

Premier Health Insuring Corporation

POLICY AND PROCEDURE MANUAL

Policy Number: PA.011.PC
Last Review Date: 09/10/2015
Effective Date: 01/01/2016
Renewal Date: 01/01/2017

PA.011.PC – Non-Invasive Bone Growth Stimulators

This policy applies to the following line(s) of business:

- ✓ Premier Health Insuring Corporation MA – DSNP

Premier Health Insuring Corporation considers Non-Invasive Bone Growth Stimulators (BGS) medically necessary for the following indications:

Non-Spinal BGS:

1. Non-union fracture of a long bone;
2. Failed fusion, where a minimum of 9 months has elapsed since the last surgery;
3. Congenital pseudoarthrosis

Exception: *Non-spinal BGS is covered following initial/index surgical procedures to repair non-union fracture of long bones when at least 90 days has lapsed since the index procedure, and when radiographs show no clinically significant signs of healing during the final six weeks of this 90 day period.*

Spinal BGS:

When used as an adjunctive therapy with spinal fusion for members considered at high risk for pseudo-arthrosis. This includes those with the following conditions:

1. One or more previous failed spinal fusions where a minimum of nine months has elapsed
2. Grade II or worse spondylolisthesis
3. A multiple level fusion involves 3 or more vertebrae (e.g. L3-L5, L4-S1, etc.), or
4. A disease process or condition which interferes with the healing process (i.e. diabetes, renal disease, alcoholism, morbid obesity, or smoking)

Ultrasonic Bone Growth Stimulator:

1. Non-union fracture of any bone except vertebrae or skull, and fracture is not tumor related.

Exception: *Non-spinal BGS is covered following initial/index surgical procedures to repair non-union fracture of long bones when at least 90 days has lapsed since the index procedure, and when radiographs show no clinically significant signs of healing during the final six weeks of this 90 day period.*

Or

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2. For accelerating the time to a healed fracture for fresh fractures (occurring within 7 days) of the following bones:
 - Scaphoid (wrist)
 - Talus (this is a rare indication)
 - Proximal 5th metatarsal (Jones' fracture)
 - Segmental fracture of the tibial shaft
 - Distal tibial pilon fracture

NOTE: Bone stimulators are generally used daily for a period of three to nine months. Periodic radiographic monitoring at three month intervals is required to document continued effectiveness of treatment.

Limitations

1. If there is no evidence of healing within nine months of using the BGS, continued use of the unit is not covered.
2. 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.

Background

BGS is the technique of promoting bone growth in difficult to heal fractures by applying a low electrical current or ultrasound to the fracture. Bone growth stimulation is done when satisfactory healing is not occurring naturally or when the pace of healing is too slow as documented by serial x-rays. BGS are classified as electrical spinal, electrical non-spinal, and ultrasonic in nature.

Electrical Osteogenic Stimulators: 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.

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Ultrasonic Osteogenic Stimulators: 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.

Codes:

CPT/HCPCS Codes	
Code	Description
20974	Electrical stimulation to aid bone healing; non-invasive (non-operative)
20979	Low intensity ultrasound stimulation to aid bone healing
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

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8. U.S. Food and Drug Administration (FDA): PreMarket Approval (PMA) No. P910066/S11. SpinaLogic. Summary of Safety and Effectiveness. Approved Dec. 17, 1999. http://www.accessdata.fda.gov/cdrh_docs/pdf/P910066S011b.pdf

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