NOTE: This policy has been revised. The revised policy will be effective January 1, 2015. To view the revised policy, click here.

IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

Electrical bone growth stimulators (EBGS) are devices that use electrical currents to promote bone growth and healing. Three types of EBGS are available:

- **Noninvasive EBGS**

  Noninvasive EBGS are externally worn devices that generate a weak electric current within the target site using either pulsed electromagnetic fields, capacitive coupling, or combined magnetic fields. The electrodes are usually placed on the skin and, depending on the technology, worn from ½ to 24 hours per day until healing occurs (up to 9 months).

- **Invasive EBGS**

  Invasive EBGS use direct current and require surgical implantation of both the current generator and an electrode. Usually, the generator is implanted in an intramuscular or subcutaneous space, and an electrode is implanted within the target bone site. The device typically remains functional for six to nine months after implantation. Upon completion of treatment, the generator is removed in a second surgical procedure. The electrode may or may not be removed.
Semi-invasive EBGS

Semi-invasive (semi-implantable) EBGS use direct current supplied by an external power generator and percutaneously placed electrodes.

Regulatory Status

A number of bone growth stimulators from several manufacturers have received premarket approval from the U.S. Food and Drug Administration (FDA).

MEDICAL POLICY CRITERIA

I. Non-invasive electrical bone growth stimulation (EBGS) may be considered medically necessary as treatment of any of the following conditions:

   A. 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.

   B. Congenital pseudoarthroses

   C. Fracture nonunions meeting all of the following criteria:

      1. Location in the appendicular skeleton (the appendicular skeleton includes the bones of the shoulder girdle, upper extremities, pelvis, and lower extremities);

      2. At least 3 months have passed since the date of fracture;

      3. Serial radiographs have confirmed that no progressive signs of healing have occurred over the most recent three month period following fracture or open reduction;

      4. The fracture gap is one cm or less; and

      5. The patient can be adequately immobilized and is of an age where he/she is likely to comply with non-weight bearing.

II. Either invasive or non-invasive EBGS may be considered medically necessary as an adjunct to spinal fusion surgery for patients with any of the following risk factors for failed fusion (see criterion I.A. for definition of failed fusion):

   A. One or more previous failed spinal fusion(s)

   B. Grade III or worse spondylolisthesis

   C. Fusion to be performed at more than one level

   D. Current smoking habit (Note: Other tobacco use such as chewing tobacco is not considered a risk factor)
E. Diabetes
F. Renal disease
G. Alcoholism
H. Significant osteoporosis which has been demonstrated on radiographs
I. Systemic steroid use (e.g. daily dose ≥5 mg prednisone or equivalent for ≥ three months) associated with low bone mass or bone loss.

III. Either invasive or noninvasive EBGS is considered investigational for the treatment of all other conditions, including but not limited to the following:

A. Fresh fractures, defined as receiving treatment within one week of injury or open reduction
B. Delayed union, defined as a decelerating fracture healing process as identified by serial x-rays
C. Acute or chronic spondylolysis (pars interarticularis defect) with or without spondylolisthesis
D. Failed joint fusion following arthrodesis

Failed joint fusion is defined as a joint fusion which has not healed at a minimum of 6 months after the arthrodesis, as evidenced by serial x-rays over a course of 3 months.

IV. Semi-invasive EBGS is considered investigational for the treatment of all conditions.

SCIENTIFIC EVIDENCE

Evidence from randomized controlled trials (RCTs) is needed to establish safety and efficacy of electrical bone growth stimulators (EBGS) as a treatment for any indication.

Despite the lack of reliable evidence, both invasive and non-invasive EBGS have evolved into a standard of care for certain conditions. The focus of this summary is on the uses of EBGS that are considered investigational.

Invasive EBGS (Except as an Adjunct to Spinal Fusion Surgery)

Technology Assessments

The 1992 BlueCross BlueShield Association (BCBSA) Technology Evaluation Center (TEC) assessment of invasive EBGS for the treatment of delayed union or nonunion in long bones was based on a case series of 84 patients, the only published study on the topic at the time.[1] The assessment concluded that “the evidence does not permit conclusions about whether health outcomes are improved, for either nonunion or delayed union” as a result of EBGS therapy.

