Osteogenic Stimulators (NCD 150.2)

Policy Number	150.2	Approved By	UnitedHealthcare Medicare Reimbursement Policy Committee	Current Approval Date	08/13/2014

IMPORTANT NOTE ABOUT THIS REIMBURSEMENT POLICY

This policy is applicable to UnitedHealthcare Medicare Advantage Plans offered by UnitedHealthcare and its affiliates.

You are responsible for submission of accurate claims. This reimbursement policy is intended to ensure that you are reimbursed based on the code or codes that correctly describe the health care services provided. UnitedHealthcare reimbursement policies 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.

This reimbursement policy applies to all health care services billed on CMS 1500 forms and, when specified, to those billed on UB04 forms (CMS 1450). Coding methodology, industry-standard reimbursement logic, regulatory requirements, benefits design and other factors are considered in developing reimbursement policy.

This information is intended to serve only as a general resource regarding UnitedHealthcare's reimbursement policy for the services described and is not intended to address every aspect of a reimbursement situation. Accordingly, UnitedHealthcare may use reasonable discretion in interpreting and applying this policy to health care services provided in a particular case. Further, the policy does not address all issues related to reimbursement for health care services provided to UnitedHealthcare enrollees. Other factors affecting reimbursement may supplement, modify or, in some cases, supersede this policy. These factors may include, but are not limited to: legislative mandates, the physician or other provider contracts, and/or the enrollee's benefit coverage documents. Finally, this policy may not be implemented exactly the same way on the different electronic claims processing systems used by UnitedHealthcare due to programming or other constraints; however, UnitedHealthcare strives to minimize these variations.

UnitedHealthcare may modify this reimbursement policy at any time by publishing a new version of the policy on this Website. However, the information presented in this policy is accurate and current as of the date of publication.

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Application

This reimbursement policy applies to services reported using the Health Insurance Claim Form CMS-1500 or its electronic equivalent or its successor form, and services reported using facility claim form CMS-1450 or its electronic equivalent or its successor form. This policy applies to all products, all network and non-network physicians, and other health care professionals.

Osteogenic Stimulators (NCD 150.2)

Summary

Overview

Electrical Osteogenic Stimulators

General

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

General

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.

Reimbursement Guidelines

Electrical Osteogenic Stimulators

Nationally Covered Indications

1. 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;
   - Effective July 1, 1996, as an adjunct to 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. A multiple level fusion involves 3 or more vertebrae (e.g., L3-L5, L4-S1, etc).
   - Effective September 15, 1980, nonunion of long bone fractures is considered to exist only after 6 or more months have elapsed without healing of the fracture.
   - Effective April 1, 2000, nonunion of long bone fractures is considered to exist 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.

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2. Invasive (Implantable) Stimulator

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

- Nonunion of long bone fractures;
- Effective July 1, 1996, as an adjunct to 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. A multiple level fusion involves 3 or more vertebrae (e.g., L3-L5, L4-S1, etc).
- Effective September 15, 1980, nonunion of long bone fractures is considered to exist only after 6 or more months have elapsed without healing of the fracture.
- Effective April 1, 2000, nonunion of long bone fractures is considered to exist 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

Effective January 1, 2001, 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.
- Effective April 27, 2005, upon reconsideration of ultrasound stimulation for nonunion fracture healing, CMS determines that the evidence is adequate to conclude that 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 remains non-covered.

CPT / HCPCS Codes

Code	Description
E0747	Osteogenesis stimulator, electrical, noninvasive, other than spinal applications
E0748	Osteogenesis stimulator, electrical, noninvasive, spinal applications
E0749	Osteogenesis stimulator, electrical, surgically implanted
E0760	Osteogenesis stimulator, low intensity ultrasound, noninvasive
E1399	Durable medical equipment, miscellaneous “Other ultrasound stimulation”

Modifiers

Code	Description
EY	No physician or other licensed health care provider order for this item or service
KF	Item designated by FDA as class III device

References Included (but not limited to):

CMS NCD

NCD 150.2 Osteogenic Stimulators

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CMS LCD(s)

Numerous LCDs

CMS Articles(s)

Numerous Articles

CMS Claims Processing Manual

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

CMS Transmittals

Transmittal 41, Change Request 3836, Dated 06/24/2005 (Osteogenic Stimulators)

Transmittal 597, Change Request 3836, Dated 06/24/2005 (Coverage and Billing for Ultrasound Stimulation for Nonunion Fracture Healing)

Transmittal 816, Change Request 4085, Dated 01/20/2006 (Coverage and Billing for Ultrasound Stimulation for Nonunion Fracture Healing)

UnitedHealthcare Medicare Advantage Coverage Summaries

Stimulators-Osteogenic Stimulators

UnitedHealth Group Medical Policies

Electrical and Ultrasound Bone Growth Stimulators

MLN Matters

Article MM8304 Revised, Detailed Written Orders and Face-to-Face Encounters

Article MM4296 Revised, New Durable Medical Equipment Prosthetic, Orthotics & Supplies (DMEPOS) Certificates of Medical Necessity (CMNs) and DME Medicare Administrative Contractor (MAC) Information Forms (DIFS) for Claims Processing

Article MM3836, Coverage and Billing for Ultrasonic Stimulators for Nonunion Fracture Healing

Article MM4085, Coverage and Billing for Ultrasound Stimulation for Nonunion Fracture Healing

Article MM3836, Coverage and Billing for Ultrasonic Stimulators for Nonunion Fracture Healing

History

Date	Revisions
08/13/2014	• Annual review • Administrative updates
07/10/2013	Administrative updates
11/30/2011	Annual review, no changes