Medical Policy

PARAMOUNT

HMO AND PPO
ELITE (MEDICARE ADVANTAGE)
MARKETPLACE

Bone Growth Stimulating Services/Devices (Osteogenic Stimulators)

Policy Number: PG0232
Last Review: 05/01/2023

GUIDELINES:

- This policy does not certify benefits or authorization of benefits, which is designated by each individual policyholder terms, conditions, exclusions, and limitations contract. It does not constitute a contract or guarantee regarding coverage or reimbursement/payment. Self-Insured group specific policy will supersede this general policy when group supplementary plan document or individual plan decision directs otherwise.
- Paramount applies coding edits to all medical claims through coding logic software to evaluate the accuracy and adherence to accepted national standards.
- This medical policy is solely for guiding medical necessity and explaining correct procedure reporting used to assist in making coverage decisions and administering benefits.
- Durable Medical Equipment (DME) frequency limitations are calculated based on The Center for Medicare and Medicaid Services (CMS) criteria and guidelines, National Coverage Determinations (NCD), and Local Coverage Determinations (LCD) rules and regulations.

SCOPE:

X Professional
_ Facility

DESCRIPTION:

Electrical Bone Growth Stimulation describes the use of a device (either implanted into the body or worn externally), that uses an electric field or current to stimulate the growth of bone tissue. These devices have been proven effective in the treatment of many conditions of failed bone growth.

- **Invasive**: The implantable current generator is surgically placed in an intramuscular or subcutaneous space, while an electrode is implanted within the fragments of bone graft at the targeted fusion site. The implanted device is usually functional for 6 to 9 months at which point the current generator is removed in a second surgical procedure, while the electrodes may or may not be removed. Implantable bone growth stimulators are used as an adjunct to spinal fusion surgery and implanted at the time of surgery. They have been investigated for use in the appendicular skeleton.
- **Non-Invasive**: An external power source generates a weak electrical current to the target sites using either pulsed electromagnetic fields, capacitive coupling or combined magnetic fields.

Ultrasonic Bone Growth Stimulation describes the use of a non-invasive device that emits low intensity, pulsed ultrasound to accelerate bone repair. The device is characterized by a main operating unit with an external power supply that is connected to a treatment head module affixed to a mounting fixture and centered over the fracture site. This device is specifically programmed to promote accelerated fracture healing. It does not increase the temperature of the tissue; therefore, can be administered by the patient at home in one daily 20-minute treatment.

POLICY:

Paramount Commercial Insurance Plans and Elite (Medicare Advantage) Plans

Bone Growth Stimulating Services/Devices (Osteogenic Stimulators) (E0747, E0748, E0749 & E0760) require prior authorization.

Elite (Medicare Advantage) Plans

Code E0749 is non-covered for Elite (Medicare Advantage) Plans

COVERAGE CRITERIA:
Paramount Commercial Insurance Plans and Elite (Medicare Advantage) Plans

Bone Growth Stimulating Services/Devices (Osteogenic Stimulators) are considered covered services, applying the products to the member's Durable Medical Equipment (DME) benefit, and any related surgical procedure to the medical benefit.

ELECTRICAL BONE GROWTH STIMULATOR: NON-SPINAL (HCPCS code E0747, E0749)
A non-spinal electrical osteogenesis stimulator (20974, 20975, E0747, E0749) is covered only if any of the following criteria are met:
1. Nonunion of a long bone fracture (see Appendices section) defined as radiographic evidence that fracture healing has ceased for three or more months prior to starting treatment with the osteogenesis stimulator, or
2. Failed fusion of a joint other than in the spine where a minimum of nine (9) months has elapsed since the last surgery, or
3. Congenital pseudarthrosis.

Nonunion of a long bone fracture must be documented by 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 views of the fracture site, and with a written interpretation by a physician stating that there has been no clinically significant evidence of fracture healing between the two sets of radiographs.

A non-spinal electrical osteogenesis stimulator will be denied as not medically necessary if none of the criteria above are met.

The use of an electrical bone growth stimulator (non-invasive or invasive) is non-covered for ANY other indication, including ANY of the following, because it is considered experimental, investigational, or unproven:
- treatment of fresh fractures
- when used to enhance healing of fractures that are at high risk for delayed union or nonunion (e.g., smoking, diabetes, renal disease)
- stress fracture

ELECTRICAL BONE GROWTH STIMULATOR: SPINAL (HCPCS Codes E0748, E0749)
A spinal electrical osteogenesis stimulator (20974, 20975, E0748, E0749) is covered only if any of the following criteria are met:
1. Failed spinal fusion where a minimum of nine (9) months has elapsed since the last surgery, or
2. Following a multilevel spinal fusion surgery (see Appendices section), or
3. Following spinal fusion surgery where there is a history of a previously failed spinal fusion at the same site.

A spinal electrical osteogenesis stimulator will be denied as not medically necessary if none of the criteria above are met.

ULTRASOUND BONE GROWTH STIMULATOR (HCPCS code E0760)
An ultrasonic osteogenesis stimulator (20974, E0760) is covered only if all the following criteria are met:
1. Nonunion of a fracture documented by a minimum of two sets of radiographs obtained prior to starting treatment with the osteogenesis stimulator, separated by a minimum of 90 days. Each radiograph set must include multiple views of the fracture site accompanied by 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
2. The fracture is not of the skull or vertebrae; and
3. The fracture is not tumor related.

An ultrasonic osteogenesis stimulator will be denied as not medically necessary if any of the criteria above are not met.

Use of an ultrasonic osteogenesis stimulator for the treatment of a fresh fracture or delayed union will be denied as not medically necessary.

Ultrasound conductive coupling gel (A4559) is covered and separately payable if an ultrasonic osteogenesis stimulator is covered.

