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DATE OF REVIEW: 02.29.08

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

3 day inpatient stay anterior interbody fusion L5-S1 with STALIF device with additional posterior decompression L5-S1 with bilateral screw fixation and fusion.

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

This case was reviewed by a Texas licensed MD, specializing in Orthopedic Surgery. The physician advisor has the following additional qualifications, if applicable:

ABMS Orthopaedic Surgery
TX DWC ADL

REVIEW OUTCOME:

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

Upheld

Health Care Service(s) in Dispute	CPT Codes	Date of Service(s)	Outcome of Independent Review
3 day inpatient stay anterior interbody fusion L5-S1 with STALIF device with additional posterior decompression L5-S1 with bilateral screw fixation and fusion.		-	Upheld

INFORMATION PROVIDED TO THE IRO FOR REVIEW:

No	Document Type	Provider or Sender	Page Count	Service Start Date	Service End Date
1	Diagnostic Testing	Imaging	5	04.27.07	04.27.07
2	Testing	Dr.	2	05.03.07	05.03.07
3	Office Visit	Dr.	11	07.18.07	01.23.08
4	Psych Evaluation	Clinic	2	08.03.07	08.03.07

5	Office Visit	Dr.		08.30.07	10.11.07
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PATIENT CLINICAL HISTORY [SUMMARY]:

The request is for an IRO regarding anterior L5S1 lumbar fusion with STALIF device, TLSO and a three day hospital stay.

The patient is a lady who injured her low back while lifting and pushing sheets weighing 100 pounds at a hospital where she works as a . She has failed chiropractic care, aqua therapy, ESIs and home exercise program with pain medication.

Studies have been: MRI which only showed bulges at L3-4, L4-5, L5S1 without herniations stenosis or nerve compression with desiccation changes in lower two levels. Also, there was facet hypertrophy, especially of the lower two lumbar levels; EMG with NCV which only revealed a suggestion of right L5S1 irritation with no denervation; and a four level discogram without a control disc, reportedly concordant at all four levels; a psychological pre-discogram screen that revealed depression and psycho-social stressors. Physical findings by Dr., neurologist, showed normal tone, bulk and strength and normal neurologic exam. A designated doctor in January 2008 also documented normal physical findings and found her to be at MMI with zero percent impairment. An FCE done at that time revealed inconsistent effort throughout the testing, producing an undetermined PDL, suggesting a myriad of problems, such as somatoform disorder, lack of effort malingering or self limitation due to pain. Dr. stated the patient had a 3/5 dorsal eversion right foot weakness but negative SLRs and LeSague signs. Radicular complaints by the patient were non-dermatomal.

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

The patient is not a surgical candidate because there are no consistent objective documentation of nerve root compression, radiculopathy or instability. Dr. diagnosed radiculopathy based on a "suggestion" of right L5S1 level nerve irritation. He did not support this EMG finding with objective physical findings. In fact, he documented an essentially normal exam except for pain. Dr. is the only provider that documented weakness of right foot dorsal eversion but with negative nerve root stretch signs. This finding is confusion and inconsistent with the other physical findings of negative nerve root stretch findings and incompatible with an essentially unremarkable lumbar MRI and an EMG subtle changes at best. EMGs are known to carry a false positive rate of about 20%. For a drop foot to develop, a fairly large disc herniation needs to be present most commonly at L4-5 in order to entrap the L5 nerve root which is normally the cause for the drop foot. Therefore, the drop foot is not supported by other providers' exams or by diagnostic studies. The examinee also is known not to give consistent effort as noted by the FCE results. The requested procedure seems to be based largely on the results of a discogram. Discography is quite a controversial diagnostic tool because it does not identify the symptomatic high intensity zone, is highly inaccurate in patients with psychosocial issues, such as depression, which this patient has, and in patients with chronic pain (ACOEM, Chapter 12, page 303, 2004). Discography is also known to be positive in controls (patients without LBP) (Carragee, 2001).

