



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

DATE OF REVIEW: May 27, 2009

IRO Case #:

Description of the services in dispute:

1. Items in dispute: L4-5, L5-S1, TLIF, PSF L4 to S1, exploration of fusion L2-L4, removal of instrumentation and spinal monitoring.

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

The physician who provided this review is a fellow of the American Board of Orthopaedic Surgery. This reviewer is a fellow of the North American Spine Society and the American Academy of Orthopaedic Surgeons. This reviewer has been in active practice since 1990.

Review Outcome

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

Upheld

The request for L4-5 and L5-S1 TLIF, PSF L4-S1, exploration of fusion from L2-L4, removal of instrumentation and spinal monitoring is not medically necessary.

Information provided to the IRO for review

Records received from State:

Confirmation of Receipt of a Request for Review by an Independent Review Organization (IRO) – 8 pages

Letter dated 4/7/09 – 1 page

Letter dated 4/7/09 – 1 page

Letter dated 5/1/09 – 1 page

Letter dated 5/1/09 – 1 page

Notice of Medical Review Institute of America of Case Assignment – 1 page

Records received from Utilization Management:

Prospective Review (M2) Response dated 5/12/09 – 4 pages

Single page noting "Exhibit 1" – 1 page

Confirmation of Receipt of a Request for Review by an Independent Review Organization (IRO) – 8 pages – 4 pages
Single page noting “Exhibit 2” – 1 page
Request for Review by an Independent Review Organization – 3 pages
Letter, MD 5/7/09 – 2 pages
Letter, MD 4/22/09 – 2 pages
Single page noting “Exhibit 3” – 1 page
Letter dated 4/7/09 – 1 page
Letter dated 4/7/09 – 1 page
Preauth – 1 page
Preauth – 1 page
Preauth – 1 page
Preauthorization – 1 page
Single page noting “Exhibit 4” – 1 page
Letter dated 5/1/09 – 1 page
Letter dated 5/1/09 – 1 page
Preauth – 1 page
Preauthorization – 4 pages
Email Correspondence – 1 page
Information re: – 2 pages
Single page noting “Exhibit 5” – 1 page
Electrodiagnostic Interpretation report dated 5/4/07 – 4 pages
Single page noting “Exhibit 6” – 1 page
Letter from, MD dated 11/21/08 – 2 pages
EMG & NCV report 11/21/08 – 3 pages
Single page noting “Exhibit 7” – 1 page
MRI Lumbar Spine without Contrast 4/4/07 – 3 pages
Single page noting “Exhibit 8” – 1 page
X-ray lumbar spine 10/27/08 – 1 page
X-ray lumbar spine 8/18/08 – 1 page
Single page noting “Exhibit 9” – 1 page
Lumbar Myelogram and CT report 11/24/08 – 2 pages
Single page noting “Exhibit 10” – 1 page
Report of Medical Evaluation dated 12/12/07 – 3 pages
Single page noting “Exhibit 11” – 1 page
Office visit with, PhD dated 7/21/08 – 5 pages
Fax Transmission Sheet 4/30/09 – 1 page
Single page noting “Exhibit 12” – 1 page
Report of Medical Evaluation dated 11/11/08 – 1 page
Designated Doctor Exam dated 10/23/08 – 5 pages
Fax cover sheet (date unknown) – 1 page
Single page noting “Exhibit 13” – 1 page

Return Patient Visit with Dr. dated 7/30/07 - 1 page
Return Patient Visit with Dr. dated 9/17/07 - 1 page
Return Patient Visit with Dr. dated 11/20/07 - 1 page
Return Patient Visit with Dr. dated 1/7/08 - 1 page
Return Patient Visit with Dr. dated 4/14/08 - 1 page
Return Patient Visit with Dr. dated 6/9/08 - 1 page
Return Patient Visit with Dr. dated 8/25/08 - 1 page
Return Patient Visit with Dr. dated 10/27/08 - 1 page
Return Patient Visit with Dr. dated 12/15/08 - 1 page
Office visit with Dr. dated 3/30/09 - 2 pages
Return Patient Visit with Dr. dated 3/30/09 - 1 page
Single page noting "Exhibit 14" - 1 page
Follow up note from Dr. dated 2/6/09 - 1 page
Operative Report dated 2/18/09 - 2 pages
Operative Report dated 2/18/09 - 2 pages (duplicate)

