Non-invasive electrical bone growth stimulation MAY BE ELIGIBLE FOR COVERAGE as treatment of fracture nonunions or congenital pseudoarthroses in the appendicular skeleton (the appendicular skeleton includes the bones of the shoulder girdle, upper extremities, pelvis, and lower extremities). The diagnosis of fracture nonunion must meet ALL of the following criteria:

- at least 3 months have passed since the date of fracture;
- serial radiographs have confirmed that no progressive signs of healing have occurred;
- the fracture gap is one cm or less; and
- the patient can be adequately immobilized and is of an age where likely to comply with non-weight bearing.

Either invasive or noninvasive methods of electrical bone growth stimulation MAY BE ELIGIBLE FOR COVERAGE as an adjunct to spinal fusion surgery for patients with any of the following risk factors for failed fusion:

- one or more previous failed spinal fusion(s);
- grade III or worse spondylolisthesis;
- fusion to be performed at more than one level;
- current smoking habit;
- diabetes;
- renal disease; or
- alcoholism.

Noninvasive electrical bone stimulation MAY BE ELIGIBLE FOR COVERAGE as a treatment of patients with failed spinal fusion. Failed spinal fusion is defined as a spinal fusion which has not healed at a minimum of 6 months after the original surgery, as evidenced by serial x-rays over a course of 3 months.

Electrical bone growth stimulation in the treatment of fresh fractures or delayed union is considered investigational and NOT ELIGIBLE FOR COVERAGE. Delayed union is defined as a decelerating fracture healing process, as identified by serial x-rays.
DESCRIPTION:

Noninvasive and invasive methods of electrical bone growth stimulation are available.

Noninvasive bone growth stimulators use either pulsed electromagnetic fields or capacitative coupling to generate a weak electric current through the target site. Noninvasive bone growth stimulators are used to treat fracture nonunions in the appendicular skeleton, failed fusion after spinal fusion surgery, or as an adjunct to spinal fusion surgery to decrease the incidence of failed fusion (i.e., arthrodesis).

Invasive bone growth stimulators require surgical implantation of a current generator in an intramuscular or subcutaneous space while an electrode is implanted within the fragments of bone graft at the fusion site. Invasive devices use direct current. The power source is removed in a second surgical procedure when stimulation is completed. Invasive bone growth stimulation is used as an adjunct to spinal fusion surgery and is implanted at the time of surgery. Invasive bone growth stimulation is not used in the appendicular skeleton.

The FDA has recently approved labeling changes that do not impose a time frame for the diagnosis of nonunion. Delayed union refers to a decelerating bone healing process, as identified in serial x-rays. (In contrast, nonunion serial x-rays show no evidence of healing.) When lumped together, delayed union and nonunion are sometimes referred to as "ununited fractures."

RATIONALE:

The policy regarding electrical bone stimulation as an adjunct to spinal fusion surgery or as a treatment of failed spinal fusion surgery (i.e., salvage therapy) is based on two TEC assessments, which offered the following conclusions: Data from a randomized controlled clinical trial of patients meeting the criteria for high risk for development of failed fusion suggests that invasive or noninvasive electrical bone stimulation as an adjunct to spinal fusion surgery is associated with a significantly higher spinal fusion success rate in the treated group compared with the control group. Data from uncontrolled studies of patients with failed spinal fusion suggests that noninvasive electrical stimulation result in a significantly higher fusion rate. The lack of controlled clinical trials is balanced by the fact that these patients served as their own control. The policy regarding electrical bone stimulation as a treatment of nonunion of fractures of the appendicular skeleton is based on the FDA-labeled indications. It should be noted that the labeled indications include nonunions or congenital pseudoarthroses of bones of the appendicular skeleton. No distinction is made between long and short bones. The original FDA labeling of fracture nonunions defined nonunions as those fractures that had not shown progressive healing after at least 9 months from the original injury. This time frame is not based on physiologic principles, but was included as part of the research design for FDA approval as a means of ensuring homogeneous populations of patients, many of whom were serving as their own controls. As mentioned above, the presence of a nonunion is related to a variety of factors, such as fracture type and location, degree of soft tissue damage, vascularization, and bone stock. Some fractures may show no signs of healing, based on serial radiographs, as early as 3 months, while a fracture nonunion may not
be diagnosed in others until well after 9 months. At the present
time, the FDA has approved labeling changes for electrical bone growth
stimulators which remove any time frame for the diagnosis. The current
policy of requiring a 3-month time frame is still arbitrary, but
appears to be consistent with the definition of nonunion, as described
in the clinical literature. The policy regarding electrical
stimulation of delayed unions is based on a 1992 TEC assessment, which
offered the following conclusions: While data from a double-blind
randomized controlled clinical trial (and additional long-term outcome
data provided by the investigator) of patients with delayed unions
suggests that a 12 week course of noninvasive electrical bone
stimulation is associated with a significantly higher healing rate
than a control group with a dummy device, there are inadequate data
regarding the final health outcome of the patient, i.e., regained use
of limb, minimal pain, avoidance of subsequent surgery. All patients
in the trial had an unhealed fracture at an average of 23.8 weeks
after injury; all fracture gaps were under 0.5 cm. In terms of long-
term outcome, a significantly greater proportion of the treated
patients avoided any further surgery.

DISCLAIMER:

State and federal law, as well as contract language, including
definitions and specific inclusions/exclusions, takes precedence over
Medical Policy and must be considered first in determining coverage.
The member’s contract benefits in effect on the date that services are
rendered must be used. Any benefits are subject to the payment of
premiums for the date on which services are rendered. Medical
technology is constantly evolving, and we reserve the right to review
and update Medical Policy periodically.
HMO Blue Texas physicians who are contracted/affiliated with a
capitated IPA/medical group must contact the IPA/medical group for
information regarding HMO claims/reimbursement information and other
general polices and procedures.

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