In this case discography reportedly produced concordant pain at the lower 4 lumbar levels still without a control disc as is strongly recommended. A four level fusion is certainly out of the question. Similarly, if one believes on the value of discography as a diagnostic tool, an L5S1 fusion will not address the other concordant painful discs and thus, the procedure would be for naught. As for the L5S1 posterior decompression, it is unclear what is to be "decompressed" since there is no nerve root compression per imaging studies or clinical evaluations. Therefore, based upon the above rationale and peer reviewed guidelines, the requested ALIF procedure is not certified. Also, the three day hospital stay and TLSO brace are not certified.

The ODG on-line states regarding fusion: Not recommended for patients who have less than six months of failed recommended conservative care unless there is objectively demonstrated severe structural instability and/or acute or progressive neurologic dysfunction, but recommended as an option for spinal fracture, dislocation, spondylolisthesis or frank neurogenic compromise, subject to the selection criteria outlined in the section below entitled, "[Patient Selection Criteria for Lumbar Spinal Fusion](#)," after 6 months of conservative care. For workers' comp populations, see also the heading, "[Lumbar fusion in workers' comp patients](#)." After screening for psychosocial variables, outcomes are improved and fusion may be recommended for degenerative disc disease with spinal segment collapse with or without neurologic compromise after 6 months of compliance with recommended [conservative therapy](#). [For spinal instability criteria, see AMA

Guides ([Andersson, 2000](#)) 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 success for fusion in carefully selected patients. ([Gibson-Cochrane, 2000](#)) ([Savolainen, 1998](#)) ([Wetzel, 2001](#)) ([Molinari, 2001](#)) ([Bigos, 1999](#)) ([Washington, 1995](#)) ([DeBarard-Spine, 2001](#)) ([Fritzell-Spine, 2001](#)) ([Fritzell-Spine, 2002](#)) ([Devo-NEJM, 2004](#)) ([Gibson-Cochrane/Spine, 2005](#)) ([Soegaard, 2005](#)) ([Glassman, 2006](#)) ([Atlas, 2006](#)) 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 2-year follow up it appeared that pain had significantly increased in the surgical group from year 1 to 2. 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](#)) A recently published well respected international guideline, the “European Guidelines,” concluded that fusion surgery for nonspecific chronic LBP cannot be recommended unless 2 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 2-level degenerative disc disease. ([Airaksinen, 2006](#)) For chronic LBP, 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](#)) In acute spinal cord injury (SCI), if the spine is unstable following injury, surgical fusion and bracing may be necessary. ([Bagnall-Cochrane, 2004](#)) ([Siebenga, 2006](#)) A study on improving quality through identifying inappropriate care found that use of guideline-based Utilization Review (UR) protocols resulted in a denial rate for lumbar fusion 59 times as high as denial rates using non-guideline based UR. ([Wickizer, 2004](#)) The profit motive and market medicine have had a significant impact on clinical practice and research in the field of spine surgery. ([Weiner-Spine, 2004](#)) ([Shah-Spine, 2005](#)) ([Abelson, 2006](#)) Data on geographic variations in medical procedure rates suggest that there is significant variability in spine fusion rates, which may be interpreted to suggest a poor professional consensus on the appropriate indications for performing spinal fusion. ([Devo-Spine, 2005](#)) ([Weinstein, 2006](#)) Outcomes from complicated surgical fusion techniques (with internal fixation) may be no better than the traditional posterolateral fusion. ([van Tulder, 2006](#)) ([Maghout-Juratli, 2006](#)) Despite the new technologies, reoperation rates after lumbar fusion have become higher. ([Martin, 2007](#)) 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 for elderly patients. ([CMS, 2006](#)) When lumbar fusion surgery is performed, either with lateral fusion alone or with interbody fusion, unlike cervical fusion, there is no absolute contraindication to patients returning even to contact sports after complete recovery from surgery. Like patients with a thoracic injury, those with a lumbar injury should be pain free, have no disabling neurological deficit, and exhibit evidence of bone fusion on x-ray films before returning. ([Burnett, 2006](#)) A recent randomized controlled trial comparing decompression with decompression and instrumented fusion in patients with foraminal stenosis and single-level degenerative disc disease found that patients universally improved with surgery, and this improvement was maintained at 5 years. However, no obvious additional benefit was noted by combining decompression with an instrumented fusion. ([Hallett, 2007](#)) Discography may be supported if the decision has already been made to do a spinal fusion, and a negative discogram could rule out the need for fusion on that disc (but a positive discogram in itself would not justify fusion). Discography may help distinguish asymptomatic discs among morphologically abnormal discs in patients without psychosocial issues. Precise prospective categorization of discographic diagnoses may predict outcomes from treatment, surgical or otherwise. ([Derby, 2005](#)) ([Derby2, 2005](#)) ([Derby, 1999](#)) New research shows that healthcare expenditures for back and neck problems have increased substantially over time, but with little improvement in healthcare outcomes such as functional disability and work limitations. Rates of imaging, injections, opiate use, and spinal surgery have increased substantially over the past decade, but it is unclear what impact, if any, this has had on health outcomes. ([Martin, 2008](#)) Lumbar spinal fusion surgeries use bone grafts, and are sometimes combined with 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.