Patient clinical history [summary]

The patient is a female who is reported to have sustained work related injuries to her low back on xx-xx-xx. It was reported that on the date of injury she was moving some furniture up an incline when she experienced severe back pain. The back pain became much more severe over the next 1-2 days with radiation into the left greater than right lower extremities. She subsequently underwent MRI of the lumbar spine and she is reported to have had a huge central disc between L2-3 and 4.6 mm disc between L3 and L4. The record contains an MRI of the lumbar spine dated 04/04/07. This study reports a 7 mm disc at L2-3 with descending fragment overlying the posterior border of the L3 vertebra. This causes indentation of the thecal sac but no lateral recess or intervertebral foraminal stenosis and no vertebral abnormalities were seen. The zygapophysial joints show no change. At L3-4 there is a large central HNP which lateralizes slightly to the left measuring 4.6 mm but there is no lateral recess or intervertebral foraminal stenosis seen. The zygapophysial joints show no degenerative changes. On 05/04/07 the patient underwent EMG/NCV study which suggests involvement in the left L4 distribution.

On 12/12/07 the patient was evaluated by designated doctor. The designated doctor notes the history above and he reports that the patient has had at least 2 sets of epidural steroid injections and subsequently had undergone fusion at L2-3 and L3-4. She has had some post operative therapy. Dr. opines that the patient's depression is related to the compensable injury. On 07/21/08 the patient was evaluated by, PhD and he has diagnosed the patient with attention deficit hyperactivity disorder and reports that she has guarded prognosis and is responding well to medication.

Radiographic report of the lumbar spine performed on 08/18/08 indicates that the patient underwent surgery with pedicle screws present at L2, L3 and L4 with intervertebral disc spacers at L2-3 and L3-4. There is posterior laminectomy defect at L3. On 10/27/08 the patient underwent

radiographs of the lumbar spine. This study indicates that there are post surgical changes with evidence of decompressive laminectomies with osseous fusion mass. A previously reported neurostimulator wire is no longer present.

On 11/21/07 the patient was referred for repeat electrodiagnostic studies which indicate bilateral L5 and S1 lumbosacral radiculopathy with both acute and chronic features. On 11/24/08 the patient underwent CT myelogram of the lumbar spine. This study indicates that there is fixation present at L2, L3 and L4 with interbody cages at L2-3 and L3-4 with posterolateral bony fusion masses which appears to be solidly conformed. There is a 1 mm small posterolateral hard disc with annular calcification on the right at L5-S1 approaching the right S1 nerve root sleeve medial to the foramen. There is a minimal if any soft disc component and no root sleeve displacement or underfilling and there is bilateral minimal facet joint spurring present at L5-S1 and discography could be considered at L5-S1 to assess whether changes at this level are related to the patient's complaint.

The patient underwent a caudal epidural steroid injection on 02/18/09. The patient subsequently came under the care of Dr. on 03/30/09. She is reported to now be having back and right leg pain. She is reported to have a solid fusion from L2-L4. EMG/NCV study dated 11/20/08 reveals acute and chronic changes at L5-S1 bilaterally with radiculopathy. CT myelogram indicates 1 mm hard disc with annular calcification on the right at L5-S1 approaching the right S1 root sleeve. There is bilateral minimal facet joint spurring at L5-S1 and on physical examination the patient is 5'3" tall and weighs 135 pounds. The left Achilles reflex is absent. Motor strength is intact. The patient subsequently is recommended to undergo an L4-5 and L5-S1 TLIF with PSF L4-S1. On 04/07/07 the request was reviewed by Dr. Dr. opines that the request is not medically necessary and he notes that the patient has no instability and has questionable S1 nerve root involvement on EMG but no clinical supporting findings. He reports a fairly unremarkable MRI.

On 04/22/09 Dr. addresses the previous review. On 05/01/09 the request was reviewed by Dr. Dr. opines that the request is not medically necessary noting the lack of objective clinical or imaging evidence of spinal instability, hardware failure, failure of fusion, progressive radiculopathy and neurologic deficit. This was again rebutted by Dr. on 05/07/09.

