Osteogenic Stimulators (NCD 150.2)

Guideline Number: MPG226.07
Approval Date: September 8, 2021

Overview

**Electrical Osteogenic Stimulators**

Electrical stimulation to augment bone repair can be attained either invasively or non-invasively. Invasive devices provide electrical stimulation directly at the fracture site either through percutaneously placed cathodes or by implantation of a coiled cathode wire into the fracture site. The power pack for the latter device is implanted into soft tissue near the fracture site and subcutaneously connected to the cathode, creating a self-contained system with no external components. The power supply for the former device is externally placed and the leads connected to the inserted cathodes. With the non-invasive device, opposing pads, wired to an external power supply, are placed over the cast. An electromagnetic field is created between the pads at the fracture site.

**Ultrasonic Osteogenic Stimulators**

An ultrasonic osteogenic stimulator is a noninvasive device that emits low intensity, pulsed ultrasound. The device is applied to the surface of the skin at the fracture site and ultrasound waves are emitted via a conductive coupling gel to stimulate fracture healing. The ultrasonic osteogenic stimulators are not be used concurrently with other non-invasive osteogenic devices.

Guidelines

**Electrical Osteogenic Stimulators**

Nationally Covered Indications

- Noninvasive Stimulator
  - 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
    - With spinal fusion surgery for patients at high risk of pseudarthrosis due to previously failed spinal fusion at the same site or for multiple level fusions involving 3 or more vertebrae
    - Nonunion of long bone fractures (only after 6 or more months have elapsed without healing of the fracture)
    - Nonunion of long bone fractures (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
Invasive (Implantable) Stimulator

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

- Nonunion of long bone fractures
- With 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 fusion involving 3 or more vertebrae
- Nonunion of long bone fractures (only after 6 or more months have elapsed without healing of the fracture)
- Nonunion of long bone fractures 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 Stimulators

Nationally Covered Indications

Ultrasonic osteogenic stimulators are covered as medically reasonable and necessary for the treatment of nonunion fractures. In demonstrating non-union fractures, CMS expects:

- 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; and,
- Indications that the patient failed at least one surgical intervention for the treatment of the fracture.

Noninvasive ultrasound stimulation for the treatment of nonunion bone fractures prior to surgical intervention is reasonable and necessary. In demonstrating non-union fractures, CMS expects:

- 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.

Nationally Non-Covered Indications

- Nonunion fractures of the skull, vertebrae, and those that are tumor-related are excluded from coverage.
- Ultrasonic osteogenic stimulators may not be used concurrently with other non-invasive osteogenic devices.
- Ultrasonic osteogenic stimulators for fresh fractures and delayed unions remain non-covered.

Documentation Requirements - General

There are numerous CMS manual requirements, reasonable and necessary requirements, benefit category, and other statutory and regulatory requirements that must be met in order for payment to be justified. In the event of a claim review, a DMEPOS supplier must provide sufficient information to demonstrate that the applicable criteria have been met thus justifying payment. Refer to the LCD, NCD or other CMS Manuals for more information on what documents may be required.

See Article A55426 Standard Documentation Requirements for All Claims Submitted to DME MACs.

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this guideline does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

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<th>HCPCS Code</th>
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<td>E0747</td>
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### HCPCS Code

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<td>E0748</td>
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<td>E0749</td>
<td>Osteogenesis stimulator, electrical, surgically implanted</td>
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<td>E0760</td>
<td>Osteogenesis stimulator, low intensity ultrasound, noninvasive</td>
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### Modifier

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<td>EY</td>
<td>No physician or other licensed health care provider order for this item or service</td>
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### References