Lumbar fusion in workers' comp patients: In cases of workers' compensation, patient outcomes related to fusion may have other confounding variables that may affect overall success of the procedure, which should be considered. 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 in subgroups of patients who were receiving compensation or involved in litigation. ([Fritzell-Spine, 2001](#)) ([Harris-JAMA, 2005](#)) ([Maghout-Juratli, 2006](#)) ([Atlas, 2006](#)) Despite poorer outcomes in workers' compensation patients, utilization is much higher in this population than in group health. ([Texas, 2001](#)) ([NCCI, 2006](#)) Presurgical 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. Other predictors of poor results were number of prior low back operations, low household income, and older age. ([DeBerard-Spine, 2001](#)) ([DeBerard, 2003](#)) ([Devo, 2005](#)) ([LaCaille, 2005](#)) ([Trief-Spine, 2006](#)) Obesity and litigation in workers' compensation cases predict high costs associated with interbody cage lumbar fusion. ([LaCaille, 2007](#)) A recent study of 725 workers' comp patients in Ohio who had lumbar fusion found only 6% were able to go back to work a year later, 27% needed another operation, and over 90% were in enough pain that they were still taking narcotics at follow-up. ([Nguyen, 2007](#))

Lumbar fusion for spondylolisthesis: Recommended as an option for spondylolisthesis. Patients with increased instability of the spine after surgical decompression at the level of degenerative spondylolisthesis are candidates for fusion. ([Eckman, 2005](#)) This study found only a 27% success from spinal fusion in patients with low back pain and a positive single-level low-pressure provocative discogram, versus a 72% success in patients having a well-accepted single-level lumbar pathology of unstable spondylolisthesis. ([Carragee, 2006](#)) Unilateral instrumentation used for the treatment of degenerative lumbar spondylolisthesis is as effective as bilateral instrumentation. ([Fernandez-Fairen, 2007](#)) Patients with degenerative spondylolisthesis and spinal stenosis who undergo standard decompressive laminectomy (with or without fusion) showed substantially greater improvement in pain and function during a period of 2 years than patients treated nonsurgically, according to the recent results from the Spine Patient Outcomes Research Trial (SPORT). ([Weinstein-spondylolisthesis, 2007](#)) ([Devo-NEJM, 2007](#)) For degenerative lumbar spondylolisthesis, spinal fusion may lead to a better clinical outcome than decompression alone. No conclusion about the clinical benefit of instrumenting a spinal fusion can be made, but there is moderate evidence that the use of instrumentation improves the chance of achieving solid fusion. ([Martin, 2007](#)) A recent systematic review of randomized trials comparing lumbar fusion surgery to nonsurgical treatment of chronic back pain associated with lumbar disc degeneration, concluded that surgery may be more efficacious than unstructured nonsurgical care but may not be more efficacious than structured cognitive-behavior therapy. Methodological limitations of the randomized trials prevented firm conclusions. ([Mirza, 2007](#))

