Bone Growth Stimulators

Clinical Guidelines for Medical Necessity Review

Version: 1.0
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Important Notices

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Guideline Information:

Specialty Area: Diseases & Disorders of the Musculoskeletal System (M00-M99)
Guideline Name: Bone Growth Stimulators - Single Service

Literature review current through: 11/3/2023
Document last updated: 11/3/2023
Type: [**X**] Adult (18+ yo) | [_] Pediatric (0-17yo)

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Medical Necessity Criteria

Service: Bone Growth Stimulators

General Guidelines

- **Units, Frequency, & Duration:** None.
- **Criteria for Subsequent Requests:** Approval when the patient meets the medical necessity criteria below.
- **Recommended Clinical Approach:** None.
- **Exclusions:** Nonunion fractures of the skull, vertebrae, or tumor-related fractures; ultrasonic osteogenic stimulators used in conjunction with other non-invasive osteogenic devices; and ultrasonic osteogenic stimulators used for fresh fractures and delayed unions.

Medical Necessity Criteria

Indications

➔ **Bone Growth Stimulators** are considered appropriate if **ALL** of the following are **TRUE**:

- ◆ The device is **ANY** of the following:
  - Non-invasive stimulator device; **OR**
  - Invasive stimulator device and **ALL** of the following are **TRUE**[1]:
    - The above indications for a non-invasive have been met; **AND**
    - Surgery is already planned for a non-union fracture; **AND**
    - Patient compliance with a non-invasive bone stimulator is a concern; **AND**
- ◆ **ANY** of the following is **TRUE**[1]:
  - Documented non-union (greater than 3 months since the time of the fracture) of a fracture; **OR**
  - Failed fusion, where a minimum of 9 months has elapsed since the last surgery; **OR**
  - Congenital pseudarthroses; **OR**
  - As an adjunct to spinal fusion surgery when **ANY** of the following is **TRUE**:
    - Patient has a high-risk of pseudarthrosis due to a prior failed spinal fusion at same site; **OR**

    - A multiple level fusion is planned (e.g., involving three or more vertebrae [L3 to L5, L4 to S1, etc.]); **OR**
    - **ANY** of the following comorbidities:
        - Diabetes; **OR**
        - Inflammatory arthritis (e.g., rheumatoid arthritis) that has required long-term corticosteroid therapy; **OR**
        - Immunocompromised (e.g., undergoing chemotherapy and radiation therapy to the spine, hypogammaglobulinemia, granulocytopenia, acquired immune deficiency syndrome, chronic granulomatous disease); **OR**
        - Systemic vascular disease; **OR**
        - Osteopenia or osteoporosis; **OR**
        - Smoker; **OR**
- Two or more radiographs showing confirmation that fracture healing has ceased for three or more months prior before the start of treatment with electrical osteogenic stimulator

Non-Indications

➔ **Bone Growth Stimulators** are not considered appropriate if **ANY** of the following is **TRUE**:[1-2]

- Pregnancy; **OR**
- Infection; **OR**
- Malignancy; **OR**
- Nonunion fractures of the skull; **OR**
- Nonunion fractures of vertebrae; **OR**
- Nonunion fractures of that are tumor-related; **OR**
- Ultrasonic osteogenic stimulators used in conjunction with other non-invasive osteogenic devices; **OR**
- Ultrasonic osteogenic stimulators for fresh fractures and delayed unions; **OR**
- For a patient with cardiac pacemakers or defibrillators: Consultation with a cardiologist is indicated prior to the use of electrical stimulation for any patient who has a cardiac pacemaker or defibrillator.[7]

Level of Care Criteria

Outpatient.

Procedure Codes (HCPCS/CPT)

HCPCS/CPT Code	Code Description
20974	Electrical stimulation to aid bone healing; noninvasive (nonoperative)
20975	Electrical stimulation to aid bone healing; invasive (operative)
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

Medical Evidence

The **American Association of Neurological Surgeons (AANS)** and **Congress of Neurological Surgeons (CNS)** published guidelines on the performance of fusion procedures for degenerative disease of the lumbar spine. The literature supports the procedures to increase fusion rates for patients who have an above-average risk of non-fusion.[3]

The **North American Spine Society (NASS)** published coverage recommendations for *Electrical Stimulation for Bone Healing.* The evidence does not support coverage for low-intensity pulsed ultrasound or combined magnetic field technology for spinal use. The NASS supports electrical stimulation for augmentation of spinal fusion for all regions of the spine in patients with above average risk for pseudoarthrosis with specific criteria (e.g., correction of previous spinal fusion, fusion of three or more vertebrae, presence of comorbidities, patient unable to cease smoking before fusion).[2]

The **National Institute for Health and Care Excellence (NICE)** published three interventional procedure guidelines:

- *Low-Intensity Pulsed Ultrasound to Promote Healing of Fresh Fractures at Low Risk of Non-Healing [IPG621].* While safety concerns are minimal, the medical literature does not have a high level of efficacy.[4]

- *Low-Intensity Pulsed Ultrasound to Promote Healing of Fresh Fractures at High Risk of Non-Healing [IPG622]*. Current medical literature indicates that the procedure is suitable in a research context. Future research should focus on patient selection, fracture site, and risk factors or comorbidities that may delay healing. There are no safety concerns in the guidance.[5]

- *Low-Intensity Pulsed Ultrasound to Promote Healing of Delayed-Union and Non-Union Fractures [IPG623]*. Evidence supports the use of ultrasound with other treatments for delayed-union and non-union fractures.[6]

References

1. Centers for Medicare and Medicaid Services (CMS). National coverage determination: Osteogenic stimulators (150.2). Effective Date April 27, 2005. Accessed October 26, 2023. https://www.cms.gov/medicare-coverage-database/search.aspx.
2. North American Spine Society (NASS). NASS coverage policy recommendations: Electrical stimulation for bone healing. Published October 2016. Accessed October 27, 2023. https://www.spine.org/.
3. Kaiser MG, Eck JC, Groff MW, et al. Guideline update for the performance of fusion procedures for degenerative disease of the lumbar spine. Part 17: Bone growth stimulators as an adjunct for lumbar fusion. J Neurosurg Spine. 2014 Jul;21(1):133-9. doi: 10.3171/2014.4.SPINE14326. PMID: 24980594.
4. National Institute for Health and Care Excellence (NICE). Low-intensity pulsed ultrasound to promote healing of fresh fractures at low risk of non-healing [IPG621]. Published July 31, 2018. Accessed October 24, 2023. https://www.nice.org.uk/guidance/ipg621.
5. National Institute for Health and Care Excellence (NICE). Low-intensity pulsed ultrasound to promote healing of fresh fractures at high risk of non-healing [IPG622]. Published July 31, 2018. Accessed October 25, 2023. https://www.nice.org.uk/guidance/ipg622.
6. National Institute for Health and Care Excellence (NICE). Low-intensity pulsed ultrasound to promote healing of delayed-union and non-union fractures [IPG623]. Published July 31, 2018. Accessed October 25, 2023. https://www.nice.org.uk/guidance/ipg623.
7. North American Spine Society (NASS). NASS coverage policy recommendations: Electrical stimulation for bone healing. Published October 2016.

Clinical Guideline Revision History/Information

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Review History	