

Policy: MP029

Section: Medical Benefit Policy

Subject: Bone Growth Stimulator

Applicable Lines of Business

| | | | |
|------------|---|------|---|
| Commercial | X | CHIP | X |
| Medicare | X | ACA | X |
| Medicaid | X | | |

I. Policy: Bone Growth Stimulator

II. Purpose/Objective:

To provide a policy of coverage regarding Bone Growth Stimulator

III. Responsibility:

- A. Medical Directors
- B. Medical Management Department

IV. Required Definitions

1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions

Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

- a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- b. provided for the diagnosis, and the direct care and treatment of the Member's condition, illness disease or injury;
- c. in accordance with current standards of good medical treatment practiced by the general medical community;
- d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

Medicaid Business Segment

Medically Necessary — A service, item, procedure, or level of care that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

- Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
- Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an

illness, condition, injury or disability.

- Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age

DESCRIPTION:

Bone growth stimulation is a medical procedure to aid in bone healing. Both internal (invasive) and external (non-invasive) devices are available. Non-invasive stimulators use either pulsed electromagnetic fields, capacitive coupling, or ultrasound. Electrical stimulators generate a weak electric current through the fracture site. Ultrasonic stimulators emit low intensity, pulsed ultrasonic energy. Invasive stimulation requires surgical implantation of a direct current generator while an electrode is implanted within the fragments of bone graft at the fusion site. The power source is removed in a second surgical procedure when stimulation is completed. The following are considered to be long bones: clavicle, humerus, radius, ulna, femur, tibia, fibula, metatarsals, and metacarpals.

INDICATIONS:

A Electrical bone growth stimulation (invasive or non-invasive) is considered medically necessary for **ANY** of the following indications:

1. Fracture non-union of long bones
 - a) Location in the appendicular skeleton; **AND**
 - b) At least 3 months have elapsed since the date of fracture; **AND**
 - c) A minimum of 2 sets of radiographs obtained prior to initiation of the osteogenesis stimulator, separated by a minimum of 90 days, including multiple views of the fracture site and a written interpretation by a physician that documents that there has been no clinically significant evidence of fracture healing between the two sets of radiographs;
 - d) The fracture gap is 1cm or less; **AND**
 - e) The fracture has been adequately immobilized, and compliance with non-weight bearing activity has been achieved.
2. As an adjunct to spinal fusion surgery when **ANY** of the following are met
 - a) Failed spinal fusion is defined as having not healed as evidenced by a minimum of 9 months has elapsed since the last surgery and a minimum of 2 sets of radiographs obtained prior to initiation of the osteogenesis stimulator, separated by a minimum of 90 days, including multiple views of the fracture site and a written interpretation by a physician that documents that there has been no clinically significant evidence of fracture healing between the two sets of radiographs; **OR**
 - b) Risk of failed fusion as evidenced by **ANY** of the following indications:
 - (1) Grade III or worse spondylolisthesis; **OR**
 - (2) Multiple level fusion (involves 3 or more vertebrae); **OR**
 - (3) Documented history of previously failed fusion at the same site; **OR**
 - (4) Presence of **ANY** risk factors for non-healing such as:
 - (a) Smoking;
 - (b) Diabetes;
 - (c) Renal Disease;
 - (d) Long-term steroid treatment;
 - (e) Poor nutritional status;
 - (f) Other metabolic disease where bone healing is likely to be compromised;
3. Failed fusion of a joint, other than the spine, in which a minimum of 9 months has elapsed since the last surgery; **OR**
4. Congenital pseudoarthrosis

B Low-intensity non-invasive ultrasound stimulation is considered medically necessary for **ANY** of the following indications:

1. For the treatment of fresh, closed fractures with closed reduction in skeletally mature adults for **ANY** of the following acute fracture indications:
 - a) Fresh (i.e. less than 7 days), closed, grade I open, tibial diaphyseal fractures; **OR**
 - b) Fresh (i.e. less than 7 days), closed fractures of the distal radius (Colles' fracture)

- c) Fresh (i.e. less than 7 days), closed fractures at high risk for non-union due to position and poor vascular supply including but not limited to: carpal navicular/scaphoid fractures, Jones/5th metatarsal fracture, talar neck, tarsal navicular
2. For the treatment of *non-union fractures* when **ALL** of the following criteria are met:
- a) At least 3 months have elapsed since the date of fracture; **AND**
 - b) A minimum of two sets of radiographs obtained prior to starting treatment with the osteogenesis stimulator, separated by a minimum of 90 days, each including multiple view of the fracture site, and 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**
 - c) The fracture is not of the skull or vertebrae; **AND**
 - d) The fracture is not tumor related **AND**
 - e) The fracture has been adequately immobilized, and compliance with non-weight bearing activity has been achieved.

