



Medical Review Institute of America, Inc.
America's External Review Network

DATE OF REVIEW: July 31, 2007

IRO Case #:

Description of the services in dispute:

Pre-authorization;

2-day inpatient stay

Implantation stimulator (EBI) L4-5 and L5-S1

Additional level decompression

Examination under anesthesia

Microdissection technique

Discography

Arthrodesis lateral

Application of intervertebral biomechanical device

Bone graft

Posterior non-segmental instrumentation

Invasive electrical stimulator

Lumbar Laminectomy/discectomy (#63042) @ L3-4, L4-5, L5-S1

Reduction subluxation

Posterior instrumentation using cages

Anterior lumbar arthrodesis

A description of the qualifications for each physician or other health care provider who reviewed the decision

The physician providing this review is board certified in Orthopaedic Surgery. The reviewer has held academic appointments as Assistant Instructor at a state university, Assistant Professor of Orthopaedics, Assistant Professor of Neurosurgery and Director of an orthopaedic hospital spine center. The reviewer has been extensively published and has given numerous presentations and organized seminars in his field of expertise. The reviewer has been in active private practice since 1983.

Review Outcome

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

Upheld

Provide a description of the review outcome that clearly states whether or not medical necessity exists for each of the health care services in dispute.

Medical necessity is not established for the proposed surgery:

2-day inpatient stay

Implantation stimulator (EBI) L4-5 and L5-S1

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Information provided to the IRO for review

Records From the State:

- Confirmation of Receipt of Request for Review by an Independent Review Organization, 7/13/07
- Request for Review by an Independent Review Organization, 6/26/07
- 7/11/2007 letter from denying the request
- Notice to Medical Review
- Notice of Determination, 6/18/07

Records from the Provider:

- Notice of Assignment of Independent Review Organization, 7/16/07
- Office notes, xx/xx/xx – x-rays of the pelvis showed total hip replacement left side. Lumbar spine radiographs flexion/extension shows no evidence of anterior instability but there is retrolisthesis 5 mm in extension L5/S1
- Consultation report, 5/2/06
- Office notes, 5/2/06, 8/1/06, 8/22/06
- 9/19/06 progress report – the patient is on methadone
- 10/17/06 progress report, pain specialist – the patient is on fentanyl skin patch and is also

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requested an epidural steroid injection

- 10/31/06 progress report – the doctor recommends diskogram and consideration of surgery
- 12/5/06 progress report
- 1/5/07 progress report pain specialist – Two epidural steroid injections with "excellent" results are reported
- 1/9/07 progress report
- 3/2/07 progress report, pain specialist
- 4/10/07 progress report
- 4/18/07 procedure report – epidural steroid injection
- 4/18/07 progress report
- 4/24/07 progress report – Subsequent injury at work xx/xx/xx
- xx/xx/xx MRI scan lumbar spine identifies mild stenosis of L3/4, L4/5, foraminal encroachment L3/S1 bilaterally
- 4/27/07 MRI scan lumbar spine report identifies postsurgical change is L3/S1 laminotomy with facet joint arthropathy bilateral left greater than right foraminal narrowing. The MRI scan report indicates only mild central stenosis at L3/4.
- 5/1/07 progress report
- 5/2/07 progress report physical therapist
- 5/22/07 lumbar diskogram identifies pain and L3/4, L4/5, L5/S1 concord and pain in the back and both legs severe
- 5/29/07 progress report
- 7/10/07 progress report

Records from the Insurance Company:

- Fax Coversheet
- Surgical procedure codes
- Fax requesting appeal of the denial for the request for surgery
- Request for preauthorization

Patient clinical history [summary]

The date of injury xx/xx/xx. The patient complains of pain of the lower back, he has had some physical therapy with little relief.

Examination shows paraspinal muscle spasm, positive flip test, Lasegue's test positive L4/5, there is decreased knee and ankle reflex on the left, there is some hip flexion, ankle flexion and first toe dorsiflexion weakness on the left. There is no sensory deficit. He has limited range of motion of the back. He has reduced endurance and is limited in walking for 30 feet.

