



Medicare Part C Medical Coverage Policy

Electrical Stimulators- Osteogenesis

Origination: June 30, 1988

Review Date: July 15, 2020

Next Review: July, 2022

******This policy applies to all Blue Medicare HMO, Blue Medicare PPO, Blue Medicare Rx members, and members of any third-party Medicare plans supported by Blue Cross NC through administrative or operational services. ******

DESCRIPTION OF PROCEDURE OR SERVICE

Electrical osteogenesis stimulators fall into one of two categories: invasive, or noninvasive.

- Invasive osteogenesis stimulators, also called implantable electrical stimulators, utilize a direct current that is delivered internally via implanted electrodes to a non-healing fracture or bone fusion site.
- Noninvasive systems utilize treatment coils situated externally around the fracture and an external power supply. Noninvasive osteogenesis stimulators deliver an electrical current to the fracture site via capacitive coupling, pulsed electromagnetic field (PEMF), or combined magnetic field technology. The goal of applying electrical energy to the bone is to induce osteogenesis, which will then stimulate bone growth and promote fracture healing.

Ultrasound stimulation 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 diagnosis of a nonunion fracture is based on pain and motion at the fracture site and on findings using radiography, fluoroscopy, intraosseous venography, technetium scintigraphy, or magnetic resonance imaging that shows no visible signs of healing (defined as no progression of callous formation or lack of callous formation for 90 days as determined by serial radiographs), continued fracture gap of less than 1.0cm, and the fracture site has been adequately immobilized. In addition, the member must comply with weight bearing restrictions.

POLICY STATEMENT

Coverage will be provided for osteogenesis stimulators when it is determined to be medically necessary because the medical criteria and guidelines shown below are met.

BENEFIT APPLICATION

Please refer to the member's individual Evidence of Coverage (E.O.C.) for benefit determination. Coverage will be approved according to the E.O.C. limitations, if the criteria are met.

Coverage decisions will be made in accordance with:

- The Centers for Medicare & Medicaid Services (CMS) national coverage decisions;
- General coverage guidelines included in original Medicare manuals unless superseded by operational policy letters or regulations; and
- Written coverage decisions of local Medicare carriers and intermediaries with jurisdiction for claims in the geographic area in which services are covered.

Benefit payments are subject to contractual obligations of the Plan. If there is a conflict between the general policy guidelines contained in the Medical Coverage Policy Manual and the terms of the member's particular Evidence of Coverage (E.O.C.), the E.O.C. always governs the determination of benefits.

INDICATIONS FOR COVERAGE:

Preauthorization by the Plan is required prior to the stimulator being dispensed by the vendor;

AND

A documented care plan indicating the stimulator use and expected outcome must be submitted by the physician;

AND

A. Non –Invasive Stimulator

An electrical osteogenesis stimulator (E0747) is covered only if any of the following criteria are met:

1. Nonunion of a long bone fracture defined by radiographic evidence, which includes 2 sets of x-rays with multiple views, 90 days apart, confirming fracture healing has ceased for 3 or more months prior to starting treatment with the osteogenesis stimulator; **or**
2. Failed fusion of a joint other than in the spine where a minimum of 9 months has elapsed since the last surgery; **or**
3. Congenital pseudoarthrosis, **or**

In regard to the spine –E0748

4. Adjunct to spinal fusion for patients at high risk of pseudarthrosis due to:
 - Failed spinal fusion where a minimum of 9 months has elapsed since the last surgery **OR**
 - For Members undergoing multiple level spinal fusion (involving 3 or more vertebrae) **OR**
 - Previously failed spinal fusion at the same site

B. Invasive (Implantable) Stimulator

An Invasive electrical osteogenesis stimulator (E0749) is covered only if any of the following criteria are met:

1. Non union of long bone fractures only when serial radiographs have confirmed that fracture healing has ceased for 3 or more months. Serial radiographs must include a minimum of 2 sets of radiographs with multiple views, separated by 90 days.

Regarding the Spine:

2. As an adjunct to failed spinal fusion surgery for patients at high risk for pseudarthrosis due to failed spinal fusion at the same site or for those undergoing multiple level fusion (at least 3 vertebra involved) where a minimum of 9 months has elapsed since the last surgery.

