP, NV
L37360 (A55531)	Peripheral Nerve Stimulation	Part A and B MAC	Noridian Healthcare Solutions, LLC	AK, AZ, ID, MT, ND, OR, SD, WA, UT, WY
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Policy History/Revision Information

Date	Summary of Changes
01/10/2024	Coverage Guidelines
	 Vagus Nerve Stimulation for Treatment of Chronic Pain Syndrome (new to policy) Added language to indicate: Medicare does not have a National Coverage Determination (NCD) for implantable vagus nerve stimulation for the treatment of chronic pain syndrome Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) do not exist at this time For coverage guidelines, refer to the UnitedHealthcare Commercial Medical Policy titled Vagus and External Trigeminal Nerve Stimulation
	Definitions
	Removed definition of "Spinal Cord Stimulation"
	Supporting Information
	 Updated list of available LCDs/LCAs to reflect the most current information
	Archived previous policy version MCS090.10

Instructions for Use

This information is being distributed to you for personal reference. The information belongs to UnitedHealthcare and unauthorized copying, use, and distribution are prohibited. This information is intended to serve only as a general reference resource and is not intended to address every aspect of a clinical situation. Physicians and patients should not rely on this information in making health care decisions. Physicians and patients must exercise their independent clinical discretion and judgment in determining care. Each benefit plan contains its own specific provisions for coverage, limitations, and exclusions as stated in the Member's Evidence of Coverage (EOC)/Summary of Benefits (SB). If there is a discrepancy between this policy and the member's EOC/SB, the member's EOC/SB provision will govern. The information contained in this document is believed to be current as of the date noted.

The benefit information in this Coverage Summary is based on existing national coverage policy; however, Local Coverage Determinations (LCDs) may exist and compliance with these policies are required where applicable.

UnitedHealthcare follows Medicare coverage guidelines found in statutes, regulations, NCDs, and LCDs to determine coverage. The clinical coverage criteria governing the items or services in this coverage summary have not been fully established in applicable Medicare guidelines because there is an absence of any applicable Medicare statutes, regulations, NCDs, or LCDs setting forth coverage criteria and/or the applicable NCDs or LCDs include flexibility that explicitly allows for coverage in circumstances beyond the specific indications that are listed in an NCD or LCD. As a result, UnitedHealthcare applies internal coverage criteria in the UnitedHealthcare commercial policies referenced in this coverage summary. The coverage criteria in these commercial policies was developed through an evaluation of the current relevant clinical evidence in acceptable clinical literature and/or widely used treatment guidelines. UnitedHealthcare evaluated the evidence to determine whether it was of sufficient quality to support a finding that the items or services discussed in the policy might, under certain circumstances, be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

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