## Coverage Summary

### Stimulators: Electrical and Spinal Cord Stimulators

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<tbody>
<tr>
<td>Approved by:</td>
<td>UnitedHealthcare Medicare Benefit Interpretation Committee</td>
<td>Last Review Date: 01/15/2019</td>
</tr>
</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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**II. DEFINITIONS**
I. COVERAGE

**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.

- **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. (Accessed October 2, 2018)

**Guidelines/Notes:**

1. **Neuromuscular Electrical Stimulator (NMES)**
   NMES is covered when criteria are met. See the NCD for Neuromuscular Electrical Stimulation (160.12). (Accessed October 2, 2018)

   For coverage of supplies necessary for NMES, see the NCD for Supplies Used in the Delivery of Transcutaneous Electrical Nerve Stimulation (TENS) and Neuromuscular Electrical Stimulation NMES (160.13). (Accessed October 2, 2018)

2. **Spinal Cord Stimulators (i.e., Dorsal Column Stimulators and Depth Brain Stimulators)**
   Spinal cord stimulators are covered when criteria are met. See the NCD for Electrical Nerve Stimulators (160.7). (Accessed October 2, 2018)

   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/overview-and-quick-search.aspx. (Accessed February 21, 2019)

3. **Implanted Peripheral Nerve Stimulators**
   Electrical nerve stimulators are covered when criteria are met. See the NCD for Electrical Nerve Stimulators (160.7). (Accessed January 10, 2019)

   Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) exist and compliance
with these policies is required where applicable. These LCDs/LCAs are available at 

Notes:
   - When CPT code 64590 is used for gastric electrical stimulation therapy, see the Coverage Summary for Stimulators: Gastroesophageal and Gastrointestinal (GI) Services and Procedures.
   - For sacral nerve stimulation for incontinence, see the Coverage Summary for Incontinence: Urinary and Fecal Incontinence, Diagnosis and Treatments.

4. Transcutaneous Electrical Nerve Stimulator (TENS)
   Transcutaneous Electrical Nerve Stimulator (TENS) are covered when coverage criteria are met. See the NCD for Transcutaneous Electrical Nerve Stimulator (TENS) for Acute Post-operative Pain (10.2). (Accessed October 2, 2018)

Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) exist and compliance with these policies is required where applicable. See the DME MAC LCD for Transcutaneous Electrical Nerve Stimulators (TENS) (L33802). (Accessed February 21, 2019)

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 October 2, 2018)

For an explanation of coverage for assessing patients suitability for electrical nerve stimulation therapy, see the NCD for Assessing Patient's Suitability for Electrical Nerve Stimulation Therapy (160.7.1). (Accessed October 2, 2018)

Also see the Coverage Summary Durable Medical Equipment (DME), Prosthetics, Corrective Appliances/Orthotics (Non-Foot Orthotics) and Medical Supplies Grid.

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 October 2, 2018)


5. Phrenic Nerve Stimulators
   Phrenic nerve stimulator is covered for selected patients with partial or complete respiratory insufficiency; see the NCD for Phrenic Nerve Stimulator (160.19). (Accessed October 2, 2018)

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 October 2, 2018)
7. **Electrical Stimulation for the Treatment of Dysphagia (e.g., VitalStim®)**
   - Medicare does not have a National Coverage Determination (NCD) for electrical stimulation for the treatment of dysphagia (e.g., VitalStim®)
   - 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 [LCD Availability Grid](attachment:A).
   - For states with no LCDs/LCAs, see the Novitas [LCDs for Speech-Language Pathology (SLP) Services: Dysphagia; Includes VitalStim® Therapy (L34891)] for coverage guideline. ([IMPORTANT NOTE: After checking the LCD Availability Grid and searching the Medicare Coverage Database, if no state LCD/LCA is found, then use the above referenced policy.])
   - Committee approval date: October 16, 2018
   - Accessed February 21, 2019

   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 October 2, 2018)

   ([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.])

9. **Percutaneous Electrical Nerve Stimulation (PENS) as Diagnostic Procedure**

   This diagnostic procedure which involves stimulation of peripheral nerves by a needle electrode inserted through the skin is performed only in a physician's office, clinic, or hospital outpatient department. Therefore, it is covered only when performed by a physician or incident to physician's service. If pain is effectively controlled by percutaneous stimulation, implantation of electrodes is warranted. See the [NCD for Assessing Patient's Suitability for Electrical Nerve Stimulation Therapy (160.7.1)] (Accessed October 2, 2018)

10. **Percutaneous Electrical Nerve Stimulation (PENS)/Percutaneous Neuromodulation Therapy (PNT) for Pain Therapy (e.g., BioWave)**
    - Medicare does not have a National Coverage Determination (NCD) for PENS and PNT for pain therapy.
    - 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 [LCD Availability Grid (Attachment B)].
    - For states with no LCDs/LCAs, see the UnitedHealthcare Commercial Medical Policy for Electrical Stimulation for the Treatment of Pain and Muscle Rehabilitation for coverage guideline. ([IMPORTANT NOTE: After checking the LCD Availability Grid and searching the Medicare Coverage Database, if no state LCD/LCA is found, then use the above referenced policy.])
    - Committee approval date: October 16, 2018
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 October 2, 2018)

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 February 21, 2019)

