MEDICAL POLICY

Excellus

MEDICAL POLICY DETAILS	
Medical Policy Title	**BONE GROWTH STIMULATORS; INVASIVE AND NONINVASIVE ELECTRICAL STIMULATION OF THE SPINE**
Policy Number	**7.01.40**
Category	**Equipment/Supplies**
Effective Date	**11/19/99**
Revised Date	**11/02/00, 02/21/02, 01/16/03, 02/19/04, 02/24/05, 02/23/06, 12/07/06, 10/24/07, 08/28/08, 10/28/09, 04/28/11, 04/26/12, 06/28/12, 04/25/13, 04/24/14, 04/23/15, 06/22/16, 06/22/17, 02/22/18, 02/28/19**
Product Disclaimer	• *If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.* • *If a commercial product (including an Essential Plan product) or a Medicaid product covers a specific service, medical policy criteria apply to the benefit.* • *If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.*

POLICY STATEMENT

I. Based upon our criteria and review of the peer reviewed literature, invasive (inserted at the time of surgery) or non-invasive (beginning at any time from the time of surgery until up to 6 months after surgery) electrical bone growth stimulation are considered **medically necessary** for lumbar/lumbosacral spinal fusion surgery in individuals at high risk for pseudoarthrosis with one or more of the following risk factors for fusion failure:

A. One or more previous failed spinal fusions; or
B. Multi-level lumbar/lumbosacral fusion including three or more vertebrae; or
C. Grade III or worse lumbar/lumbosacral spondylolisthesis; or
D. Smoking history; or
E. Alcoholism; or
F. Diabetes, renal disease, or other metabolic diseases when bone healing is likely to be compromised; or
G. Nutritional deficiency/malnutrition; or
H. Osteoporosis defined as a T-score of less than -2.5 on a recent (within one year) DEXA; or
I. Body Mass Index (BMI) greater than 30; or
J. Severe anemia; or
K. Glucocorticoid dependent; or
L. Spinal malignancy.

II. Based upon our criteria and review of the peer reviewed literature, noninvasive electrical bone growth stimulation may be considered **medically necessary** as a treatment for individuals with ***failed*** lumbar spinal fusion when both of the following criteria are met:

A. A minimum of 6 months has passed since the date of the original surgery; and
B. Serial radiographs or appropriate imaging studies confirm there is no evidence of progression of healing/consolidation of the spinal fusion for 3 months during the latter portion of the 6 month post-fusion surgery period.

III. Based upon our criteria and review of the peer reviewed literature, invasive and noninvasive electrical stimulation are considered **investigational** for:

A. Acute or chronic lumbar spondylolysis (pars interarticularis defect) with or without spondylolisthesis; or
B. As an adjunct to cervical/thoracic spine fusion surgery, and for failed cervical/thoracic spine fusion, or failed cervical or lumbar disc arthroplasty.

IV. Based upon our criteria and review of the peer reviewed literature, semi-invasive electrical bone growth stimulation or low intensity ultrasound stimulation is considered **investigational** for any indication due to lack of sufficient evidence of their effectiveness.

Refer to Corporate Medical Policy #1.01.53 regarding Bone Growth Stimulators for the Appendicular Skeleton

POLICY GUIDELINES

I. Prior authorization is contract dependent. Please refer to your Customer (Member/Provider) Services Department for contract information.

II. Durable Medical Equipment rider/coverage is required.

III. The Federal Employee Health Benefit Program (FEHBP/FEP) requires that procedures, devices or laboratory tests approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational and thus these procedures, devices or laboratory tests may be assessed only on the basis of their medical necessity.

DESCRIPTION

Electrical bone growth stimulators are used to induce the growth of bones in cases of delayed union or non-union of fractures. Two methods of electrical bone growth stimulation are available:

Non-invasive stimulators use an external power supply and externally applied coils that produce an electrical current to the fracture site via Pulsed Electromagnetic Fields (PEMFs), Combined Electromagnetic Eield technology, or capacitive coupling to stimulate bone growth.

Invasive stimulators use a current generator that is surgically implanted in an intramuscular subcutaneous space and connected to an electrode that is implanted within the bone fragments that are hoped to be fused. The power source is removed in a second surgical procedure once it has discharged.

Failed spinal fusion is defined as a spinal fusion that 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.