Patient Selection Criteria for Lumbar Spinal Fusion:

For chronic low back problems, fusion should not be considered within the first 6 months of symptoms, except for fracture, dislocation or progressive neurologic loss. Indications for spinal fusion may include: (1) Neural Arch Defect - Spondylolytic spondylolisthesis, congenital neural arch hypoplasia. (2) Segmental Instability (objectively demonstrable) - Excessive motion, as in degenerative spondylolisthesis, surgically induced segmental instability and mechanical intervertebral collapse of the motion segment and advanced degenerative changes after surgical disectomy. [For excessive motion criteria, see AMA Guides, 5th Edition, page 384 (relative angular motion greater than 20 degrees). ([Andersson, 2000](#)) ([Luers, 2007](#))] (3) Primary Mechanical Back Pain (i.e., pain aggravated by physical activity)/Functional Spinal Unit Failure/Instability, including one or two level segmental failure with progressive degenerative changes, loss of height, disc loading capability. In cases of workers' compensation, patient outcomes related to fusion may have other confounding variables that may affect overall success of the procedure, which should be considered. There is a lack of support for fusion for mechanical low back pain for subjects with failure to participate effectively in active rehab pre-op, total disability over 6 months, active psych diagnosis, and narcotic dependence. [For spinal instability criteria, see AMA Guides, 5th Edition, page 379 (lumbar inter-segmental movement of more than 4.5 mm). ([Andersson, 2000](#))] (4) Revision Surgery for failed previous operation(s) if significant functional gains are anticipated. Revision surgery for purposes of pain relief must be approached with extreme caution due to the less than 50% success rate reported in medical literature. (5) Infection, Tumor, or Deformity of the lumbosacral spine that cause intractable pain, neurological deficit and/or functional disability. (6) After failure of two disectomies on the same disc, fusion may be an option at the time of the third disectomy, which should also meet the ODG criteria. (See [ODG Indications for Surgery -- Disectomy.](#))

Pre-Operative Surgical Indications Recommended: Pre-operative clinical surgical indications for spinal fusion should 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-rays demonstrating spinal instability and/or myelogram, CT-myelogram, or discography (see [discography criteria](#)) & MRI demonstrating disc 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 surgery and during the period of fusion healing. ([Colorado, 2001](#)) ([BlueCross BlueShield, 2002](#))

The ODG online regarding discography states:

