



## Medica Central Utilization Management Policy

**Title:** Bone Growth Stimulators -Electrical (Long Bones) And Ultrasound MP9076 (III-DEV.07)

**Effective Date:** October 1, 2024

*This policy was developed with input from specialists in orthopedics, orthopedic surgery, and neurosurgery and endorsed by the Medical Policy Committee.*

NOTE: Medica is using clinical criteria for noninvasive electrical stimulation of the spine developed by Carelon, a utilization management (UM) program third-party vendor, to assist in administering medical necessity criteria.

### IMPORTANT INFORMATION – PLEASE READ BEFORE USING THIS POLICY

*These services may or may not be covered by all Medica Central plans. Coverage is subject to requirements in applicable federal or state laws. Please refer to the member’s plan document for other specific coverage information. If there is a difference between this general information and the member’s plan document, the member’s plan document will be used to determine coverage. With respect to Medicare, Medicaid, and other government programs, this policy will apply unless these programs require different coverage.*

*Members may contact Medica Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions may call the Provider Service Center. Please use the Quick Reference Guide on the Provider Communications page for the appropriate phone number. <https://mo-central.medica.com/Providers/SSM-employee-health-plan-for-IL-MO-OK-providers>*

*Medica Central coverage policies are not medical advice. Members should consult with appropriate health care providers to obtain needed medical advice, care, and treatment.*

### PURPOSE

To promote consistency between utilization management reviewers by providing the criteria that determines the medical necessity.

### BACKGROUND

#### I. Definitions

- A. **Delayed union** is when the healing process continues, but the fracture takes longer than usual to heal. The fact that a bone is delayed in its union does not mean that it will become a non-union. Reasons for delayed union may include inadequate reduction, inadequate immobilization, poor calcium and vitamin D3 intake, and impaired blood supply.
- B. **Electrical bone growth stimulators** use electromagnetic current to stimulate osteogenesis (bone growth).

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- C. **Non-union fracture** is the result of an arrest in the healing process and is defined by the following three findings:
1. Motion at the fracture site,
  2. Radiographic evidence showing the persistence of the fracture line without bridging callus,
  3. Incomplete progression toward radiographic healing in the expected length of time for the given bone and further healing not expected.
- D. **Long bones** are bones that consist of a cylindrical shaft (body) with a central cavity and two extremities, which are usually expanded for purposes of articulation and muscular attachment. Long bones are the femur, tibia, fibula, humerus, radius, ulna, clavicle, metacarpal, metatarsal, and phalanges.
- E. **Skeletal maturity** occurs when bone growth ceases after puberty and refers to demonstration of fusion of skeletal bones. Females reach skeletal maturity at approximately 16 years of age, while males reach skeletal maturity around 18 years of age. Radiographs of either the knee or of the hand and wrist with subsequent mathematical calculations are often used when exact measurement of skeletal maturity is warranted.
- F. **Ultrasound bone growth stimulators** are external devices that apply low-intensity, pulsed, acoustical pressure, and ultrasound waves to the skin surface above fracture sites. Although the exact mechanism of action is unclear, it is known that pressure waves provide micromechanical stress and strain to bone and surrounding tissue. It is speculated that this stress and strain leads to biochemical alterations at the cellular level that leads to enhanced bone formation.
- II. Comments
- A. The most common symptoms of non-union fracture are pain and motion at the fracture site.
- B. Electrical bone growth stimulators fall into one of three categories: invasive, semi-invasive or non-invasive.
1. Invasive and semi-invasive devices use direct current that is delivered internally to the fracture site via implanted electrodes.
  2. Non-invasive devices use an external power supply to create pulsed electromagnetic fields (PEMF), combined magnetic fields (CMF), or direct current. Leads are placed over the cast and the electromagnetic field is established between the leads and fracture site.
- C. Ultrasound bone growth stimulation has not been adequately tested in children; in pregnant or nursing women; in individuals with sensory paralysis, vascular insufficiency, thrombophlebitis, abnormal skin sensitivity, nutritional deficiency, or alcoholism; or with patients receiving medications known to affect bone metabolism.
- D. A 2001 specialty panel of local orthopedic surgeons indicated that generally there is no medically appropriate use for ultrasound bone growth stimulators for fresh radial fractures. However, for a very small population of fresh tibial fractures, the panel felt it may be useful.

### BENEFIT CONSIDERATIONS

1. Prior authorization **is required** for bone growth stimulation.
  - Please see the prior authorization list for product specific prior authorization requirements.
  - Coverage is limited to devices that have FDA approval for use on the involved bone.
2. Coverage may vary according to the terms of the member's plan document.

