# Coverage Summary

## Stimulators: Electrical and Spinal Cord Stimulators

<table>
<thead>
<tr>
<th>Policy Number:</th>
<th>Products: UnitedHealthcare Medicare Advantage Plans</th>
<th>Original Approval Date:</th>
<th>Approved by: UnitedHealthcare Medicare Benefit Interpretation Committee</th>
<th>Last Review Date:</th>
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<tr>
<td>S-007</td>
<td>UnitedHealthcare Medicare Advantage Plans</td>
<td>12/15/2008</td>
<td>UnitedHealthcare Medicare Benefit Interpretation Committee</td>
<td>09/19/2017</td>
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</tbody>
</table>

**Related Medicare Advantage Policy Guidelines:**

- Electrical Nerve Stimulators (NCD 160.7)
- Electrotherapy for Treatment of Facial Nerve Paralysis (Bell’s Palsy) (NCD 160.15)
- Neuromuscular Electrical Stimulation-NMES (NCD 160.12)
- Phrenic Nerve Stimulator (NCD 160.19)
- Spinal Cord Stimulators for Chronic Pain
- Supplies Used in the Delivery of Transcutaneous Electrical Nerve Stimulation (TENS) and Neuromuscular Electrical Stimulation (NMES) (NCD 160.13)
- Transcutaneous Electrical Nerve Stimulation (TENS) for Acute Post-Operative Pain (NCD 10.2)
- Transcutaneous Electrical Nerve Stimulation (TENS) for Chronic Low Back Pain (CLBP) (NCD 160.27)
- Treatment of Motor Function Disorders with Electric Nerve Stimulation (NCD 160.2)

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4. Transcutaneous Electrical Nerve Stimulator (TENS)
5. Phrenic Nerve Stimulators
6. Electric Nerve Stimulators for the Treatment of Motor Function Disorders
7. Electrical Stimulation for the Treatment of Dysphagia (e.g., VitalStim®)
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### II. DEFINITIONS

### III. REFERENCES

### IV. REVISION HISTORY

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**Coverage Statement:** Electrical and spinal cord stimulators are covered in accordance with Medicare
coverage criteria.

Notes:

- **DME Face to Face Requirement**
  Effective **July 1, 2013**, 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 for scoliosis; neuromuscular stimulator electric shock unit; transcutaneous electrical joint stimulation system; functional neuromuscular stimulator; and FDA approved nerve stimulator for treatment of nausea & vomiting*). For DME Face to Face Requirement information, refer to the [Coverage Summary for Durable Medical Equipment (DME), Prosthetics, Corrective Appliances/Orthotics (Non-Foot Orthotics) and Medical Supplies Grid](https://www.cms.gov/outreach-and-education/medicare-learning-network-mln/MLNMattersArticles/downloads/mm8645.pdf). (Accessed August 29, 2017)

- **Specific Coding and Pricing Issues for HCPCS codes L8680 and CPT 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; see the MLN Matters® Article MM8645 dated March 11, 2014 at [https://www.cms.gov/outreach-and-education/medicare-learning-network-mln/MLNMattersArticles/downloads/mm8645.pdf](https://www.cms.gov/outreach-and-education/medicare-learning-network-mln/MLNMattersArticles/downloads/mm8645.pdf). (Accessed August 29, 2017)

**Guidelines/Notes:**

1. **Neuromuscular Electrical Stimulator (NMES)**

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

3. **Implanted Peripheral Nerve Stimulators**

4. **Transcutaneous Electrical Nerve Stimulator (TENS)**
   Also see the [Coverage Summary Durable Medical Equipment (DME), Prosthetics, Corrective Appliances/Orthotics (Non-Foot Orthotics) and Medical Supplies Grid](https://www.cms.gov/outreach-and-education/medicare-learning-network-mln/MLNMattersArticles/downloads/mm8645.pdf). (Accessed August 29, 2017)
For coverage of supplies necessary for TENS; see the NCD for Supplies Used in the Delivery of Transcutaneous Electrical Nerve Stimulation (TENS) and Neuromuscular Electrical Stimulation (NMES) (160.13). (Accessed August 29, 2017)


Note:
Transcutaneous Electrical Nerve Stimulation (TENS) for Chronic Low Back Pain (CLBP): Effective June 8, 2012, the Centers for Medicare & Medicaid Services (CMS) allowed coverage for TENS for CLBP only when the criteria outlined in the NCD for Transcutaneous Electrical Nerve Stimulation (TENS) for Chronic Low Back Pain (CLBP) (160.27) are met. As part of the Medicare clinical trial program, CMS will make payments for MA enrollees on a fee-for-service basis for covered clinical trial costs for TENS for CLBP. (Accessed August 29, 2017)

See the Coverage Summary for Experimental Procedures and Items, Investigational Devices and Clinical Trials for coverage and payment rules for clinical trials. Also see the Coverage Summary for Pain Management and Pain Rehabilitation.

