

Bulletin Number: MSA 08-08

Distribution: Medical Suppliers

Issued: March 1, 2008

Subject: Policy Revision for Osteogenesis Stimulators

Effective: April 1, 2008

Programs Affected: Medicaid, Children's Special Health Care Services

The purpose of this bulletin is to inform Medical Suppliers of policy revision for coverage of Osteogenesis Stimulators. This revision will establish current guidelines, coverage, and documentation requirements.

Revisions include additions to the definition, expansion of standards of coverage, a new section of non-covered items, and enhanced documentation requirements.

The following will replace section 2.29 Osteogenesis Stimulators in the current Medical Supplier chapter of the Michigan Medicaid Provider Manual.

2.29 OSTEOGENESIS STIMULATORS

<p>Definition</p>	<p>An 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.</p> <p>A multilevel spinal fusion is one which involves three or more vertebrae (e.g. L-3-L-5, L-4-S-1, etc.).</p> <p>A long bone is limited to a clavicle, humerus, radius, ulna, femur, tibia, fibula, metacarpal, or metatarsal.</p> <p>The stimulator includes, but is not limited to, the osteogenesis stimulator, electrical, noninvasive, other than spinal applications and the osteogenesis stimulator, electrical, noninvasive, spinal applications.</p>
<p>Standards of Coverage</p>	<p>A nonspinal electrical osteogenesis stimulator may be covered when other treatment methods have been ineffective and when one of the following applies:</p> <ul style="list-style-type: none"> • There is a nonunion of a long bone fracture, with radiographic evidence which indicates that the fracture healing has ceased for three or more months prior to starting treatment with the osteogenesis stimulator. • There is a nonunion of a nondisplaced scaphoid fracture.

	<ul style="list-style-type: none"> • If there is failed fusion of a joint, other than in the spine, where a minimum of nine months has elapsed since the surgery. • Congenital Pseudoarthrosis not due to lack of skeletal maturity. • The fracture gap is ≤ 1 cm. • A nonunion of a long bone fracture is described by ICD-9-CM code 733.82 plus the code for the fracture site:-810.00-810.13, 812.00-813.93, 815.00-815.19, 820.00-821.39, 823.00-824.9, 825.25-825.35. <p>A spinal electrical osteogenesis stimulator may be covered when other treatment methods have been ineffective and when one of the following applies:</p> <ul style="list-style-type: none"> • There is a failed spinal fusion (ICD-9-CM code V45.4) where a minimum of nine months has elapsed since the last surgery. • Following multi-level (three or more vertebrae) spinal fusion surgery (ICD-9-CM code V45.4) without instrumentation. • Clinical indication in cervical spine fusions with instrumentation (reviewed on case by case basis). • Following spinal fusion surgery (ICD-9-CM code V45.4) where there is a history of a previously failed spinal fusion at the same level(s). How long ago was the failure? • May also be indicated as an adjunct to high-risk fusion; cases that meet one or more of the following criteria: <ul style="list-style-type: none"> ○ Smoking (Cessation attempts) ○ Diabetes ○ Metabolic disease where bone healing is likely to be compromised ○ Grade III or greater spondylolisthesis
<p>Non-covered Conditions</p>	<p>Medicaid does not cover the use of a bone growth stimulator for any of the following indications as it is considered experimental, investigational, or unproven (not all inclusive):</p> <ul style="list-style-type: none"> • Fresh fractures (other than when using ultrasound bone stimulation for the tibia or radius) • Toe fractures • Sesamoid fractures • Avulsion fractures • Osteochondral lesions • Stress fractures • Displaced fractures with malalignment • Synovial pseudoarthrosis • Fractures related to malignancy • The bone gap is either > 1 cm or $>$ one-half the diameter of the bone • Primary surgeries with current internal fixation techniques, i.e., pedicle screw fixation and variants • Lack of skeletal maturity (refer to congenital pseudoarthrosis)

Documentation	Documentation must be less than 90 days old and include all of the following: <ul style="list-style-type: none">• Diagnosis/medical condition related to the need for the device.• Alternative treatment methods tried and results.• For a diagnosis of fracture nonunion, reports of sequential x-ray results for a period of no less than 90 days, office records, including previous treatments and operative procedures (if any).• For a spinal fusion procedure, pertinent office and/or hospital records as well as a legible, complete description of indications for electrical stimulation. A copy of the operative report(s) may be required.• Other modalities still to be used (include type and location).
PA Requirements	PA is required and evaluated on a case by case basis.
Payment Rules	Osteogenesis stimulators are considered a purchase only item and are inclusive of the following: <ul style="list-style-type: none">• All accessories needed to use the unit (e.g., electrodes, wires, cables, etc.).• Education on the proper use and care of the equipment.• Routine servicing and all necessary repairs or replacement to make the unit functional based on manufacturer warranty.

Manual Maintenance

Retain this bulletin until the information has been incorporated into the Michigan Medicaid Provider Manual.

Questions

Any questions regarding this bulletin should be directed to Provider Inquiry, Department of Community Health, P.O. Box 30731, Lansing, Michigan 48909-8231, or e-mail at ProviderSupport@michigan.gov. When you submit an e-mail, be sure to include your name, affiliation, and phone number so you may be contacted if necessary. Providers may phone toll-free 1-800-292-2550.

Approved



Paul Reinhart, Director
Medical Services Administration