

Related Change Request (CR) #: 3836

MLN Matters Number: MM3836

Related CR Release Date: June 24, 2005

Related CR Transmittal #: 41 and 597

Effective Date: April 27 2005

Implementation Date: August 1, 2005

Coverage and Billing for Ultrasonic Stimulators for Nonunion Fracture Healing

Note: Note: This article was updated on March 28, 2013, to reflect current Web addresses. All other information remains unchanged.

This article was revised on July 30, 2007, to add a reference to CR4085, which changed some of the business requirements in CR3836 effective April 27, 2005. CR4085 may be found at <http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R816CP.pdf> on the CMS website. The related article (MM4085) may be found at <http://www.cms.gov/outreach-and-education/medicare-learning-network-mln/mlnmattersarticles/downloads/MM4085.pdf> on the CMS website.

Provider Types Affected

Physicians, providers, and suppliers billing Medicare carriers and intermediaries, including Regional Home Health Intermediaries (RHHIs) and Durable Medical Equipment Medicare Administrative Contractors (DME MACs), for ultrasonic osteogenic stimulators

Provider Action Needed



STOP – Impact to You

This article is based on Change Request (CR) 3836, which informs physicians, providers, and suppliers that the Centers for Medicare & Medicaid Services (CMS) announced a reconsideration of the National Coverage Determination (NCD) covering the use of Ultrasonic Osteogenic Stimulators, effective April 27, 2005.



CAUTION – What You Need to Know

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Upon reconsideration of the existing policy, CMS determined that Ultrasound Stimulation for Nonunion Fracture Healing will remain covered with an additional expansion of coverage to patients without prior surgeries to the non-healing fracture.



GO – What You Need to Do

See the *Background* section of this article for further details regarding this change.

Background

The Centers for Medicare & Medicaid Services (CMS) announced a Reconsideration of the National Coverage Determination (NCD) covering the use of Ultrasonic Osteogenic Stimulators, effective April 27, 2005.

An ultrasonic osteogenic stimulator is a non-invasive device that emits low intensity, pulsed ultrasound signal to stimulate fracture healing. 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. An ultrasonic osteogenic stimulator:

- Is not to be used concurrently with other non-invasive osteogenic devices; and
- Is intended for use with cast immobilization.

Nationally Covered Indications

Ultrasonic osteogenic stimulators are covered as medically reasonable and necessary for the treatment of non-union fractures when the following is demonstrated:

- A minimum of two sets of radiographs is obtained prior to starting treatment with the osteogenic stimulator, each separated by a minimum of 90 days. Each radiograph must include multiple views of the fracture site accompanied by a written interpretation by a physician stating that there has been no clinically significant evidence of fracture healing between the two sets of radiographs.

The national noncoverage policy relating to ultrasonic osteogenic stimulators for fresh fractures and delayed unions remains in place. In addition, nonunion fractures of the skull, vertebrae and tumor-related fractures are excluded from coverage.

Effective for services performed on or after April 27, 2005 Medicare will cover an osteogenic stimulator for beneficiaries who meet the criteria described above carriers & RHHs will allow payment for an osteogenic stimulator with the following CPT Code:

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- 20979 Low intensity ultrasound stimulation to aid bone healing, noninvasive (nonoperative)
- DME MACs will allow payment for osteogenic stimulators with the following HCPCS Codes :
 - Healthcare Common Procedure Coding System (HCPCS) codes:
 - E0760 for low intensity ultrasound, or
 - E1399 for other ultrasound stimulation.
- Regional Home Health Intermediaries (RHHIs) pay for the Ultrasonic Osteogenic Stimulator only when the services are submitted on types of bills (TOBs) 32X, 33X, or 34X.
- **Home Health Agencies (HHAs) need to know** that this Ultrasonic Osteogenic Stimulator must be in the patient's home health plan of care if billed on TOBs 32X or 33X. HHAs billing on TOBs 32X, 33X and 34X for the osteogenic stimulator will be paid based on the Durable Medical Equipment Prosthetics, Orthotics, and Supplies (DMEPOS) fee schedule.
- **Hospitals need to know** that they can not bill for the Ultrasonic Osteogenic Stimulator. Hospitals may only instruct patients on how to use the Ultrasonic Osteogenic Stimulator and **not** provide the Ultrasonic Osteogenic Stimulator.

Additional Information

See the Medicare National Determinations Manual (Pub. 100-03), Section 160.11 (Osteogenic Stimulators) at http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/ncd103c1_Part2.pdf on the CMS website.

For more information about the medical coverage of clinical trials, please go to <http://www.cms.gov/Medicare/Coverage/ClinicalTrialPolicies/index.html> on the CMS website.

For complete details on this change, please see the official instruction issued to your carrier/DME MAC/intermediary regarding this change. That instruction may be viewed by going to <http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R41NCD.pdf> and <http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R597CP.pdf> on the CMS website.

The file with transmittal number 41 is the NCD itself and the file with transmittal number 597 contains the billing requirements.

If you have any questions, please contact your carrier/DME MAC/intermediary at their toll-free number, which may be found at <http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/provider-compliance-interactive-map/index.html> on the CMS website.

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