C. **An ultrasonic osteogenesis stimulator (E0760)** is covered only if all of the following criteria are met:

1. Non-invasive ultrasound stimulation for the treatment of nonunion fractures. Nonunion fractures should be documented by a minimum of 2 sets of radiographs (with multiple views) obtained prior to starting treatment, separated by a minimum of 90 days. This can be applied prior to surgical intervention.

WHEN COVERAGE WILL NOT BE APPROVED

1. Conditions that do not meet the coverage criteria.
2. Non-union fractures of the skull, vertebrae and those that are tumor related.
3. Ultrasonic osteogenic stimulators may not be used concurrently with other non-invasive osteogenic devices.
4. Ultrasonic osteogenic stimulators for fresh fractures and delayed unions remains non-covered.

BILLING/ CODING/PHYSICIAN DOCUMENTATION INFORMATION

This policy may apply to the following codes. Inclusion of a code in the section does not guarantee that it will be reimbursed.

Applicable Codes: Osteogenic Stimulator: E0747, E0748, E0749, E0760 and A4559

CPT codes: 20974, 20975, and 20979

The Plan may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

SPECIAL NOTES

1. Code E0762, Transcutaneous Electrical Joint Stimulating Device: Administered by a noninvasive device that delivers electrical stimulation intended to reduce level of pain

and symptoms associated with arthritis. According to LCD L34821 there is insufficient evidence to support that any indication for these devices or any related accessories/supplies are medically reasonable and necessary.

2. Osteogenic units are purchased and worn until healing occurs.

References:

1. Medicare National Coverage Determination for Osteogenic Stimulators (ID #150.2); Effective Date: 8/1/05, Accessed via Internet site www.cms.gov/mcd/viewed on, 7/6/20.
2. Medicare Local Coverage Determination for Osteogenesis Stimulators, CGS Administrators (L33796); Effective Date 10/01/2015, Accessed via www.cms.gov/mcd/viewlcd 7/6/20.
3. Medicare Local Coverage Determination Article: Osteogenesis Stimulators (A52513); Effective Date: 10/01/2015, Accessed via www.cms.gov/mcd/viewlcd 7/6/20.
4. Medicare Local Coverage Determination for Transcutaneous Electrical Joint Stimulation, CGS Administrators (L34821); Effective Date 10/01/2015, Accessed via www.cms.gov 7/6/20.

Policy Implementation/Update Information:

Revision Date: January 8, 2002; January 10, 2002; February 23, 2005; August 24, 2005

November 30, 2006: Revised to include CPT codes 20974, 20975, and 20979. Clarified coverage for ultrasound stimulation, clarified definition of "visible signs of healing", added "Jones fracture of the 5th metatarsal" under criteria for coverage.

Revision Date: September 2009: No changes proposed

Revision Date: September 15, 2010: removed Scaphoid nonunion fractures and Jone's fracture. Both were added in 2006 and not current with CMS policies. Code E0762 added along with CMS language to remain current with CMS. Added code A4559 for coupling gel/paste as it is currently listed in CMS policy as being used with the ultrasound device.

Revision Date: April 17, 2013: Reformatted to mirror NCD.

Revision Date: April 6, 2015: Minor edits to Special Notes referencing Transcutaneous Electrical Joint Stimulating Device related to LCD L28616. Reference section updated. No other revisions to policy. October 29, 2015 updated LCD due to ICD-10 update only.

Revision Date: March 15, 2017: Annual Review; Indications for Coverage: Removed "nonunion status confirmed by x-ray" from #1 as this doesn't apply to all stimulators.

Revision Date: October 17, 2018: Converted Indications for Coverage A) 4. –into a list for quick reference and added subpoint #1. "Failed spinal fusion where a minimum of 9 months has elapsed since the last surgery" to make consistent with the LCD.

Revision Date: July 15, 2020; Annual Review. No CMS Updates. Minor Revisions Only.

Approval Dates:

Medical Coverage Policy Committee:

July 15, 2020

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