

Bone Growth Stimulator Coverage Guidelines

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Purpose:

The Medical Technology Assessment Committee will review published scientific literature and information from appropriate government regulatory bodies (when available) related to bone growth stimulation in order to determine inclusion in the benefit plan.

Compliance Status:

- Centers for Medicare & Medicaid Services (CMS)

Recommendation:

A recommendation was made by the MTAC following discussion by committee members based on current literature:

Eligibility Criteria

Ultrasonic bone growth stimulators are covered (up to the Member's contractual DME limits) for ANY of the following conditions:

- a.) When used as an adjunct to closed reduction and immobilization for ANY of the following acute fracture indications:
- Closed or grade I open, tibial diaphyseal fractures;
 - Closed fractures of the distal radius (Colles' fracture);
 - Closed fractures when there is suspected high risk for delayed fracture or nonunion as a result of either of the following:
 - Due to location and poor blood supply (e.g., scaphoid, 5th metatarsal);
 - The presence of any risk factor such as smoking, diabetes, renal disease, or other metabolic disease where bone healing is likely to be compromised.
- b.) For non-union of fractures when ALL of the following criteria are met:
- The treatment is for non-union of bones other than the skull or vertebrae (e.g., radius, ulna, humerus, clavicle, tibia, femur, fibula, carpal, metacarpal, tarsal, or metatarsal);
 - The non-union is not related to malignancy;
 - It is \geq three (3) months from the date of injury or initial treatment;
 - The fracture non-union is documented by at least two (2) sets of appropriate imaging studies separated by a minimum of 90 days confirming that clinically significant fracture healing has not occurred.
- c.) For treatment of a stress fracture that has failed to heal after minimum of 90 days of conventional, non-surgical management and demonstrates a fracture line that has not healed on imaging studies.

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Recommendation, continued:

Eligibility Criteria, continued

Electrical bone growth stimulators (non-invasive only) are covered (up to the Member's contractual DME limits) for ANY of the following conditions:

- a.) The treatment is for a fracture non-union and ALL of the following criteria are met:
 - The non-union is located in a long bone (i.e., clavicle, humerus, radius, ulna, femur, tibia, fibula, metacarpal or metatarsal bone) or the carpal and tarsal bones;
 - The fracture gap is ≤ 1 cm;
 - The fracture non-union is documented by at least two (2) sets of appropriate imaging studies;
 - Separated by a minimum of 90 days confirming that clinically significant fracture healing has not occurred.

- b.) When used in conjunction with surgical intervention for the treatment of an established fracture non-union.

- c.) For failed fusion of a joint other than the spine when a minimum of three (3) months has elapsed since the time of initial surgery.

- d.) For treatment of a stress fracture that has failed to heal after a minimum of 90 days of conventional, non-surgical management and demonstrates a fracture line that has not healed on imaging studies.

- e.) As an adjunct to spinal fusion surgery when ANY of the following criteria are met:
 - History of prior spinal fusion failure;
 - Multi-level fusion to be performed;
 - Presence of any risk factor for non-healing such as: smoking, diabetes, renal disease, or other metabolic disease where bone healing is likely to be compromised.

Exclusions

The following indications are not covered as they are considered experimental or investigational (this list is not be considered all-inclusive):

Toe fractures	Sesamoid fractures
Avulsion fractures	Osteochondral lesions
Displaced fractures with misalignment	Synovial pseudoarthrosis
The bone gap is either >1 cm or $>$ one-half the diameter of the bone	Treatment of Charcot foot
Avascular necrosis of the hip	Fractures of the scapula or pelvis

References:

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1. Agency for Healthcare Research and Quality (AHRQ). The role of bone growth stimulating devices and orthobiologics in healing nonunion fractures. Technology assessment program. September 21, 2005.
2. Centers for Medicare & Medicaid (CMS).Services. Local Coverage Determinations (LCD). LCD for osteogenesis stimulators (L5012).
3. Centers for Medicare & Medicaid (CMS).Services. National Coverage Determinations. Osteogenic Stimulation. Publication Number 6, Transmittal Number 131. January 2001.
4. Centers for Medicare and Medicaid Services. National Coverage Policy Revision. Electrical stimulation for fracture healing (CAG-00022). Decision Memorandum. July 2000.
5. HAYES Medical Technology Directory™. Electrical Bone Growth Stimulation, Invasive. Lansdale PA: HAYES, Inc. ©2008 Winifred S. Hayes, INC. 2004 February.
6. Hotta S. Electrical bone-growth stimulation and spinal fusion. Health technology assessment review No. 8. 1998. Agency for Health Care Policy and Research (AHCPR) Pub No. 94-0014.

Disclaimer Information:

Coverage Issues Guidelines and Medical Technology Assessment Recommendations are developed to determine coverage for AvMed Health Plans' benefits, and are published to provide a better understanding of the basis upon which coverage decisions are made. AvMed Health Plans makes coverage decisions using these guidelines, along with the Member's benefit document. The use of this guideline is neither a guarantee of payment nor a final prediction of how specific claim(s) will be adjudicated.

Coverage Issues Guidelines and Medical Technology Assessment Recommendations are developed for selected therapeutic or diagnostic services found to be safe, but proven effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the AvMed Health Plans service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations.

Treating providers are solely responsible for the medical advice and treatment of Members. This guideline may be updated and therefore is subject to change.