



MEDICAL COVERAGE GUIDELINES
SECTION: SURGERY

ORIGINAL EFFECTIVE DATE: 03/18/14
LAST REVIEW DATE:
LAST CRITERIA REVISION DATE:
ARCHIVE DATE:

BONE GROWTH STIMULATION OF THE SPINE AS AN ADJUNCT TO SPINAL FUSION PROCEDURES, ELECTRICAL

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Medical Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Medical Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Medical Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

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Description:

Electrical bone growth stimulators used as an adjunct to spinal fusion surgery include:

Invasive:

The implantable current generator is surgically placed in an intramuscular or subcutaneous space, while an electrode is implanted within the fragments of bone graft at the targeted fusion site. The implanted device is usually functional for 6 to 9 months at which point the current generator is removed in a second surgical procedure, while the electrodes may or may not be removed. Implantable bone growth stimulators are implanted at the time of surgery.

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Description: (cont.)

Noninvasive:

An external power source generates a weak electrical current to the target sites using either pulsed electromagnetic fields, capacitive coupling or combined magnetic fields.

Semi-Invasive (Percutaneous):

An external power supply is connected to electrodes that are inserted through the skin to the targeted fusion site. The FDA has not approved semi-invasive electrical bone growth stimulators.

Criteria:

- Invasive and noninvasive electrical bone growth stimulation are considered **medically necessary** as an adjunct to lumbar spinal fusion surgery with documentation of **ANY** of the following risk factors for subsequent failed fusion:
 1. History of one or more failed spinal fusion surgeries
 2. Grade III or greater spondylolisthesis
 3. Fusion to be performed at more than one level
 4. Current nicotine use
 5. Diabetes
 6. Renal disease
 7. Alcoholism
 8. Steroid use
- Noninvasive electrical bone stimulation is considered **medically necessary** for failed lumbar spinal fusion with documentation of **ANY** of the following:
 1. Minimum of 6 months has elapsed since date of original fusion surgery
 2. Serial X-rays over a course of 3 months confirm fusion has not healed
- Invasive and noninvasive electrical bone growth stimulation for all other indications not previously listed or if above criteria not met is considered **experimental or investigational** based upon insufficient evidence to support improvement of the net health outcome.

These indications include, *but are not limited to:*

- Adjunct to cervical fusion surgery
- Failed cervical spine fusion surgery



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Criteria: (cont.)

- Semi-invasive electrical bone growth stimulation for all indications is considered ***experimental or investigational*** based upon:

1. Lack of final approval from the Food and Drug Administration, and
2. Insufficient evidence to support improvement of the net health outcome

These indications include, *but are not limited to*:

- Adjunct to cervical or lumbar fusion surgery
- Failed cervical or lumbar spine fusion surgery

Resources:

1. 7.01.85 BCBS Association Medical Policy Reference Manual. Electrical Stimulation of the Spine as an Adjunct to Spinal Fusion Procedures. Re-issue date 10/10/2013, issue date 12/18/2002.