UPMC Health Plan
POLICY AND PROCEDURE MANUAL

SUBJECT: **Bone Growth Stimulators, Non-Invasive**
INDEX TITLE: **Medical Management**
ORIGINAL DATE: **November 2005**

This policy applies to the following lines of business: (Check those that apply.)

COMMERCIAL	CMS-MA	DHS-MA	ANCILLARY
HMO ( )	PA (X)	Health Choices /PH (X)	Dental ( )
PPO ( )		Health Choices/BH ( )	Vision ( )
Fully Insured ( )		All ( )	COBRA ( )
Self-funded ( )			All ( )
Marketplace HMO ( )		**PID-CHIP**	**WORK PARTNERS**
Marketplace PPO ( )	HMO (X)	CHIP (X)	Commercial WC ( )
Marketplace EPO ( )	PPO (X)		Disability Svcs. /TPA ( )
Indiv.Off Exchange ( )	CSNP (X)		Health Promotion ( )
All (X)	DSNP (X)		All ( )
CDHP	ISNP (X)		
HSA ( )	Part D ( )		**LIFE SOLUTIONS**
HRA ( )	All ( )		LifeSolutions ( )
HIA ( )			
FSA ( )			
All ( )			

I. POLICY

It is the policy of UPMC Insurance Services Division to cover non-invasive bone growth stimulators (BGS) when they are medically and covered under the member's specific benefit plan. UPMC Insurance Services Division recognizes non-invasive methods of bone growth stimulation as medically necessary and consistent with good medical practice in circumstances requiring enhanced or accelerated healing of bone.

All denials are based on medical necessity and appropriateness as determined by a UPMC Insurance Services Division Medical Director (Medical Director).

II. DEFINITIONS

Fresh Fracture is a fracture which has occurred within 7 days. A fracture is defined as "fresh" for 7 days after the fracture occurs.

TOP

Long Bone is limited to a clavicle, humerus, ulna, radius, femur, tibia, fibula, metacarpal, or metatarsal for the purposes of this policy.

Multi-level spinal fusion is one which involves three or more vertebrae (e.g. L3-L5, L4-S1, etc)

Non-Union of a Fracture is defined as:

> Absence of radiographic signs of fracture healing over the course of at least 90 days. This requires submission of two sets of radiographs, separated by at least 90 days, each including multiple views of the fracture site, and each accompanied by a written interpretation by a physician and indicating that there has been no clinically significant evidence of fracture healing between the two sets of radiographs.

III. PURPOSE

The purpose of this policy is to define the criteria for appropriate coverage of Non-Invasive Bone Growth Stimulators (BGS).

IV. SCOPE

This policy applies to various UPMC Insurance Services Division departments as indicated by the Benefit and Reimbursement Committee. These include but are not limited to Medical Management, Benefit Configuration and Claims departments.

V. PROCEDURE

A. Medical Description / 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.

Non-Invasive Electrical Bone Stimulators - opposing pads, wired to an external power supply, are placed over the cast or over the skin. An electromagnetic field is created between the pads at the fracture site.

- Electrical Spinal BGS deliver electrical current via cutaneous electrodes that are placed at the site of a spinal fusion.

- Electrical Non-Spinal BGS are used to deliver electrical current via cutaneous electrodes placed around the fracture site in the treatment of non-union fractures, fusions and congenital pseudoarthrosis.

Ultrasonic Bone Growth Stimulators 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 deliver low intensity pulsed ultrasonic waves to accelerate healing in areas that are difficult to heal.

B. Specific Indications

Electrical Bone Growth Stimulation

Non-Spinal BGS (E0747) is considered medically necessary in the treatment of any of the following conditions:
1. Non-union fracture of a long bone (as defined in Section I, Definitions, of this policy)
2. The treatment of failed joint fusion (non-spinal) where a minimum of nine months has elapsed since the last surgery
3. Congenital pseudo-arthrosis

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 6 weeks of this 90 days period.

Spinal BGS (E0748) is considered medically necessary in the treatment of any of the following conditions:
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. Fusion which involves three 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 (E0760)

Considered medically necessary when either of the following criteria is met:
1. Non-union fracture (as defined in Section I, Definitions, of this policy**)** 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 6 weeks of this 90 days period.

Or

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.

C. 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. Bone Growth Stimulators (electric and ultrasound) are not covered for:
   - Pathological fractures;
   - Stress fractures;
   - When used with other non-invasive bone growth stimulators.
3. Electrical BGS methods are contraindicated for the following:
   - Pregnant or nursing women;
   - Fractures of children's epiphysis;
   - Severe osteoporosis;
   - Systemic disorders (i.e. lupus, multiple sclerosis, etc.);
   - Members with demand pacemakers unless consultation and monitoring with cardiologist occurs;
   - Non-union fractures when the fracture gap is one cm;
   - Members who are uncooperative, and/or have mental or physical conditions that preclude compliance.
4. Ultrasonic BGS are contraindicated for the following:
   - In non-union fractures of the skull, vertebrae and those that are tumor-related;
   - Concurrent use with non-invasive electric bone growth stimulators;
   - In pregnant or nursing women;
   - Members with active implantable devices, such as cardiac pacemakers without evaluation by the attending cardiologist or physician;
   - For more than one treatment period of twenty minutes each day;
   - Members less than17 years of age;

- Members who are uncooperative, and/or have mental or physical conditions that preclude compliance.