5. Phrenic Nerve Stimulators
Phrenic nerve stimulator is covered for selected patients with partial or complete respiratory insufficiency; see the NCD for Phrenic Nerve stimulatory (160.19) (Accessed August 29, 2017)

6. Electric Nerve Stimulators for the Treatment of Motor Function Disorders
Electric nerve stimulators for the treatment of motor function disorders are not covered. See the NCD for Treatment of Motor Function Disorders with Electric Stimulation (160.2) (Accessed August 29, 2017)

7. Electrical Stimulation for the Treatment of Dysphagia (e.g., VitalStim®)
Electrical stimulation for the treatment of dysphagia (e.g., VitalStim) is not covered. See the NCD for Treatment of Motor Function Disorders with Electric Stimulation (160.2) (Accessed August 29, 2017)

Local Coverage Determinations (LCDs) exist and compliance with these LCDs is required where applicable. These LCDs all align which state electrical stimulation for the treatment of dysphagia is not covered. Refer to the LCD Availability Grid (Attachment A). (Accessed August 29, 2017)

For speech-language pathology services for the treatment of dysphagia, see the Coverage Summary for Rehabilitation: Medical Rehabilitation (OT, PT and ST, including Cognitive Rehabilitation).

8. Electrotherapy for the Treatment of Facial Nerve Paralysis (Bell's Palsy)
Electrotherapy for the treatment of facial nerve paralysis (Bell's Palsy) is not covered-because its clinical effectiveness has not been established; see the NCD for Electrotherapy for Treatment of Facial Nerve Paralysis (Bell's Palsy) (160.15). (Accessed August 29, 2017)

(Note: Electrotherapy for the treatment of facial nerve paralysis is the application of electrical stimulation to affected facial muscles to provide muscle innervation with the intention of preventing muscle degeneration. A device that generates an electrical current with controlled
frequency, intensity, wave form and type (galvanic or faradic) is used in combination with a pad electrode and a hand applicator electrode to provide electrical stimulation.

II. 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 (160.12)*. (Accessed August 29, 2017)

**Spinal Cord Stimulation:** Blocks pain conduction pathways and stimulates endorphins. The neurostimulator electrodes used for this purpose are implanted percutaneously in the epidural space through a special needle. *LCD for Spinal Cord Stimulation (Dorsal Column Stimulation) (L35450)*. (Accessed August 29, 2017)

III. REFERENCES

See above

IV. REVISION HISTORY

- **09/17/2017** Annual review; no updates.
- **09/20/2016** Annual review with the following updates:
  - Guideline 1 (Neuromuscular Electrical Stimulator) – deleted specific criteria in the Coverage Summary; criteria can be accessed in the reference NCD.
  - Guideline 2 [Spinal Cord Stimulators (i.e., Dorsal Column Stimulators] – updated to align with the reference NCD, added “*and Depth Brain Stimulators*” to the title.
  - Guideline 3 (Electrical Nerve Stimulators to treat Chronic Intractable Pain) – updated to align with the reference NCD
    - Changed guideline title to “Implanted Peripheral Nerve Stimulators”
    - Deleted the following from the guideline “*to treat chronic intractable pain (i.e., peripheral nerve stimulators and central nervous system stimulators)*”
- **01/19/2016** Added following language regarding *HCPCS* codes L8680 and 63650:
  
  “Specific Coding and Pricing Issues for *HCPCS* codes L8680 and 63650
  Note: 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; see the MLN Matters® Article MM8645 dated March 11, 2014 at https://www.cms.gov/outreach-and-education/medicare-learning-network-mln/lnhmattersarticles/downloads/mm8645.pdf. (Accessed January 7, 2016)”

- Updated reference link(s) of the applicable LCDs to reflect the new condensed LCD link(s).
- **10/20/2015** Annual review; no updates
- **10/21/2014** Annual review with the following updates:
  - Removed detailed DME Face-to-Face Requirement information and replaced with
Guideline #2 (Spinal Cord Stimulators)-Removed Utilization Guidelines section which was based on the available LCDs.