III. REFERENCES
See above

IV. REVISION HISTORY

04/01/2019  • Updated policy introduction; added language to clarify:
  o There are instances where [the Coverage Summary] may direct readers to a UnitedHealthcare Commercial Medical Policy, Medical Benefit Drug Policy, and/or Coverage Determination Guideline (CDG)
  o In the absence of a Medicare National Coverage Determination (NCD), Local Coverage Determination (LCD), or other Medicare coverage guidance, CMS allows a Medicare Advantage Organization (MAO) to create its own coverage determinations, using objective evidence-based rationale relying on authoritative evidence (Medicare IOM Pub. No. 100-16, Ch. 4, §90.5)

1/15/2019  Re-review with the following updates:

Guideline 3 (Implanted Peripheral Nerve Stimulators):
• Added a general statement that there are available LCDs.
• Added the following notes:
  o When CPT code 64590 is used for gastric electrical stimulation therapy, see the Coverage Summary for Stimulators: Gastroesophageal and Gastrointestinal (GI) Services and Procedures.
  o For sacral nerve stimulation for incontinence, see the Coverage Summary for Incontinence: Urinary and Fecal Incontinence, Diagnosis and Treatments
  o For sacroiliac joint injections for pain management, see the Coverage Summary for Pain Management and Pain Rehabilitation.

10/16/2018  Annual review with the following updates:

Guideline 2 [Spinal Cord Stimulators (i.e., Dorsal Column Stimulators and Depth Brain Stimulators)] – Updated language from “See the LCDs/LCAs for Spinal Cord Stimulation (Dorsal Column Stimulation) and LCDs/LCAs for Spinal Cord Stimulators for Chronic Pain” to “These LCDs/LCAs are available”.
Guideline 7 [Electrical Stimulation for the Treatment of Dysphagia (e.g., VitalStim®)] –

Removed the following language “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)/Local Coverage Articles (LCAs) exist and compliance with these policies is required where applicable. These LCDs/LCAs all align which state electrical stimulation for the treatment of dysphagia is not covered. Refer to the LCD Availability Grid (Attachment A). (Accessed August 7, 2018)”

Added the following language:

- “Medicare does not have a National Coverage Determination (NCD) for electrical stimulation for the treatment of dysphagia (e.g., VitalStim®)
- 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 LCD Availability Grid (Attachment A).
- For states with no LCDs/LCAs, see the Novitas LCDs for Speech-Language Pathology (SLP) Services: Dysphagia; Includes VitalStim® Therapy (L34891) for coverage guideline. (IMPORTANT NOTE: After checking the LCD Availability Grid and searching the Medicare Coverage Database, if no state LCD/LCA is found, then use the above referenced policy.)
- Committee approval date: October 16, 2018
- Accessed September 18, 2018”

09/18/2018 Updated Local Coverage Determination (LCD) Availability Grids; removed instruction to “use the applicable LCD based on member’s residence/place and type of service” (this note only applies when selecting the appropriate DME LCD Policy)

03/20/2018 Re-review with the following updates:

Guideline 4 [Transcutaneous Electrical Nerve Stimulator (TENS)]
- Added a reference link to NCD for Assessing Patient’s Suitability for Electrical Nerve Stimulation Therapy (160.7.1) for explanation of coverage assessing patient’s suitability for electrical nerve stimulation therapy.
- Added a reference link to the list of Medicare approved clinical trials for TENS for CLBP

Guideline 9 [Percutaneous Electrical Nerve Stimulation (PENS) as Diagnostic Procedure] - added guideline

Guideline 10 [Percutaneous Electrical Nerve Stimulation (PENS)/Percutaneous Neuromodulation Therapy (PNT) for Pain Therapy (e.g., BioWave)] - added new guideline

01/16/2018 Re-review with the following update:

Guideline 7 [Electrical Stimulation for the Treatment of Dysphagia (e.g., VitalStim®)] - Updated the applicable LCDs to include the most recent website links and effective dates related to the Cahaba-Palmetto jurisdiction transition; no change in guideline.

09/17/2017 Annual review; no updates.
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)”

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/mlnmattersarticles/downloads/mm8645.pdf. (Accessed January 7, 2016)”

Updated reference link(s) of the applicable LCDs to reflect the new condensed LCD link(s).

Annual review; no updates

Annual review with the following updates:

- Removed detailed DME Face-to-Face Requirement information and replaced with a reference link to the DME, Prosthetics, Corrective Appliances/Orthotic and Medical Supplies Grid.
- 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)

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).

Annual review; no updates.

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 February 21, 2019

<table>
<thead>
<tr>
<th>LCD ID</th>
<th>LCD Title</th>
<th>Contractor Type</th>
<th>Contractor</th>
<th>States</th>
</tr>
</thead>
<tbody>
<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>
</tr>
<tr>
<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 AL, GA, TN</td>
</tr>
</tbody>
</table>

End of Attachment A

### Attachment B - LCD Availability Grid

**Percutaneous Electrical Nerve Stimulation (PENS)/Percutaneous Neuromodulation Therapy (PNT) for Pain Therapy (e.g., BioWave)**

CMS website accessed February 21, 2019

<table>
<thead>
<tr>
<th>LCD ID</th>
<th>LCD Title</th>
<th>Contractor Type</th>
<th>Contractor</th>
<th>States</th>
</tr>
</thead>
<tbody>
<tr>
<td>A54794</td>
<td>Percutaneous Electrical Nerve stimulation (PENS) and Percutaneous Neuromodulation Therapy (PNT)</td>
<td>A and B MAC</td>
<td>First Coast Service Options, Inc.</td>
<td>FL, PR, VI</td>
</tr>
</tbody>
</table>

End of Attachment B