#### CMS National Coverage Determinations (NCDs)

**NCD 150.2 Osteogenic Stimulators**

#### CMS Local Coverage Determinations (LCDs) and Articles

<table>
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<tr>
<th>LCD</th>
<th>Article</th>
<th>Contractor</th>
<th>DME MAC</th>
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<tr>
<td>L33796 Osteogenesis Stimulators</td>
<td>A52513 Osteogenesis Stimulators – Policy Article</td>
<td>CGS</td>
<td>AL, AR, CO, FL, GA, IL, IN, KY, LA, MI, MN, MS, NC, NM, OH, OK, PR, SC, TN, TX, VA, VI, WI, WV</td>
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#### CMS Claims Processing Manual

**Chapter 32; § 110 Coverage and Billing for Ultrasound Stimulation for Nonunion Fracture Healing**

#### UnitedHealthcare Commercial Policy

**Electrical and Ultrasound Bone Growth Stimulators**

### Guideline History/Revision Information

Revisions to this summary document do not in any way modify the requirement that services be provided and documented in accordance with the Medicare guidelines in effect on the date of service in question.

<table>
<thead>
<tr>
<th>Date</th>
<th>Summary of Changes</th>
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<tr>
<td>09/08/2021</td>
<td>- Routine review; no change to guidelines</td>
</tr>
<tr>
<td></td>
<td>- Archived previous policy version MPG226.06</td>
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### Purpose

The Medicare Advantage Policy Guideline documents are generally used to support UnitedHealthcare Medicare Advantage claims processing activities and facilitate providers’ submission of accurate claims for the specified services. The document can be used as a guide to help determine applicable:

Osteogenic Stimulators (NCD 150.2)
UnitedHealthcare Medicare Advantage Policy Guideline

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Approved 09/08/2021
UnitedHealthcare follows Medicare guidelines such as NCDs, LCDs, LCAs, and other Medicare manuals for the purposes of determining coverage. It is expected providers retain or have access to appropriate documentation when requested to support coverage. Please utilize the links in the References section below to view the Medicare source materials used to develop this resource document. This document is not a replacement for the Medicare source materials that outline Medicare coverage requirements. Where there is a conflict between this document and Medicare source materials, the Medicare source materials will apply.

**Terms and Conditions**

The Medicare Advantage Policy Guidelines are applicable to UnitedHealthcare Medicare Advantage Plans offered by UnitedHealthcare and its affiliates.

These Policy Guidelines are provided for informational purposes, and do not constitute medical advice. Treating physicians and healthcare providers are solely responsible for determining what care to provide to their patients. Members should always consult their physician before making any decisions about medical care.

Benefit coverage for health services is determined by the member specific benefit plan document* and applicable laws that may require coverage for a specific service. The member specific benefit plan document identifies which services are covered, which are excluded, and which are subject to limitations. In the event of a conflict, the member specific benefit plan document supersedes the Medicare Advantage Policy Guidelines.

Medicare Advantage Policy Guidelines are developed as needed, are regularly reviewed and updated, and are subject to change. They represent a portion of the resources used to support UnitedHealthcare coverage decision making. UnitedHealthcare may modify these Policy Guidelines at any time by publishing a new version of the policy on this website. Medicare source materials used to develop these guidelines include, but are not limited to, CMS National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Medicare Benefit Policy Manual, Medicare Claims Processing Manual, Medicare Program Integrity Manual, Medicare Managed Care Manual, etc. The information presented in the Medicare Advantage Policy Guidelines is believed to be accurate and current as of the date of publication and is provided on an “AS IS” basis. Where there is a conflict between this document and Medicare source materials, the Medicare source materials will apply.

You are responsible for submission of accurate claims. Medicare Advantage Policy Guidelines are intended to ensure that coverage decisions are made accurately based on the code or codes that correctly describe the health care services provided. UnitedHealthcare Medicare Advantage Policy Guidelines use Current Procedural Terminology (CPT®), Centers for Medicare and Medicaid Services (CMS), or other coding guidelines. References to CPT® or other sources are for definitional purposes only and do not imply any right to reimbursement or guarantee claims payment.

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*For more information on a specific member’s benefit coverage, please call the customer service number on the back of the member ID card or refer to the Administrative Guide.