

Osteogenesis Stimulators

For any item to be covered by The Health Plan, it must:

1. Be eligible for a defined Medicare or The Health Plan benefit category
2. Be reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body member
3. Meet all other applicable Medicare and/or The Health Plan statutory and regulatory requirements

For the items addressed in this medical policy, the criteria for "reasonable and necessary" are defined by the following indications and limitations of coverage and/or medical necessity. *Please refer to individual product lines certificates of coverage for possible exclusions of benefit.*

For an item to be covered by The Health Plan, the supplier must receive a written, signed, and dated order before a claim is submitted to The Health Plan. If the supplier bills for an item addressed in this policy without first receiving the completed order, the item will be denied as not reasonable and necessary.

Suppliers are to follow The Health Plan requirements for precertification as applicable.

Osteogenesis (bone growth) stimulators require precertification and physician face-to-face.

National Coverage Determination Policy	CMS Publication 100-3, Medicare National Coverage Determinations Manual, Chapter 1, Section 150.2
Local Coverage Determination Policy	J- B/C
Effective Date	For services performed on or after 10/31/13
Review/Revisions Date	01/19, 10/18, 06/05/18, 07/01/17, 06/01/16
The Health Plan	Plans will follow Coverage Determination posted on the CGS website unless otherwise indicated in sections of this policy, contractual agreements, or benefit plan documents.

DESCRIPTION

Electrical stimulation to augment bone repair can be attained either invasively or noninvasively. This policy will be referring to noninvasive types of devices. With the noninvasive 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.

COVERAGE GUIDELINES

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

1. Nonunion of a long bone fracture. A long bone is limited to a clavicle, humerus, radius, ulna, femur, tibia, fibula, metacarpal, or metatarsal), defined as radiographic evidence that fracture

healing has ceased for three or more months prior to starting treatment with the osteogenesis stimulator, or

2. Failed fusion of a joint other than in the spine (ICD-10 code M96.0/Z98.1) where a minimum of nine months has elapsed since the last surgery, or
3. Congenital pseudarthrosis (ICD-10 code Q74.8).

Nonunion of a long bone fracture must be documented by a minimum of two sets of radiographs obtained prior to starting treatment with the osteogenesis stimulator. Radiographs should be separated by a minimum of 90 days, each including multiple views of the fracture site. It should include a written interpretation by a physician stating that there has been no clinically significant evidence of fracture healing between the two sets of radiographs.

A nonspinal electrical osteogenesis stimulator will be denied as not medically necessary if none of the criteria above are met.

A **spinal** electrical osteogenesis stimulator (**E0748**) is covered only if any of the following criteria are met:

1. Failed spinal fusion (ICD-10 code M96.0/Z98.1) where a minimum of nine months has elapsed since the last surgery, or
2. Following a multilevel spinal fusion surgery. A multilevel spinal fusion is one which involves three or more vertebrae (e.g., L3-L5, L4-S1, etc.), or
3. Following spinal fusion surgery where there is a history of a previously failed spinal fusion at the same site.

A spinal electrical osteogenesis stimulator will be denied as not medically necessary if none of the criteria above are met.

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

1. Nonunion of a fracture documented by a minimum of two 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 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; and
2. The fracture is not of the skull or vertebrae; and
3. The fracture is not tumor related.

An ultrasonic osteogenesis stimulator will be denied as not medically necessary if any of the criteria above are not met.

NONCOVERAGE STATEMENT

The PRECICE Intramedullary Limb Lengthening System by NuVasive is not covered at this time considered investigational. Providers may submit with codes E0747 and E0760 and G0283.

Use of an ultrasonic osteogenic stimulator for the treatment of a fresh fracture or delayed union will be denied as not medically necessary.

An ultrasonic osteogenesis stimulator will be denied as not medically necessary if it is used with other noninvasive osteogenesis stimulators.

REPAIR, REPLACEMENT AND REASONABLE USEFUL LIFETIME

Replacements and repairs require precertification. See **Replacement and Repair** policy.

Repairs are not separately payable during rental period.

Replacements are not covered due to neglect or misuse.