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

The request for L4-5 and L5-S1 TLIF, PSF L4-S1, exploration of fusion from L2-L4, removal of instrumentation and spinal monitoring is not medically necessary. The submitted clinical record indicates that the patient had a history of low back pain secondary to a work place event that ultimately resulted in fusion at L2-3 and L3-4. Post operatively the patient is reported to have improvement and then subsequently developed more low back pain with radiation into the lower extremities. The patient has undergone EMG/NCV study which indicates a bilateral L5-S1 radiculopathy. However, clinical examination does not provide any objective findings which correlate with this electrodiagnostic study. It is further noted that the patient has not undergone

lumbar flexion and extension radiographs to establish that there is instability at 1 or both of these motion segments. It is further noted that current evidence based guidelines require that all patients who potentially are undergoing lumbar fusion undergo a pre operative psychiatric evaluation to address any potential confounding issues which would impact the patient's recovery. It is noted that previously the patient has been diagnosed with ADHD and was receiving accurate treatment for this as well as her reports of anxiety and depression during the course of the patient's treatment period. Given the lack of documentation to support instability and lack of clear correlation between imaging studies indicating that both the L4-5 and L5-S1 are symptomatic and the lack of pre operative psychiatric evaluation, the request would not be considered medically necessary and the previous determinations are upheld.

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

The Official Disability Guidelines, 13th edition, The Work Loss Data Institute.

Low Back Chapter: Spinal 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. 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." 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. For chronic LBP, exercise and cognitive intervention may be equivalent to lumbar fusion

without the potentially high surgical complication rates. In acute spinal cord injury (SCI), if the spine is unstable following injury, surgical fusion and bracing may be necessary. 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. The profit motive and market medicine have had a significant impact on clinical practice and research in the field of spine surgery. 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. Outcomes from complicated surgical fusion techniques (with internal fixation) may be no better than the traditional posterolateral fusion. Despite the new technologies, reoperation rates after lumbar fusion have become higher. 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. 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. 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. 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. 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. 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. This study showed that fusion for chronic lower back pain was the least successful common orthopaedic surgery. The study compared the gains in quality of life achieved by total hip replacement, total knee replacement, surgery for spinal stenosis, disc excision for lumbar disc herniation, and arthrodesis for chronic low back pain. For chronic lower back pain, improvements were statistically significant but clinically negligible. Although pain was reduced and function improved slightly, outcomes remained in the moderately affected range, quality of life was not improved and rendered worse, on

average. While surgery for spinal stenosis and for disc herniation compare well with archetypical orthopaedic operations, the outcomes of surgery for chronic lower back pain do not even approach those of other orthopaedic procedures, and the data show that patients with back pain are rendered worse off by surgery. Recent studies document a 220% increase in lumbar spinal fusion surgery rates, without demonstrated improvements in patient outcomes or disability rates. In a study of workers' compensation claimants who underwent fusion to assess the frequency, timing, and causes of death, the 3-year cumulative mortality rate post-fusion was 1.93% and analgesic-related deaths were responsible for 21% of all deaths and 31.4% of all potential life lost. A study to compare the surgical experience, clinical outcomes, and effect on body weight between obese and morbidly obese patients undergoing lumbar spine fusion surgery concluded that clinical outcomes were independent of the BMI of the patient, but the incidence of postoperative complications was significant in 45% of morbidly obese and 44% of obese patients. The authors proposed that morbidly obese patients should undergo bariatric surgery before spine surgery in nonemergent situations. For nonradicular low back pain with common degenerative changes, there is fair evidence that fusion is no better than intensive rehabilitation with a cognitive-behavioral emphasis for improvement in pain or function, and less than half of patients experience optimal outcomes (defined as no more than sporadic pain, slight restriction of function, and occasional analgesics) following fusion. 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. Despite poorer outcomes in workers' compensation patients, utilization is much higher in this population than in group health. 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. Obesity and litigation in workers' compensation cases predict high costs associated with interbody cage lumbar fusion. A recent study of workers' comp patients 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.

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. 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. Unilateral instrumentation used for the treatment of degenerative lumbar spondylolisthesis is as effective as bilateral instrumentation. 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). 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. 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.

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.

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 discectomy. [For excessive motion criteria, see AMA Guides, 5th Edition, page 384 (relative angular motion greater than 20 degrees). (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). (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.