NOTE: Where applicable, coverage for non-invasive bone growth stimulator will be subject to the limitations of the applicable benefit document. Coverage for invasive electrical bone growth stimulator is considered a medical benefit and is NOT subject to limitations of the Durable Medical Equipment benefit.

EXCLUSIONS: (Apply to both invasive and non-invasive stimulators)

- Non-union fractures of short bones
- Treatment of delayed union (a decelerating fracture healing process, as identified by serial x-rays)
- Fresh fractures (other than when using ultrasound bone stimulation for the tibia or radius)
- Phalanx fractures
- Sesamoid fractures without evidence of nonunion
- Avulsion fractures
- Osteochondral lesions
- Stress fractures without evidence of nonunion and in the absence of a minimum of 90 days of non-surgical management including continued non weight-bearing
- Displaced fractures
- Synovial pseudoarthrosis
- The bone gap is either greater than 1 cm or greater than one-half the diameter of the bone
- Treatment of Charcot foot, avascular necrosis of the hip and fractures of the scapula or pelvis
- To speed recovery based on convenience or athletic status and non-surgical management has not been in place for 90 days included continued non-weight bearing

Medicaid Business Segment:

Any requests for services, that do not meet criteria set in the PARP, may be evaluated on a case by case basis.

CODING ASSOCIATED WITH: Bone Growth Stimulator

The following codes are included below for informational purposes and may not be all inclusive. Inclusion of a procedure or device code(s) does not constitute or imply coverage nor does it imply or guarantee provider reimbursement. Coverage is determined by the member specific benefit plan document and any applicable laws regarding coverage of specific services. Please note that per Medicare coverage rules, only specific CPT/HCPCS Codes may be covered for the Medicare Business Segment. Please consult the CMS website at www.cms.gov or the local Medicare Administrative Carrier (MAC) for more information on Medicare coverage and coding requirements

Coding associated with: Electrical Stimulation

CPT Codes

- 20974 Electrical stimulation to aid bone healing; noninvasive
- 20975 invasive
- 20979 low intensity ultrasound stimulation to aid bone healing, noninvasive (nonoperative)

HCPCS Codes

- E0747 Osteogenesis stimulator, electrical, noninvasive, other than spinal applications
- E0748 Osteogenesis stimulator, electrical, noninvasive, spinal applications
- E0749 Osteogenesis stimulator, electrical (surgically implanted)
- E0760 Osteogenesis stimulator, low intensity ultrasound, non-invasive

Current Procedural Terminology (CPT®) © American Medical Association: Chicago, IL

LINE OF BUSINESS:

Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy. For Medicare, applicable LCD's and NCD's will supercede this policy. For PA Medicaid Business segment, this policy applies as written

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This policy will be revised as necessary and reviewed no less than annually.

Devised: 9/26/01

Revised: 2/04 (indications, criteria, coding) 10/04 (coverage change for invasive and US stimulation); 5/05 (CMS criteria change); 5/06 (Indications/Criteria/coding/format); 5/07 (criteria); 5/08 (criteria), 10/14 (criteria); 10/16 (criteria, removed P/A) , 9/17 (clarified exclusions); 1/21 (remove PA language held in error); 1/23 (add covered fracture types)

Reviewed: 9/02, 9/09, 10/10, 10/11, 10/12, 10/13, 10/15, 9/18, 9/19, 9/20, 1/22, 1/24

CMS UM Oversight Committee Approval: 12/23

Geisinger Health Plan may refer collectively to health care coverage sponsors Geisinger Health Plan, Geisinger Quality Options, Inc., and Geisinger Indemnity Insurance Company, unless otherwise noted. Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

Coverage for experimental or investigational treatments, services and procedures is specifically excluded under the member's certificate with Geisinger Health Plan. Unproven services outside of an approved clinical trial are also specifically excluded under the member's certificate with Geisinger Health Plan. This policy does not expand coverage to services or items specifically excluded from coverage in the member's certificate with Geisinger Health Plan. Additional information can be found in MP015 Experimental, Investigational or Unproven Services.

Prior authorization and/or pre-certification requirements for services or items may apply. Pre-certification lists may be found in the member's contract specific benefit document. Prior authorization requirements can be found at <https://www.geisinger.org/health-plan/providers/ghp-clinical-policies>

Please be advised that the use of the logos, service marks or names of Geisinger Health Plan, Geisinger Quality Options, Inc. and Geisinger Indemnity Insurance Company on a marketing, press releases or any communication piece regarding the contents of this medical policy is strictly prohibited without the prior written consent of Geisinger Health Plan. Additionally, the above medical policy does not confer any endorsement by Geisinger Health Plan, Geisinger Quality Options, Inc. and Geisinger Indemnity Insurance Company regarding the medical service, medical device or medical lab test described under this medical policy.