5. Ultrasound conductive coupling gel is covered if the ultrasound device is covered.

D. Information Required for Review

In order for medical necessity to be established, adequate information must be furnished by the treating physician. Necessary information includes the following:

1. A physician's prescription or certificate of medical necessity.
2. Documentation supporting the member's need for a bone growth stimulator that includes:
   - The member's diagnosis;
   - Exact fracture site;
   - When appropriate evidence of history of failed conservative fracture treatment for a period of three months or more, evidence of previous history of failed surgery or high risk factors that may delay healing.
3. Radiographic reports or documentation indicating a failed or non-union fracture and distance between fractured bone ends.
4. Type of bone growth stimulator to be used, including CPT and/or HCPCS code.
5. A Certificate of Medical Necessity (CMN) must be completed, signed, and dated by the treating physician and be kept on file by the supplier making available upon request. The CMN may act as a substitute for a written order if it contains all of the required elements of an order.

E. Variations

N/A

F. Codes

The following codes for treatments and procedures applicable to this policy are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

CPT/HCPCS Codes Applicable

Code:	**Description:**
20974	Electrical stimulation to aid bone healing; non-invasive (non-operative)
20979	Low intensity ultrasound stimulation to aid bone healing, noninvasive (non-operative)
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

G. Review Process

1. The Medical Management staff assigned to review obtains the clinical information to determine if there is adequate clinical information. If the case does not meet the established criteria, it is referred to a Medical Director.
2. If referred, the Medical Director determines if the requested service is medically necessary and appropriate
3. The Medical Management staff completes the review process and communicates the review decision according to the Timeliness of UM Decisions policy for the member's benefit plan

H. Records Retention

Records Retention for documents, regardless of medium is provided within the UPMC Health System Policy for Records Retention, Management and Retirement, and as indicated in the UPMC Insurance Services Division Policy and Procedure for Records Retention.

Unless otherwise mandated by Federal or State law, or unless required to be maintained for litigation purposes, any communications recorded pursuant to this Policy are maintained for a minimum of ten (10) years from the date of recording.

I. References

Reference Disclaimer:

Please note the following:

- The links and the dates of publication and/or latest revisions for all references below are current as of the Revision Date of this policy.
- Not all the links are free-access. Some of the references may require site registration, subscription and/or purchase to download the information cited.

Medical Literature/Clinical Information:

1. ECRI Institute. Health Technology Assessment Information Service. Hotline Response: Electric bone growth stimulating devices for treating acute and nonunion bone fractures. Published: July 15, 2012. Updated: 07/15/2014. https://www.ecri.org/components/Hotline/Pages/13033.aspx
2. American Academy of Orthopaedic Surgeons (AAOS): OrthoInfo. Nonunions. Last reviewed: March 2014. Available at: http://orthoinfo.aaos.org/topic.cfm?topic=A00374

3. Foley KT, Mroz TE, Arnold PM, et al. Randomized, prospective, and controlled clinical trial of pulsed electromagnetic field stimulation for cervical fusion. Spine J. 2008 May-Jun;8(3):436-442. Epub 2007 Jul 17. http://ac.els-

cdn.com/S1529943007002501/1-s2.0-S1529943007002501-main.pdf?_tid=711ce6ac-1675-11e3-9dc9-00000aab0f02&acdnat=1378418121_a6b3e3bd2fe505ad1206d6ff8cec0817

4. Anglen J: The clinical use of bone stimulators. J South Orthop Assoc. 2003 Summer; 12(2): 46-54. http://www.ncbi.nlm.nih.gov/pubmed/12882239
5. Oishi M, Onesti ST: Electrical bone graft stimulation for spinal fusion: a review, Neurosurgery. 2000 Nov; 47(5):1041-1056. http://graphics.tx.ovid.com/ovftpdfs/FPDDNCDCPBDLBB00/fs027/ovft/live/gv008/00006123/00006123-200011000-00005.pdf

Regulatory/Government Source:

1. Centers of Medicare and Medicaid Services (CMS). Local Coverage Determination (LCD) No. L11501. Osteogenesis Stimulators. (Contractor-NHIC, Corp.): Revision Effective Date: 10/31/2014. http://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=11501&ContrId=137&ver=38&ContrVer=1&DocType=All&bc=AgIAAAAACAAAAA%3d%3d&
2. Centers of Medicare and Medicaid Services (CMS). Local Coverage Determination (LCD) No. L33796. Osteogenesis Stimulators. (Contractor-NHIC, Corp.). [FUTURE]: Original Effective Date:10/01/2015. http://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33796&ContrId=137&ver=4&ContrVer=1&DocType=All&bc=AgIAAAAAAAAAAA%3d%3d&
3. Centers for Medicare and Medicaid Services (CMS). National Coverage Determination (NCD) No. 150.2 . Osteogenic Stimulators. Effective April 27, 2005. http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=65&ncdver=2&bc=AgAAgAAAAAAAAA%3d%3d&
4. 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

Disclaimer: UPMC Health Plan medical payment and prior authorization policies do not constitute medical advice and are not intended to govern or otherwise influence the practice of medicine. The policies constitute only the reimbursement and coverage guidelines of UPMC Health Plan and its affiliated managed care entities. Coverage for services varies for individual members in accordance with the terms and conditions of applicable Certificates of Coverage, Summary Plan Descriptions, or contracts with governing regulatory agencies.

UPMC Health Plan reserves the right to review and update the medical payment and prior authorization guidelines in its sole discretion. Notice of such changes, if necessary, shall be provided in accordance with the terms and conditions of provider agreements and any applicable laws or regulations.

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