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Department of Origin: Integrated Healthcare Services	**Effective Date:** 09/10/24
Approved by: Medical Policy Quality Management Subcommittee	**Date Approved:** 09/10/24
Clinical Policy Document Bone Growth Stimulators (Osteogenic), Electrical and Ultrasonic	**Replaces Effective Clinical Policy Dated:** 09/28/23
Reference #: MC/F021	**Page:** 1 of 6

PURPOSE:
The intent of this clinical policy is to ensure services are medically necessary.

Please refer to the member's benefit document for specific information. To the extent there is any inconsistency between this policy and the terms of the member's benefit plan or certificate of coverage, the terms of the member's benefit plan document will govern.

POLICY:
Benefits must be available for health care services. Health care services must be ordered by a provider. Health care services must be medically necessary, applicable conservative treatments must have been tried, and the most cost-effective alternative must be requested for coverage consideration.

GUIDELINES:
Medical Necessity Criteria - Must satisfy any of the following: I or II

I. Electrical Bone Growth Stimulator (invasive or non-invasive [external]) – must satisfy any of the following: A - D

   A. As treatment of members with failed spinal fusion (HCPCS E0748 [non-invasive]) – must satisfy all of the following: 1 and 2
      1. Previously failed spinal fusion (where a minimum of 6 months has elapsed since surgery); and

      2. Serial radiographs or other appropriate imaging studies confirm no evidence of progression of healing for 3 or more months during the latter portion of the 6-month period.

   B. As an adjunct to spinal fusion surgery (HCPCS E0748 [non-invasive] or E0749 [invasive]) – must satisfy any of the following: 1 - 3
      1. Multi-level (two or more interspaces, three or more vertebrae) spinal fusion to be performed; or

      2. *Grade III* or worse *spondylolisthesis*; or

      3. Presence of risk factors for fusion failure – any of the following: a - f
         a. Smoking; or
         b. Diabetes; or
         c. Renal disease; or
         d. Obesity (BMI greater than or equal to 30); or
         e. Alcoholism; or
         f. Chronic steroid therapy.

   C. Fracture non-union of the appendicular skeleton (includes bones of the shoulder girdle, upper extremities, pelvis, and lower extremities) (HCPCS E0747) – must satisfy all of the following: 1 and 2
      1. Fracture gap is less than or equal to 1 cm; and

2. Serial radiographs or other appropriate imaging studies confirm no evidence of progression of healing for a minimum of 3 months prior to starting treatment with electrical bone growth stimulator despite appropriate fracture care**.**

D. Congenital pseudoarthrosis

II. Ultrasonic Bone Growth Stimulators (HCPCS E0760) – must satisfy any of the following: A - B

A. As an adjunct to conventional fracture management of fresh, closed fracture when any of the following are present: 1 - 5
   1. Closed distal radius fracture (Colles'); or
   2. Fifth metatarsal fracture (Jones'); or
   3. Scaphoid/ navicular carpal fracture; or
   4. Tibial diaphyseal fracture.
   5. Fractures at high-risk for non-union due to any of the following: a - c
      a. Poor vascular supply at site of fracture; or
      b. Extensive soft tissue or vascular damage; or
      c. Presence of comorbidities, which include any of the following: 1) – 7)
         1) Smoking; or
         2) Diabetes, renal disease, or any metabolic diseases; or
         3) Alcoholism; or
         4) Nutritional deficiency; or
         5) Obesity (BMI greater than or equal to 30); or
         6) Anemia; or
         7) Steroid therapy

B. Fracture non-union of the appendicular skeleton (includes bones of the shoulder girdle, upper extremities, pelvis, and lower extremities) - must satisfy all of the following: 1 - 2
   1. Fracture gap is less than or equal to 1cm; and
   2. Serial radiographs or other appropriate imaging studies confirm no evidence of progression of healing for 3 or more months prior to starting treatment with ultrasonic bone growth stimulator despite appropriate fracture care.