Randomized Controlled Trials (RCT)
There are no published randomized controlled trials on the use of invasive EBGS for any indications other than as an adjunct to spinal fusion surgery.

**Case Series, Retrospective Reviews, and Other Non-randomized Comparative Studies**

Two small observational studies reported experiences of patients at high risk for nonunion who received invasive EBGS to enhance the foot and ankle arthrodeses.\[2,3\] While these studies contribute to the body of knowledge by providing direction for future research, evidence from these studies is unreliable due to significant design flaws, such as non-random allocation of treatment and lack of (adequate) comparison groups.

**Noninvasive EBGS**

**Delayed Unions**

**Technology Assessments**

The 1992 BCBSA TEC assessment\[1\] did not find sufficient evidence to support the use of noninvasive EBGS for the treatment of delayed union in long or short bones.

The assessment of EBGS for the treatment of delayed union in long bones was based on one published randomized controlled trial. The assessment concluded that “the health outcomes data in this study do not show that noninvasive EBGS delivers an advantage over placebo.”\[1\] In addition, the assessment identified two significant limitations of this trial:

- The long-term follow-up data on functional healing and need for subsequent surgery were not reported.
- Radiographic (intermediate outcome) evidence was difficult to interpret due to inconsistent rating methods and uncertain comparability in their findings.

The assessment identified no randomized trials of noninvasive EBGS for the treatment of delayed union in short bones. Instead, the assessment is based on three small case series and it concludes that the “evidence does not permit conclusions about whether health outcomes are improved” as a result of EBGS therapy.

**Randomized Controlled Trials (RCTs)**

There are no new published RCTs on the use of noninvasive EBGS for the treatment of delayed unions.

**Case Series, Retrospective Reviews, and Other Non-randomized Comparative Studies**

There are no new published observational studies on the use of noninvasive EBGS for the treatment of delayed unions.

**Fresh/Acute Fractures**

**Randomized Controlled Trials (RCTs)**
One sham-controlled RCT evaluated the impact of pulsed electromagnetic stimulation for acute tibial shaft fractures on the rate of surgical revision due to delayed union or non-union. At a 12-month follow-up, no significant between-group differences were found on surgical intervention for any reason.

**Semi-invasive EBGS**

Semi-invasive EBGS is no longer in wide use. Consequently, there are no recently published studies of semi-invasive EBGS for the treatment of any condition.

**Clinical Practice Guidelines**

Currently, there are no published, evidence based guidelines which recommend the use of electrical bone growth stimulation for the treatment of any condition, except as an adjunct to spinal fusion surgery.

**Summary**

Overall, the evidence for the investigational indications (see policy criteria) is limited. There are no well-designed, well-executed, prospective, randomized controlled trials (RCT) on the effectiveness of:

- Invasive electrical bone growth stimulation (EBGS) for the treatment of any conditions except as an adjunct to spinal fusion surgery
- Noninvasive EBGS for the treatment of delayed unions
- Semi-invasive EBGS for the treatment of any conditions

- It is uncertain whether EBGS offers any additional benefit compared to standard treatments alone (e.g. immobilization with casts or braces, surgery etc.) for the investigational indications.
- The evidence from the only published RCT on EBGS in treatment of the delayed union in long bones is limited by the lack of data on the long-term outcomes of functional healing or need for subsequent surgical interventions. In addition, the radiographic (intermediate outcome) data was unreliable due to inconsistent methodology (e.g. use of different radiographic definitions or rating systems among the raters).
- Evidence on EBGS for fresh/acute fractures is limited to one RCT. This trial suggests that bone stimulation does not change the rate of surgical revision due to delayed union or non-union.

Therefore, except in a select group of patients identified in the policy criteria, EBGS is considered investigational.

**REFERENCES**


**CROSS REFERENCES**

*Electrical Stimulation Devices Index*, DME, Policy No. 83

*Lumbar Spinal Fusion*, Surgery, Policy No. 187

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