## Coverage Summary

### Stimulators: Electrical and Spinal Cord Stimulators

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<tbody>
<tr>
<td>Approved by:</td>
<td></td>
<td></td>
<td>UnitedHealthcare Medicare Benefit Interpretation Committee</td>
<td>Last Review Date:</td>
<td>09/18/2018</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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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 is required where applicable.
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 April 27, 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 August 29, 2017)

   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 August 29, 2017)

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 August 29, 2017)

   Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) exist and compliance with these policies is required where applicable. See the LCDs/LCAs for Spinal Cord Stimulation (Dorsal Column Stimulation) and LCDs/LCAs for Spinal Cord Stimulators for Chronic Pain at https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx. (Accessed August 7, 2018)

3. **Implanted Peripheral Nerve Stimulators**

   Electrical nerve stimulators are covered when criteria are met. See the NCD for Electrical Nerve Stimulators (160.7). (Accessed August 29, 2017)

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 August 29, 2017)
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 August 7, 2018)

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 March 7, 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 March 7, 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 August 29, 2017)


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)/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)

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.)

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 March 7, 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 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: March 20, 2018
   - Accessed August 7, 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 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 7, 2018)

III. REFERENCES

See above
IV. REVISION HISTORY

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.

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

Updated reference link(s) of the applicable LCDs to reflect the new condensed LCD link(s).
UHC MA Coverage Summary: Stimulators: Electrical and Spinal Cord Stimulators

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## V. ATTACHMENT(S)

### Attachment A - LCD Availability Grid

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

CMS website accessed August 7, 2018

<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>
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<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 August 7, 2018

<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>
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</table>

End of Attachment B