The diagnosis is post-laminectomy syndrome lumbar spine, thoracic lumbosacral neuritis, lumbago. The patient has had lumbar L3-S1 surgery without benefit. The patient has had physical therapy,

positive diskogram L3–S1, CT scan results are not known. MRI scan xx/xx/xx shows postoperative changes and 3/S1 with facet joint arthropathy, ligamentum flavum hypertrophy with only mild central canal stenosis L3/4, disc bulging of 2/3, L3/4. Flexion extension radiographs are reported to show retrolisthesis 5 mm correcting in flexion.

Analysis and explanation of the decision include clinical basis, findings and conclusions used to support the decision.

The provided medical records do not identify spondylolisthesis. The requested spinal fusion is not indicated based on the Official Disability Guidelines.

The patient has only mild central stenosis at L3/4. The MRI scan report does not indicate stenosis of the central canal at other levels. Though the doctor reports retrolisthesis with extension and correction in flexion there is no evidence of neurogenic claudication. The doctor reports clinical weakness but the physical therapy reports indicate a grade 4–/5 strength in the lower extremities.

Clinically the patient has some left–sided abnormal changes with a documentation of left–sided weakness. However the patient is reported to be working at his usual occupation, and has pain which has become intolerable.

The patient is on chronic pain medication and narcotics. He has had extensive nonsurgical treatment. The indications for surgery are the doctor's consideration of instability and stenosis though the MRI scan reports only mild stenosis at L3/4.

There is no electrodiagnostic confirmation of radiculopathy, there is no psychological evaluation clearance. The patient's functional status has not been identified besides noting that he is working. Physical therapy reports, exercise programs, psychological evaluation and support, trunk strengthening and core stabilization programs have not been described. Alternate measures for pain control have not been described. The ratio between the back and the leg pain has not been described. Consideration of facet joint nonsurgical pain control measures for control of pain have not been considered or described.

There is no description of the physical therapy treatment program. There is no description of any trunk strengthening and core stabilization program, functional capacity is not provided. Nonorganic findings are not reported. There is no psychological evaluation and clearance. There is no electrodiagnostic confirmation of significant radiculopathy.

A description and the source of the screening criteria or other clinical basis used to make the decision:

The role of spinal fusion in the treatment of degenerative disorders of the lumbar spine is

controversial. Most patients with these conditions can be successfully treated nonoperatively. The potential benefits to be obtained by means of lumbar fusion must be measured against the risks. Lumbar fusion is indicated as an adjunct to decompression for patients with spinal stenosis associated with degenerative or iatrogenic spondylolisthesis and in the treatment of progressive degenerative lumbar scoliosis and iatrogenic instability resulting from extensive decompression. The occurrence of two or more episodes of disk herniation at the same segment is a relative indication for lumbar fusion.

Lumbar fusion has a poor success rate when used to treat back pain associated with multilevel disk degeneration seen on magnetic resonance images. In patients with incapacitating non-radicular back pain, lumbar fusion should be a consideration only after failure of a trial of nonoperative treatment lasting more than 12 months and after secondary gain issues (e.g., workmen's compensation) have been adequately resolved.

With chronic back pain following previous surgery, especially with some stenosis or instability, surgery has more indication [Lumbar Spine Fusion in the Treatment of Degenerative Conditions: Current Indications and Recommendations. HN Herkowitz and KS Sidhu J. Am. Acad. Ortho. Surg., May 1995; 3: 123 – 135].

Diskography is not recommended for assessing patients with low back symptoms. [1]

Recent studies on diskography do not support its use as a preoperative indication for either intradiskal electrothermal (IDET) annuloplasty or fusion.

Diskography does not identify the symptomatic high-intensity zone, and concordance of symptoms with the disk injected is of limited diagnostic value (common in non-back issue patients, inaccurate if chronic or abnormal psychosocial tests), and it can produce significant symptoms in controls more than a year later. Tears may not correlate anatomically or temporally with symptoms.

Diskography in subjects with emotional and chronic pain problems has been linked to reports of significant back pain for prolonged periods after injection, and therefore should be avoided. [1]

There is no scientific evidence about the long-term effectiveness of any form of surgical decompression or fusion for low back pain compared with natural history, placebo, or conservative treatment. There is no good evidence from controlled trials that spinal fusion alone is effective for treating any type of low back problem, in the absence of spinal fracture, dislocation, or spondylolisthesis if there is instability and motion in the segment operated on. [ACOE Chapter 12 –page 300]

It is important to note that although it is being undertaken, lumbar fusion in patients with other types of low back pain very seldom cures the patient.