Not recommended. In the past, discography has been used as part of the pre-operative evaluation of patients for consideration of surgical intervention for lower back pain. However, the conclusions of recent, high quality studies on discography have significantly questioned the use of discography results as a preoperative indication for either IDET or spinal fusion. These studies have suggested that reproduction of the patient's specific back complaints on injection of one or more discs (concordance of symptoms) is of limited diagnostic value. (Pain production was found to be common in non-back pain patients, pain reproduction was found to be inaccurate in many patients with chronic back pain and abnormal psychosocial testing, and in this latter patient type, the test itself was sometimes found to produce significant symptoms in non-back pain controls more than a year after testing.) Also, the findings of discography have not been shown to consistently correlate well with the finding of a High Intensity Zone (HIZ) on MRI. Discography may be justified if the decision has already been made to do a spinal fusion, and a negative discogram could rule out the need for fusion (but a positive discogram in itself would not allow fusion). ([Carragee-Spine, 2000](#)) ([Carragee2-Spine, 2000](#)) ([Carragee3-Spine, 2000](#)) ([Carragee4-Spine, 2000](#)) ([Bigos, 1999](#)) ([ACR, 2000](#)) ([Resnick, 2002](#)) ([Madan, 2002](#)) ([Carragee-Spine, 2004](#)) ([Carragee2, 2004](#)) ([Maghout-Juratli, 2006](#)) ([Pneumaticos, 2006](#)) ([Airaksinen, 2006](#)) Discography may be supported if the decision has already been made to do a spinal fusion, and a negative discogram could rule out the need for fusion on that disc (but a positive discogram in itself would not justify fusion). Discography may help distinguish asymptomatic discs among morphologically abnormal discs in patients without psychosocial issues. Precise prospective categorization of discographic diagnoses may predict outcomes from treatment, surgical or otherwise. ([Derby, 2005](#)) ([Derby2, 2005](#)) ([Derby, 1999](#)) Positive discography was not highly predictive in identifying outcomes from spinal fusion. 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 discogram, versus a 72% success in patients having a well-accepted single-level lumbar pathology of unstable spondylolisthesis. ([Carragee, 2006](#)) The prevalence of positive discogram may be increased in subjects with chronic low back pain who have had prior surgery at the level tested for lumbar disc herniation. ([Heggeness, 1997](#)) Discography involves the injection of a water-soluble imaging material directly into the nucleus pulposus of the disc. Information is then recorded about the pressure in the disc at the initiation and completion of injection, about the amount of dye accepted, about the configuration and distribution of the dye in the disc, about the quality and intensity of the patient's pain experience and about the pressure at which that pain experience is produced. Both routine x-ray imaging during the injection and post-injection CT examination of the injected discs are usually performed as part of the study. There are two diagnostic objectives: (1) to evaluate radiographically the extent of disc damage on discogram and (2) to characterize the pain response (if any) on disc injection to see if it compares with the typical pain symptoms the patient has been experiencing. Criteria exist to grade the degree of disc degeneration from none (normal disc) to severe. A symptomatic degenerative disc is considered one that disperses injected contrast in an abnormal, degenerative pattern, extending to the outer margins of the annulus and at the same time reproduces the patient's lower back complaints (concordance) at a low injection pressure. Discography is not a sensitive test for radiculopathy and has no role in its confirmation. It is, rather, a confirmatory test in the workup of axial back pain and its validity is intimately tied to its indications and performance. As stated, it is the end of a diagnostic workup in a patient who has failed all reasonable conservative care and remains highly symptomatic. Its validity is enhanced (and only achieves potential meaningfulness) in the context of an MRI showing both dark discs and bright, normal discs -- both of which need testing as an internal validity measure. And the discogram needs to be performed according to contemporary diagnostic criteria -- namely, a positive response should be low pressure, concordant at equal to or greater than a VAS of 7/10 and demonstrate degenerative changes (dark disc) on MRI and the discogram with negative findings of at least one normal disc on MRI and discogram. See also [Functional anesthetic discography](#) (FAD).

While not recommended above, if a decision is made to use discography anyway, the following criteria should apply:

- o Back pain of at least 3 months duration
- o Failure of recommended conservative treatment including active physical therapy
- o An MRI demonstrating one or more degenerated discs as well as one or more normal appearing discs to allow for an internal control injection (injection of a normal disc to validate the procedure by a lack of a pain response to that injection)
- o Satisfactory results from detailed psychosocial assessment (discography 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)

- o Intended as a screen for surgery, i.e., the surgeon feels that lumbar spine fusion is appropriate but is looking for this to determine if it is not indicated (although discography is not highly predictive) ([Carragee, 2006](#)) NOTE: In a situation where the selection criteria and other surgical indications for fusion are conditionally met, discography can be considered in preparation for the surgical procedure. However, all of the qualifying conditions must be met prior to proceeding to discography as discography should be viewed as a non-diagnostic but confirmatory study for selecting operative levels for the proposed surgical procedure. Discography should not be ordered for a patient who does not meet surgical criteria.
- o Briefed on potential risks and benefits from discography and surgery
- o Single level testing (with control) ([Colorado, 2001](#))
- o Due to high rates of positive discogram after surgery for lumbar disc herniation, this should be potential reason for non-certification

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

ODG Online 03/03/08