

**Notice of Independent Review Decision
Amended Notice**

DATE OF REVIEW: 9/28/09

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE

Non-Invasive Bone Growth Stimulator, adjunct to surgery 08/12/2009

A DESCRIPTION OF THE QUALIFICATIONS FOR EACH PHYSICIAN OR OTHER HEALTH CARE PROVIDER WHO REVIEWED THE DECISION

Certified by the American Board of Orthopaedic Surgery

REVIEW OUTCOME

Upon independent review the reviewer finds that the previous adverse determination should be:

- Upheld (Agree)
- Overturned (Disagree)
- Partially Overturned (Agree in part/Disagree in part)

Injury date	Claim #	Review Type	ICD-9 DSMV	HCPCS/ NDC	Upheld/ Overturned
		Prospective	V45.4		Overturned
		Prospective	722.4		Overturned
		Prospective	723.0	E0748	Overturned

INFORMATION PROVIDED TO THE IRO FOR REVIEW

Correspondence throughout appeal process, including first and second level decision letters, reviews, letters and requests for reconsideration, and request for review by an independent review organization.

Request for Authorization dated 9/17/09

Letter dated 9/18/09

Practitioner notes dated 3/30/09, 1/12/09, 12/30/08, 10/7/08

Myelogram/x-ray report dated 3/13/09, 9/28/08, 9/8/08

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Diagnostic Ultrasound/exam reports dated 9/17/08
Official Disability Guidelines cited-Neck &Upper Back, Low Back Chapter Bone-growth
stimulators (BGS)

PATIENT CLINICAL HISTORY:

The patient is a male who is reported to have sustained work related injuries on xx/xx/xx. The submitted clinical records indicate that the patient underwent an extensive course of conservative care and ultimately was referred for CT myelography on 03/13/09. The patient reports paresthesias in the bilateral upper extremities. CT myelogram reports a grade I spondylolisthesis at C4-5 with 3 mm of posterior subluxation of the C4 vertebra at neutral and extended positions of the neck. There is a reduction of the vertebral body subluxation and cervical flexions. There are large anterior extradural defects at C3-4 and C4-5. There are mild anterior extradural defects at C2-3, C5-6, C6-7 and C7-T1. There is minimal degenerative hypertrophic spondylosis at C4-5. CT indicates a 3 mm posterior central disc protrusion at C2-3 which mildly impinges upon the thecal sac. There is a 5 mm posterior central disc protrusion at C3-4 which moderately effaces the thecal sac and also contacts the anterior surfaces of the cervical spinal cord causing mild central canal stenosis. There is a disc protrusion which results in moderate lateral recess stenosis. At C3-4 and C4-5 there is moderate bilateral foraminal stenosis from degenerative uncovertebral and facet joint hypertrophy. At C4-5 there is a 5 mm left paracentral disc protrusion which impinges upon the thecal sac in the anterior surface of the cervical spinal cord causing moderate central spinal canal stenosis and severe lateral recess stenosis. At C5-6 there is a 3 mm right paracentral disc protrusion which mildly impinges upon the thecal sac. There is mild bilateral foraminal stenosis at C5-6. The patient ultimately underwent a 3 level ACDF incorporating C3, C4, C5 and C6 on 08/12/09. The submitted clinical records indicate that the patient has a past medical history of smoking and has not smoked since 2008. He is reported to be 6'0" tall and weigh 270 pounds resulting in a BMI of 36.6.

ANALYSIS AND EXPLANATION OF THE DECISION INCLUDING CLINICAL BASIS, FINDINGS AND CONCLUSIONS USED TO SUPPORT THE DECISION

In the Reviewer's opinion, the requested non invasive bone growth stimulator as an adjunct to a 3 level fusion is medically necessary. According to the Reviewer, the patient is a xx-year-old male who has a history of cervical pain and radiculopathy who failed conservative care. He ultimately was taken to surgery and underwent an ACDF from C3-C6 on 08/12/09. The submitted clinical records indicate that the patient is obese and has a remote history of smoking. The fact that the patient underwent a 3 level fusion would establish the medical necessity for post operative bone growth stimulator. It is noted that the patient is at inordinately high risk for the development of pseudoarthrosis and the current standard of care would be for post operative bone growth stimulation to reduce the potential for pseudoarthrosis. It is further noted that the patient has a remote history of smoking, quitting in 2008, and most likely has some degree of microvascular damage

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secondary to this history and the patient is also noted to be markedly obese which would place him at a higher risk for the potential development of pseudoarthrosis. Based upon the totality of the clinical information and noting that the patient has undergone a 3 level ACDF, the bone growth stimulator would be considered medically necessary and appropriate and standard of care within the community.