RATIONALE

The FDA has given premarket approval for the SpinalPak, Spinal-Stim Lite, Physio-Stim Life, OrthoPak, and SpinaLogic external stimulators and SpF implanted spinal fusion stimulators.

For individuals who are at high risk of lumbar spinal fusion failure surgery who receive invasive or noninvasive electrical bone growth stimulation, the evidence includes systematic reviews, a BCBSA Technology Evaluation Center (TEC) Assessment, and randomized controlled trials (RCTs). Relevant outcomes are symptoms, change in disease status, and functional outcomes. Results from these trials have indicated that, in patients with risk factors for failed fusion, either invasive or noninvasive electrical bone stimulation increases the fusion rate. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have failed lumbar spinal fusion surgery who receive noninvasive electrical bone growth stimulation, the evidence includes a TEC Assessment and studies with patients serving as their own controls. Relevant outcomes are symptoms, change in disease status, and functional outcomes. Data have shown that noninvasive electrical stimulation improves fusion rates in this population. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who are undergoing cervical spinal fusion surgery or have failed cervical spine fusion who receive invasive or noninvasive electrical bone growth stimulation, the evidence includes 1 RCT. Relevant outcomes are symptoms, change in disease status, and functional outcomes. The only controlled trial published to date had methodologic limitations and the efficacy of electrical stimulation in the cervical spine has not been established. The evidence is insufficient to determine the effects of the technology on health outcomes.

In 2016, the North American Spine Society (NASS) issued a coverage recommendation for electrical bone growth stimulators. This includes recommendations for augmentation of spinal fusion in any and all regions of the spine of 2 or more motion segments (3 vertebrae) (even though there is less support for areas other than lumbar spine) and in patients who have co-morbidities that may put them at risk for delayed bone healing (e.g., smoking history, diabetes, immunocompromised). However the Rationale section of the recommendations do not mentions any level of evidence or any specific referenced articles.

The American Academy of Orthopedic Surgeons (AAOS) publishes information bone healing. Some broken bones do not heal even when they get the best surgical or nonsurgical treatment because of inadequate stability, the blood supply is limited or lack of good nutrition to promote healing. Some bones can be expected to heal with minimal treatment due to inherent stability and excellent blood supply (toe bones). Other bones may not heal as quickly due to a limited blood supply (femoral head and neck, small wrist bone (scaphoid). Bones with moderate blood supply (tibia) may not heal quickly because the skin and muscle over the bone was damaged and the external blood supply was impaired. In addition, certain risk factors make it more likely that a bone will fail to heal. These risk factors include tobacco or nicotine use in any form, older age, severe anemia, diabetes, hypothyroidism, infection, certain medications, and low vitamin D level.

CODES

- *Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.*
- *CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.*
- *Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.*

CPT Codes

Code	Description
20974	Electrical stimulation to aid bone healing; non-invasive (non-operative)
20975	invasive (operative)
20979	Low intensity ultrasound stimulation to aid bone healing, noninvasive (nonoperative)

HCPCS Codes

Code	Description
E0747	Osteogenesis stimulator, electrical, non-invasive; other than spinal applications
E0748	spinal applications
E0749	Osteogenesis stimulator, electrical, surgically implanted
E0760	Osteogenesis stimulator, low intensity ultrasound, non-invasive

ICD10 Codes

Code	Description
M43.22-M43.23	Fusion of spine, cervical region, cervicothoracic region (code range)
M43.27-M43.28	Fusion of spine, lumbosacral, sacral and sacrococcygeal region (code range)
M51.04-M51.9	Thoracic, thoracolumbar, and lumbosacral intervertebral disc disorders (code range)
M53.2x7-M53.2x8	Spinal instabilities, lumbosacral, sacral and sacrococcygeal region (code range)
M53.3	Sacrococcygeal disorders, not elsewhere classified
M53.86-M53.88	Other specified dorsopathies, lumbosacral, sacral and sacrococcygeal region (code range)

REFERENCES

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*Key Article

KEY WORDS

Bone Growth Stimulator, Osteogenic Stimulator, SAFHS, Ultrasonic Bone Growth Stimulator, US.

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

There is currently a National Coverage Determination (NCD) for Osteogenic Stimulators. Please refer to the following NCD website for Medicare Members: http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=65&ncdver=2&bc=BAABAAAAAAAA&