An ultrasonic osteogenesis stimulator will be denied as not medically necessary if it is used with other noninvasive osteogenesis stimulators.

An ultrasound bone growth stimulator is non-covered for ANY other indication, including ANY of the following, because it is considered experimental, investigational, or unproven:

- as part of the acute treatment (i.e., preoperative, immediately postoperative) of any fracture requiring open reduction and internal fixation (ORIF)
- fresh fractures (other than for the above listed indications)
- stress fracture

APPENDICES

- A multilevel spinal fusion is one which involves 3 or more vertebrae (e.g., L3-L5, L4-S1, etc.).
- A long bone is limited to a clavicle, humerus, radius, ulna, femur, tibia, fibula, metacarpal, or metatarsal.

Paramount Commercial Plans and Elite (Medicare Advantage) Plans
The use of an electrical bone growth stimulator (spinal, non-spinal, invasive, non-invasive) is non-covered for ANY other indication, including the following, because it is considered experimental, investigational, or unproven (this list may not be all inclusive):

- toe fracture
- sesamoid fracture
- avulsion fracture
- osteochondral lesion
- displaced fractures with malalignment
- synovial pseudoarthrosis
- the bone gap is either > 1cm or > one-half the diameter of the bone
- pars interarticularis defect (i.e., spondylolysis, spondylolisthesis)
- as an adjunct to cervical spinal fusion surgery
- stress fracture

CODING/BILLING INFORMATION:
The appearance of a code in this section does not necessarily indicate coverage. Codes that are covered may have selection criteria that must be met. Payment for supplies may be included in payment for other services rendered.

CPT CODES	
20974	Electrical stimulation to aid bone healing; non-invasive (non-operative); for both the osteogenic stimulator non-invasive, and osteogenic stimulator, non-invasive spinal application
20975	Electrical stimulation to aid bone healing; invasive (operative); surgical code for osteogenesis stimulator surgically implanted
20979	Low intensity ultrasound stimulation to aid bone healing, non-invasive (non-operative)
HCPCS CODES	
A4559	Coupling gel or paste, for use with ultrasound device, per oz.
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, noninvasive

REVISION HISTORY EXPLANATION: ORIGINAL EFFECTIVE DATE: 06/01/2009

Date	Explanation & Changes
01/14/2014	• Removed ICD-9 procedure codes 78.9 & 99.86 • ICD-10 Codes added from ICD-9 conversion • Policy reviewed and updated to reflect most current clinical evidence • Approved by Medical Policy Steering Committee as revised
06/13/2017	• Procedure codes 20974-20979 do not require prior authorization • ICD-9 codes removed • Policy reviewed and updated to reflect most current clinical evidence per Medical Policy Steering Committee
03/30/2018	• Added Appendices section as referenced in the criteria per CMS guidelines
04/26/2018	• Reviewed and confirmed the use of an electrical bone growth stimulator (spinal, non-spinal, invasive, non-invasive) is non-covered as an adjunct to cervical spinal fusion surgery • Policy reviewed and updated to reflect most current clinical evidence per The Technology Assessment Working Group (TAWG)
09/27/2018	• Clarified that code E0749 is non-covered for Advantage & Elite per ODM & CMS guidelines • Effective 10/09/18 adjunct to cervical spinal fusion surgery is no longer a non-covered indication for Advantage per ODM guidelines • Policy reviewed and updated to reflect most current clinical evidence per The Technology Assessment Working Group (TAWG)
12/16/2020	• Medical policy placed on the new Paramount Medical Policy Format
02/15/2023	• Medical Policy updated to reflect Medicaid coverage to Anthem as of 02/01/2023
05/01/2023	• Medical Policy updated to reflect DME limits calculated by CMS criteria/guidelines • Policy reviewed and updated to reflect the most current clinical evidence
03/05/2024	• Medical Policy placed on the new Paramount Medical Policy format

Paramount reserves the right to review and revise our policies periodically when necessary. When there is an update, we will publish the most current policy to https://www.paramounthealthcare.com/providers/medical-policies/policy-library

REFERENCES/RESOURCES

Centers for Medicare and Medicaid Services, CMS Manual System and other CMS publications and services https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs

American Medical Association, *Current Procedural Terminology (CPT®)* and associated publications and services https://www.ama-assn.org/amaone/cpt-current-procedural-terminology

Centers for Medicare and Medicaid Services, Healthcare Common Procedure Coding System, HCPCS Release and Code Sets https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/HCPCS-Quarterly-Update

U.S. Preventive Services Task Force, https://www.uspreventiveservicestaskforce.org/uspstf/
Industry Standard Review

Hayes, Inc., https://www.hayesinc.com/

Industry Standard Review

Medical Policy History – Prior to 03/05/2024

Paramount Commercial Insurance Plans, Medicare Advantage Plans and Paramount Advantage Medicaid

Bone Growth Stimulating Services/Devices (Osteogenic Stimulators) (E0747, E0748, E0749 & E0760) require prior authorization.

Medicare Advantage Plans and Paramount Advantage Medicaid
Code E0749 is non-covered for Medicare Advantage Plans and Paramount Advantage Medicaid.

Paramount Advantage Medicaid
The use of an electrical bone growth stimulator (spinal, non-spinal, invasive, non-invasive) is non-covered for ANY other indication, including the following, because it is considered experimental, investigational, or unproven (this list may not be all inclusive):

- toe fracture
- sesamoid fracture
- avulsion fracture
- osteochondral lesion
- displaced fractures with malalignment
- synovial pseudoarthrosis
- the bone gap is either > 1cm or > one-half the diameter of the bone
- pars interarticularis defect (i.e., spondylolysis, spondylolisthesis)
- stress fracture