Updated the following definitions to include the applicable CMS references:
- Neuromuscular Electrical Stimulation (NMES)-Added reference link to the NCD for Neuromuscular Electrical Stimulation (160.12)
- Spinal Cord Stimulation-Added reference link to the LCD for Spinal Cord Stimulation (Dorsal Column Stimulation) (L34705)

05/20/2014 Guideline #7 (Electrical Stimulation for the Treatment of Dysphagia) - Replaced coverage guidelines with the language indicating:
Electrical stimulation for the treatment of dysphagia (e.g., VitalStim) is not covered. See the NCD for Treatment of Motor Function Disorders with Electric Stimulation (160.2)

- Local Coverage Determinations (LCDs) exist and compliance with these LCDs is required where applicable. These LCDs all align which state electrical stimulation for-the-treatment of dysphagia is not covered. Refer to the LCD Availability Grid (Attachment A).

10/24/2013 Annual review; no updates.

08/20/2013
- Added a note pertaining to the DME Face-to-Face Requirement in accordance with Section 6407 of the Affordable Care Act as defined in the 42 CFR 410.38(g).
- Guidelines #2.1 Spinal Cord Stimulators -Added applicable utilization guidelines (new to policy).

12/17/2012 Annual review; Guidelines #4 (Transcutaneous Electrical Nerve Stimulator) updated to include the information pertaining to the CMS coverage for Transcutaneous Electrical Nerve Stimulation for Chronic Low Back Pain (CLBP) based on the Medicare NCD for Transcutaneous Electrical Nerve Stimulation (TENS) for Chronic Low Back Pain (CLBP) (160.27). As confirmed by UnitedHealthcare Regulatory Department with CMS, this benefit is part of the Medicare clinical trial program, therefore, CMS will make payments for MA enrollees on a fee-for-service basis for covered clinical trial costs for TENS for CLBP.

12/19/2011 Annual review; Guidelines #1 Spinal cord stimulators updated; deleted the use of L20379 as basis for guidelines for states with no LCDs and added the reference to the NCD for Electrical Nerve Stimulators (160.7).

08/24/2011 LCD Availability Grids (Attachments A & B) reviewed and updated.

02/21/2011 Updated Guidelines #2 Spinal Cord Stimulators using the standard Coverage Summary language format. Also updated Guidelines #8 Electrical Stimulation for the Treatment of Dysphagia using the standard Coverage Summary language format; deleted the guidelines and reference to the specific LCDs as all states now have LCDs.
V. ATTACHMENT(S)

# Attachment A-LCD Availability Grid

**Electrical Stimulation for the Treatment of Dysphagia (e.g., VitalStim ®)**

CMS website accessed August 29, 2017

IMPORTANT NOTE: Use the applicable LCD based on member’s residence/place of service AND type of service.

<table>
<thead>
<tr>
<th>LCD ID</th>
<th>LCD Title</th>
<th>Contractor Type</th>
<th>Contractor</th>
<th>States</th>
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<tbody>
<tr>
<td>L34307</td>
<td>Medicine: Dysphagia/Swallowing Therapy</td>
<td>A and B MAC</td>
<td>Cahaba Government Benefit</td>
<td>AL, GA, TN</td>
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<td></td>
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<td></td>
<td>Administrators®, LLC</td>
<td></td>
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<tr>
<td>L34891</td>
<td>Speech-Language Pathology (SLP) Services: Dysphagia; Includes VitalStim®️ Therapy</td>
<td>A and B MAC</td>
<td>Novitas Solutions, Inc.</td>
<td>AR, CO, DC, DE, LA, MD, MS, NM, OK, PA, TX</td>
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<td>L34578</td>
<td>Surface Electrical Stimulation in the Treatment of Dysphagia</td>
<td>A and B MAC</td>
<td>Palmetto GBA</td>
<td>NC, SC, VA, WV</td>
</tr>
</tbody>
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End of Attachment A