Before referral for surgery, clinicians should consider referral for psychological screening to improve surgical outcomes, possibly including standard tests such as the second edition of the Minnesota Multiphasic Personality Inventory (MMPI-2). In addition, clinicians may look for Waddell signs during the physical exam.

Surgery benefits fewer than 40% of patients with questionable physiologic findings. Moreover, surgery increases the need for future surgical procedures with higher complication rates. [Subach BR, et al. Do current outcomes data support the technique of lumbar interbody fusion? *Clinical Neurosurgery* 2001;48: 204-18.]

Given the above this patient is not a surgical candidate for consideration of a lumbar fusion.

The Official Disability Recommendations Guidelines for spinal fusion are as follows:

Spinal fusion surgery is not recommended for workers compensation patients in the absence of spinal fracture, dislocation, spondylolisthesis with instability, and selected other conditions outlined below. In cases other than workers compensation, after screening for bio- psycho-social variables, outcomes are improved and fusion may be recommended for degenerative disc disease after at least six months of conservative therapy. For complete references see separate document with all studies focusing on fusion [spinal].

There is limited scientific evidence about the long-term effectiveness of fusion for degenerative disc disease compared with natural history, placebo or conservative treatment, studies conducted in order to compare different surgical techniques have shown successful fusion in carefully selected patients. [Gibson-Cochran, 2000, Savolainen 1998, Wetzel 2001, Molinari 2001, Bigos 1999, Washington 1995, DeBarard Spine 2001, Fritzell Spine 2001, Fritzell Spine 2002, Deyo NEJM 2004, Gibson Cochran/spine, 2005]

According to the recently released AANS/NASS guidelines, lumbar fusion is recommended as a treatment for carefully selected patients with disabling low back pain due to one or two level degenerative disc disease after failure of an appropriate period of conservative care. This recommendation was based on one study that contained numerous flaws, including a lack of standardization of conservative care in the control group. At the time of the two-year follow-up it appeared that pain had significantly increased in the surgical group from year one to two. Follow-up post study is still pending publication. In addition there remains no direction regarding how to define the carefully selected patient. [Resnick 2005, Fritzell 2004]. Until further research is conducted there remains insufficient evidence to recommend fusion for chronic low back pain in the

absence of stenosis and spondylolisthesis, and this treatment for this condition remains under study.

It appears that workers compensation populations require particular scrutiny when being considered for fusion for chronic low back pain, as there is evidence of poorer outcomes and subgroups of patients who were receiving compensation or involved in litigation. [Fritzell Spine 2001, Harris JAMA 2005]. Despite poorer outcomes in workers compensation patients, utilization is much higher in this population than in group health. [NCCI 2006]. A recently published well-respected international guideline, the European guidelines, concluded that fusion surgery for nonspecific chronic low back pain cannot be recommended unless two years of all other recommended conservative treatments including multidisciplinary approaches with combined programs of cognitive intervention and exercises have failed, or such combined programs are not available, and only then in carefully selected patients with maximum to level degenerative disc disease. [Airaksinen 2006]. For chronic low back pain exercise and cognitive intervention may be equivalent to lumbar fusion without the potentially high surgical complication rates. [Ivar Brox Spine 2003, Keller spine 2004, Fairbank BMJ 2005, Brox 2006]. Patients with increased instability of the spine after surgical decompression at the level of degenerative spondylolisthesis may be candidates for fusion. [Eckman 2005]. In acute spinal cord injury if the spine is unstable following injuries, surgical fusion and bracing may be necessary. [Bagnall Cochran 2004].

A study on improving quality to identifying inappropriate care found that the use of guideline based utilization review protocols resulted in the denial rate for lumbar fusion 59 times as high as denial rates using non-guideline-based utilization review. [Wickizer 2004]. The profit motive and market medicine have had a significant impact on clinical practices and research in the field of spine surgery. [Weiner Spine 2004, Shah Spine 2005].

