Coverage Summary

Stimulators: Electrical and Spinal Cord Stimulators

Approved by: UnitedHealthcare Medicare Benefit Interpretation Committee  Last Review Date: 09/17/2019

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)

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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.

There are instances where this document may direct readers to a UnitedHealthcare Commercial Medical Policy, Medical Benefit Drug Policy, and/or Coverage Determination Guideline (CDG). 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).

INDEX TO COVERAGE SUMMARY

I. COVERAGE
   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)
   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®)
   8. Electrotherapy for the Treatment of Facial Nerve Paralysis (Bell's Palsy)
   9. Percutaneous Electrical Nerve Stimulation (PENS) as Diagnostic Procedure
   10. Percutaneous Electrical nerve stimulation (PENS) and Percutaneous Neuromodulation Therapy (PNT) for Pain Therapy (e.g., BioWave)

II. DEFINITIONS

III. REFERENCES

IV. REVISION HISTORY
V. ATTACHMENTS

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 August 27, 2019)

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 27, 2019)

   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 27, 2019)

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 27, 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 https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx.

3. **Implanted Periperal Nerve Stimulators**
   Electrical nerve stimulators are covered when criteria are met. See the NCD for Electrical Nerve Stimulators (160.7). (Accessed August 27, 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 https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx.

Notes:

- When CPT code 64590 is used for gastric electrical stimulation therapy, see the Coverage Summary for Stimulators: Gastroesophageal and Gastrointestinal (GI) Services and
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 27, 2019)

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 March 19, 2020)

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 27, 2019)

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 August 27, 2019)

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; and member enrolled in an approved clinical study within three years after the publication of the CMS statement for TENS for Chronic Low Back Pain (i.e., June 8, 2015) under coverage with evidence development (CED) available at http://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/TENS.html. (Accessed August 27, 2019)

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

5. Phrenic Nerve Stimulators

Phrenic nerve stimulator is covered for selected patients with partial or complete respiratory insufficiency; see the NCD for Phrenic Nerve Stimulationary (160.19). (Accessed August 27, 2019)

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 27, 2019)

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/LCA Availability Grid (Attachment A).
- For states with no LCDs/LCAs, see the Novitas LCD/LCA for Speech-Language Pathology (SLP) Services: Dysphagia; Includes VitalStim® Therapy (L34891) for coverage guideline.
(IMPORTANT NOTE: After checking the LCD/LCA Availability Grid and searching the Medicare Coverage Database, if no state LCD/LCA is found, then use the above referenced policy.)

- Committee approval date: September 17, 2019
- Accessed May 18, 2020

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 27, 2019)

(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 August 27, 2019)

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/LCA 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/LCA Availability Grid and searching the Medicare Coverage Database, if no state LCD/LCA is found, then use the above referenced policy.)
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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 27, 2019)
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 March 19, 2020)*

III. REFERENCES

See above

IV. REVISION HISTORY

09/17/2019  Guideline 4 [Transcutaneous Electrical Nerve Stimulator (TENS)]
- Revised notation pertaining to TENS for chronic low back pain (CLBP):
  - Added language to indicate the member [must be] enrolled in an approved clinical study within three years after the publication of the Centers for Medicare and Medicaid Services (CMS) statement for TENS for Chronic Low Back Pain (i.e., June 8, 2015) under coverage with evidence development (CED)
  - Removed language indicating CMS will make payments for MA enrollees on a fee-for-service basis for covered clinical trial costs for TENS for CLBP

Attachments
- Updated Local Coverage Determination (LCD) Availability Grids to reflect the most current reference links

V. ATTACHMENTS

**Attachment A – LCD/LCA Availability Grid**

**Electrical Stimulation for the Treatment of Dysphagia (e.g., VitalStim®)**
CMS website accessed May 18, 2020

<table>
<thead>
<tr>
<th>ID #</th>
<th>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>AL, GA, NC, SC, TN, VA, WV</td>
</tr>
<tr>
<td>L34565</td>
<td>Home Health – Surface Electrical Stimulation in the Treatment of Dysphagia</td>
<td>A and B MAC</td>
<td>Palmetto GBA</td>
<td>AL, AR, FL, GA, IL, IN, KY, LA, MS, NC, NM, OH, OK, SC, TN, TX</td>
</tr>
</tbody>
</table>

End of Attachment A

**Attachment B – LCD/LCA Availability Grid**

**Percutaneous Electrical Nerve Stimulation (PENS)/Percutaneous Neuromodulation Therapy (PNT) for Pain Therapy (e.g., BioWave)**
CMS website accessed May 18, 2020

<table>
<thead>
<tr>
<th>ID #</th>
<th>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>
<tr>
<td>A56062</td>
<td>Percutaneous Electrical Nerve Stimulation (PENS) and Percutaneous Neuromodulation Therapy (PNT)</td>
<td>MAC Part A</td>
<td>Wisconsin Physicians Service Insurance Corporation</td>
<td>AK, AL, AR, AZ, CA, CO, CT, DE, FL*, GA, HI, IA, ID, IL, IN, KS, KY, LA, MA, MD, ME, MI, MO, MS, MT,</td>
</tr>
</tbody>
</table>
## Attachment B – LCD/LCA Availability Grid

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

CMS website accessed May 18, 2020

<table>
<thead>
<tr>
<th>ID #</th>
<th>Title</th>
<th>Contractor Type</th>
<th>Contractor</th>
<th>States</th>
</tr>
</thead>
<tbody>
<tr>
<td>A56062</td>
<td><strong>Percutaneous Electrical Nerve Stimulation (PENS) and Percutaneous Neuromodulation Therapy (PNT)</strong></td>
<td>MAC Part B</td>
<td>Wisconsin Physicians Service Insurance Corporation</td>
<td>NC, ND, NE, NH, NJ, NM, NV, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI, WV, WY (Note: States notated with an asterisk should follow the other available state-specific LCD/LCA listed on this grid. This WPS LCD/LCA only applies to states without asterisk.) IA, IN, KS, MI, MO, NE</td>
</tr>
</tbody>
</table>