CODING INFORMATION

CPT/HCPCS codes: The appearance of a code in this section does not necessarily indicate coverage.

HCPCS MODIFIERS

EY	NO PHYSICIAN OR OTHER LICENSED HEALTH CARE PROVIDER ORDER FOR THIS ITEM OR SERVICE
KF	FDA CLASS III DEVICE

**HCPCS CODES
EQUIPMENT**

E0747	OSTEOGENESIS STIMULATOR, ELECTRICAL, NON-INVASIVE, OTHER THAN SPINAL APPLICATIONS
E0748	OSTEOGENESIS STIMULATOR, ELECTRICAL, NON-INVASIVE, SPINAL APPLICATIONS
E0760	OSTEOGENESIS STIMULATOR, LOW INTENSITY ULTRASOUND, NON-INVASIVE
G0283	PRECICE LIMB LENGTHENING SYSTEM/DEVICE

**HCPCS CODES
SUPPLIES/OTHER**

A4559	COUPLING GEL OR PASTE, FOR USE WITH ULTRASOUND DEVICE, PER OZ
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The presence of a diagnosis or ICD-10 code referenced in this policy is not sufficient by itself to assure coverage. Refer to coverage guidelines and documentation requirements sections for more information.

HCPCS CODE E0748

<https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33796&ContrID=140>

HCPCS CODE E0760

<https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33796&ContrID=140>

DOCUMENTATION REQUIREMENTS

For the purposes of this policy, it is expected that the medical record will support the need for the care provided. It is generally understood that the medical record includes the physician's office records, hospital records, nursing home records, home health agency records, records from other healthcare professionals and test reports.

This documentation must be available with precertification.

Medicare has made changes to its requirements for dispensing orders, detailed written orders, and proof of delivery. The Health Plan will require the following:

1. Physician detailed written order. Order must include the following:
 - a. Member's name
 - b. Date
 - c. Description of item. The medical record must contain the information that supports the request for each item, and must be submitted with the precertification if the item requires precertification, or with the claim, if no precertification was required
 - d. Order must include diagnosis code
 - e. Physician signature with date. Date stamps are not appropriate
 - f. Quantity of items required and duration. A new order is required if there is an increase in the quantity of the supply used per month and/or the type of supply used

The supplier is to contact The Health Plan in this instance to update referral

2. There must be documentation in the supplier's records to support the medical necessity of that item. This information must be available upon request usually with precertification per The Health Plan policy.
3. Proof of delivery to be kept on file by the provider of the item.

Note: If templates or forms are submitted, (i.e., a Medicare Certificate of Medical Necessity, and/or a provider created form), and all of the required information is not included, The Health Plan reserves the right to request the medical record, that may include, but not limited to, the physician office notes, hospital and nursing facility records, and home health records.

Note: Template provider forms, prescriptions, and attestation letters are not considered part of the medical record, even if signed by the ordering physician.

Providers may submit the Medicare CMN Form 847 (DME form 04.04C) for osteogenesis stimulation as part of the clinical note. However, The Health Plan reserves the right to request the physician notes in addition to the CMN.

All claims for an osteogenesis stimulator and related supplies must include an ICD-10 code that describes the condition requiring the device and/or supply.

STIMULATOR PROVIDED WHILE MEMBER IN PART A FACILITY

Reimbursement for osteogenesis stimulation provided to a member while the member is covered in a Part A facility will be included in the facility reimbursement if the device is intended for use while the member is in the facility for acute inpatient treatment or rehabilitation. In order for it to be billed separately, it must be given two days or less before discharge from a Part A covered stay and it must meet the above guidelines and be medically necessary for home use.

Reimbursement for an osteogenesis stimulator provided while a member is in a SNF receiving Part A services, is reimbursed according to individual facility contracts.

BILLING GUIDELINES

Ultrasound conductive coupling gel is covered and separately payable if an ultrasonic osteogenesis stimulator is covered.

The ultrasonic osteogenesis stimulator is in the inexpensive or routinely purchased (IRP) payment category.