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3. Concurrent use of electrical and ultrasound stimulation devices is not eligible for coverage.
4. Electrical bone growth stimulation *is investigative and therefore not covered* for all indications not specifically mentioned in the Medical Necessity Criteria section, including but not limited to: (1) long bone, fresh fractures; (2) nonunion of appendicular bones other than long bones; (3) delayed union of long bone fractures, (4) biologically inert nonunions better suited to bone grafting, and (5) scaphoid fractures (all types: e.g., nonunion, acute/fresh, delayed union).
5. Ultrasound bone growth stimulation *is investigative and therefore not covered* for all indications not specifically mentioned in the Medical Necessity Criteria section, including but not limited to: (1) delayed union fractures; (2) non-union fractures of the skull, vertebrae, and those that are tumor-related; (3) fresh non-tibial fractures and (4) scaphoid fractures, other than nonunions (e.g. acute/fresh, delayed union).
6. Interferential current stimulation *is investigative and therefore not covered*. Please see Coverage Policy, *Interferential Current Stimulation*.
7. If the Medical Necessity Criteria and Benefit Considerations are met, The Health Plan will authorize benefits within the limits in the member's plan document.
8. If it appears that the Medical Necessity Criteria and Benefit Considerations are not met, the individual's case will be reviewed by the medical director or an external reviewer. Practitioners are advised of the appeal process in their administrative handbook.

### MEDICAL NECESSITY CRITERIA

#### **Electrical bone growth stimulators**

Electrical bone growth stimulator is considered medically necessary when documentation in the medical records indicates that **one of the following** are met:

#### **A. Long bone fracture**

**All of the following** criteria must be met:

1. The fracture was acquired secondary to trauma or surgery
2. There is evidence of adequate fracture care (e.g., casting, immobilization, internal fixation)
3. The fracture gap is less than or equal to 1 centimeter
4. Documented confirmation that the fracture is an **established non-union** as indicated by **all of the following**:
  - a. The non-union fracture is defined in the medical record by radiographic evidence that fracture healing has ceased for three or more months *prior to* starting treatment with the osteogenesis stimulator
  - b. The non-union fracture is documented in the medical record by interpretation of a minimum of two sets of radiographs obtained *prior to* starting treatment with the osteogenic stimulator, with radiographic sets separated by a minimum of 90 days (measured from the date of the most recent medical or surgical intervention).

#### **B. Congenital pseudoarthroses** using only non-invasive electrical bone growth stimulator.

#### **Ultrasound bone growth stimulators**

Ultrasound bone growth stimulator is considered medically necessary when documentation in the medical records indicates that **one of the following** are met:

#### **A. Fresh fracture**

**All of the following** criteria must be met:

1. Fresh fracture of the tibia
2. Orthopedic closed management with or without reduction
3. Fracture less than seven days old

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4. The fracture gap is less than or equal to 1 centimeter
5. Skeletal maturity evidenced
6. None of the following contraindications are present:
  - a. Fracture that is pathological or associated with malignancy
  - b. Fracture that is unstable, or requires surgical intervention or internal or external fixation
  - c. Postreduction displacement greater than 50 percent or postreduction angulation or malalignment
  - d. Presence of pacemaker or implantable defibrillator
  - e. Concurrent use of electrical stimulation.

**B. Non-union fracture** (including scaphoid)

**All of the following** criteria must be met:

1. The fracture does not involve the skull or vertebrae, and is not tumor related
2. The fracture was acquired secondary to trauma or surgery
3. There is evidence of adequate fracture care (e.g., casting, immobilization, internal fixation)
4. The fracture gap is less than or equal to 1 centimeter
5. Documented confirmation that the fracture is an **established non-union** as indicated by **all of the following**:
  - a. The non-union fracture is defined in the medical record by radiographic evidence that fracture healing has ceased for three or more months *prior to* starting treatment with the osteogenesis stimulator
  - b. The non-union fracture is documented in the medical record by interpretation of a minimum of two sets of radiographs obtained *prior to* starting treatment with the osteogenic stimulator, with radiographic sets separated by a minimum of 90 days (measured from the date of the most recent medical or surgical intervention).

**NOTE:** Ultrasound bone growth stimulation for the treatment of **fresh fracture of the radius** is **not medically necessary**.

### CENTERS FOR MEDICARE & MEDICAID SERVICES (CMS)

- For Medicare members, refer to the following, as applicable at:  
<https://www.cms.gov/medicare-coverage-database/new-search/search.aspx>

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### DOCUMENT HISTORY

Document	Committee/Source	Date(s)
<b>Created:</b>	Medical Policy Committee/Health Services Division	February 20, 2019
<b>Revised:</b>	Medical Policy Committee/Health Services Division	August 19, 2020
	Medical Policy Committee/Health Services Division	August 18, 2021
	Medical Policy Committee/Health Services Division	May 18, 2022
	Medical Policy Committee/Health Services Division	May 17, 2023
	Medical Policy Committee/Health Services Division	May 15, 2024
<b>Reviewed:</b>	Medical Policy Committee/Health Services Division	August 19, 2020
	Medical Policy Committee/Health Services Division	August 18, 2021
	Medical Policy Committee/Health Services Division	May 18, 2022
	Medical Policy Committee/Health Services Division	May 17, 2023
	Medical Policy Committee/Health Services Division	May 15, 2024

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No new references

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No new references

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No new references

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No new references.