Data on geographic variations in medical procedure rates suggests that there is significant variability in spinal fusion rates, which may be interpreted to suggest a poor professional consensus on the appropriate indications for performing spinal fusion. [Deyo Spine 2005, Weinstein 2006].

Workers compensation has been associated with especially poor outcomes after surgery. [Harris JAMA 2006]. Out comes from demanding surgical fusion techniques [with internal fixation] are no better than the traditional posterolateral fusion. [Van Tulder 2006, Maghout 2006].

Pre-surgical biopsychosocial variables predict patient outcomes from lumbar fusion, which may help improve patient selection. Workers compensation status, smoking, depression and litigation were the most consistent presurgical predictors of poorer patient outcomes. Also predictors were number of prior low back operations, low household income, and older age. [Deberard spine 2001, Debarard spine 2003, Lecaille 2005, Trief spine 2006].

A major study is underway which aims to identify characteristics that result in better patient selection for surgery. [Deyo 2005]. A recent study found only a 27% success from spinal fusion in patients with low back pain and a positive single level low-pressure provocative diskogram, versus a 72% success in patients having a well accepted single level lumbar pathology of unstable spondylolisthesis [Carragee 2006]. According to the recent Medicare Coverage Advisory Committee Technology Assessment, "the evidence for lumbar spinal fusion does not conclusively demonstrate short-term or long-term benefits compared with nonsurgical treatment" [CMS 2006].

Lumbar spinal fusion surgeries use bone grafts, and are sometimes combined with a metal devices to produce a rigid connection between two or more adjacent vertebrae. The therapeutic objective of spinal fusion surgery for patients with low back problems is to prevent any movement in the intervertebral spaces between the fused vertebrae, thereby reducing pain and any neurological deficits.

Patient selection criteria for lumbar spinal fusion:

For chronic low back problems, fusion should not be considered within the first six months of symptoms, except for fracture or dislocation. Indications for spinal fusion may include: 1] new arch defect-spondylolytic spondylolisthesis, congenital unilaterally neural arch hypoplasia. 2] segmental instability-excessive motion, as in degenerative spondylolisthesis, surgically induced segmental instability. 3] primary mechanical back pain/functional spinal unit failure [in cases other than workers compensation]. 4] revision surgery for failed previous operations is significant functional gains are anticipated. Revision surgery for purposes of pain relief must be approached with extreme caution due to less than 50% success rate reported in medical literature. 5] infection, tumor or deformity of the lumbar sick of spine that causes intractable pain, neurological deficit and/or functional disability.

Preoperative surgical indications required:

preoperative clinical surgical indications for spinal fusion include all of the following: 1] all pain generators are identified and treated 2] all physical medicine and manual therapy interventions are completed 3] x demonstrating spinal instability and/or MRI or CT discography demonstrating this pathology 4] spine pathology limited to two levels 5] psychosocial screen with confounding issues addressed 6] for any potential fusion surgery it is recommended that the injured worker refrain from smoking for at least six weeks prior to fusion surgery and during the period of fusion healing [Colorado 2001 Blue Cross Blue Shield 2002].

- What is the appropriate length of stay?

The appropriate length of stay is 3 postoperative days. This type of surgery will involve general

anesthesia, and abdominal approach and will require recovery of intestinal activity allowing the patient to get off intravenous fluids and resume oral diet and oral pain medication before he can be discharged.

[Milliman – Inpatient and surgical care, ninth edition. Lumbar fusion Indications for surgery.]

1. Official disability guidelines
2. ACOEM, Chapter 12, pages 303–305
3. J Neurosurg Spine. 2005 Jun;2(6): 662–9. Guidelines for the performance of fusion procedures for degenerative disease of the lumbar spine. Part 6: magnetic resonance imaging and discography for patient selection for lumbar fusion. Resnick DK, Choudhri TF, Dailey AT, Groff MW, Khoo L, Matz PG, Mummaneni P, Watters WC 3rd, Wang J, Walters BC,
4. ACOEM Chapter 12 –page 300
5. ACOEM Table 12–8 page 309
6. Milliman – In patient and surgical care, ninth edition. Lumbar fusion Indications for surgery.
7. Subach BR, et al. Do current outcomes data support the technique of lumbar interbody fusion? Clinical Neurosurgery 2001;48: 204–18.

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