EXCLUSIONS (not limited to):
Refer to member's Certificate of Coverage or Summary Plan Description

The following are considered investigative (see Investigative List): I - II

I. Electrical Bone Growth Stimulator
   A. Avascular necrosis of the hip; or
   B. Charcot arthropathy; or
   C. Charcot foot; or
   D. Draining osteomyelitis; or

E. Fresh fracture; or
F. Synovial pseudoarthrosis; or
G. Scapula or pelvis fracture; or
H. Lunate fracture.

II. Ultrasonic Bone Growth Stimulator
A. As an adjunct to bunionectomy; or
B. Fracture, failed fusion, or non-union of the axial skeleton (skull or vertebrae); or
C. Congenital pseudoarthrosis; or
D. Fresh fractures that require surgical intervention; or
E. Fresh fractures that are Grade II or III; or
F. Pathological fracture; or
G. Tibial stress fracture.

DEFINITIONS:

Electrical bone growth stimulator:
A stimulator utilizing electrical current to promote bone healing and may either be situated outside the skin or surgically implanted.

Fresh fracture:
Less than or equal to 7 days duration

Invasive stimulator:
A surgically implantable electrical bone growth stimulator that sends direct current to the fracture or non-fusion site to promote healing.

Long bones:
These are bones consisting of a diaphysis (shaft) and 2 epiphyses (ends), and are usually found in the extremities (eg, clavicle, humerus, radius, ulna, femur, tibia, fibula, metacarpals, metatarsals, phalanges).

Non-invasive stimulator:
An electrical bone growth stimulator comprised of a power supply and treatment coils placed outside of the skin on the fracture or non-fusion site. The three types of non-invasive stimulators are: Capacitive Coupling (CC) devices, Pulsed Electromagnetic Field (PEMF) devices, and Combined Magnetic Field (CMF) devices.

Pseudoarthrosis:
A condition in which a bone does not heal after fracture.

Spondylolisthesis:
A condition in which a vertebra usually located in the lower region of the spine slips from its original position and slides forward over the vertebra located below it.

Spondylolisthesis Grades:

Grade I	25% of vertebral body has slipped forward
Grade II	50%
Grade III	75%
Grade IV	100%
Grade V	Vertebral body completely fallen off (ie, spondyloptosis)

Ultrasound bone growth stimulator:
A stimulator placed outside the skin over the fracture or non-fusion site and emit low-intensity ultrasound signals to the fracture or non-fusion site to promote healing.

Prior Authorization: No

CODING:
CPT® or HCPCS
E0747 Osteogenesis stimulator, electrical, noninvasive, other than spinal applications (eg, OrthoLogic 1000)
E0748 Osteogenesis stimulator, electrical, noninvasive, spinal applications (eg, Spinal Stim)
E0749 Osteogenesis stimulator, electrical, surgically implanted (eg, SpF-2)
E0760 Osteogenesis stimulator, low intensity ultrasound, noninvasive (eg, Sonic Accelerated Fracture Healing System [SAFHS])

REFERENCES:
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3. Centers for Medicare and Medicaid Services (CMS). National coverage determination (NCD) for osteogenic stimulators. 04/27/2005. Manual Section Number:150.2. Retrieved from https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=65&ncdver=2&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=Minnesota&KeyWord=osteogenic+stimulato&KeyWordLookUp=Title&KeyWordSearchType=And&bc=gAAAACAAAAAAAA%3d%3d&. Accessed 06-26-24.
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- Written information in other formats (large print, audio, accessible electronic formats, other formats)

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PreferredOne Community Health Plan
PO Box 59052
Minneapolis, MN 55459-0052
Phone: 1.800.940.5049 (TTY: 763.847.4013)
Fax: 763.847.4010
customerservice@preferredone.com

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You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:

U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
1-800-368-1019, 800-537-7697 (TDD)

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Fax: 763.847.4010
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U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
1-800-368-1019, 800-537-7697 (TDD)

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