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# CMS Manual System

## Pub. 100-03 Medicare National Coverage Determinations

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Department of Health &  
Human Services (DHHS)  
Centers for Medicare &  
Medicaid Services (CMS)

Transmittal 41

Date: JUNE 24, 2005

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CHANGE REQUEST 3836

**SUBJECT: Osteogenic Stimulators**

**I. SUMMARY OF CHANGES:** Effective April 27, 2005, CMS determines that the evidence is adequate to conclude that non-invasive ultrasound stimulation for the treatment of nonunion bone fractures prior to surgical intervention is reasonable and necessary.

(This revision to section 150.2 to Pub. 100-03, is a national coverage determination (NCD) made under section 1862(a)(1) of the Social Security Act. NCDs are binding on all carriers, fiscal intermediaries, quality improvement organizations, health maintenance organizations, competitive medical plans, health care prepayment plans, the Medicare Appeals Council, and administrative law judges (see 42 CFR 405.1064, effective May 1, 2005). An NCD that expands coverage is also binding on a Medicare advantage organization. In addition, an administrative law judge may not review an NCD. (See §1869(f)(1)(A)(i) of the Social Security Act.)

**NEW/REVISED MATERIAL - EFFECTIVE DATE: April 27, 2005**

**\*IMPLEMENTATION DATE: August 1, 2005**

**II. CHANGES IN MANUAL INSTRUCTIONS:**

**(R = REVISED, N = NEW, D = DELETED)**

<b>R/N/D</b>	<b>CHAPTER/SECTION/SUBSECTION/TITLE</b>
<b>R</b>	1/Table of Contents
<b>R</b>	1/150.2/Osteogenic Stimulators

**\*III. FUNDING:**

**These instructions shall be implemented within your current operating budget.**

**IV. ATTACHMENTS:**

	<b>Business Requirements</b>
<b>X</b>	<b>Manual Instruction</b>
	<b>Confidential Requirements</b>
	<b>One-Time Notification</b>
	<b>Recurring Update Notification</b>

**\*Medicare contractors only**

## **150.2 - Osteogenic Stimulators (Various Effective Dates Below)**

**(Rev.41, Issued: 06-24-05, Effective: 04-27-05, Implementation: 08-01-05)**

CIM-35-48

### *Electrical Osteogenic Stimulators*

#### **A. 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.

#### **B. 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.*

##### **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

### A. 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.

### B. 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.*

*C. 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.

*(This NCD last reviewed June 2005.)*