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DATE OF REVIEW: 07/11/2008

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

Removal L4-S1 Screws/Fusion Exploration Assistant Surgeon

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

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
Removal L4-S1 Screws/Fusion Exploration Assistant Surgeon	22612, 22830, 22841, 22852	-	Upheld

PATIENT CLINICAL HISTORY [SUMMARY]:

On xx/xx/xx, the patient was xx-years-old. She had two failed back surgeries (L5-S1 discectomy). She had chronic low back pain and bilateral leg symptoms. It was thought she had pain due to an annular tear at L4-5 as well. She underwent L4-S1 fusion, anterior and posterior, with instrumentation.

On November 8, 2005, the patient was stated to be one year after fusion, with 70% improvement in back pain, and occasional radiating symptoms to the right calf. She was working. She took 3-4 Vicodin per week.

Seventeen months later, on June 1, 2007, the patient presented with a new complaint of leg symptoms when flexing neck. Her back pain was noted to be only an intermittent ache. Dr. stated "the leg symptoms aren't due to her lumbar spine." To date, this is the most recent office note that includes a physical exam (now over 13 months). The exam was essentially normal, without evidence of significant neurologic or other findings.

On September 14, 2007, the doctor noted that the patient had pain when flexing the neck that traveled "all the way down to both legs." Cervical and thoracic MRIs were reviewed and found to be normal. The lumbar MRI from August 2007 was found to have some signal change in the L5 vertebral body, possibly an acute compression fracture. A CT was ordered.

On October 9, 2007, the doctor reviewed the new CT, finding no evidence of fracture or infectious process, stating "I do not see any evidence of fracture. I think she is definitely fused. I do not see any loosening around the screws; I do not see any osteolytic activity." He recommended blood analysis.

On October 12, 2007, the doctor found no abnormalities in the bloodwork. He authored a definitive declarative statement, stating "I have ruled out inaccurate pedicle screw placement, fracture, infection, pseudoarthrosis and any residual neural impingement. Therefore, I do not see any indication whatsoever for any other surgery." He recommended pain management.

The patient has continued to seek treatment with Dr., who has later begun to contemplate "possible" L4-5 pseudoarthrosis, based on a new CT with myelogram from March 10, 2008. The radiologist report was not available to Dr. at the time he formulated this opinion. The radiologist, in his report, found no evidence of any significant process; he found a solid fusion mass at both levels.

Dr. now recommends HWR, fusion exploration, and re-fusion if necessary. The most recent visit is from March 13, 2008. It is noted that the patient wants surgery. A second opinion was to be obtained, but that opinion has not been produced for review herewith.

Request for this surgery has been reviewed twice through the typical preauthorization process, and on both occasions found not to be medically reasonable or necessary.

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

The requested procedure is not medically reasonable or necessary, as there are numerous inconsistencies and insufficiencies in the medical documentation to support the request. The two preauthorization denials appear to be reasonable. There is insufficient evidence of any significant abnormal neurologic or other physical findings that can be correlated to any specific pathoanatomic lesion. Although the patient's subjective symptoms are worsening over time, they are completely inexplicable clinically, particularly the new constellation of cervical symptoms radiating to the legs. The most recent documented physical exam was over 15 months ago, and at that time there were no significant neurologic or other pertinent positive findings. There is nothing on the numerous imaging studies to suggest a significant pathoanatomic entity that would require de facto exploratory surgery. Moreover, it remains unexplained by Dr. as to how his opinion on the necessity for surgery has turned polar opposite, despite the lack of imaging or clinical findings of proportionate magnitude. Likewise, it remains unexplained as to why pain management is no longer a reasonable option, having been recommended previously. In contradistinction to potential physical etiologies for this claimant's worsening subjective back and leg symptoms (those already definitively ruled-out by Dr. 9 months ago), potential psychological issues have not been mentioned or evaluated, much less definitively ruled-out.

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

ODG:

Fusion (spinal)	<p>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, "<u>Patient Selection Criteria for Lumbar Spinal Fusion</u>," after 6 months of conservative care. For workers' comp populations, see also the heading, "<u>Lumbar fusion in workers' comp patients</u>." 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 <u>conservative therapy</u>. [For spinal instability criteria, see AMA Guides (<u>Andersson, 2000</u>)] For complete references, see separate document with all studies focusing on <u>Fusion (spinal)</u>. 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. (<u>Gibson-Cochrane, 2000</u>) (<u>Savolainen, 1998</u>) (<u>Wetzel, 2001</u>) (<u>Molinari, 2001</u>) (<u>Bigos, 1999</u>) (<u>Washington, 1995</u>) (<u>DeBarard-Spine, 2001</u>) (<u>Fritzell-Spine, 2001</u>) (<u>Fritzell-Spine, 2002</u>) (<u>Deyo-NEJM, 2004</u>) (<u>Gibson-Cochrane/Spine, 2005</u>) (<u>Soegaard, 2005</u>) (<u>Glassman, 2006</u>) (<u>Atlas, 2006</u>) 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." (<u>Resnick, 2005</u>) (<u>Fritzell, 2004</u>) 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. (<u>Airaksinen, 2006</u>) For chronic LBP, exercise and cognitive intervention may be equivalent to lumbar fusion without the potentially high surgical complication rates. (<u>Ivar Brox-Spine, 2003</u>) (<u>Keller-Spine, 2004</u>) (<u>Fairbank-BMJ, 2005</u>) (<u>Brox, 2006</u>) In acute spinal cord injury (SCI), if the spine is unstable following injury, surgical fusion and bracing may be necessary. (<u>Bagnall-Cochrane, 2004</u>) (<u>Siebenga, 2006</u>) 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. (<u>Wickizer, 2004</u>) The profit motive and market medicine have had a significant impact on clinical practice and research in the field of spine surgery. (<u>Weiner-Spine, 2004</u>) (<u>Shah-Spine, 2005</u>) (<u>Abelson, 2006</u>) 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. (<u>Deyo-Spine, 2005</u>) (<u>Weinstein, 2006</u>) Outcomes from complicated surgical fusion techniques (with internal fixation) may be no better than the traditional posterolateral fusion. (<u>van Tulder, 2006</u>) (<u>Maghout-Juratli, 2006</u>) Despite the new technologies, reoperation rates after lumbar fusion have become higher. (<u>Martin, 2007</u>) 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</p>
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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 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) The efficacy of surgery for nonspecific back pain is uncertain. There may be some patients for whom surgery, fusion specifically, might be helpful, but it is important for doctors to discuss the fact that surgery doesn't tend to lead to huge improvements on average, about a 10- to 20-point improvement in function on a 100-point scale, and a significant proportion of patients still need to take pain medication and don't return to full function. (Chou, 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. See also Adjacent segment disease/degeneration (fusion) & Iliac crest donor-site pain treatment.

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](#)) ([Deyo-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](#))

Lumbar fusion for Scheuermann's kyphosis: Recommended as an option for adult patients with severe deformities (e.g. more than 70 degrees for thoracic kyphosis), neurological symptoms exist, and pain cannot be adequately resolved non-operatively (e.g. physical therapy, back exercises). Good outcomes have been found in a relatively large series of patients undergoing either combined anterior-posterior or posterior only fusion for Scheuermann's kyphosis. ([Lonner, 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 discectomies on the same disc, fusion may be an option at the time of the third discectomy, which should also meet the ODG criteria. (See ODG Indications for Surgery -- Discectomy.)

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)