The invasive osteogenesis stimulator is not processed under the DME benefit.

Ultrasound conductive coupling gel is billed using code A4559.

E0747, E0748, and are class III devices, which must be submitted with a KF modifier.

KX, GA, and GZ MODIFIERS

Suppliers may submit a claim with a KX modifier only if all the criteria for that item are met.

If the coverage criteria are not met, the GA or GZ modifier must be used. When there is an expectation of a medical denial, suppliers must enter the GA modifier on the claim line if they have obtained a properly executed Advance Beneficiary Notice (ABN) or the GZ modifier if they have not obtained a valid ABN.

ADVANCED BENEFICIARY NOTICE

The Health Plan expects providers to follow the Medicare policy on ABN across all Medicare, Medicaid, and Commercial plans.

NOTE: Providers may be held financially responsible if they furnish the above items without notifying the member, verbally and in writing, that the specific service being provided is not covered. This must be done prior to the dispensing of the device. The provider must submit the waiver or ABN to The Health

Plan with the claim showing the member agreed to pay for the device. Generalized statements on waivers or ABN are not acceptable.

PRICING, DATA ANALYSIS, AND CODING (PDAC)

The Health Plan has implemented use of Medicare's PDAC contractor for review of authorizations. Please refer to PDAC website for the appropriate product classification list. dmepdac.com/

MEDICARE DEFINITIONS AND DESCRIPTION

A multilevel spinal fusion is one that involves three or more vertebrae (e.g., L3 - L5, L4 - S1, etc.).

A long bone is limited to a clavicle, humerus, radius, ulna, femur, tibia, fibula, metacarpal, or metatarsal.

An electrical osteogenesis stimulator is a device that provides electrical stimulation to augment bone repair. A noninvasive electrical stimulator is characterized by an external power source, which is attached to a coil or electrodes placed on the skin or on a cast or brace over a fracture or fusion site.

An ultrasonic osteogenesis stimulator is a noninvasive device that emits low intensity, pulsed ultrasound. The ultrasound signal is applied to the skin surface at the fracture location via ultrasound conductive coupling gel in order to stimulate fracture healing.

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INTERNET LINKS AND SOURCES

National Government Services website. Medical Policy Center. Durable Medical Equipment. Local Coverage Determination and Article Jurisdiction B. Osteogenesis Stimulation. LCD L27026 Article A47113. Last accessed 10/30/18. Retrieved from <http://ngsmedicare.com>

CGS Medicare: A Celerian Group Company. Local Coverage Determination Policy. Osteogenesis Stimulation. Jurisdiction C. LCD L5012. Article A25956. Last accessed 10/30/18. Retrieved from cgsmedicare.com/jc/coverage/lcdinfo.html

PRECICE System (NuVasive Inc.) for Leg Length Discrepancy. Hayes INC. September 2018, Last Accessed December 2018. Retrieved from :
https://www.hayesinc.com/subscribers/displaySubscriberArticle.do?articleId=92426&searchStore=%24search_type%3Dall%24icd%3D%24keywords%3Dprecice%24status%3Dall%24page%3D1%24from_date%3D%24to_date%3D%24report_type_options%3D%24technology_type_options%3D%24organ_system_options%3D%24specialty_options%3D%24order%3DasearchRelevance

West Virginia Medicaid Internet Provider Manual. Chapter 506. Covered Services, Limitations, and Exclusions for DME Medical Supplies. Last accessed 10/30/18. Retrieved from dhhr.wv.gov/bms/Pages/default.aspx

CMS. Gov. Centers for Medicare and Medicaid Services website. National Coverage Determination 150.2. Osteogenic Stimulators. Last accessed 10/30/18. Retrieved from cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=65&ncdver=2&IsPopup=y&NCAId=24&NcaName=Electrical+Stimulation+for+Fracture+Healing&bc=AAAAAAAAAAAA%3D%3D&

The Health Plan Provider Procedural Manual. Payment Voucher, Section 14, Page 11

Forms:

Form 847 (DME for 04.04C) cms.hhs.gov/cmsforms/downloads/CMS847.pdf