References:

The 2009 Official Disability Guidelines, 14th edition, The Work Loss Data Institute. Online edition.

Bone growth stimulators (BGS)

Criteria for use for invasive or non-invasive electrical bone growth stimulators:

Either invasive or noninvasive methods of electrical bone growth stimulation may be considered medically necessary as an adjunct to spinal fusion surgery for patients with any of the following risk factors for failed fusion: (1) One or more previous failed spinal fusion(s); (2) Grade III or worse spondylolisthesis; (3) Fusion to be performed at more than one level; (4) Current smoking habit (Note: Other tobacco use such as chewing tobacco is not considered a risk factor); (5) Diabetes, Renal disease, Alcoholism; or (6) Significant osteoporosis which has been demonstrated on radiographs. ([Kucharzyk, 1999](#)) ([Rogozinski, 1996](#)) ([Hodges, 2003](#))

Resnick DK, Choudhri TF, Dailey AT, Groff MW, Khoo L, Matz PG, Mummaneni P, Watters WC 3rd, Wang J, Walters BC, Hadley MN; American Association of Neurological Surgeons/Congress of Neurological Surgeons. Guidelines for the performance of fusion procedures for degenerative disease of the lumbar spine. Part 17: bone growth stimulators and lumbar fusion. *J Neurosurg Spine*. 2005 Jun;2(6):737-40.

Current recommendations for the use of bone growth stimulation units are:

1. Non-unions, failed fusions, and congenital pseudarthrosis where there is no evidence of progression of healing for three or more months despite appropriate fracture care, *or*
2. Delayed unions of fractures or failed arthrodesis at high risk sites (i.e., open or segmental tibial fractures, carpal navicular fractures), *or*
3. Patients who have failed spinal fusion or are at high risk for fusion failure when *any* of the following criteria is met:
 - One or more failed fusions, *or*
 - Grade II or worse spondylolisthesis, *or*
 - A multiple level fusion with extensive bone grafting is required, *or*
 - Other risk factors for fusion failure are present, including gross obesity, degenerative osteoarthritis, severe spondylolisthesis, current smoking, previous fusion surgery, previous disc surgery, or gross instability.

**A DESCRIPTION AND THE SOURCE OF THE SCREENING CRITERIA OR
OTHER CLINICAL BASIS USED TO MAKE THE DECISION:**

- ACOEM- AMERICAN COLLEGE OF OCCUPATIONAL & ENVIRONMENTAL MEDICINE UM KNOWLEDGEBASE
- AHCPR- AGENCY FOR HEALTHCARE RESEARCH & QUALITY GUIDELINES
- DWC- DIVISION OF WORKERS COMPENSATION POLICIES OR GUIDELINES
- EUROPEAN GUIDELINES FOR MANAGEMENT OF CHRONIC LOW BACK PAIN
- INTERQUAL CRITERIA
- MEDICAL JUDGEMENT, CLINICAL EXPERIENCE AND EXPERTISE IN ACCORDANCE WITH ACCEPTED MEDICAL STANDARDS
- MERCY CENTER CONSENSUS CONFERENCE GUIDELINES
- MILLIMAN CARE GUIDELINES
- ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES
- PRESSLEY REED, THE MEDICAL DISABILITY ADVISOR
- TEXAS GUIDELINES FOR CHIROPRACTIC QUALITY ASSURANCE & PRACTICE PARAMETERS
- TEXAS TACADA GUIDELINES
- TMF SCREENING CRITERIA MANUAL
- PEER REVIEWED NATIONALLY ACCEPTED MEDICAL LITERATURE (PROVIDE A DESCRIPTION)
- OTHER EVIDENCE BASED, SCIENTIFICALLY VALID, OUTCOME FOCUSED GUIDELINES (PROVIDE A DESCRIPTION)